ecopa messenger

Spring edition, April 06, 2009, edition #19

Dear *ecopa* messenger subscriber,

The EU 7th Framework Programme research project, START-UP, which is coordinated by *ecopa*, went into its second year with the First Workshop on Refinement, the most challenging area within the 3Rs, in Rome, Italy, on Feb. 26/27, 2009. The presentations and the way of presenting it in an open discussion and debate format were well received.

Final Programme: START-UP Workshop Refinement (22 kb)

The internal project reports of the preceding expert meetings of 2008 of the START UP project were finalized and basis for the intense presentations and discussion. The next START-UP-workshop on Reduction is going to take place in Austria, organized by the Austrian and Dutch organizations. Please note the changed date: July 3 and 4, 2009 and place: Innsbruck. The draft program is currently being worked on.

ecopa has had its Annual Meeting addressing deadlines in the EU (in regard to animal testing and use of alternatives), but also issues for alternative methodology in the new Directive 86/609-draft, see Links for presentations and pictures here.

Presentations of the 9th Annual *ecopa* Workshop

Photos of the 9th Annual *ecopa* Workshop

In the meantime, issues which were addressed by *ecopa* in terms of being seen as critical, are now popping up accordingly, as there are:
- the difficulties of "global" waiving of animal testing in REACH, consequently the need for a data trading system, balanced and confidential, and, finally,
- the problem with the soft and unclear definition of "suitable" methods in the REACH-legislation resp. addendum XI (see editorial and letters to editors, addressing it), as well as the issue of validity, see references:

The 'µEST' in vitro test for embryotoxicity – Validated and endorsed or not? (132 kb)

Response to "The µEST in vitro test for embryotoxicity – A case of mistaken identity?" (128 kb)

ecopa is currently partner of 2 submissions to the most recent HEALTH call of the FP7; another series of calls is to be expected by July 2009 the latest in order to cover the 2010 starting period. Due to the fact that a major part of the *ecopa*-Board will terminate their tenure with the next Annual in November 2009, the Board convened before the START-UP-workshop in Rome in February to organize for an adequate procedure for the next elections and follow-up; a nomination/selection committee will contact the platforms within short.

Minutes *ecopa* Board Meeting of February 25, 2009, in Rome, Italy (113 kb)

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

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

Issue # 19 (April 2009)

top

I. *ecopa*:

I.1. General News

top

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)

top

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

top

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/uc.htm

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

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

NEWS:

Progress report 2008 published:

http://ec.europa.eu/enterprise/epaa/3_activities/32_progress_reports/epaa_report_final_081020.pdf

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

Last year's annual meeting has taken place on November 3, 2008 in Brussels. Topic in 2008 was "3 Rs - Research", the title being: "Research into alternative approaches (3Rs) in regulatory testing: Are we on the right track?". The 3Rs Declaration can be found here:

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

The Mirror Group of stakeholders including the EP, animal welfare organizations (until recently), institutions and patient groups *ecopa* is represented by four of it's members. Next meeting of the Mirror Group will be on April 22, 2009.

Eurogroup had withdrawn from EPAA:
Eurogroup for animals has decided to withdraw from the European Partnership on Alternative Approaches (EPAA) after receiving word that the European Commission had yet again delayed the publication of the proposal for new legislation on the protection of research animals.

Eurogroups letter to the Commission:
http://www.eurogroupforanimals.org/members_only/pdf/withdrawalEPAA171008.pdf

http://imi.europa.eu

top

I.1.3. IMI is launched

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

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

IMI First Call for proposals: Stage 2
• Open 23 October 2008 - 20 January 2009
• One Full Project Proposal per Topic
• Merger of the best Applicant Consortium and the EFPIA Consortium for each Topic
• Expert recommendations in the Evaluation Consensus Form must be taken into account for the Full Project Proposal

• Evaluation by independent experts February- beginning March 2009

More information can be found here:

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

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

I.2. Other News

top

I.2.1. Nanotech

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

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

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

See resp. paper here:

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

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

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

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

I.2.2. Review of Directive 86/609

The new version finally is out, since November 5th, 2008, and currently being discussed in the member states and its administrative representative groups in March and April under Czech Council presidency. 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

top

II.1.1.1. Recent News on FP6 and FP7 projects

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

- October 1, 2009 in Budapest, Hungary

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) are representatives on the Supervising Board, and *ecopa* is seconding in the dissemination of results.
- *START-UP* – START-UP is the *ecopa*-follow-up-project for CONAM.
- *ESNATS* - *ecopa* is lead part of the dissemination workpackage.
- *ecopa* – latest *ecopa*-Board meeting took place on February 25, 2009 in Rome, Italy. Get the minutes here:

Minutes *ecopa* Board Meeting of February 25, 2009, in Rome, Italy (113 kb)

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

You can download it from this link:

http://www.ecopa.eu/download.php?file=alternative-test-strat_en.pdf
A new brochure is in the making.

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 15th Linz-congress has taken place on September 19-21, 2008.
- Outcome:

http://www.zet.or.at/node,3,de,kongress.php

II.1.1.2.2. Belgian Platform
» Foundation Prince Laurent

II.1.1.2.3. Czech Platform
» CZECOPA

II.1.1.2.4. Danish Platform
» DACOPA

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

PDF: Latest issue of the NCA newsletter, published on November 25, 2008

II.1.1.2.6. Finnish Platform
» Fincopa

- A new board has been elected in Fincopa. The chair will be from now on Kirsi Vähäkangas, from the University of Kuopio, the position of vice chair will be taken by Tuula Heinonen, from the University of Tampere and Eila Kaliste, from the State Provincial Office of Southern Finland will be secretary. The treasurer still is Marianna Norring, from the University of Helsinki. Other members are: Päivi Alajuuma, Hannele Huuskonen and Helinä Ylisirniö.
  The vice members are: Immo Rantala, Heidi Diallo, Marika Mannerström, Paula Vesa, Christina Björklund, Kati Pulli and Paula Hirsjärvi.
- 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

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

On the homepage of the website, set offensively asks scientists to refer to the set's sponsoring programme and hand in scientific applications.

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

PDF: set Activity Report (76 kb)

II.1.1.2.9. Hungarian Platform
» Hucopa

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

  In context with the forthcoming START-UP event in Budapest in October 2009 addressing Replacement, jointly organized by the Hungarian and the German Platform, there will be a local Hucopa-event taking place as well.

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 organizes a third international consensus meeting, on the care and use of fish in research: Harmonisation of the Care and Use of Fish in Research, which will take place at the Oslo airport Gardermoen on September 22 – 24, 2009. International experts will present the latest updates on, among other topics, husbandry environmental enrichment, humane endpoints, welfare indicators, anaesthesia, analgesia and humane killing, guidelines for fish research.
  » For more information: http://www.norecopa.no/sider/tekst.asp?side=53
  » For more information: http://www.norecopa.no/norecopa/vedlegg/8programme-190309.pdf
- The Norwegian Animal Research Authority asked Norecopa to evaluate toe clipping as a means of identification and tissue sampling in mice. The Board produced an 18-page document, which has been circulated to all members. The document includes an evaluation of alternative methods for the identification and genotyping of rodents, with a literature references.
  » Translation of the final version: http://www.norecopa.no/norecopa/vedlegg/Norecopa-toeclip.pdf
- Norecopa's website, which contains a calendar of events, in Norwegian language with an overview page in English, can be reached here:
  http://www.norecopa.no/

II.1.1.2.13. Polish Platform
» Polcopa

II.1.1.2.14. Spanish Platform
» REMA – Red Española para el Desarrollo de Métodos Alternativos a la Experimentación Animal

- REMA has organized a meeting in parallel with the START-UP-expert meeting in Madrid in May 2008. This meeting took place in the building of the Ministry of Health.
- The REMA activities can be found can at (Spanish version):

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

II.1.1.2.15. Swedish Platform
» Swecopa

- **Government support for 3Rs research**
  The Swedish government has promised an increase in funding for 3Rs alternatives: 13 million SEK in 2009 instead of the 8 millions that was allocated in 2008. This is still far from the 18,5 millions that was allocated in 2006, but a step in the right direction compared to the decreases faced in the last 2 years.
- 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 us at info@swecopa.se if you want to receive the newsletter.

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

• The website of the Swiss Platform contains recent information on activities, events and developments.

Update on Activities:
April, 2009: Four new projects initiated by the 3R Research Foundation Switzerland.

Establishment of an organ ex-vivo tissue slice model for cardiovascular research in particular for therapeutic atherosclerosis targeting
Xueya Wang, Rahel Bänziger and Patrick Hunziker
Medical Intensive Care Unit, University Hospital Basel, Petersgraben 4, CH-4031 Basel, Switzerland

http://www.forschung3r.ch/en/projects/pr_111_08.html

A novel in-vitro model for the holistic assessment and optimisation of engineered tissue for functional cartilage repair
Zhijie Luo and Bahaa Seedhom
Leeds Dental Institute, Clarendon Way, Leeds LS9 9LU, UK

http://www.forschung3r.ch/en/projects/pr_112_08.html

Generic in-vitro evaluation assay for immunological correlates of protection to replace animal challenge infections
Kenneth McCullough and Artur Summerfiedl
Institute of Virology and Immunoprophylaxis (IVI), CH-3147 Mittelhäusern, Switzerland

http://www.forschung3r.ch/en/projects/pr_113_08.html

Reduction of the number of animals used in the Fish Acute Toxicity Test
Hans Rufli
ecotoxsolutions, CH-4058 Basel, Switzerland

http://www.forschung3r.ch/en/projects/pr_114_08.html

Call for Grant Applications

The 3R Research Foundation invites interested scientists to propose a project which falls within the principal areas for financial support. The duration of the project proposed should preferably be between 1 and 3 years and the necessary budget should be Sfr. 50 000.00 - Sfr. 250 000.00. Successful projects will be selected according to the Foundation's Criteria for evaluating applications and projects as well as financial capacity.
The Foundation would like to point out that in the year 2009 about Sfr. 500 000.00 (310 000.00 EURO) are available for research grants.
Use the application form (by e-mail) and set up the proposal according to the instructions for applicants.

Deadline is September 1, 2009

Approach the Scientific Adviser for more information and material:

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

Further details on the website:

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

Latest bulletin of February 2009 "Detection of Pain in Laboratory Animals via Gene Expression?" to be found here:

http://www.forschung3r.ch/en/publications/bu39.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 top

II.1.2. ReProTect

This 6th FP-project, that *ecopa* had co-initiated and in which *ecopa* is represented with 3 members in the Supervising Board including the Chairperson, was started in 2003 with 21 partners.

The overall funding is scheduled to be 9.1 mio EUR, resp. 13.5 mio EUR. Contract with the EU was signed on July 1, 2004; the administration is performed by Prof. Michael Schwarz, University of Tübingen.

II.1.2.1. Recent News

The latest Supervising Board Meeting was held on July 8, 2008 in Dresden, Germany.

The Joint Annual Research Area meeting (November 27-28, 2008) and a Meeting on further 'strategic' planning (November 26-27, 2008) were held at Ispra, Italy at ECVAM. A brochure on the ongoing activities within ReProTect is available.

The interim annual report was recently prepared

PDF: ReProTect Brochure

PDF: Executive Summary (224 kb)

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

PDF: ReProTect Flyer (320 kb)

ecopa is involved in the Board and the results dissemination.

www.acutetox.org top

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: www.expertradet.se, www.acutetox.org

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

ACuteTox goes into a new phase

The testing within the ACuteTox project has been finalised and data has been quality checked. The data is now being analysed with partial least squares regression (PLS) analyses in order to find the combination of assays giving the best prediction.

However, so far different combinations of basal cytotoxicity tests and specific tests only marginally improve the prediction compared to using basal cytotoxicity tests alone. By taking kinetic factors into account, the prediction could be approved further. The following four kinetic factors seem to be important: oral absorption, clearance, lipophilicity and protein binding. It has been concluded that further data analysis and data mining is needed before the construction of the testing strategy can be initiated. This data analysis and data mining will be carried out by an independent expert that has not been involved in the assay development and testing. These analyses will start in November 08.

The first results shall be delivered after 3 months from the start of the contract and a report with a list of selected assays (maximum 10) shall be provided within 6 months. This short list will be further discussed with the ACuteTox Management and Advisory Board who will decide on the methods to be taken up in the challenging exercise (pre-validation).

At least three testing strategies will be selected. These strategies will be challenged with the new data generated during the prevalidation and the best performing strategy will thereafter be proposed.

www.sens-it-iv.eu

top

II.1.4. Sens-it-iv

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

II.1.4.1. Recent News

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

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

The first Sens-it-iv Newsletter appeared on December 14, 2006 and now the 26th edition is available via the website or the link below. *ecopa* is part of work package 9 and is responsible for "Technology transfer and Dissemination". The newsletter is coordinated by the WP9 leader.

Newsletter Nr. 26 is out:

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

Newsletter-subscription possibility on the website.

The yearly organised General Assembly has taken place on October 21-23, 2008, in Maribo, Denmark.

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

top

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

Report by Flavia Zucco, BioSim Advisory Scientific Board:

The 4th BioSim Conference was held in Budapest from September 24 to 27, 2008. The advancements of this NoE are impressive and strong networking collaborations have been by now established. It is worthwhile to mention the books published, which make this network the leader in Europe in opening the way to integrated research in the interdisciplinary area of biological system simulations.

Martin Bertau, Erik Mosekilde and Hans Westerhoff have edited a book for Wiley-VCH on *'Biosimulation in Drug Development'* with contributions from a significant number of BioSim-partners. With its 512 pages and 18 chapters, the book provides what can be considered the first comprehensive presentation of some of the most important aspects of modeling and simulation in drug development and health care.

Fred Boogerd, Frank Bruggeman, Jan-Hendrik Hofmeyr, and Hans Westerhoff (partner 3) have published a book entitled: *'Systems Biology: Philosophical Foundations'* that touches on the problem of whether Biology is entitled to its own scientific foundation rather than being subjected to existing frameworks.

Olga Sosnovtseva and Erik Mosekilde (partner 1) have edited a special issue of Journal of Biological Physics on *'Biosimulation'* with a significant number of BioSim-contributions, and Morten Brøns (also partner 1) is co-editor of a special issue of the *American Physical Society Journal Chaos* on *'Multi-mode Dynamics'*.

One of the most important aspects of that project is that it has been trying to cover the wide approach to the different levels of complexity of the living organism: it has always tried to couple the micro to the macro levels, from the molecular to the physiological and clinical ones. However the main problem is now how to go on, since it is goes to the end by November 2009 and no NoE calls are available in the 7FP. The hope is that the partners which have been the core of BioSim will be able to sort out an IP of about 15 participants, taking on the most promising lines of research produced by BioSim. The next final Conference is scheduled for the end of August 2009 in Copenhagen, the town of the Coordinator Prof Erik Mosekilde.

http://www.biosim-network.net

Liintop

top

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

top

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 is being organized by the carcinoGENOMICS project, the subject is 'Genomics in Cancer Risk Assessment'. It will take place on August 27 - 28, 2009 on San Servolo Island, Venice, Italy. This is 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 Augustus 30 –September 3, 2009 in Rome.

Draft Programme:

August 27th 2009
Keynote Address I: Genomics at the FDA
Session I: Current Approaches in Cancer Risk Assessment for Drugs and Chemicals
Session II: In Vivo Approaches in Carcinogen Risk Assessment
Session III: In Vitro Approaches in Carcinogen Risk Assessment

August 28th 2009
Session IV: Human Carcinogen Risk Assessment
Session V: 'Omics' and Risk Assessment in the 21st Century
Session VI: Challenges for the Future in Carcinogen Risk Assessment
Keynote Address II: Omics in the Present and Future of Human Medicine
Session VII: Panel Discussion - The Way Forward and the Role of Genomics

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

top

SusChem
European Technology Platform For SUSTAINABLE CHEMISTRY

SusChem

top

II.2.1. Sustainable Chemistry (SusChem)

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

http://www.suschem.org/

The tenth SusChem newsletter is now online:

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

A detailed review of the SusChem platform activities can be found in a supplement of the September 22 issue 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 top

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 will be preceded by 3 Expert Meetings redefining and prioritising current bottlenecks in 3Rs methodology; with EPI, drug discovery and development. Each phase has its own specific needs, and analysing the present limitations and gaps needs to be addressed, e.g., many cell systems do not yet have the required stability for genomics, proteomics or metabonomics analysis; many current *in vitro* cell systems lack crucial bioactivation capability. Consequently, the status of satisfactory "predictive" pharmacology and toxicology *in vitro* has not yet been reached.

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

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

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

PDF: Presentation by Prof. Vera Rogiers (1,2 MB)

NEWS: The first START-UP expert meeting has taken place in Madrid, Spain, on June 19, 2008. On June 20, 2008, there was following a public meeting, organized by REMA together with ecopa. The second expert meeting has taken place in Basle, Switzerland, on the Novartis Campus, with participation of industry representatives on September 5, 2008. The third expert meeting was organized together with the eSI workshop. This has taken place in Pueblo Acantilado, Alicante, Spain from October 16 to 19, 2008.

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, will be held on July 3-4, 2009, in Innsbruck, Austria. The third workshop, on Replacement, will be held on October 2-3, in Budapest, Hungary.

ESNATS

top

II.2.4. ESNATS

Project acronym: ESNATS
Project full title: Embryonic Stem cell-based Novel Alternative Testing Strategies
Grant agreement no.: FP7 - 201619.

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

ecopa has taken over some tasks in disseminating results of this project, developed the logo, and is leading the respective workpackage.

NEWS:
ESNATS is coming to the end of its first project year and is now busy with the annual reporting. The next ecopa newsletter will include the main achievements of the project unto now.

ESNATS is having a conference, co-organised with NESCI (North East England Stem Cell Institute), on Stem cell-based Toxicology and Drug Screening on April 22, 2009. This will take place at the Centre for Life Conference Suite in Newcastle upon tyne, UK. This conference provides an overview of the applications and recent advances of embryonic stem cell technology in the area of toxicology. The topics which will be covered are: Stem Cells in Reproductive Toxicology, Industrial Applications of human Embryonic stem cells in toxicology, Application of embryonic stem cell model for drug discovery and development, Stem Cell based Toxicology and Stem Cell Approaches in Neurotoxicolgy.

For more information, please follow this link:

http://www.nesci.ac.uk/news/events/item/?nesci-esnats-conference-on-stem-cell-based-toxicology-and-drug-screening

Miscellaneous

top

III.1. Events

III.1.1. *ecopa* events

III.1.1.1. 9th Annual *ecopa* Workshop

The 9th Annual *ecopa* Workshop has taken place on November 29-30, 2008 in Brussels, at the Sheraton Airport Hotel.

Presentations of the 9th Annual *ecopa* Workshop

Photos of the 9th Annual *ecopa* Workshop

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

III.1.1.2. *ecopa* Board meeting

Minutes *ecopa* Board Meeting of February 25, 2009, in Rome, Italy (113 kb)

The next *ecopa* Board meetings (addressing also the START-UP project):
- October 1, 2009 in Budapest, Hungary

eSI - *ecopa* Science Initiative

top

III.1.1.3. eSI: *ecopa* Science initiative

The eSI-Conference under the general heading: "Reaching the young scientist" is an initiative organised by *ecopa* aimed at bringing together senior as well as young researchers to discuss about the new technologies and their applicability in '*in vitro*' research as well as to improve creativity and innovation in the search for alternative methods. *ecopa* had performed a detailed literature analysis of the last 5 years of research in alternative methods and had concluded that this area of applied research is drying out.

The full report, presentations, and the final program are listed on the *ecopa* website in the archive section.

NEWS: The latest workshop has taken place in Pueblo Acantilado; Alicante, Spain on October 16-19, 2008, with the attendance of senior scientists and young researchers of 14 countries. It focussed on "Recent developments and potentially novel approaches of science to alternative testing of cosmetics and pharmaceuticals". It was held together with the European Partnership for Alternative Approaches to Animal Testing, EPAA.

New aspects of pharmaceutical and cosmetic research are covered also in regard to the START-UP project. Sponsoring was provided by Badecos/Rogiers, Bayer, set and EPAA.

Presentations of the eSI Meeting

Photos of the eSI Meeting

III.1.2. other events

III.1.2.1. Translational Imaging in Drug Development Enhancing Imaging Techniques and Technologies to Streamline Drug Development
April 2-3, 2009 + London, UK
This marcus evans forum brings together the key industry and academic experts analysing cutting edge issues in imaging as a tool for successful translation of preclinical research to clinical efficacy with emphasis on challenges common to fields of neurology and oncology.

For more information:
» pharmaconferences@marcusevansuk.com
For a full program and registration information please reply to this Email with "more info imaging " in the subject field.

III.1.2.2. The Forinvitox Forum event
May 12-14, 2009 in Stockholm, Sweden
The First Market place in Europe for inventions, applications and products for in vitro toxicology testing methods. This is a forum where inventors of in vitro methods have a chance to meet producers, end users and regulators.

For more information:
» http://www.forinvitox.org/docs/forinvitox.pdf

III.1.2.3. 2nd Annual Antibody Discovery & Development Forum 2009
May 12-14, 2009 in Berlin, Germany
This forum will provide ample opportunity to network with peers and key opinion leaders in the antibody field and discuss winning strategies to successfully harness this technological know-how and drive progress.

For more information:
» pharmaconferences@marcusevansuk.com
For a full program, pricing and registration information please reply to this Email with "more info Antibody" in the subject field.

III.1.2.4. 5th Annual Biomarker World Congress
May 27-29, 2009 | Loews Philadelphia Hotel, Philadelphia, USA.

For more information:
» www.BiomarkerWorldCongress.com

III.1.2.5. FP7 – Financial & Project Management
June 11 – 12, 2009 in Budapest, Hungary.
This is training course is highly interactive and takes participants through the practicalities of implementing an FP7 project, from effective negotiation skills to how to allocate costs and survive EC audits. This isn't just a sit-and-listen course, but participants actually work through the troublesome areas of projects to better understand reporting and management.
For those interested only in audit or only in negotiation skills, please note, that a one-day intensive

course on Financial Reporting & Audits of EC Projects on 8th May, 2009 and a Negotiation Skills one-day course on 15th May, 2009 are organized.

For more information:
» http://www.eutrainingsite.com/open_courses.php

III.1.2.6. New Paradigms in Laboratory Animal Science
June 14-17, 2009 in Helsinki, Finland.
The FELASA meeting, organized every third year, is the largest European laboratory animal science meeting. The programme provides various topics of current interest, covering both scientific and practical aspects. Along with plenary presentations, oral presentations and posters are welcomed. In addition to scientific sessions, workshops and round table discussions, with interactive participation, will be included into the program.

For more information:
» http://www.felasa2010.eu/

III.1.2.7. Replacement of mammalian models: the role of in vitro techniques with fish and invertebrates
June 28-29, 2009 in Glasgow SECC, UK.
The overall aim of this symposium is to seek new opportunities for the replacement of mammalian models by drawing together the long standing expertise of the comparative physiologists who pioneered and developed in vitro systems in non-mammalian species, and to share this expertise with the toxicology community including mammalian toxicologists, ecotoxicologists, policy makers and regulators, who are increasingly interested in the role of alternative models in hazard assessment. This meeting is organised by popular demand, following a session held on in vitro techniques at the Society for Experimental Biology (SEB) annual meeting in 2007. The symposium in 2009 will gather the most up-to-date information on in vitro techniques with fish and invertebrates, and explore the applications of this work in fundamental toxicology research and the regulatory arena.

For more information:
» http://www.sebiology.org/meetings/Glasgow/glasgow.html

III.1.2.8. Workshop "Implementation of Genomic Approaches with both In Vitro and In vivo Models for Use in Cancer Risk Assessment"
August 27-28 2009, Venice, Italy.
A joint action of the carcinoGENOMICS project, NTC Netherlands, *ecopa*, ECVAM, Pfizer US, NIH/NIEHS US and ILSI Health and Environmental Sciences Institute (HESI). Target is a high-level meeting with participants from science and policymakers.

This workshop is accepted as a parallel meeting of the "10th International Conference on Environmental Mutagens"in Firenze (Aug. 20-25) and the "7th World Congress on alternatives and animal use in the life sciences" Rome, Aug. 30-sept 3, 2009.

For more information refer to the link below, more details will appear on their congress website soon.
» http://www.sanservolo.provincia.venezia.it

Workshop: Genomics in Cancer Risk Assessment (99 kb)

"Implementation of Genomic Approaches with both In Vitro and In Vivo Models for Use in Cancer Risk Assessment" (45 kb)

III.1.2.9. SECOND ANNOUNCEMENT for the 7th WORLD CONGRESS on Alternatives
August 30 to September 3, 2009 in Rome, Italy.

For more information:
» http://services.aimgroup.it/AIMDLArea/Public/?code=5ce0d035-56d9-4fac-bf04-073e29fdc8ef

III.1.2.10. 27th workshop,of the Scandinavian Society for Cell Toxicology (SSCT)
September 16-19, 2009.

For more information:
» http://www.ssct.net

III.2. Awards and Publications

III.2.1. Booklet on Alternative Testing Strategies

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

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

III.2.2. The European Medicines Agency (EMEA) has published a draft document for consultation

'EMEA/CHMP Working Group with Healthcare Professionals - Recommendations and Proposals for Action' (EMEA/185036/2008).

The document is available here:
» http://www.emea.europa.eu/pdfs/human/hcpwg/18503608en.pdff

III.2.3.The European Medicines Agency (EMEA) has published a concept paper on 'single dose/acute toxicity'

The document is available here:
» http://www.emea.europa.eu/pdfs/human/swp/30241308en.pdf

III.2.4. NC3Rs Newsletter 20, March 2009 and Information Portal – Species selection

The 20th edition of the NC3Rs-newsletter (March 2009) is available now.
You can subscribe for this here: http://www.nc3rs.org.uk/signup-newsletters.asp

The NC3Rs has an extensive Information Portal where to find a wide range of references and links for guidance on implementing the 3Rs. A new section on species selection has recently been added. Where animal use is necessary in research or testing, the choice of species (and breed/strain) should always be carefully considered and justified. This page sets out some of the factors to consider, particularly in relation to the 3Rs.

III.2.5. NC3Rs 2008 annual report

In 2008, with new Government funding, NC3R increased investment in 3Rs research with a total of ten grants awarded, totalling £2.6 million. A survey of project and personal licence holders working under the Animals (Scientific Procedures) Act 1986 was made to understand their views on the 3Rs.

The results of this are summarised in the annual report and also in more detail at:
» http://www.nc3rs.org.uk/opinionsurvey

III.2.6. New Book out regarding "Safety Assessment of Cosmetics in Europe"

For more information:
» http://www.ecopa.eu/download.php?file=Book_Pauwels_Rogiers_advert.pdf

III.2.7. Launch of the new TSAR website to inform about the development of alternative methods:

The European Commission has launched a new website, the so-called 'Tracking System for Alternative test methods Review Validation and Approval (TSAR)', designed to track the development of new alternative test methods which should replace, reduce and refine current animal testing.

The purpose of TSAR is to enable citizens and other interested parties to track progress of the review, validation and approval of alternative test methods, ensuring greater transparency of the process. The ultimate aim will be to cover each and every step of the validation route, from submission of a new method for pre-validation through to final adoption by its inclusion in EU legislation and/or related Guidance Documents. It will also explain the decisions that have been made at every step of the process. When the final decision on a proposed test method is negative, TSAR will clearly indicate the reasons why this decision has been taken. The website will be updated whenever a phase in the process is completed, ensuring the latest information is always available. However, to enable a rapid launch, the initial version covers only the part of regulatory approval of methods in the field of chemicals.

The website is managed by the Joint Research Centre's Institute for Health and Consumer Protection.

Website address:
» http://ihcp.jrc.ec.europa.eu/tsar
For more information, see also: SPEECH/08/574

III.2.8. Article in Altex: Research Expenditure for 3R Alternatives

Title: A Review of National Public Funding Programmes in European Countries
Authors: Tonia Devolder, Kirsty Reid, Vera Rogiers, Simon Webb and David Wilkins

Summary: A survey of publicly funded research specifically targeting alternatives to animal testing was conducted over 2006/2007. Responses were received from 16 European countries (Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Netherlands, Norway, Slovakia, Spain, Sweden, Switzerland and the United Kingdom). The responses were compiled by national agencies or national consensus platforms. The current annual total across the 16 countries was estimated as € 17 million. The largest contribution came from Germany with € 4.6 million (27% of the total). Also collated was information on the existence of a national strategy on alternatives research, the focus of any such strategies, the research priority setting process, stakeholder consultation in that process, project funding preferences or limits, coordination mechanisms and the separation of responsibilities of competent authorities (i.e. for research support, laboratory animal welfare and chemicals management). Countries with national strategies (France, Germany, the Netherlands, Sweden, Switzerland and the UK) are skewed towards the higher end of the spending distribution. These 6 countries account for over € 12 million, i.e. >70% of the overall total of national spending identified. Most countries have national consensus platforms. These should help to both stimulate stakeholder consultation and further national spending on alternatives research. The situation regarding the separation of responsibilities of competent authorities (i.e. for research support, laboratory animal welfare and chemicals management) is mixed. A degree of overlap exists in many cases. A research strategy that is receptive to and reflects regulatory developments – such as REACh with its marked resultant increase in animal use – is an obvious need that is as yet unmet in many of the countries surveyed. The need for a mechanism to collate details of active research projects within Europe as a whole was also identified.

For more information:
» http://www.altex.ch/en/index.html?id=50&iid=101&PHPSESSID=6995a484cc861ac613

III.2.9. ECVAM website extension has been changed

The website address of the ECVAM and DB-ALM have been changed. As one may have noticed, the previous addresses http://ecvam.jrc.cec.eu.int and http://ecvam-dbalm.jrc.cec.eu.int do not work anymore and one will not be redirected to the new addresses..

With immediate effect, please only refer to the following website address:
» http://ecvam.jrc.ec.europa.eu for the ECVAM, and
» http://ecvam-dbalm.jrc.ec.europa.eu for the DB-ALM.

III.2.10. Performance Standards for the Local Lymph Node Assay endorsed

The ECVAM Scientific Advisory Committee (ESAC) has endorsed the scientific validity of the harmonised ECVAM performance standards for the Local Lymph Node Assay (LLNA) at its 29th meeting held in November 2008. The LLNA is a scientifically validated and regulatory accepted method for assessing the skin sensitisation potential of chemicals. Detailed information can be found on the ECVAM's website NEWS/EVENTS and MEETINGS section.

III.2.11. Stem cells online journal

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

III.2.12. Recognition and Alleviation of Pain in Laboratory Animals

An article, entitled 'Recognition and Alleviation of Pain in Laboratory Animals' will be published by the Committee on Recognition and Alleviation of Pain in Laboratory Animals, the Institute for Laboratory Animal Research and the Division on Earth and Life Studies.

Prepublication available with National Academic Press, 2009:
» http://www.nap.edu/catalog.php?record_id=12526

III.2.13. EPA Releases New Strategic Plan for Evaluating the Toxicity of Chemicals

EPA is releasing a new approach to advance the science upon which the agency bases its regulatory decisions and policies, resulting in better protection for human health and the environment. EPA released the "U.S. Environmental Protection Agency's Strategic Plan for Evaluating the Toxicity of Chemicals." This strategic plan outlines a new scientific approach that will allow EPA to assess risks from many chemicals and mixtures by adopting new toxicity testing methods that use recent advances in molecular biology, genomics, and computational sciences. When fully implemented, EPA will be able to screen thousands of environmental chemicals quickly for potentially harmful effects. The strategic

plan will also allow EPA scientists to look at how children may react differently to the same chemicals as adults, thus providing better health protection for children

Strategic Plan for Evaluating the Toxicity of Chemicals:
» http://www.epa.gov/osa/spc/toxicitytesting

III.3. Calls and Vacancies

III.3.1. Erasmus Mundus grant to teach on the EUROPUBHEALTH Masters Course

Europubhealth is a two-year fully integrated European Masters Course coordinated by EHESP French School of Public Health and supported by the Erasmus Mundus programme. It includes five other partners: University of Rennes 1 (France), University of Copenhagen (Denmark), Andalusian School of Public Health (Spain), University of Sheffield (United Kingdom) and and Jagiellonian University of Cracow (Poland).

The Erasmus Mundus programme offers grants to third countries scholars (teachers) who are interested in carrying out research, teaching assignments and scholarly work for 3 months linked to the Europubhealth Masters Course.

For more information:
» http://www.europubhealth.org/us/teacheph/index.php

III.3.2. Call for applications 2009 – Second Programme of Community action in the field of Health (2008-2013)

Deadline:
The deadline for submissions of the proposals under each call is **20 May 2009**.

Details:
The EU Health Programme 2008-13 has three general objectives:
- to improve citizens' health security;
- to promote health, including the reduction of health inequalities;
- to generate and disseminate health information and knowledge.

This call for applications has a budget of 48m and consists of the following parts
- a call for proposals for the award of a financial contribution to specific actions in the form of projects, (~50% of the budget)
- a call for proposals for the award of a financial contribution to specific actions in the form of conferences,
- a call for proposals for the award of a financial contribution to the functioning of non governmental bodies and specialised networks (operating grants),
- an invitation to Member States and participating countries (Norway, Iceland, Liechtenstein, Croatia), for submission of joint actions.

Further information
All the information, including the Commission Decision of 23 February 2009 on the adoption of the work plan for 2009 for the implementation of the second programme of Community action in the field of health (2008-2013), and on the selection, award and other criteria for financial contributions to the actions of this programme, are available on the website of the Executive Agency for Health and Consumers at the following address:
» http://ec.europa.eu/eahc

Source: OJC 47 (26 February 2009)

III.4 VARIA

III.4.1. The DB-ALM has published a new data sector

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

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

III.4.2. CARDAM: Centre for Advanced Research & Development of Alternative Methods

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

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

III.4.3. VirtualToxLab is available on the internet

In the past year, VirtualToxLab™ — an in silico tool for predicting the toxic (endocrine-disrupting) potential of drugs, chemicals, and natural products — has been thoroughly tested and is now available for all interested parties: universities, environmental NPOs, governmental agencies, regulatory bodies, hospitals and particularly for the chemical, pharmaceutical, cosmetics, food and biotech industry. The fully automated protocol estimates the binding affinity for any molecule of interest towards a series of 12 proteins, known or suspected to trigger adverse effects by simulating and quantifying their interactions with the human protein using automated, flexible docking combined with multi-dimensional QSAR. The VirtualToxLab™ is accessible over the Internet from any computer hardware and operating system. The VirtualToxLab™ allows to rationalize a prediction at the molecular level by analyzing ligand binding at all protein targets in real-time 3D. Details are given in the Winter 2008/9 newsletter.

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

III.4.4. Framework for International Cooperation on Alternative Test Methods (ICATM) adopted by ECVAM

A framework has been adopted to increase international cooperation, collaboration and communication on alternative test methods.
The International Cooperation on Cosmetics Regulation (ICCR) invited the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)- National Toxicology Program Interagency Center for the Evaluation of Alternative Methods (NICEATM), the European Centre for the Validation of Alternative Methods (ECVAM), the Japanese Centre for the Validation of Alternative Methods (JaCVAM) and a knowledgeable representative of the Government of Canada to address the issue of recognizing the importance of replacing, reducing, and refining animal testing and to propose options to ensure a collaborative approach in September 2007.

For more information:
» http://ecvam.jrc.ec.europa.eu/f_home.cfm?voce=m&idvoce=6

III.4.5. ECVAM has endorsed two in-vitro skin irritation tests

The ECVAM Scientific Advisory Committee (ESAC) has endorsed the scientific validity of two further in-vitro skin irritation tests on its 29th meeting held in November 2008. Both models (SkinEthic RHE and EpiDerm SIT) are based on reconstructed human epiderms and measure or predict the same biological or toxic effect as the fully validated and accepted reference method.

For more information:
» http://ecvam.jrc.ec.europa.eu/f_home.cfm?voce=m&idvoce=6