

Dear ecopa messenger subscriber,

With the finalization of the [REACH-impact report](#) of the CONAM Chemical Policy Working Group and the distribution of it across Europe, this topic will be getting less attention from *ecopa* during the coming months. However, for *ecopa* and the stakeholders involved resp. impacted, the implementation and the real net-outcome during the next years to come will be important. We will keep you updated, and will certainly do a follow-up check in the following months' time.

Printed brochures of the a.m. report can also be acquired from the [ecopa-secretariate](#).

In the meantime, let us focus on the 6th and 7th Framework R&D-Programmes of the EU-commission, and the information, know-how and results that come or will come out in the future of their respective projects. Accordingly, there are updates in this newsletter on the 6th EU Framework Programme projects that *ecopa* is participating in, such as ReProTect, PREDICTOMICS and Sens-it-iv, Liintop, Bio-Sim, carcinoGENOMICS.

One topic evolves already by now from the projects which *ecopa* will, therefore, feature in its annual Workshop in November 2007, i.e. "Status of alternative method development in cell systems". Though some people might think there is a lot of basis existing in regard to the cell culture systems for alternative methods in almost all framework programme-projects it became apparent that there is no relevant cell system around as a gold standard.

Another topic will be addressed in the next eSi-Workshop in Alicante in September: though e.g. the "cosmetic ban" is imminent in the EU, the potential alternative methods in this area as well as in the pharmaceuticals are not generally known. *ecopa* will demonstrate the progress made.

And, finally, *ecopa* with its member national NCP platforms has submitted an application for START-UP, a follow-up project to CONAM in the 7th Framework Programme.

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.



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

Beyond the EU 6th FP project CONAM, the *ecopa*-Chemical Policy Working Group will now focus on aspects of implementation of REACH.

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.

A conference in Bonn, supposed to inform a broad audience was over-subscribed within short. ("REACH Workshop: The "R" in REACH – who has to fulfill what and when?", June 21, 2007) Info and program see here:



<http://www.bmu.de/chemikalien/reach/doc/39100.php>

I.1.2. European Partnership on Alternative Approaches to Animal Testing (EPAA)



<http://www.epaa.eu.com>

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:

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

organized by WG 5

scheduled June 18-19, 2007, Brussels, Belgium

and upcoming:

Conference "Europe Goes Alternative"

Scheduled November 5, 2007

European Commission, DG Enterprise and Industry, Brussels, Belgium; the topic will be the regulatory acceptance at large

Presentations and further information on the website:



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

Progress report:



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).

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 7, 2007. The minutes of this meeting are soon to be found on the EPAA website. *ecopa* is represented here by three of its members.



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>

Also, there is a nanotechnology consultation process initiated by the EU Commission/DG SANCO on the preliminary opinion of SCCP on nanomaterials in cosmetics.



http://ec.europa.eu/health/ph_risk/committees/04_sccp/sccp_cons_04_en.htm

Deadline: September 06, 2007.

I.2.2. Review of Directive 86/609

On 25 June 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



II.1.1.1. Recent News on FP6 and FP7 projects

The next *ecopa* Board will be held on September 27, 2007 in Linz, Austria, before the 14th Congress on Alternatives to Animal Testing.

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.

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.



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

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 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.

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 next Linz-congress will take 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.

 [PDF: Announcement and call for papers \(52 kb\)](#)

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

- Prof. Ove Svendsen stepped down as chairman of Dacopa and is now followed-up by Prof. Jann Hau. We welcome Jann, and say thanks to Ove for his efforts to finalize the implementation of a Danish platform.

II.1.1.2.5. Dutch Platform

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

II.1.1.2.6. Finnish Platform

» [Fincopa](#)

- The yearly meeting of FINCOPA took place on 23 May 2007 in Helsinki. Prof. Kai Savolainen, of the Institute of Finnish Occupational Health, was invited to give a lecture: "The safety of chemicals in the tomorrow's Europe - > Helsinki as the home of the chemical agency". The chair Hanna Tähti gave a presentation about the principles of Fincopa and *ecopa*.

 [PDF: Fincopa Activity Report 2006 \(21 kb\)](#)

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

- The set up of the French platform has been announced and at the moment, one is proceeding to the visa of the convention which is the link between the partners (12 partners from public health, industry, animal welfare groups, regulatory bodies). The official meeting for the visa procedure is scheduled for July 6, 2007. A press release will come out after this date. The full session will be held next September in Paris. Isabelle Fabre will present the French platform at the next *ecopa* meeting in November 2007.

In summary, Afssaps (Agence Française de Sécurité Sanitaire des Produits de Santé) will be the coordinator of this project and will probably 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 also included in this platform.

- 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 just been approved by the council on June 28, 07 and will soon be 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.
A board meeting took place on June 20, 2007.

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](#)

- The Norwegian Ministries involved want to establish a permanent, *ecopa*-style, National Consensus Platform in Norway Spring 2007. The details are currently being worked out. Funding will be probably be channeled through the National Veterinary Institute.

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 for 2006, can be found can at (Spanish version):

 <http://www.remanet.net/actividades/>

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 threatened? March 2007**

The Swedish Animal Welfare Agency is to be 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.

This is the consequence of a proposal from the new Swedish government, which was approved by the Parliament in December. Most of the tasks of the Animal Welfare Agency are to be taken over by the National Board of Agriculture, but the responsibility for funding research may be moved to another government authority, FORMAS (www.formas.se) according to one proposal.

The budget for funding research into the 3Rs in the future is still not decided. For 2007 only 5 million SEK has been made available to fund research into alternative, a major cutback compared to previous years.

During its three years of existence, the Animal Welfare Agency has had a budget of at least 15 million SEK per year for funding 3Rs research. An additional 1 million SEK has been provided by AstraZeneca. The future plans for governmental funding of 3Rs research are unknown at the moment.

Due to the situation, the following was agreed by the board: Swecopa will continue its low profile existence, focusing mainly on distributing information to members and to reply to requests for information from *ecopa* and other national platforms.

The next AGM initially foreseen for spring 2007 has been postponed to August 2007. The board will then give the members a report of activities and finances for 2005 and 2006.

- 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>

Swiss Platform holds a Special meeting to mark the 20th anniversary of the 3R Research Foundation and the 20th anniversary of the Swiss Laboratory Animal Science Association (May 2007) Details on the website:

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

On 26 March 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](#)

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

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

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

II.1.1.4. 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.



www.reprotect.eu

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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.

II.1.2.1. Recent News

The recent 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 has just been held in Tuebingen, Germany on June 11/12, 2007. A brochure on the ongoing activities has been drafted.

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

Also, please find a respective flyer below, and the brochure with first results will soon be released.

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

ecopa is involved in the Board and the results dissemination.

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 web with several improvements to facilitate the dissemination of the research done. In the public accessible part, clear and easy to understand information is provided to a general reader, as well links to contact the individual groups through the webmaster.

The 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 \(392 kb\)](#)



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 with amongst others a summary of the project results accomplished during the first project year.

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>



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.

The eighth Sens-it-iv newsletter will appear duly. We invite you to subscribe to the Sens-it-iv newsletter on the Website:

 <http://www.sens-it-iv.eu>

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

The General Assembly Sens-it-iv and Meeting of Sens-it-iv Management Team, Steering Committee will take place on October 22-26, 2007, place to be determined.



<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 second scientific conference for the BioSim Network took place in the island of Mallorca, Spain, from October 18, 2006 to October 21, 2006 at the Cala Viñas hotel.

The objectives of the conference were:

- to present significant new scientific results obtained by the BioSim participants
- to provide a global overview of the advances in the network during its second year, and
- to foster collaboration among network participants.

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

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

The Advisory Scientific Board Meeting of BioSim is scheduled for 10-13 May, 2007 in Budapest.

The BioSim NoE (2004-2009) made progress in the second year of activity, especially in the areas of pancreatic cells, neurological and cardiovascular diseases. Many papers have been published in outstanding journals in the respective fields. The dissemination activity in general has been very wide and the web-site itself has been improved (www.biosim-network.net).

More integration in the network is still needed for some area (biochemistry and genetics), for which a mathematical modelling, seems still very far, probably due also to difficulties in communication and transfer of appropriate information. Also difficulties in having big companies as partners have been mentioned. However the advancement of the overall project is impressive and exchanges of PhD students have already been started to strength the integration.

The conference day took place at SOLVO, a Hungarian SME, located in a technology Park outside Budapest.

Most of the interesting presentations were made by the young collaborators of the two Hungarian groups (Solvo and the Institute of Enzymology of the Hungarian Academy of Sciences). Solvo's research is dealing mainly with drug transporters and drug interactions with the binding site, while the University is studying the different activities of the steric configuration of the TPPP/p25 protein (Tubulin Polymerization Promotion Protein).

Other presentation concerned: the forthcoming meeting with the European Regulators in The Hague concerning the authorisation process; a new WP on industrial collaboration in the area of software elaboration; the Liintop Project and the activity of a Latvian group on mathematical modelling.

The next meeting in 2007 will be on October 10-14, 2007 in Potsdam, on the occasion of the 3rd BioSim Conference.

 **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 recent Management Team Meeting, held June 18, 2007 in Manchester, UK, can be found on the website.

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

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 second Board Meeting took place on May 10, 2007 in Brussels.

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.

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



EU 7th Framework Programme Projects / preparation: SusChem

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.

The workshop was meant to coincide with the official launch event for FP7 under the German European presidency. Under the motto "SusChem - winning the innovation challenge", the workshop included a review of SusChem achievements and sessions on the role of SMEs in sustainable chemistry research & development and innovation (R&D&I), what makes for successful technology transfer and an insight on project evaluation during FP7. The role and value of national SusChem platforms was also featured, as well as a poster session on the work of SusChem relevant ERAnets and other Technology Platforms. Proceedings of the meeting will be available soon on the website.

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 \(Alternatives and Drug Discovery / Development\) \(88 kb\)](#)

II.2.3. A look into the future

Update 7th EU RTD- Framework Programme

The first call for the FP7 Environment theme is closed:

More than 600 proposals addressing the 72 open topics for research have been successfully submitted in response to the FP7-ENV-2007-1 call that closed on 2 May 2007. The overall requested EC contribution exceeds €1 700 million.

In accordance with the FP7 "Rules for submission of proposals, and the related evaluation, selection and award procedures" (ftp://ftp.cordis.europa.eu/pub/fp7/docs/calls/fp7-evrules_en_pdf.zip), the EC services will verify the eligibility of the submitted proposals before proceeding with its evaluation.

There will be normally no further contacts between the Commission and the applicants regarding their proposal until the evaluation and corresponding internal procedures are completed, which is expected by the end of July 2007.

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.

The respective information and forms for interested parties can be found and downloaded on:

III.1.1. *ecopa* events

III.1.1.1. 7th Annual *ecopa* Workshop

The 7th Annual *ecopa* Workshop took place on November 25-26, 2006, in the Brussels Sheraton Airport hotel, in Brussels, Belgium, covering REACH: "REACH for help: science back up?" The presentations of this event and photos can be consulted on the *ecopa* website:

 <http://www.ecopa.eu/content/archive.php>

 [PDF: Minutes of the 7th Annual *ecopa* Workshop \(116 kb\)](#)

The next, 8th Annual *ecopa* Workshop is to take place in November in Brussels. It will feature the topic "Status of alternative method development in cell systems – what is still lacking resp. what is the right system?"

III.1.1.2. 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 2007 in Pueblo Acanilado; Alicante, Spain. Exact date to be published soon. 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. ICT XI - International Congress of Toxicology

July 15-19, 2007 Montreal, Canada.

For more information about this meeting, please visit the website:

» <http://www.ict2007.org>

III.1.2.2. The 6th World Congress on Alternatives & Animals in the Life Sciences

August 21-25, 2007, Tokyo, Japan.

The on-line abstract submission and registration is now available:

» <http://www.ech.co.jp/wc6/>

Deadline for abstracts is April 20, 2007.

The programme is available at:

» <http://www.knt.co.jp/ec/2007/wc6/sc.html>

III.1.2.3. A two day training course on "Developability Assessment, The Logical Approach to Discovery Lead Selection"

This training course will run in conjunction with our "Reduced Animal Testing" conference. The training course will be held on July 24-25.

2007 followed by the conference on July 26-27 2007 in Zurich, Switzerland

For more information on the course and conference:

» <http://www.mondialresearchgroup.com/index.php?whereTo=ratest>

III.1.2.4. The 44th CONGRESS OF THE EUROPEAN SOCIETIES OF TOXICOLOGY

October 7-10, 2007, Amsterdam, The Netherlands.

The scientific programme is available. For more information please visit:

» www.eurotox2007.org

Early fee registration deadline is on August 1, 2007

There will be a round-table-discussion on REACH with Bernward Garthoff as the moderator and with toxicologists on October 8, 2007.

III.1.2.5. "Evidence-Based Toxicology (EBT)" forum in 2007

How to reshape toxicology to meet the safety challenges of today and tomorrow? ECVAM will hold a forum on "Evidence-Based Toxicology".

ECVAM is currently organising a forum on evidence-based toxicology to be held in October 2007. The forum is predominantly aimed at exploring the potential use of methodology developed and used in evidence-based medicine (EBM), a recent movement in clinical medicine aiming to make transparent and scientifically justified decisions for patient care using the best evidence available. Moreover, the future practical implementation of evidence-based tools in toxicology shall be analysed.

Date: October 15-18, 2007

Place: Conference Centre Spazio Villa Erba, Cernobbio, Lake Como, Italy

More information and FREE REGISTRATION:

» <http://www.ebtox.org>

III.1.2.6. Symposium: Toxicogenomics and Replacement of Animal Testing

October 26, 2007, Brussels, Belgium.

This workshop will discuss several challenges of Toxicogenomics and current In-Vitro strategies as alternatives for In-Vivo animal testing.

Topics:

- Reference Database
- Mechanistic Toxicology
- In vitro-In vivo testing strategies
- Replacement of Animal Testing
- In-vitro/In-vivo: Sensitivity/Accuracy

Target Audience:

Scientists, representatives of chemical/pharmaceutical industries, representatives of the Belgian government and governmental institutions.

Register at www.microarrays.be

III.1.2.7. The 4th International Workshop on the Assessment of Animal Welfare at Farm and Group Level (WAFL)

September 10-13, 2008, Ghent, Belgium.

This combination of congress and workshops will be of great interest to all scientists, practitioners and other stakeholders involved in the field of animal behaviour, health and welfare related to the assessment of welfare of farmed and laboratory animals housed and managed in groups. The preliminary programme for the event, including important dates, is available on the website at

» <http://www.wafl2008.com>

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. ECVAM database service on alternative methods to animal experimentation (DB-ALM)

On occasion of its 15th anniversary, the European Centre for the Validation of Alternative Methods (ECVAM) has launched its entire database service on alternative methods to animal experimentation (DB-ALM) on the Internet. ECVAM belongs to the Institute for Health and Consumer Protection (IHCP) of the European Commission's Joint Research Centre (JRC). DB-ALM owes its origin to a Communication from the European Commission to Council and European Parliament SEC (91)1794. The service shall provide scientists, authorities and also non-experts with factual information presented as evaluated data-sheets (ready-to-use information) on various aspects of advanced and alternative techniques for toxicology assessments. The information made available by DB-ALM includes method-summary descriptions and protocols for their performance (INVITTOX Protocols), evaluation studies, details on formal validation studies and individual test results.

The DB-ALM replaces the Scientific Information Service (SIS) -online version which could refer to more than 5000 registered users from various countries.

ECVAM thanks for the interest shown in this service and hopes to welcome them back to consult DB-ALM at the address:

» <http://ecvam-dbalm.jrc.ecc.eu.int>

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. ESAC statement on the validation of five alternative tests

The ECVAM Scientific Advisory Committee (ESAC) has announced the validation of five alternative tests - (4 in vitro assays and 1 in vivo test), which take an important step towards ending the practice of using animals in skin and eye irritancy testing and for skin sensitisation." The ESAC statements as well as first background documents are available for public access on the ECVAM website.

Please follow this link: <http://ecvam.jrc.it/index.htm>, http://ecvam.jrc.it/f_home.cfm?voce=m&idvoce=6

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Institute for Health & Consumer Protection (IHCP)
European Commission - Joint Research Centre (EC-JRC)

III.2.6. Report: Five /In Vitro/ Test Methods Proposed for Assessing Potential Pyrogenicity of Pharmaceuticals and Other Products

The "Independent Peer Review Panel

Report: Five /In Vitro/ Test Methods Proposed for Assessing Potential Pyrogenicity of Pharmaceuticals and Other Products*" has been published on the ICCVAM web site. FYI, please find the link here:

» http://iccvam.niehs.nih.gov/methods/pyrogen/pyr_PeerPanel.htm

III.3. Calls

III.3.1. The US- NICEATM requests for Comments, Nominations of Scientific Experts, and Submission of Data on the Murine Local Lymph Node Assay (LLNA)

ECVAM wishes to inform that the US - National Toxicology Program (NTP), Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) has published in the Federal Register a request for comments, nominations of Scientific Experts, and submission of data on the Murine Local Lymph Node Assay (LLNA) to evaluate the validation status as a stand-alone assay for determining potency (including severity) for the purpose of hazard classification.

The official request has been published on the May 17, 2007 in the US-Federal Register/Notices.

Deadline for submitting comments/nominations/data was June 15, 2007.

(However data will be accepted after this date and considered when feasible.)

More information: is available on the [NICEATM-ICCVAM website](#) or read directly in the [US Federal Register/Notices](#).

View information about the NICEATM-ICCVAM 2008-2012 Five-Year Plan:

» <http://iccvam.niehs.nih.gov/>

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:

» <http://www.eclameslavfoundation.org/promotion/2007Flyer.pdf>

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.

III.4.3. Course in Receptor-mediated toxicity

Karolinska Institutet, Stockholm, Sweden holds the a.m. course on October 22-26, 2007. Objective of the course is to provide state-of-the-art knowledge of toxicological mechanisms mediated by endocrine disrupters.

The course will include the following topics: Molecular mechanisms of hormone receptor signalling, Signalling pathways targeted by endocrine disrupting chemicals, Emerging techniques to identify and screen for endocrine disrupters and Mode-of-action implications in risk assessment.

The course is intended for PhD students, post docs, senior scientists and other professionals. Funding for travel, subsistence and course fee is available for PhD students and post docs.

The course is organised by RA-COURSES, a project funded by European Union Marie Curie Actions, in collaboration with CASCADE Network of Excellence and the Postgraduate programme in Environmental Factors and Health at Karolinska Institutet.

Details on registration and further information:

» www.cascadenet.org/~RA-COURSES and www.cascadenet.org

Registration deadline is August 24, 2007