ecopa messenger

Xmas edition, December 21, 2009, edition #22

Dear *ecopa* messegner subscriber,

At its 2009 Annual Meeting, the tenth since its foundation, *ecopa* had a major change when addressing the past ten years of its success story, the election of a new Board.

This year's Annual Meeting took place on November 28/29, 2009 at the Brussels Sheraton Airport Hotel, as usual.

Photos of NCPs Friday meeting and Sunday Annual Meeting

Photos of Scientific Workshop at Annual Meeting Saturday

An intense preparation of the election process had preceded the event (thanks to Peter Maier, Stijn Budts and the NCPs).

This year, besides the scientific workshop on Saturday as usual, there was a preceding meeting of the National Consensus Platforms on Friday afternoon, preparing the elections for the new *ecopa* Board, performed then subsequently on Sunday morning. The elections resulted in the re-election of the 3 Board Members not yet at the end of their term, plus seven new Members. For the future Management Board Adela Lopez de Cerain (Spain) as chair, Odile De Silva (France) as co-chair and Lisbeth E. Knudsen (Denmark) as treasurer were identified and elected. And congratulations, of course, to all newly elected and appointed Board members

Contact page of *ecopa* website

A hand over meeting of the former and future Management Board is scheduled for December 22, 2009 in Brussels at the Navarra Regional Representation. In that context, the NCP of the new chair, i.e. REMA, the Red Espanola para el Desarrollo de Métodos Alternativos a la Experimentación Animal, had it's 'X Anniversario' as well. This was celebrated in Madrid, on December 1, 2009. Congratulations to REMA and the new elected chair of *ecopa*.

Bernward Garthoff
On behalf of the former and future *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.

Issue # 22 (December 2009)

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I.1. General News

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I.1.1. Recent News on REACH and GHS

First REACH list of dangerous chemicals agreed:

http://www.euractiv.com/en/environment/reach-list-dangerous-chemicals-agreed/_article-176244

EU Member States approve world-wide rules for labelling of chemicals

The European Commission welcomed the agreement by the EU Member States to align EU legislation on classification, labelling and packaging of substances and mixtures to the United Nations Globally Harmonised System (GHS). This new system is supposed to ensure that the same hazards will be described and labelled in the same way all around the world. By using internationally agreed classification criteria and labelling elements, it is expected to facilitate trade and to contribute towards global efforts to protect humans and the environment from hazardous effects of chemicals. The new regulation will complement the REACH regulation on the registration, evaluation, authorisation and restriction of chemicals. The European Parliament already the 3rd of September this year approved the GHS regulation. The next step will be its publication in the Official Journal of the EC.

The regulation will require companies to classify, label and package appropriately their hazardous chemicals before placing them on the market. It aims to protect workers, consumers and the environment by means of labelling which reflects possible hazardous effects of the chemical, while also taking over from REACH notification of classifications to the European Chemicals Agency (ECHA) in Helsinki.

The regulation will after a transitional period replace the current rules on classification, labelling and packaging of substances (Directive 67/548/EEC) and mixtures (Directive 1999/45/EC). After entry into force, the deadline for substance classification according to the new rules will be 1 December 2010 and for mixtures 1 June 2015.

More information about the new rules can be found under:

http://ec.europa.eu/enterprise/reach/index_en.htm

http://ec.europa.eu/environment/chemicals/ghs/index_en.htm

Whether the highly acclaimed expectations are later met by reality, has to be seen.

ECHA (European Chemical Agency)

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European Chemicals Agency (ECHA) runs the REACH-IT portal

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

ECHA held its first stakeholder's day on October 10, 2008. The outcome is published here:

http://echa.europa.eu/home_en.asp

General information and more events by ECHA, related to REACH, see the website:

http://echa.europa.eu/home_en.asp

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 Mirror Group meetings and the last workshops, see the EPAA-website:

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

EPAA-newsletter of September 2009 is published and can be read here:

http://ec.europa.eu/enterprise/epaa/epaa_newsletter_200903.pdf

NEWS:

EPAA Annual Meeting 2009 has taken place on Nov. 6, 2009 in Brussels in the premises of the European Commission (Charlemagne Building) The conference theme was "dissemination of 3R-aspects". A press release and the presentations can be downloaded on the following link.

http://ec.europa.eu/enterprise/epaa/4_2_conf_2009.htm

A poster exhibition and competition was held in the context of the EPAA 2009 Annual Conference dedicated to dissemination of 3Rs information.
EPAA invited companies, academia, research institutes and other organisations to provide posters describing, in lay language, initiatives related to the dissemination of 3Rs information and expected 3Rs impact (enhancing 3Rs development, uptake and regulatory acceptance). The aim of the poster session was to gather and highlight dissemination initiatives at national or international level with indication of synergies and complementarity of different approaches. The 2009 award was granted to: M. Vivier and V. Rogiers of *ecopa*/VUB, for their poster entitled: "*ecopa*, partner in dissemination of results in different EU projects".

http://ec.europa.eu/enterprise/epaa/4_events/ann_conf_2009/posters_13_v_rogiers.pdf

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

http://imi.europa.eu

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I.1.3. IMI is launched

The Innovative Medicines Initiative (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.

Executive Director appointed

At its meeting of June 10, 2009 the Innovative Medicines Initiative Joint Undertaking's Governing Board took the decision to appoint **Professor Michel Goldman** as Executive Director of the IMI JU. Professor Goldman was chosen out of a shortlist of candidates following the selection and appointment procedures. He will take his position once the employment contract with the IMI JU has been finalized and signed.
Michel Goldman is Professor of immunology at the Faculty of Medicine of the Université Libre de Bruxelles (ULB) in Belgium.

Outcome of First Call published. More see here:

http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/802

A working group with IP experts and representatives of the IMI Founding members and of the Member States has been set up at the request of the IMI JU Governing Board. The aim is to exchange views on the IMI IP policy and coordinate a targeted dialogue between interested parties. Clarification note - IMI IP policy available. More info see here:

http://www.imi.europa.eu/intellectual-property_en.html

More information can be found here:

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

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

See the website of IMI here and check the upcoming events:

http://www.imi.europa.eu/index_en.html

I.2. Other News

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I.2.1. Nanotech, Ecological Risk Asessment Symposium

The US Environmental Protection Agency (EPA) and its Science Policy Council had issued a nanotechnology white paper. The paper was 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

US Environmental Protection Agency (EPA) and its Science Policy Council has also installed a

Framework for Application of the Toxicity Equivalence Methodology for Polychlorinated Dioxins, Furans, and Biphenyls in Ecological Risk Assessment

Organized in accordance with EPA's Guidelines for Ecological Risk Assessment, this framework is intended to assist EPA scientists in using the toxicity equivalence methodology in ecological risk assessments that involve dioxins and dioxin-like chemicals, as well as to inform EPA decision makers, other agencies, and the public about this methodology.

More information see here:

http://www.epa.gov/osa/raf/teffframework/index.htm

I.2.2. Review of Directive 86/609

The new version is out since November 5th, 2008, and being discussed in the member states and its administrative representative groups. Article 44-46 in chapter IV, address alternatives specifically.

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 will be determined following the *ecopa* Annual Meeting and the hand over Meeting of December 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 was the representative in the Advisory Board, the project has been finalized.
- *Liintop* – Horst Spielmann is the representative in the Advisory Board.
- *ReProTect* – arin Gabrielson, Vera Rogiers and Bernward Garthoff (Chair) were representatives on the Supervising Board, and *ecopa* was seconding in the dissemination of results. The project has ended with December 2009.
- *START-UP* – START-UP is the *ecopa*-follow-up-project for CONAM and will end in the first quarter of 2010.
- *ESNATS - ecopa* is lead part of the dissemination workpackage.
- *ecopa* – latest *ecopa*-Board meeting took place on October 1, 2009 in Budapest/Hungary. The minutes

of the *ecopa*-Board Meeting can be obtained here:

Minutes *ecopa* Board Meeting of February 25, 2009, in Rome, Italy (33 kb)

The hand over Meeting of the Management Board will take place on December 22, 2009; further info follows thereafter.

The European Commission has published a booklet on all European FP7-projects concerned with alternative testing, it was also distributed by ecopa. You can download it from this link:

http://www.ecopa.eu/download.php?file=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 16th Congress on Alternatives to Animal Testing – Linz 2010 is being prepared, it will take place on September 3-5, 2010 in Linz, Austria.

II.1.1.2.2. Belgian Platform
» Foundation Prince Laurent

II.1.1.2.3. Czech Platform
» CZECOPA

II.1.1.2.4. Danish Platform
» DACOPA

II.1.1.2.5. Dutch Platform
» Not active at the moment!

- ZonMW, which has taken over activities from NCA (Dutch Center for Alternatives), presented their activities during the Annual *ecopa* Workshop. In 2009 an information day for the general public and a presentation of the "W. van Heumen" award (25.000 Euro) to Prof. T. Huizinga were held. A new programme ("Dierproeven Begrensd III") for M€ 2,2 was started, and a "Pearl" presentation of an alternatives for animal use project for the development of a skin model that can be used to test the safety of chemicals and medicines as well as be of use in cancer research. ZonMW also co-organised the Workshop on Reduction of the START-UP project in Austria. A commission of analyses of trends in society and science in animal experimentation and a commission of setting the (research) agenda for priorities for alternatives in animal use (which will be used to advise the Dutch government) were formed.

  Plans for 2010 include a new call for grant applications, deliver reports on trend analyses and (research) priorities and an exploration of combining calls on alternatives for animal use and stem cells. ZonMW will also enhance its efforts in *ecopa*.

II.1.1.2.6. Finnish Platform
» Fincopa

- Fincopa 's website:
  http://www.uta.fi/jarjestot/fincopa/

II.1.1.2.7. French Platform
» Plateforme Nationale pour le développement des Méthodes alternatives à l'experimentation animale

II.1.1.2.8. German Platform
» Stiftung set

- Stiftung set organized, together with the Hungarian platform hucopa, the Workshop on Replacement on October 2-3, 2009. This Workshop was part of the FP7 EU-project START-UP.

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

II.1.1.2.9. Hungarian Platform
» Hucopa

- In 2009, hucopa was mainly engaged in organizing the 3rd START-UP Workshop, a workshop on Replacement held in Budapest, at Ferihegy Airport on 2-3 October 2009. hucopa organized the workshop in cooperation with the German Platform, the Foundation for the Promotion of Alternate and Complementary Methods to Reduce Animal Testing (SET). Following the START-UP workshop, as a joint event, a local conference of the Hungarian platform was held on the 3R topicalities in Hungary.

  Furthermore, the beagle and laboratory rodent adoption/retirement project of hucopa remained to be successful. Future plans of hucopa for the next years:
  To draw public into the 3R sphere and to distribute information about animal welfare efforts in research, hucopa plans to organize a conference for the public on 3Rs. Furthermore, we will continue the successful adoption/retirement project of lab animals. On the side of education (and future veterinarians) the Department of Physiology and Biochemistry, Faculty of Veterinary Sciences (Budapest) aims to introduce a new elective course on 3Rs and alternatives to animal testing for veterinary students in Hungarian and in English. In addition, the Department plans to improve their recently renewed, 3R-conscious Physiology lab course and aims at enriching their tools with Team-based Learning and Distance Learning, in cooperation with the Purdue University (IN, USA).

  More emphasis will be put on the expansion of hucopa and on building new public and professional relations. As an organic part of it, hucopa intends to search for new funds. Last but not least, hucopa plans to improve the webpage and to develop its English version.

  http://www.hucopa.hu/

II.1.1.2.10. Italian Platform
» IPAM - Italian Platform on Alternative Methods

II.1.1.2.11. Irish Platform

II.1.1.2.12. Norwegian Platform
» Norecopa

- Norecopa, Norway's National Consensus-Platform (www.norecopa.no) was established in October 2007. It receives an annual budget of approx. 100,000 euro from the Ministries of Agriculture & Fisheries. In addition, about 50 organisations and institutions are members of Norecopa (for a nominal subscription of approx. 60 Euros per year), while a small number of individuals pay approx. 15 euro for personal membership.

  Norecopa also cooperates closely with the Laboratory Animal Unit at the Norwegian School of Veterinary Science (http://oslovet.veths.no). This Centre has recently opened a Multimedia Room / Training Clinic equipped with a large range of manikins, interactive computer simulations and other training equipment to replace or reduce the need for animals in the teaching and training of veterinary students, veterinary nurses, researchers and technicians (http://oslovet.veths.no/multimedia). Norecopa has sponsored the running of this facility.

  Norecopa is still campaigning hard to win political support for the establishment of an independent state fund for research and development of 3Rs alternatives. Norecopa's yearly activities are approved by the Annual General Meeting in June and then managed by the Board and its secretary. Among the activities this past year are:
  - An International Consensus Meeting entitled "Harmonisation of the Care and Use of Fish in Research", held at Gardermoen, Oslo 22-24 September
    http://www.norecopa.no/sider/tekst.asp?side=89
  - Cooperation with the Norwegian Research Council. This has resulted in the production of a 100-page report (in Norwegian) on research needs within animal welfare of fish used in experiments
  - The production of science-based position statements
    http://www.norecopa.no/sider/tekst.asp?side=50 on
    a. The use of toe clipping to identifiy and genotype young rodents
    b. Food deprivation in rodents
  - Development of the Norecopa website to include an A-Z of guidelines that can be used when planning animal experiments
    http://www.norecopa.no
  - Translation into English of a compendium in Laboratory Animal Science for fish researchers
    http://oslovet.veths.no/dokument.aspx?dokument=208
  - A scientific seminar on statistical design
    http://www.norecopa.no/sider/tekst.asp?side=77
  - Financial support for individuals wishing to attend 3Rs meetings
  - Focus on the use of fish as research animals, including vaccine development and the need for more knowledge on how to optimalise fish welfare (including environmental factors, humane endpoints, welfare indicators, anaesthesia and analgesia)
  - A newsletter produced approx. every 5-6 weeks

  http://www.norecopa.eu/

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 celebrated its 10th anniversary on December 1, 2009 in Madrid. A presentation of Bernward Garthoff on behalf of *ecopa* was disseminated.
- The REMA activities can be found at (Spanish version):

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

II.1.1.2.15. Swedish Platform
» Swecopa

- Swecopa held its 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), Rebecca Ceder (Karolinska Institute) and Helena Elofsson (Board of Agriculture).
- News from Swecopa is published 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 at info@swecopa.se if you want to receive the newsletter.

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

- Decisions on new projects will be taken by the end of the year.

  Further details on the website:
  http://www.forschung3r.ch/
- Latest bulletin of October 2009 "A novel in-vitro cell model of the human airway epithelium" to be found here:
  http://www.forschung3r.ch/en/publications/bu41.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

As part of the project, a review "of the Implementation of the Embryonic Stem Cell Test (EST)" has been published in ATLA, see publication section. The final Annual General Meeting was held near Ispra, Italy on December 7, 2009.

The last Supervising Board Meeting, held on December 8, 2009 by teleconference. The project is close to end herewith.

A brochure on the ongoing activities within ReProTect is available on the website:

http://www.reprotect.eu/

Publishable executive summary 2008

A publishable executive summary for the year 2008 can be downloaded from the website:

http://www.reprotect.eu/index.php?id=11004

You find an informative flyer below, as well as the brochure presenting the first results.

PDF: ReProTect Brochure

PDF: ReProTect Flyer (320 kb)

ecopa is involved in the Board and the results dissemination.

www.acutetox.org

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II.1.3. ACuteTox

II.1.3.1. 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: http://www.expertradet.se, http://www.acutetox.org
http://www.ecopa.eu/download.php?file=ACuteTox_e-learning_abstract.pdf

www.sens-it-iv.eu

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II.1.4. Sens-it-iv

Sens-it-iv is an integrated EU-funded research project (LSHB-CT-2005-018681)involving 28 partners, drawn from across Europe, of which 9 represent industry, 15 groups represent universities or research institutes, while 4 groups represent organizations. They are joined together by the common goal of developing alternative strategies to animal testing for the assessment of skin and/or respiratory sensitizing potential of chemicals. This includes the development of predictive *in vitro* methods.

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.

II.1.4.1. 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. 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 32nd edition is available via the website or the link below. The newsletter is coordinated by the WP9 leader.

The Sens-it-iv Newsletter Nr. 34 is out:

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

Newsletter-subscription possibility on the website.

The General Assembly has been held on October 5, 6 and 7, 2009, at Hotel Pueblo Acantilado, in El Campello near Alicante, Spain. A Summer school has been held from June 29th till July 2nd, 2009 with the title: practical and theoretical course on Sens-it-iv *in vitro* methods at the University of Applied Sciences HU, Utrecht, The Netherlands. The course was about theoretical and practical laboratory aspects of sensitization, pathology, cell culture models, data handling and experimental design.

A next Summer School will be organised in 2011. More information will be disseminated via the newsletters and the website.

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.1.5. 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.1.5.1. Recent News

The BioSim project is now ended. The final 5th BioSim Conference was held in Christiansborg, Copenhagen, from August 25 to 29, 2009, hosted by the Danish Parliament, and attended by about 160 participants.

The meeting, this time, covered other aspects than the scientific ones, which have been, however, the most relevant and interesting.

Presentations have been given by institutional and political representatives on the relevance of this project for the Danish institutions, in terms of international prestige, scientific and educational impact. From the University side, the relevance of interaction between natural and technical sciences has been stressed, as well as that between academia and industries. The challenge that universities are now facing is to prepare students for jobs which do not yet exists: thus there is a special need of economical but also cultural investment. A session has been devoted to "Biosimulation vis-a-vis the ethical and social issues of global drug development". Some lectures from Novo Nordisk A/S researchers and administrators on industrial research and social responsibility were given.

Moreover, the relevance gained by the Corporate Social Responsibility (CSR), which implies a change in the attitudes of the Companies in relation to ethical "hot" issue, has been illustrated by an EU Commission representative. The EU-perspective is whereby companies may integrate societal and environmental concerns in their business operations and in their interactions with the stakeholder on voluntary basis. CSR, indeed, can be a tool that not only opens the dialogue among companies and the public at large, but also may have a positive feedback on the economy of the enterprise.

The main scientific session was dealing with "Biosimulation and model-based treatment of patients" and "Application of biosimulation in drug development". The final sessions were devoted to the use of biosimulation in the health sciences and to the most recent results of the BioSim project. The issue of why, where, and when the modelling should be applied has been widely debated: still more rational approaches are needed, together with semantic clarification concerning f.i. the very concept of "system". Moreover, it should not be forgotten that modelling may start from data and not from a hypothesis and, thus, data source, mining etc., is of extreme importance. The Virtual Human and Personalised Medicine have been recurrent topics, which may look, at glance, still very far away technological goals, but scientific approaches such as biosimulation of complex system, makes them thinkable, and even feasible, in a not too far future.

It goes without saying that much appreciation has been expressed for the outstanding scientific guidance of Erik Mosekilde, which, from now on, will act as counsellor of any future plan, and for Anne Marie Clemensen, who made such a wide network to work easily and friendly, coping at the same time with the expected time schedule and administrative issues.

The principal Scientific Officer of the BioSim, presenting the next calls in the area of predictive medicine, provided ideas and information about future possibilities for this network, or at least part of it, to continue its successful journey... and we are sure that this would be the case.

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II.1.6. Liintop

II.1.6.1. 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.1.7. 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.1.7.1. Recent News

PDF: CarcinoGENOMICS Press Release (24 kb)

A workshop was organized by the carcinoGENOMICS project, the subject was 'Genomics in Cancer Risk Assessment'. It took place on August 27 - 28, 2009 on San Servolo Island, Venice, Italy. This was a parallel Satellite Workshop to the 10th International Conference on Environmental Mutagens (ICEM), on Augustus 20 - 25, 2009 in Firenze and the VIIth World Congress on Alternatives & Animal Use in the Life Sciences, on August 30 – September 3, 2009 in Rome, Italy.

PDF: CarcinoGENOMICS Workdhop Programme (225 kb)

At this workshop on Genomics in Cancer Risk Assessment the state-of-affairs in chemical cancer risk assessment was explored and the possible contribution of genomics and systems toxicology with respect to tackling the current flaws and uncertainties were discussed. Most importantly, the organizers were successful in bringing together leading experts from academia, industry and regulatory authorities for this. They were also able to identify the road lying ahead: by taking the systems toxicology approach, generating mechanistic information on toxic responses from bioassays consisting of human cells, and linking this with growing insights in molecular processes underlying human pathophysiologies.

For more information:

http://www.hesiglobal.org/i4a/pages/index.cfm?pageID=3432

The next carcinoGenomics Board Meeting will be held in Basle/Switzerland, February 11-12, 2010.

MPIMG publishes a book on systems biology methods

In this book that was partly funded within carcinoGENOMICS, basic tools and methodologies for analysing biological networks are described. The intended readership of the book are students and lecturers but also advanced researchers.

Details:
Klipp E, Liebermeister W, Wierling C, Kowald A, Lehrach H, Herwig R (2009) Systems biology - a textbook. Wiley-VCH Weinheim. In press.
Publisher's website advertisement:

http://www.wiley-vch.de/publish/en/books/bySubjectLS00/ISBN3-527-31874-7/

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

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SusChem European Technology Platform For SUSTAINABLE CHEMISTRY

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/

SusChem newsletter #12 is now online:

http://www.suschem.org/content.php?pageId=3739

A detailed review of the SusChem platform activities can be found in a supplement of the September 22 issue (2008) of the ICIS Chemical Business.

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

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. Project no. LSHB 201187.

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 was 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.

NEWS:
The first major workshop of the START-UP project, on Refinement, was held in Rome, Italy, at the L'Istituto Superiore di Sanità (ISS) on February 26-27, 2009. The second workshop, on Reduction, has been held on July 3-4, 2009, in Innsbruck, Austria. The third workshop, on Replacement, was held on October 2-3, in Budapest, Hungary.

At the moment, reports are being prepared for editing the final report to be supplied to the European Commission, by the end of February, 2010.

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:
The upcoming esnats General Meeting is scheduled for April 26-28, 2010 in Ispra/Italy.
Esnats-website: http://www.esnats.eu

Miscellaneous

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III.1. Events

III.1.1. *ecopa* events

III.1.1.1. 10th Annual *ecopa* Workshop

The future *ecopa* Annual Meetings will be:
11th: end of November 2010

III.1.1.2. *ecopa* Board meeting

The next *ecopa* Board meetings:
- Dates will be set after the 10th Annual *ecopa* Workshop

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.

III.1.2. other events

III.1.2.1. 2nd Annual: Immunogenicity 2009:Assessing the Risk and Clinical Relevance of Immunogenicity in Biotherapeutics Development
January 14–15, 2010 in Barcelona, Spain

This Marcus Evans conference offers the environment for benchmarking and networking with thought-leading researchers in immunogenicity. Scientists from pharmaceutical and biotech companies will present in-depth industry case studies and new academic findings, while representatives of regulatory agencies will give updates and answer questions from the audience.

For more information:
» http://www.marcusevans.com/html/eventdetail.asp?eventID=15911&SectorID=31

III.1.2.2. ADME, PK/TK, and Drug Metabolism in Drug Discovery and Development
January 26-27, 2010 in Brussels, Belgium

For more information:
» http://www.mondialresearchgroup.com/images/Training.pdf

III.1.2.3. 5th Annual International Conference on Predictive Human Toxicity and ADME/Tox Studies
January 28-29, 2010 in Brussels, Belgium

For more information:
» http://www.mondialresearchgroup.com/index.php?whereTo=humt10

III.1.2.4. Literacy courses in molecular biology/biotechnology

Designed for people in companies or organizations that are faced with biological information but have no formal training: attorneys, business people, chemists, computer scientists, engineers, healthcare professionals, investors, journalists, politicians, regulatory affairs specialists...

Next sessions in 2010:
January 28-29 , Rolle (Lausanne-Geneva) Red Biotechnology (medicine and pharma); February 11-12, Bern Red Biotechnology (medicine and pharma); February 18-19, Uetliberg (Zurich) General Biotechnology (red + white + green); April 8-9, Uetliberg (Zurich) Red Biotechnology (medicine and pharma)

For more information:
» http://www.loroch.ch/molbio/course_announcement.htm

III.1.2.5. 2nd International Conference on Drug Discovery and Therapy
February 1–4, 2010 in Dubai, UAE

The 2nd ICDDT 2010 will highlight cutting-edge advances in all major disciplines of Drug Discovery and Drug Therapy. This four-day event will feature recent findings from leading industrial, clinical and academic experts in the field, in the form of lectures and posters. The 2nd ICDDT 2010 will promote the translational nature of modern biomedical research, with an equal number of speakers/participants those who are basic scientists in drug discovery and those who are medical doctors associated with direct patient care and research.

For more information:
» http://www.icddt-dd.com

III.1.2.6. CEFIC-LRI Workshop 'Applicability of skin sensitization testing methods for regulatory purposes'
February 2–3, 2010 in Brussels, Belgium

The workshop welcomes stakeholders from industry sectors, academia, NGOs and regulatory agencies. The workshop is aimed at ensuring a common understanding of the applicability of the current animal tests (OECD 429/LLNA and OECD 406/guinea pig tests), consolidating industry's experience with these tests. Furthermore, to increase awareness of the strengths and gaps of these test methods in order to optimize the process of developing future non-animal alternative skin sensitization methods.

For more information:
» http://www.workshop-sensitization-methods.org/

III.1.2.7. i-SUP2010: Innovation for Sustainable Production 2010
April 18-21, 2010 in Bruges, Belgium

I-SUP2010 will focus on the intertwining of all those disciplines involved in sustainable development taking into account societal, technological and scientific issues in a broad and integrated range of domains. I-SUP2010 invites you to discuss with all stakeholders involved in this process by combining six international congresses at the same time and the same location, each aimed at a specific target audience of industry leaders, universities, research institutes and decision makers covering such fields as: Sustainable production, Sustainable chemistry, Sustainable energy, Materials for sustainable Production, Carbon Capture and Storage (CCS) and In vitro methods replacing animal testing (CARDAM).

For more information:
» http://www.i-sup2010.org

III.1.2.8. Drug Safety Conference
May 25-27, 2010 in Washington DC, USA

The objective of this new conference is to bring together the three corners of the safety triangle: Industry, Academia and Regulators. With the emergence of biologics and biologicals, and the application of new approaches and techniques for drug discovery, the need for clarity, transparency and accountability has grown. It is the expense of time, resources and effort that require attrition – not drug discovery. Therefore it is essential that the three corners of the 'safety triangle' can see one another, recognise one another's position, communicate and interact. The purpose of this meeting therefore is to highlight the gaps between industry, academia and regulators and identify ways of bridging them. To do so, participants are encouraged to consider ways of overcoming the three main obstacles to progress: the restrictions of economics, the clarity of regulatory guidance and the limits of scientific knowledge.

For more information:
» http://mail.elsevier-alerts.com/go.asp?/bECO001/m9AOD51F/uJXFV51F/x9HGV51F

III.2. Awards and Publications

III.2.1. Booklet on Alternative Testing Strategies

The European Commission has published a booklet on all European FP7-projects concerned with alternative testing.

You can download it from this link:
» http://cordis.europa.eu/documents/documentlibrary/106691831EN6.pdf

III.2.2. The revision of the EU Directive on the protection of animals used for scientific purposes

This has been published by the Authority of the House of Lords. This report is a reaction from the UK National Parliament to the Commission's proposal (COM(2008)543) for the revision of Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes.

You can download it from this link:
» http://www.publications.parliament.uk/pa/ld200809/ldselect/ldeucom/164/164i.pdf

III.2.3. The Scientist publishes a 2009 Top 10 Innovations in life sciences

Among the winners are imaging, genomics and other tools that can capture both intracellular and extracellular processes.

Read more:
» http://www.the-scientist.com/article/display/56171/

III.2.4. NC3Rs Newsletter Issue 24 released

For more information:
» http://www.nc3rs.org.uk/

III.2.5. 5th LRI Innovative Science Award

The European Chemical Industry Council (Cefic) is inviting young scientists to apply for the 5th LRI Innovative Science Award, which this year addresses the much-debated issue of exposure to multiple environmental factors. The competition is open until **March 19, 2010**. The winner will be announced in J**une 2010**

For more information:
» http://www.cefic-lri.org/

III.2.6. EFSA published an opinion on the replacement, reduction and refinement of animal testing

Existing approaches incorporating replacement, reduction and refinement of animal testing: applicability in food and feed risk assessment.

The founding Regulation of EFSA requires the Authority to contribute to a high level of protection of human life and health, and in this respect to take account of animal health and welfare. EFSA is committed to a proactive animal welfare approach, based on sound scientific principles and the need to ensure that adequate data are available for a reliable risk assessment. In this context, EFSA and its Scientific Committee recognise the importance to stimulate the use of food and feed assessment approaches that would not only minimise the number of experimental animals and any suffering, but also work towards their replacement.

For the full text:
» http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902559349.htm

III.2.7. Toxicity testing gets a makeover

The European Commission has revealed details of a major new research programme to develop a modern, high-throughput approach to repeat-dose toxicity testing.

For the full text:
» http://www.nature.com/news/2009/090908/full/461158a.html

III.2.8. Science Room eBulletin November 2009

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

III.2.9. Stem cells online journal

For more information:
» http://www.stemcellsportal.com

III.2.10. A Review of the Implementation of the Embryonic Stem Cell Test (EST)

The report and recommendations of the ECVAM/ReProTect Workshop organized in May 2008 in Frankfurt/Germany were published recently in ATLA 37, 313–328, 2009.

Board Members of *ecopa* were contributing in the organisation and critical discussions, as well as the final publication.

III.3. Calls and Vacancies

III.3.1. 4th call of the EC Seventh RTD Framework Programme

This call will address the replacement of animal tests in repeated dose systemic toxicity testing, through the topic HEALTH.2010.4.2-9 "Towards the replacement of repeated dose systemic toxicity testing in human safety assessment", of the Health Programme. The topic might be of interest to you and your project partners. It is strongly supported by industry and in particular by The European Cosmetics Association (COLIPA). More information about additional funding possibilities may be obtained from the COLIPA's website (www.colipa.eu) and in the enclosed COLIPA's leaflet. It is important to note that the funding modalities differ from the standard FP7 funding schemes.

This information is also available here:
http://cordis.europa.eu/fp7/home_en.html

III.3.2. ECVAM is renewing its Scientific Advisory Structure: Two Open Calls for Scientists

The European Centre for the Validation of Alternative Methods (ECVAM) is currently renewing its Scientific Advisory Structure.

Two Open Calls: ESAC and EEP

In the context of this renewal (more details below), ECVAM is publishing Two Open Calls for the Expression of Interest addressed to experts in life and environmental sciences, medicine, chemistry, toxicology, test method and test strategy validation, risk assessment and scientists knowledgeable in other areas such as statistics, biometry, epidemiology, modelling approaches.

• The first call is dedicated to the new **ECVAM Scientific Advisory Committee (ESAC)**. The 19 ESAC members, preferably senior scientists with a generalist profile, will be in charge of advising ECVAM on all scientific aspects of its work and in particular with regard to the scientific validity of methods which replace, reduce or refine animal experiments. **Deadline for submitting an expression of interest in the ESAC was September 30, 2009. In the mean time members were identified and informed.**

• The second call concerns the formation of an ECVAM Expert Pool (EEP), supporting ECVAM's mission through direct expert advice to ECVAM and ESAC, e.g. through their participation in ESAC Working Groups, task forces or workshops. Preference will be given to experts with profound specialist knowledge in one or few areas. The call will be published mid September. **No deadline is foreseen at present.**

All relevant information including the application procedure can be found on:
http://ecvam.jrc.ec.europa.eu/index.htm

III.3.3. 29. Tierschutzforschungspreis – Ausschreibung BMELV / Call by the German Ministry for Food, Agriculture and Consumerhealth: 29th Award of Animal Health Research

Deadline: March 31, 2010.

Details (in German only) here:

http://www.bmelv.de/SharedDocs/Standardartikel/Landwirtschaft/Tier/Tierschutz/Tierschutzpreis-Ausschreibung29.html

III.4 VARIA

III.4.1. New visual identity, web/e-mail addresses and organisation chart of the European Medicines Agency, EMEA

On December 8, 2009, the new visual identity has been launched, comprising a new logo, new colour chart, new typography and rebranded materials based on these elements. Advance notice of this was given, so that people would not be surprised when they saw new documents and other materials emerging from the Agency that do not bear the familiar 'EMEA' logo. The new visual identity is created as part of a wider effort to improve the quality and consistency of EMEA's communications with partners, stakeholders and the public. The main benefit is that EMEA's communications materials will now be based on professionally designed templates, and have a more harmonised look and feel than current materials. The cornerstone of the new identity is a new logo, which reflects more accurately the nature and character of the Agency, which has evolved significantly in the 15 years since it, and the original logo, were created.

For more information:
» http://www.emea.europa.eu/pdfs/general/direct/74766509en.pdf

III.4.2. CAAT 3Rs Centers website

Across the globe, organizations are working to reduce, refine, and replace animal experiments. You can search for these organization by the map, by name, keywords, or by associated tags. This database is provided and maintained by The Johns Hopkins University Center for Alternatives to Animal Testing (CAAT).

For more information:
» http://caat.jhsph.edu/international_alternatives/

III.4.3. Indian teachers call for replacement of dissections and animal experiments; major financial investment in life science education made

Indian university teachers meeting in Jaipur, Rajasthan for a national alternatives conference have concluded with a call for full replacement of dissections and animal experiments. In a Resolution adopted unanimously at the 'National Workshop cum Symposium on Potential Alternatives to Dissection and Animal Experimentation in Zoology and the Practical Curriculum', 19-21 November 2009, the participants called on University Boards of Studies to remove animal use from the syllabus.

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