ecopa messenger

July 3, 2008, edition #16-2008

Dear *ecopa* messenger subscriber,

The kick-off-Meeting for *ecopa*'s new EU-project START-UP was held in Leverkusen and the first of 3 expert meetings took place in Madrid, Spain, in April and May 2008. START-UP is the 7th Framework Programme-project of *ecopa* which fits into the overall scheme of *ecopa*'s goals, and which *ecopa* is following with its member NCPs.

In Madrid, the closed expert meeting was followed on the second day by a Spanish Platform-meeting, organized by REMA together with the local IMI-initiative and the Spanish Pharmaceutical Association Farmindustria. The second expert meeting "3Rs and Animal Disease Models in Pharmaceuticcal Research and Development" is to happen on September 5 in Basle/CH on invitation.

Actual time schedule of all events for *ecopa* incl. START-UP: http://www.ecopa.eu/content/events.php

Minutes START-UP Kick-Off Meeting (28 kb)
START-UP Kick-Off- and Expert-Meeting presentations
START-UP 1st Expert-Meeting, Madrid, photographs

ecopa now covers 13 countries on the European continent, including the two new member platforms, i.e. the Plateforme Nationale of France, and Norecopa from Norway, and raises now attention in the scientific and political media (see: European Biotechnology Journal) through its activities.

The theme of the next eSi (*ecopa* Science Initiative)–Workshop in Alicante/Spain will address: "Recent developments and potentially novel approaches of science to alternative testing of cosmetics and pharmaceuticals". Scheduled date is October 16-19, 2008. The European Partnership for Alternative Approaches to Animal Testing, EPAA, will most likely participate in it. The draft program will soon be shown on the *ecopa*-website.

The next *ecopa* Annual Workshop will take place on November 29 and 30, 2008 in Brussels, please note the date. Topic might be:" Cosmetics Directive, REACH legislation and novel Directive 86/609: realistic 2013 – deadline?

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

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

Impact of REACH (804 kb)

ECHA (European Chemical Agency)

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European Chemicals Agency is operational

12 months after its creation, the European Chemicals Agency (ECHA) has evolved from a few staff to a fully functioning organisation of 200 employees. On June 1, 2008, the Agency launched the REACH-IT portal and started to accept pre-registrations and other data submissions from industry. To commemorate the move from the build-up to the operational phase, a formal inauguration ceremony for the Agency was held at the Helsinki City Hall.

Commission President José Manuel Barroso, Commission Vice-President Günter Verheugen, Finnish Prime Minister Matti Vanhanen, European Parliament Vice-President Gérard Onesta, Mayor of Helsinki Jussi Pajunen, and ECHA's Executive Director Geert Dancet addressed an audience of Agency staff and guests.

More information here: http://echa.europa.eu/doc/press/
Access to REACH-IT portal: http://echa.europa.eu/reachit_en.asp

REACH registration is starting on June 1, 2008!

The table below gives an overview on REACH information requirements and timetable reg. chemicals regulation: (Source/acc. to ICIS, Nov. 4, 2007)

Volume (tons/year)	**1-10**	**10-100**	**100-1000**	**>1000**
Preregistrationss	12-18 months after entry into force (June-Nov. 2008)			
Information required	Identity of manufacturer Contact person Substance identifier Tonnage band			
Registration				
Information Annex	VII	VIII	IX	X
Chemical Safety Report	No	Yes	Yes	Yes
Time after entry into force	2018	2018	2013	End 2010
Registration	3,5 years (= End 2010)			

Important and helpful:

Price Waterhouse Coopers has conducted a global survey on REACH and it turned out that many companies are not yet aware of the consequences of the REACH legislative. The report "Global companies weigh risks and rewards of Europe's newest law on the safe use of chemicals" can be loaded

down from the PWC-website (at no cost) here:

http://echa.europa.eu/doc/press/080228_PR_MSC_1-Final%20_5.pdf

The Advisory Committee of the German Toxicology Society has recently published a review paper on the role of alternative testing methods in the frame of REACH and the Cosmetics Directive.

http://www.springerlink.com/content/55815583r850223w/

Nature published an editorial in regard to animal testing within REACH:
Nature 453, 563-564 (29 May 2008) | doi:10.1038/453563b; Published online 28 May 2008 Animal tests inescapable - The ambitious scope of Europe's chemicals legislation demands some innovative toxicology.

Read more here:

http://www.nature.com/nature/journal/v453/n7195/full/453563b.html#top

www.epaa.eu.com

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

For outcome of the recent workshop "New Perspectives on Safety", held April 28, 2008 in Brussels, see the website and the following document:

http://ec.europa.eu/enterprise/epaa/ws_new_perpectives_20080429.pdf

EPAA-newsletter of January 2008 is published and can be read here:

http://ec.europa.eu/enterprise/epaa/epaa_newsletter_200801.pdf

Progress report 2007 published:

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

EPAA-events are listed under: http://www.epaa.eu.com

This year's annual meeting is scheduled for November 3, 2008 in Brussels. Featured topic in 2008 is "3 Rs - Research". The 3Rs Declaration can be found here:

http://ec.europa.eu/enterprise/epaa/3rd.htm

NEWS: The Mirror Group of stakeholders including the EP, animal welfare organizations, institutions and patient groups *ecopa* is represented by three of it's members. Next meeting of the Mirror Group will most likely be on September 10, 2008.

http://imi.europa.eu

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I.1.3. IMI is launched

The Innovative Medicines Iniative (IMI) has been launched on April 30, 2008. This is an initiative launched by both the European Commission and the EFPIA, the European Federation of Pharmaceutical Industry Associations. The goal of this initiative is to give an impulse to biopharmaceutical innovation in Europe. Universities, hospitals and public institutions can get financing for a research project.

IMI organises annual calls to be participated by academia and small companies. The subjects are determined by the EFPIA in cooperation with the European Commission. The first calls are out by now.

More information can be found here:

http://imi.europa.eu/docs/imi-scientific-priorities2008_en.pdf

http://imi.europa.eu/calls-01_en.html

The launch was done under participation of Commissioner of Research, J. Potocnik.

I.2. Other News

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I.2.1. Nanotech

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

Chronology up to now: February 2008: Commission's Scientific Committee on Consumer Products (SCCP) published its opinion on "Safety of nanomaterials in cosmetic products.

See resp. paper here:

http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_123.pdf

June 17, 2008: The Commission is expected to publish a regulatory review to establish whether new legislation on nanomaterials is needed.

Early 2008: Establishment of an observatory to carry out dynamic assessments of nanotechnology development, use and scientific market developments, providing an 'early warning' system for the EU institutions and member states.

By July 2008: The European Food Safety Authority (EFSA) will publish its general opinion on the potential risks of the use of nanotechnologies in the food sector. After that, the opinion will be submitted for public consultation.

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

The response to the petition can be seen here:

http://ec.europa.eu/environment/chemicals/lab_animals/pdf/petitions_dir86_609.pdf

A new draft was expected by May or June 2008.

Progress can be followed under:

http://ec.europa.eu/environment/chemicals/lab_animals/nextsteps_en.htm

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

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II.1.1.1. Recent News on FP6 and FP7 projects

NEWS:
Next Board Meetings scheduled (addressing also the START-UP project):

- September 2008, during/after ESTIV–meeting, to be held on September, 25/26, 2008
- March 3, 2009
- September 16, 2009

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.
- *START-UP* – START-UP is the *ecopa*-follow-up-project for CONAM.
- *ESNATS - ecopa is lead part of the dissemination workpackage*.
- *ecopa* – latest *ecopa*-Board meeting took place on March 4, 2008 in Brussels. The minutes you can get here:

PDF: Minuts of *ecopa* Board Meeting (180 kb)

The European Commission has published a booklet on all European FP6-projects concerned with alternative testing.

You can download it from this link:

http://www.carcinogenomics.eu/files/public/home/alternative-test-strat_en.pdf

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. This year's 15th Congress on Alternatives is scheduled for September 19-21, 2008, Linz, Austria.
- Call for papers:

http://www.zet.or.at/news,46,CALL_FOR_PAPERS__Congress_Linz_2008.html

- Registration before August 25, 2008 for pre-registration conditions, higher fees after August 25, 2008, for registration material, see here:

http://www.zet.or.at/spool/download/1207667181-registration_form_linz_2008.pdf

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

II.1.1.2.5. Dutch Platform
» NCA - The Netherlands Centre Alternatives to Animal User

PDF: Latest issue of the NCA newsletter, published on May 24, 2008

II.1.1.2.6. Finnish Platform
» Fincopa

- Fincopa will organize in connection with the annual meeting in 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.

II.1.1.2.7. French Platform

- The French Platform was mentioned in the "European Biotechnology Journal" (no 5-6, volume 7, 2008) with an article. The title of the article is "Alliance to decrease animal tests". It mentions that the platform is raised by the French research ministry and the country's national medicines regulator (Afssaps). It also mentions that the French Platform is part of the *ecopa*-umbrella.

II.1.1.2.8. German Platform
» Stiftung set

- The Annual Report for 2007 has been approved by the council on June 13, 2007 and is to be found on the website of set soon. The German version will be up first, it can be found on the first page, under 'Downloads', click on 'Tätigkeitsbericht 2007'. The English version will be online a few days later.

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
» norecopa

- The Norwegian Platform has started operation of their new website:

http://www.norecopa.no/sider/tekst.asp?side=8&meny=Meeting_on_Field_Research.htm

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

- REMA has organized a meeting in parallel with the START-UP-expert meeting in Madrid in May. This meeting took place in the building of the Ministry of Health.
- The REMA activities can be found can at (Spanish version):

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

II.1.1.2.15. Swedish Platform
» Stiftelsen Forskning utan djurförsök

http://www.swecopa.se

- **Government support for 3Rs research**
  The Swedish Animal Welfare Agency was closed down in July of 2007. The National Board of Agriculture has taken over the responsibility for all tasks regarding laboratory animals and research into 3R's alternatives, from the Animal Welfare Agency. A total of 9,9 million SEK has been allocated to 3R's reseach in 2007, to be compared to 18,6 millions in 2006. The funding for 2008 has not yet been decided, but it is likely to be less than in 2007.
- **Swecopa held it's AGM on March 31**
  Karin Gabrielson Morton was re-elected to chair Swecopa. Other board members are Dr Cecilia Clemedson (Swedish Fund for Research without Animal Experiments), Professor Roland Grafström (Karolinska Institute) Dr Krister Martin (AstraZeneca), Lena Hallberg (Animal Protection Sweden), Rebecca Ceder (Karolinska Institute) and Helena Elofsson (Board of Agriculture).

  The Swedish government funding for 3R:s alternatives has been decreased substantially, down to 8 million SEK compared to 15 million earlier. It has also been split between two different funding bodies. The Board of Agriculture received 5 million SEK for this purpose and FORMAS (a Research Council) received a budget of 3 million. AstraZeneca has contributed with an additional 0,9 million SEK. The Board of Agriculture and Formas has jointly published a call for applications for a total of 8,9 million, which is available here:
  http://www.sjv.se/amnesomraden/djurveterinar/djurskydd/forsoksdjur

/utlysningavforskningsmedel.4.1c72e95711857a22453800011354.html
Last date for submitting applications was June 5, and the selection will be made by October.

The Swedish Fund for Research without Animal Experiments is a private fund, which uses donations from the public to fund research to replace animal experiments. The total amount available for funding is 1,5 million SEK per year and the call for applications ended in February. The final selection of projects to receive funding will be made in September.

News from Swecopa is publiced on the website www.swecopa.se under "News". A newsletter in Swedish is also available at http://www.swecopa.se/swe_sid5_aktuellt.html
E-mail us at info@swecopa.se if you want to receive the newsletter.

II.1.1.2.16. Swiss Platform
» 3R Research Foundation Switzerland

• Update on Activities:

Latest bulletin of January 2008 "Host pathogen interactions can be studied in amoebae instead of animals" to be found here:

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

Call for Grant Applications

The 3R Research Foundation invites interested scientists to propose a project which falls within the principal areas for financial support. Information concerning current areas can be found in 3R-Info-Bulletin no.6. The duration of the project proposed should preferably be between 1 and 3 years and the necessary budget should be Sfr. 50 000.00 - Sfr. 300 000.00.
Successful projects will be selected according to the Foundation's assessment criteria as well as financial capacity.
The Foundation would like to point out that in the year 2008 about Sfr. 500 000.00 (310 000.00 EURO) are available for research grants.
Use the application form (by e-mail) and set up the proposal according to the application format.

Deadline: September 1, 2008

Approach the Scientific Adviser for more information and material:

http://www.forschung3r.ch/en/information/adressen.html#wiss_mitarbeiter

Further details on the website:

http://www.forschung3r.ch/en/guidelines/index.html

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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II.1.2. ReProTect

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 next Supervising Board Meeting is to be held on July 8, 2008 in Dresden, Germany.

The Annual Research Area meeting and the Meeting of the Executive Committee was held in Stockholm, Sweden. A brochure on the ongoing activities within ReProTect 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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II.1.3. Predictomics

The *ecopa*-induced 6th Framework Programme project Predictomics (STREP) started in 2003, with a total of 14 partners .The overall funding is 2.3 mio EUR. The contract with the EU was signed on September 1, 2004; the administration throughout the project is done by REMA. The project will end on December 31, 2007.

II.1.3.1. Recent News

PDF: PREDICTOMICS - Specific Target Research Project (268 kb)

PDF: PREDICTOMICS - Short-term *in-vitro* assays for long term toxicity (392 kb)

ACute Tox **www.acutetox.org**

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II.1.4. ACute Tox

II.1.4.1. Recent News

A list of all publications produced by the Consortium is available on the web site as well as the project structure and a profound overview. Link below.

The latest newsletter as of February 2008 can be read here:

http://www.acutetox.org/docs/Newsletter/acutetox_newsletter_3.pdf

http://www.acutetox.org

E-learning program for *in vitro* methods

The scientific coordinator of the FP6 project ACuteTox, Expertrådet, is producing an e-learning program for the testing strategy and the methods that will be the result of the project. To get a good implementation and a wide use of the *in vitro* methods it is important to make it convenient for the industry to use them. One way is to produce interactive manuals that make it possible to attain reproducible results with high and equal quality in all laboratories.

Expertrådet has developed a pedagogic model for an interactive manual within the ACuteTox project. The SOP text is supplemented with short video sequences, photos and drawings that clarifies critical phases of the test methods. Each test will be presented in three different levels: 1) an introduction level where the tests are presented briefly to demonstrate the opportunities of the test; 2) a second level with the SOPs of the tests and with video sequences or pictures that demonstrate how to carry through the tests; 3) in the third level the scientific documentation and background of the tests could be find.

The second level is the main part of the e-learning program that will consist of the interactive manual.

This model could also be useful for the other FP6 projects within the *in vitro* area and it would certainly be convenient for the endusers if the e-learning programs from the different projects looked similar and had the same pedagogic model. Expertrådet is willing to assist other *in vitro* projects to produce similar e-learning programs.

Contact for more information: www.expertradet.se, www.acutetox.org

http://www.ecopa.eu/download.php?file=ACuteTox_e-learning_abstract.pdf

Consortium meeting held on February, 20-22, 2008 in Konstanz

After the consortium meeting held in February 2008 in Konstanz, the phase of data compilation and generation has been completed. At this meeting, new software (Acusoft) was presented which will facilitate the estimation and comparison of IC50 values from atypical dose-response curves obtained in different test systems and with different compounds. Furthermore the incorporation of chemical properties of a given compound (pH, lipophilicity, protein binding) was shown to be a good indicator of their kinetic behaviour and to be a very efficient corrector factor for the correlation between *in vivo* and *in vitro* data.
A new committee within the project was established from members of the advisory board and from ECVAM. Their task is to develop a test strategy, using the best performing assays in the testing of the 57 reference chemicals. This pre-validation phase will start in the second half 2008.

www.sens-it-iv.eu

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II.1.5. Sens-it-iv

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 is part of work package 9 and is responsible for "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 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. Technology transfer and dissemination of project results, including knowledge, will be a key activity throughout the term of the Sens-it-iv project.

The first Sens-it-iv Newsletter appeared on December 14, 2006 and now the 18th edition is available via the website or the link below. *ecopa* is part of work package 9 and is responsible for "Technology transfer and Dissemination". The newsletter is coordinated by the WP9 leader.

Newsletter Nr. 18 is out:

http://www.sens-it-iv.eu/content/newsletter.php

Newsletter-subscription possibility on the website.

A mini General Assembly has been organized with all partners involved in the project from May 26-28, 2008 in Estoril.

PDF: Sens-it-iv - First publishable summary (114 kb)

PDF: Sens-it-iv - Publishable executive summary - 2nd year (80 kb)

http://www.biosim-network.net

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II.1.6. BioSim

BioSim, or "Biosimulation A New Tool in Drug Development" started December 1, 2004. BioSim is a Network of Excellence supported by the European Commission as part of its 6th Framework Programme.

II.1.6.1. Recent News

The 4th BioSim Conference will be held from September 24 to 27, 2008 in Budapest. More information can be found on the link:

http://biosim.enzim.hu/

Liintop

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II.1.7. Liintop

II.1.7.1. Recent News

Structure of the project, information on partner and new on events can be taken from the website:

http://www.liintop.cnr.it/index.php?PG=events&action=events

carcinoGENOMICS

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II.1.8. carcinoGENOMICS

carcinoGENOMICS is an Integrated FP6 Project financially supported by the European Commission (LSHB-CT-2006-037712).19 groups are present of which 6 represent industry, 11 represent universities or research institutes, while 2 groups represent organizations.

II.1.8.1. Recent News

PDF: CarcinoGENOMICS Press Release (24 kb)

The last carcinoGENOMICS-Project Board was held on April 21/22, 2008 in Cambridge, UK.

A workshop on Regulatory Aspects with experts of that scene was held on June 9 and 10, 2008, in Brussels, Belgium, in the premises of the EU Commission.

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

II. 2. EU 7th Framework Programme Projects, Initiatives and Technology Platforms

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SusChem

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II.2.1. Sustainable Chemistry (SusChem)

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 tenth SusChem newsletter is now online:

http://www.suschem.org/content.php?pageId=3653

II.2.2. Regulations of the 7th Framework Programme

Update 7th EU RTD- Framework Programme

Though intended as part of the EU-competitive efforts in Research and Development, the EU still is behind its own targets laid down in the Lisbon Strategy. According to the EU statistics officer, the 27 EU states invested in 2006 as much (or little) as in the year before, i.e. 210 billion EURO equivalent to 1.84% of its economical output. Lisbon asks for 3% in 2010.

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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II.2.3. START-UP

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. The project was approved "Grant Agreement" No. 201187 and signed on March, 12, 2008.

II.2.3.1. 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 3 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)

NEWS: The first START-UP expert meeting has taken place in Madrid, on June 19, 2008. On June 20, 2008, there was a public meeting, organized by REMA together with *ecopa*.
The second expert meeting will take place in Basel, Switzerland, on the September 5, 2008.

ESNATS

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II.2.4. 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, developed the logo, and is leading the respective workpackage.

NEWS:
ESNATS Kick-Off meeting was held from April 21 to 23 in Cologone, Germany. Dr. Bernward Garthoff presented *ecopa* and the work which *ecopa* will do in the Workpackage 5 of ESNATS.

The above ESNATS logo was brought in by *ecopa*.

Miscellaneous

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III.1. Events

III.1.1. *ecopa* events

III.1.1.1. 9th Annual *ecopa* Workshop

The next, 9th Annual *ecopa* Workshopwill take place on November 29-30, 2008 in Brussels .

The future *ecopa* Annual Meetings will be:
10th: November 28-29, 2009
11th: end of November 2010

III.1.1.2. *ecopa* Board meeting

Minutes *ecopa* Board Meeting of March 4, 2008 (180 kb)

The next *ecopa* Board meetings (addressing also the START-UP project):
September 25 or 26, 2008 (during ESTIV-meeting in Stockholm, Sweden)
March 3, 2009
September 16, 2009

eSI - *ecopa* Science Initiative

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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.

NEWS: The next workshop is to take place in Pueblo Acantilado; Alicante, Spain on October 16-19,2008. It will focus on " Recent developments and potentially novel approaches of science to alternative testing of cosmetics and pharmaceuticals". It will most likely be held together with the European Partnership for Alternative Approaches to Animal Testing, EPAA.

III.1.2. other events

III.1.2.1. *In Vitro-in Vivo* Correlation (IVIVC) Training Course to be held on July 22, 2008 in London, UK, BSG Conference Centre

For more information visit:
» http://www.visiongain.com/
Get more information by email:
» pharmaconferences@conferencesandreports.com

III.1.2.2. Cambridge Healthtech Institute's Third Annual CELLutions SUMMIT, held from August 11-13, 2008 in Cambridge, UK, Boston Marriott Cambridge Hotel

For more information visit:
» http://www.cellutionssummit.com

III.1.2.3. Course in Regulatory Toxicology, held from August 25-29, 2008 in Kuopio, Finland Registration deadline was mentioned with May 29, 2008

For application and further information:
» http://www.cascadenet.org/~RA-COURSES

III.1.2.4. 15th Congress on Alternatives to Animal Testing, September 19-21, 2008 in Linz, Austria

For more information:
» http://www.zet.or.at

III.1.2.5. International Congress on *In Vitro* Toxicology, ESTIV2008
to be held from **September 25–28, 2008** at Djurönäset in Stockholm.

For more information:
» http://www.estiv2008.org

III.1.2.6. Biomarker Discovery Summit 2008: Bridging the Silos in Biomarker Discovery and Validation, September 29 - October 1, 2008 at the Loews Philadelphia Hotel, Philadelphia, PA, USA

For more information:
» www.BiomarkerDiscoverySummit.com

III.1.2.7. Refinement of the use of chronic implants in animal research – a joint NC3Rs/Wellcome Trust workshop, October 1, 2008, London, UK

For detailed information see here:
» http://www.nc3rs.org.uk/event.asp?id=843
» http://www.nc3rs.org.uk/chronicimplantworkshop

For all events hosted by NC3Rs see their website:
» http://www.nc3rs.org.uk/event.asp?id=33

III.1.2.8. 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:
» http://www.eurotox2008.org/

III.1.2.9. Final Symposium on RNA Interference for therapeutic approaches
organised by the RIGHT Consortium, the Symposium is taking place in Brussels on November 3-5, 2008.

For more information:
» http://www.rightsymposium2008.eu

III.1.2.10. New Horizons in Toxicity Prediction: Symposium in collaboration with the University of Cambridge, December 8-9, 2008, hosted by The University of Cambridge, Cambridge, UK

Detailed information and registration:
» http://www.lhasasymposium.com/registration-contact.html

III.2. Awards and Publications

III.2.1. Cefic-LRI and EUROTOX 2008 Innovative Science Award

The €100,000 prize, which aims to promote innovation in the field of toxicology, will be awarded this year by the LRI (Long Range Research Initiative) in conjunction with EUROTOX (Federation of European Toxicologists & European Societies of Toxicology).
The application deadline was March 03, 2008, competition is ongoing, time schedule here:
June 26, 2008
Finalists' project presentation to the selection committee in Brussels
November 20-21, 2008
Presentation by the award winner at the Cefic LRI annual Workshop, Brussels, Belgium

For more information and finalists/themes visit:
» http://www.cefic-lri.org

III.2.2. Dieter Luetticken Award

Intervet's award 2008: Deadline

The Dieter Lütticken award, established in 2004, aims to encourage research into the use of alternative models for animal testing with significant impact on the development or production of new animal health products. Intervet/Schering-Plough Animal Health welcomes submissions from scientists and public life-science institutions. The € 20,000 award is named after Dr. Dieter Lütticken, a committed researcher in microbiology and virology. He guided and shaped Intervet's R&D for more than a quarter of a century. Dr. Lütticken retired in 2003 from his position as Vice President and Head of R&D. The award's scope covers *in vitro* models used in R&D which replace animal testing for licensing purposes as well as studies avoiding the use of animals in efficacy, safety and quality testing in the production of biologicals and pharmaceuticals for animals.

A jury panel composed of experts from public institutions of the animal health/animal testing sector and Intervet representatives looks for possible candidates and makes the final selection. Intervet also welcomes submissions from all life-science research institutions. Commercial organizations are excluded.

This year's deadline is November 15, 2008.

» http://www.intervet.com

III.2.3. EPAA Newsletter, April 2008

The latest edition of the EPAA-newsletter (April 2008) is available now:
» http://ec.europa.eu/enterprise/epaa/epaa_newsletter_200804.pdf

III.2.4. InterNICHE: 2008 Humane Education Award

Interniche announces the 2008 Humane Education Award to support ethical and effective life science education and training.

The Award is a grant program to enhance biological science, medical and veterinary medical education and training. Supported by Proefdiervrij, the Award offers 20,000 Euro (US$ 25,000) to be split between

successful applicants.

Proposals are invited from all countries for initiatives to replace animal experiments and the dissection of purposely killed animals. Applicants may be teachers, students, campaigners or any other individuals committed to best practice education and training.

For more information see the website:
» http://www.interniche.org

III.2.5. Nature: Editorial – Animal tests inescapable

Nature published an editorial in regard to animal testing within REACH:

Nature **453**, 563-564 (29 May 2008) | doi:10.1038/453563b; Published online 28 May 2008 Animal tests inescapable - **The ambitious scope of Europe's chemicals legislation demands some innovative toxicology**.

Read more here:
» http://www.nature.com/nature/journal/v453/n7195/full/453563b.html#top

III.2.6. Booklet on Alternative Testing Strategies

The European Commission has published a booklet on all European FP6-projects concerned with alternative testing.

You can download it from this link:
» http://www.carcinogenomics.eu/files/public/home/alternative-test-strat_en.pdf

III.2.7. CHI's Insight Pharma Report

Systems Biology: A Disruptive Technology": This report focuses on the current and future applications of Systems Biology in drug discovery, specifically in pinpointing optimal individual targets, and combinations of targets, to overcome metabolic pathway redundancies, leading to efficacious and safe products.

For more information:
» http://www.chicorporate.com/Systems_Biology/br+dl.aspx

III.3. Calls and Vacancies

III.3.1. The ECLAM ESLAV Foundation is now accepting applications for funding in 2008-2009

It is a charitable organization 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 behavioral well being

Funding applications for 2007-2008 are closed. 2008-2009 applications are open (early 2008) for information only an application form, including guidelines for applicants and information how to submit an application, can be downloaded here: 2008 form.

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.3.2. Call for expression of interest as Members of the Board of Appeal of ECHA

The European Commission has published a call for expression of interest in the appointment as chairman and as members of the Board of Appeal of the European Chemicals Agency. For further information see the attached notice and the addresses (links) mentioned in the notice.

» http://echa.europa.eu/doc/press/20080201_PR_08_01RAC.pdf

III.3.3. Call for interest for Grantholders for Doctoral and Post-doctoral positions in ECVAM

The Institute for Health and Consumer Protection (IHCP) has launched a call for interest for Grantholders for Doctoral, Post-doctoral and Senior Research Positions. ECVAM, part of the IHCP, offers two of the Grantholders positions.

For more information:
» http://ihcp.jrc.ec.europa.eu/job/Grantholders_open_calls.htm

III.3.4. New call for Marie Curie Actions

A complete overview of relevant calls can be found at:
» http://cordis.europa.eu/fp7/dc/index.cfm?fuseaction=UserSite.FP7SubmitProposalPage

The Intra-European fellowship can be found at:
» http://cordis.europa.eu/fp7/dc/index.cfm?fuseaction=UserSite.FP7DetailsCallPage&CALL_ID=118#infopack

III.3.5. Third FP7-HEALTH call coming up

The publication of the third call for the FP7-HEALTH program, with an indicated budget of 590 million euro, has been postponed. The call will, probably, be published on September 3, 2008 with a deadline for submitting around December 3-5, 2008.

INFO ABOUT THE FP7 HEALTH CALL3

It is to be expected that there will be two parallel calls with 2 deadlines.

One in which the *single-stage hand over/evaluation* will be applied (for most of the topics)
FP7 Health-2009-single-stage (call A)
for small-scale collaborative projects
indicative budget: 476 Million €;
deadline: November 20, 2008.

A second one in which *two-stage hand over/evaluation* will take place (only for some topics)
FP-Health-2009-two-stage (call B)
indicative budget: 115 Million €.
deadline stage 1 of call B: October 21, 2008
deadline stage 2 of call B: February 19, 2009

A CORRECTED draft WP 30/04/08 (Correction 16/05/08) with the research topics which are released for the call, is to be found on the R&D website. The announced deadlines are not correct anymore.

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. The DB-ALM has published a new data sector

Probably you already know that, in addition to the new information on methods recently published, the

DataBase on ALternative Methods (DB-ALM) of the Institute for Health and Consumer Protection (IHCP) to which ECVAM belongs to has also made available for public access the directory on contact details of : "Persons & Institutions active in the Field of Alternative Methods."

For more information:
» http://ecvam-dbalm.jrc.ec.europa.eu

III.4.4. CARDAM: Centre for Advanced Research & Development of Alternative Methods

CARDAM is a newly formed institute for research and development of alternative methods.

For more information:
» http://www.cardam.eu/CARDAM

III.4.5. VirtualToxLab is available on the internet

After 25 years of research, VirtualToxLab an *in silico* tool for predicting the toxic potential of drugs and environmental chemicals is accessible through the Internet. Its fully automated protocol allows to estimate the binding affinity of any molecule of interest towards a series of proteins, known or suspected to trigger adverse effects by simulating and quantifying their interactions with the human protein at the molecular level using automated, flexible docking combined with multi-dimensional QSAR. In contrast to other approaches in the field, this technology does not only provide a binding affinity but allows to verify the result at the molecular level by interactively viewing the corresponding protein-ligand complex in 3D. Currently, the *VirtualToxLab* includes 11 validated models for the androgen, aryl hydrocarbon, estrogen, glucocorticoid, mineralocorticoid, thyroid and peroxisome proliferator-activated receptor as well as for the enzymes CYP3A4 and CYP2A13. The VirtualToxLab is accessible from any hard and software platform.

Full details are given in the Spring 2008 Newsletter which is available for download at:
» http://www.biograf.ch/downloads/newsletter.pdf