ecopa messenger

March 26, 2010, edition #23

Dear *ecopa* messenger subscriber,

The new *ecopa* Board has met on February 10, 2010 in Brussels, the minutes are available on request from the Secretary General, Stijn Budts.

In regard to the START-UP project, the organizers of the various workshops are meeting on Friday March 26, 2010 to finalize the report, issue recommendations from the discussions and come up with a road map for the EU Commission for future follow up.

Watch for the next *ecopa* messenger in June, and please direct future news updates and contributions to Troy Seidle at tseidle@hsi.org.

Bernward Garthoff

P.S.: Any proposal or recommendation regarding style, content or distribution of the newsletter is highly welcome and appreciated. If you know other people or institutions interested, have them visit our website and subscribe to this newsletter.

Issue # 23 (March 2010)

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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 is operational

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://www.epaa.eu.com/

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

http://ec.europa.eu/enterprise/epaa/5_news/epaa_newsletter_200912.pdf

NEWS:

A flash report on the Workshop on Dissemination, which took place on November 5, can now be read on the following link:

http://ec.europa.eu/enterprise/epaa/4_events/4_3_workshops/flash_report_dissimination251109.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.

Innovative Medicines Initiative (IMI): the Commission and the pharmaceutical industry have launched the second call for research proposal towards more efficient drug development methods, on November 27, 2009.
The application deadline for the new Call for proposals was February 8, 2010 and the results will be announced in Summer 2010.

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

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

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. See more under III.2.13.

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* – Karin 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 February 10, 2010 in Brussels.

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
»

- In the spring of 2009 the call for the ZonMw 'Alternatives for Animal Use' research programme was opened. The call was specifically open to projects in the phase of (pre)validation and implementation. In December 2009 nine high quality research projects were rewarded. In total, approximately 2,2 million euro was granted. The topics of the rewarded projects are:

  - 'Development of tolerogenic vaccines in animal-free models'

  - 'Implementation of (Q)SAR and physiologically-based kinetic (PBK) modeling techniques into a (Q)SAR-PBK approach for predicting dose-response relationships for rat and human and deriving safe

exposure limits in risk assessment practice'.

-'*In vitro* genotoxicity test using metabolic competent 3D human bronchial epithelial model as alternative to *in vivo* genotoxicity studies with inhalation exposure'

- 'Pre-validation of a two-tiered approach to determine the skin sensitizing capacity and potency of chemicals'

- 'Validation and implementation of rapid and cost-effective human *in vitro* screening assays to predict genotoxicity and carcinogenicity of chemicals and pharmaceuticals'

- Toxicogenomics of precision-cut liver slices for prediction of human liver toxicity, a prevalidation study' -' A human model for bone metastasis'

- 'Implementing and (pre) validation of combined existing *in vitro* assays for the hazard identification of chemicals following oral exposure'

- 'Interlaboratory study for replacement of the lethal challenge procedure by serology in lot release potency testing of whole cell pertussis vaccines'

To ensure further developments in the field of risk assessment we can now also welcome the Innovationprogramme ASAT "Assuring Safety without Animal Testing" within ZonMw. The ASAT program was initiated by the Dutch government to develop a new risk assessment method without animal use. In 2010 one of the initiatives will be to improve communication and cooperation between regulators/regulatory bodies and scientists.

Furthermore, in the beginning of this year the analyses of trends in society and science concerning animal experimentation were completed and presented to the ministry of Health, Welfare and Sports (VWS). ZonMw together with the Netherlands Knowledge Centre for Alternatives to animal use (NKCA) was commissioned to perform a programming study resulting in a Dutch (research) agenda on 3R activities. The report is expected to be finished this summer and will be presented to the ministry VWS. The ministry will send the reports on trends and the 3R agenda to the Dutch government.

II.1.1.2.6. Finnish Platform
» Fincopa

- Chair: Adjunct Prof. Tuula Heinonen, Ph.D. (director of FICAM, the Finnish Centre for Alternative Methods, http://www.ficam.fi) tuula.heinonen@uta.fi

  Secretary General: Dr Eila Kaliste, Ph.D. (presenting officer, Regional State Administrative Agency for Southern Finland), eila.kaliste@avi.fi

  In 2009 Fincopa took part in the organizations of the scientific programme of the START-UP Refinement Workshop organized by IPAM (in cowork with Fincopa and Polcopa) February 26-27, Rome.

  In connection of the 30-year Anniversary Symposium of the Finnish Society of Toxicology, FST (May 26-27.Tampere) Fincopa contributed to the organization of the session "Intelligent testing strategy".

  In 2010 Fincopa continues the cowork with the FST by organizing a half-day session in the joint symposium of FST and Fincopa, April 26-27, Helsinki. The main topic of the symposium is REACH and the testing requirements under it. Fincopa will have its Annual Meeting on April 27 at the end of the scientific symposium.

  Activities in the EU 6th Framework programme:
  - ReProTect project: Prof Kirsi Vähäkangas, partner
  - ACuteTox project: Prof. Hanna Tähti, Advisory Board Member
- 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 started 2010 by launching a totally redesigned website (www.norecopa.no), making it easier to find 3Rs resources. Although much of the site is in Norwegian, it includes English-language sections with, among other things, an A-Z of guidelines that are of use when planning experiments that may involve animals, plus all the presentations delivered at its consensus meetings on fish and wildlife research.

  Norecopa has started to plan its next international consensus meeting. This time the subject will be: Harmonisation of the Care and Use of Agricultural Animals in Research". The provisional dates for the meeting are 10th-12th May 2011 at Oslo airport, Gardermoen. Please contact Norecopa (post@norecopa.no) if you would like to suggest topics for this meeting. More information will be posted later on Norecopa's website.

  Norecopa is following up its last consensus meeting (on the care and use of fish in research) by creating a number of working groups, to tackle the specific issues raised at the meeting. These include challenges of vaccine development and testing, the production of an English-language compendium in lab animal science for fish researchers, and working groups that will produce guidelines for categories of severity and identification methods.

  An English translation is now available of the main points in a report commissioned by Norecopa and financed by the Norwegian Research Council, which looked at the research needs within welfare of fish used in research. This English summary can be accessed here:

  http://www.forskningsradet.no/servlet/Satellite ?c=Nyhet&cid=1253954265959&pagename=havbruk%2FHovedsidemal

  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.
- REMA board had a meeting in February 25th at the Instituto Nacional de Sanidad Ambiental (Instituto de Salud Carlos III) in Madrid. The Spanish platform is preparing a round table in the IUTOX Congress (http://www.iutox2010.org/) to be celebrated in Barcelona July 19-23, 2010. The title will be "Role of in vitro and in silico alternative methods and global impact for regulatory processes". The applicability of alternative methods in regulatory processes will be discussed. IUTOX will be an adequate forum for this topic because global approaches are requiring harmonised validation and acceptability. Participants representing industry and some institutions promoting alternatives have been invited. ECOPA will be represented by Adela López de Cerain. Next board meeting has been planed for June 21 in Barcelona under the sponsor of Laboratorios Ferrer.
- 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, 2009. 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

- Two new projects were funded:

  Organotypic brain slice cultures derived from regularly slaughtered animals as *in vitro* alternative for the investigation of neuroinfectious diseases in ruminants.
  See: http://www.forschung3r.ch/de/projects/pr_116_09.html

  Embryonic stem cell-derived *in vitro* model of tissue inflammation following confrontation with implant materials (INFLAPLANT).
  See: http://www.forschung3r.ch/de/projects/pr_117_09.html

  Further details on the website:
  http://www.forschung3r.ch/
- Latest bulletin of February 2010 "The blood-brain barrier in a dish: a new multicellular *in vitro* model" to be found here:
  http://www.forschung3r.ch/en/publications/bu42.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.

At the end of the year 2009, this project has ended.

A brochure on the activities within ReProTect is available:

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 by now the 37th edition is available via the website or the link below. The newsletter is coordinated by the WP9 leader.

The Sens-it-iv Newsletter Nr. 37 is out:

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

Newsletter-subscription possibility on the website.

The General Assembly will be held from April 26-28, 2010 in Berlin, Germany.

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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Liintop

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

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carcinoGENOMICS

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)

The last carcinoGENOMICS Board Meeting was held in Basel, Switzerland on February 11-12, 2010.

A workshop in regard to capacity building will be held on May 27-28, 2010 in the Crown Plaza Hotel in Brussels, in conjunction with the next Board Meeting.

http://www.carcinogenomics.eu/

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 twelfth SusChem newsletter is now online:

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

SusChem is organising a 'hybrid materials workshop' on March 3-4, 2010 in Luxembourg.

http://www.suschem.org/content.php?pageId=2494

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. 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:
- The exact date still has to be set.

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 reports, presentations, and the final programs of all the events up to now, are listed on the *ecopa* website in the archive section.

III.1.2. other events

III.1.2.1. 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.1.2.2. 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.1.2.3. Cell-Based Assays: Improved platforms and techniques for drug discovery, development and toxicity testing

April 20-22 2010 at BSG House, London , UK

For more information:
» http://www.bioportfolio.com/cgi-bin/acatalog/Cell-Based-Assays.html

III.1.2.4. IVTIP Spring Meeting 2010 Integrated *In Vitro* Testing Strategies

May 18, 2010 at Hotel Ramada Encore, CH-1227 Carouge-Geneva, Switzerland

Inspired by the latest US Environmental Protection Agency (EPA) strategic plan for evaluating the toxicity of chemicals 'Toxicity Testing in the 21st Century: A vision and a strategy', IVTIP organized a meeting (November 26th 2009, Edegem, Belgium) to discuss among scientists, key opinion leaders, developers and users of 3Rs-related tests and strategies how this vision could be transformed into a visionary reality.
One of the emerging concepts focused on integrating a defined number of tests modeling *in vivo*-relevant and well-characterized toxicity pathways representing mechanistic endpoints. Realizing that integrated *in vitro* testing strategies (ITS) currently are used in several sectors for early decision-making during product discovery and development, IVTIP have organized a meeting with the theme: Integrated *In Vitro* Testing Strategies - Implementation Challenges.

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

III.1.2.5. 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.1.2.6. Practical Methods for *In Vitro* Toxicology Workshop 2010
June 15-17, 2010 in Gaithersburg, Maryland, USA

The practical methods course combines both lecture and laboratory activities to provide a comprehensive introduction to *in vitro* toxicology.

For more information:
» http://events.constantcontact.com/register/event?oeidk=a07e2odovlhc093dc92

III.1.2.7. Skin *in Vitro* 2010
June 8-9, 2010 in Frankfurt Am Main, Germany

Human reconstructed skin models have become increasingly important during the last few years in different fields.
Reconstructed epidermis models already fully replace animal testing for skin corrosivity and skin irritation testing. They are used for substance testing in the regulatory context of the cosmetics directive and under the REACH legislation. More complex skin models are established research tools for the cosmetics and pharmaceutical industry as well as for academia. Especially in this area, the diversity of skin models and applications is rapidly growing.
The scope of this symposium is to discuss in depth the progress in use of skin models in research, efficacy and toxicity testing.

For more information:
» http://www.skininvitro2010.org

III.1.2.8. Submission of abstracts for ESTIV 2010 | EUSAAT 2010 | Linz 2010 is now open
September 2-4, 2010 in Linz, Austria

Abstracts can now be submitted for the forthcoming congress ESTIV 2010 / EUSAAT 2010 / Linz 2010. The deadline for the submission of lectures is April 30, 2010, deadline for the submission of posters is May 28, 2010.

For more information:
» http://www.eusaat.org/index.php/2010/submissionofabstracts

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. Hugo van Poelgeest award for Alternatives

Call in regard to this four-year award of 10.000 Euro for June 2010.

For more information:
» http://www.uu.nl/NL/faculteiten/diergeneeskunde/Actueel/nieuwsfaculteit/Pages/HugoPoelgeestprijs.aspx

III.2.4. NC3Rs Newsletter Issue 25 released

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

III.2.5. European Medicines Agency publishes draft paper for the strategic development until to 2015

The European Medicines Agency has published a draft paper setting out its vision for the strategic development of the Agency for the five years to 2015. Building on the progress of its previous five-year strategy, the Road Map to 2015 charts the way forward for the Agency amid rapid developments in medical science and pharmaceutical research, as well as the continuing evolution of the European and international regulatory environments. With this strategy paper to guide it, the Agency will seek to consolidate its achievements to date and further strengthen its role as a guardian of human and animal health in the European Union.

The document is available on the following webpage:
» http://www.ema.europa.eu/pdfs/general/direct/directory/29989509en.pdf

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. ESTIV Newsletter Issue 27 released

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

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. Call for research proposals – NC3Rs

Using the 3Rs as a framework for improving models of health research is a priority for the NC3Rs. Asthma has been chosen as the first priority area. NC3Rs is working with Asthma UK in seeking high quality applications to develop new experimental models of asthma with improved scientific and clinical relevance and reduced reliance on the use of animals and/or improved animal welfare.
The deadline for submitting an application is April 14, 2010.

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

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. Unilever-Hamner Postdoctoral Fellowship

Deadline: March 31, 2010.

The Hamner Institutes for Health Sciences in Research Triangle Park, North Carolina is seeking a postdoctoral fellow in its Program in Chemical Safety Sciences to study DNA damage response pathways. Under supervisions by both experimental and computational biologists, the successful candidate will use integrated systems biology approach to develop *in vitro* assays and in silico models for toxicity pathway perturbation by genotoxic agents. Applicants should have a Ph.D. or equivalent in biology, toxicology, or related discipline, supplemented with evidence of mathematical, programming, and modeling skills, or a Ph.D. in chemical/biomedical engineering, mathematics, or physics with sufficient training in molecular and cell biology. Excellent communication skills and the ability to work both independently and as part of a team will be essential.

For more information:
http://www.thehamner.org/careers/current-openings/index.html

III.3.4. Unilever-Hamner Assistant Investigator for *in vitro* Genotoxicity Research

Deadline: March 31, 2010.

The Hamner Institutes for Health Sciences is seeking an enthusiastic and innovative individual to lead a research effort to examine dose-dependencies of DNA-damage stress response pathway function with different classes of compounds. The research will be closely aligned with new testing and risk assessment initiatives proposed in the 2007 NRC report, Toxicity Testing in the 21st Century: A Vision and A Strategy. Tools involved in the research include genomics, high content assay (HCA), and computational systems modeling. Ph.D., Sc.D., DVM and/or MD plus 2-3 years of postdoctoral training and at least 5-7 years of research experience is required. Previous experience with DNA-damage/repair pathways, mutational analysis, and/or dose response modeling is preferred.

For more information:
http://www.thehamner.org/careers/current-openings/index.html

III.4 VARIA

III.4.1. Euro MP calls for action to find & fund alternatives to animal testing

Local Labour Euro MP, Arlene McCarthy is calling for European action to find more alternatives to experiments on animals. Animal Welfare Campaigner Arlene said: "But increased funding, better coordination and acceleration of administrative procedures could help even more, and I want the Commission to look at ways we can go further, faster." Arlene has added her name to a Written Declaration in the European Parliament. This calls for increased funding for the replacement of research using animals, and asks the European Commission to look into various options for increasing the funds available for this work. Arlene added "One option to fund this would be the introduction of a "research levy" of 1% of the selling price of products that contain ingredients tested on animals. This would mean that a product normally costing £5.00 would be just 5p more. "I'm aware that, at present, many researchers argue that some animal experiments are necessary to ensure the safety of products; that there just aren't sufficient alternatives available. We have to address this point." "We've taken important steps in Europe towards limiting tests on animals. The European Commission provides funding and services to promote the development and validation of alternatives to animal methods, not least through ECVAM (the European Centre for the Validation of Alternative Methods)."

For more information:
» http://www.arlenemccarthy.labour.co.uk

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. Nanotech safety bill introduced to US Senate

Nanotechnology safety legislation designed to address potential health and safety risks posed by the technology has been introduced to the US Senate.

For more information:
» http://www.in-pharmatechnologist.com/Industry-Drivers/Nanotech-safety-bill-introduced-to-US-Senate

III.4.4. First university in the Ural region signs formal agreement on stopping animal experiments

On February 4, 2010 a formal agreement between Perm State Pharmaceutical Academy and the International Network for Humane Education (InterNICHE) was signed. Perm State Pharmaceutical Academy now becomes the tenth Russian higher education institution to sign a contract with InterNICHE concerning the introduction of alternatives to animal labs. According to the contract terms, InterNICHE grants the academy computer programs for use in the classroom as an alternative to dissection and animal experimentation, while the Academy guarantees to stop all animal labs for students and commits to alternatives.

For more information:
» http://www.vita.org.ru