ecopa messenger

July 14, 2009, edition #20

Dear *ecopa* messenger subscriber,

The EU 7th Framework Programme research project START-UP directed by ecopa, had its second major workshop in this year with the Innsbruck-event last weekend on July 3/4, 2009. The presentations covered 'Reduction' in regard to bottlenecks in the pharmaceutical industry, ossibilities to further pursue the topic and identify actions for a roadmap. The way of presenting it in another format and the final roundtable were well received. All in all, 10 major pharmaceutical companies were represented, as well as 8 S M E s, at this Innsbruck Workshop only.

Workshop Programme START-UP (22 kb)

The internal project report of the preceding workshop on 'Refinement' (Rome) was finalized. The next START-UP-workshop on 'Replacement' is going to take place in Budapest (Hungary) on Oct. 2/3, 2009, organized by the Hungarian and German platform organizations. The draft program is currently being worked on.

The 2009 EU-Report on "Alternative Testing Strategies" has just been published. In this book, ecopaas a non-governmental institution is mentioned on page 19, with other organizations, such as ECVAM, EPAA, OECD, etc., and with its projects, especially the START UP-project, on page 249.

Alternative Testing Strategies - Progress Report 2009 (5.3 MB)

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, last November. Minutes of the 2008 Annual will be out soon.

Next *ecopa* Annual Meeting will take place in November 2009, as usual at the Sheraton Airport, Brussels, BE. The workshop program will cover the aspects and projects of 10 years of *ecopa*, but, even more important, at the Annual, the Board Elections will take place.

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 in regard to the next elections and the appropriate follow-up; a nomination/selection committee was put in place and has contacted the platforms.

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.

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I.1. General News

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I.1.1. Recent News on REACH and GHS

NEWS:
The EU expected 180,000 pre-registrations of 30,000 substances under the REACH system, but ECHA was overwhelmed by 2.7 mio pre-registrations of 143,000 substances said to be manufactured or imported (>1 ton); i.e. 15 times more than assumed. The next deadline is December 1, 2010 for the submission of the full REACH registration dossier. The formation of SIEFs (Substance Information Exchange Forum) and Consortia has been promoted by ECHA, but the concept has not fully been understood, including its legal implications. Yet nothing but first steps has been taken (Source: ICIS, May 11, 2009, p.15). The implications for animal testing in terms of numbers, alternative approaches and, especially, implementation of waiving procedures, accordingly, has still to be seen. Competent authorities of the 27 member countries and ECHA will be judged in the end by their willingness to accept alternative tests.

First REACH list of dangerous chemicals agreed:

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

China taking the road to REACH
(Source: ICIS, June 29, 2009, p.13)

Changes to China's Measures on the Environmental Control of New Chemical Substances (of 2003) proposes a system that underpins the EU REACH-regulations: i.e more toxicological testing and classification of chemicals into groups.

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

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

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

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

More information about the new rules can be found under:

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

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

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

ECHA (European Chemical Agency)

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

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

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

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

NEWS:
The Committee for Risk Assessment adopted its first opinion on harmonised classification and labelling.

The Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) just recently agreed not to support a proposal for EU-wide harmonised classification and labelling of diantimony trioxide as a skin irritant. The Agency will now submit this opinion to the European Commission for their decision.

More information as well as other news here:
http://echa.europa.eu/news/press_en.asp#press20090706

www.epaa.eu.com

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

For outcome of the recent Mirror Group meetings and the last workshops, see the EPAA-website:
http://ec.europa.eu/enterprise/epaa/

EPAA-newsletter of March 2009 is published and can be read here:
http://ec.europa.eu/enterprise/epaa/epaa_newsletter_200903.pdf

NEWS:

Annual Conference 2008 report 2008:
http://ec.europa.eu/enterprise/epaa/4_events/ann_conf_2008/final_report_ac_2008.pdf

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

The next annual EPAA-Annual Meeting will take place on Nov 4, 2009; the headline for 2009 is the "dissemination" theme.

Progress report 2008:
http://ec.europa.eu/enterprise/epaa/3_activities/3_2_progress_reports/epaa_report_final_081020.pdf

http://imi.europa.eu

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I.1.3. IMI is launched

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

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

Executive Director appointed

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

Outcome of First Call published. More see here:
http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/802

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

More information can be found here:

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

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

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

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

I.2. Other News

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I.2.1. Nanotech, Ecological Risk Asessment Symposium

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

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

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

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

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

More information see here:

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

The EU-Commission's Scientific Committee on Consumer Products (SCCP) had 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

Symposium on EuroNanoMedicine 2009: September 28 - 30, 2009 in Bled, Slovenia

The programme of this conference will cover current topics and recent progress in the field of nanotechnology for medical care areas and its advantages. In detail all aspects of targeted nanomedicine and therapeutic concepts, overcoming biological barriers, medical diagnostics and sensor devices, nanomedicine and regenerative medicine, nanomedicines for gene delivery, and safety aspects of nanomaterials for medical applications will be addressed.

Registration, information here:

http://events.dechema.de/euronanomedicine2009.html

I.2.2. Review of Directive 86/609

Progress can be followed under:

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

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

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II.1.1.1. Recent News on FP6 and FP7 projects

NEWS:
Next Board Meetings scheduled for (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.
- *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

- Zet was hosting, together with the Dutch working group, the recent START UP-workshop in Innsbruck, Austria, on July 3-4, 2009.

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

II.1.1.2.6. Finnish Platform
» Fincopa

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

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

II.1.1.2.8. German Platform
» Stiftung set

- set is preparing, together with the Hungarian platform, the START UP-workshop on "Replacement".

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

II.1.1.2.9. Hungarian Platform
» Hucopa

- In context with the forthcoming START-UP event in Budapest on October 2 and 3, 2009 addressing Replacement, jointly organized by the Hungarian and the German Platform, there will be a local Hucopa-event taking place as well. The draft program ist currently being worked on.

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

- The Italian platform had hosted together with the Finnish and the Polish platforms, the START UP-workshop on "Refinement" in February 2009 in Rome, Italy.

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
- Norecopa's AGM was held on June 11, 2009. A successfull scientific meeting was held beforehand. Dr. Manuel Berdoy, of Oxford University, gave three lectures within the theme of "Statistics: The Good, The Bad and The Ugly". These covered the essence of statistical thinking when planning animal experiments (p values, power analysis, determination of sample size, experimental design, analyses and control of variation) and ways to implement Reducation and Refinement.
  » His lecture notes are available here: http://www.norecopa.no/sider/tekst.asp?side=77
- Norecopa's website's page on position statements is updated, it now includes toe clipping and pain relief in young rodents. A statement on fasting of rodents will be published there very shortly: http://www.norecopa.no/sider/tekst.asp?side=50
- 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 at (Spanish version):

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

II.1.1.2.15. Swedish Platform
» Swecopa

- Swecopa held it's AGM on March 31. Karin Gabrielson Morton was re-elected to chair Swecopa. Other board members are Dr Cecilia Clemedson (Swedish Fund for Research without Animal Experiments), Professor Roland Grafström (Karolinska Institute), Dr Krister Martin (AstraZeneca), 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 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.

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.

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II.1.2. ReProTect

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

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

II.1.2.1. Recent News

The 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.

Go to the website here:

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.

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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

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 have started in November 2008.
A 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

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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 Sens-it-iv Newsletter Nr. 29 is out:

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

Newsletter-subscription possibility on the website.

The next General Assembly will be held on October 5, 6 and 7, 2009, at Hotel Pueblo Acantilado, in El Campello near Alicante, Spain.

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

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

BioSim will have it's 5th Conference on August 26 – 28, 2009 at Copenhagen, Denmark.

http://www.biosim-network.net

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II.1.6. Liintop

II.1.6.1. Recent News

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

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

carcinoGENOMICS

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II.1.7. carcinoGENOMICS

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

II.1.7.1. Recent News

PDF: CarcinoGENOMICS Press Release (24 kb)

A workshop 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 August 30 – September 3, 2009 in Rome, Italy.

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

For more information:

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

For registration:

https://ww2.eventrebels.com/er/Registration/RegistrationForm.jsp?ActivityID=3887&ItemID=14029

Potentially, student awards can be given. For information check here:

http://www.hesiglobal.org/files/public/Committees/Genomics/Meetings%20and%20Workshops/2009/CRA%20Workhshop/GenomicsWorkshop_StudentAwards.pdf

Book on systems biology methods

In this book published by MPIMG (Berlin) and partly funded within the carcinoGENOMICS project, basic tools and methodologies for analysing biological networks are described. The intended readership of the book are students and lecturers but also advanced researchers.

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

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

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

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SusChem

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II.2.1. Sustainable Chemistry (SusChem)

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

http://www.suschem.org/

SusChem newsletter #12 is now online:

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

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

II.2.2. Regulations of the 7th Framework Programme

Update 7th EU RTD- Framework Programme

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

Guidance on FP7 implementation

A number of guidance documents and preparatory work are carried out by the European Commission in view to install the basis of the FP7 implementation. The following documents are available for consultation on http://cordis.europa.eu/fp7/find-doc_en.html where they can also be downloaded:

- a standard Model Grant Agreement,
- a draft Guide for Beneficiaries,
- a draft Guide to Financial Issues,
- a draft Guide to IPR and
- a draft Checklist for the Consortium Agreement.

ecopa is interested to participate with partners in some of the calls dealing with alternative methods and being announced in the future, esp within the HEALTH resp. the ENVIRONMENT sectors of the 7th FRP.

START-UP

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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.

NEWS:
After the preceding expert meetings in 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, has been 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

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II.2.4. ESNATS

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

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

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

NEWS:
ESNATS co-organised a conference with NESCI (North East England Stem Cell Institute), on Stem cell-based Toxicology and Drug Screening on April 22, 2009. This took place at the Centre for Life Conference Suite in Newcastle upon tyne, UK. This conference provided an overview of the applications and recent advances of embryonic stem cell technology in the area of toxicology. The topics covered were: 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.

The minutes of this meeting are available here:

PDF: Minutes of the NESCI ESNATS CONFERENCE (273 kb)

Miscellaneous

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III.1. Events

III.1.1. *ecopa* events

III.1.1.1. 10th Annual *ecopa* Workshop

The 10th *ecopa* Annual Meeting will address in its scientific part the results of 10 years work of *ecopa*, and in the Member's Meeting, the election of the new Board members will take place.

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

III.1.1.2. *ecopa* Board meeting

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

eSI - *ecopa* Science Initiative

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III.1.1.3. eSI: *ecopa* Science initiative

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

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

NEWS: The 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.

The next eSi-workshop, very likely in 2010, has not been planned yet. Updates on planning and date will be published here in due time.

Presentations and photographs of the 2008-meeting:

- Presentations of the eSI Meeting
- Photos of the eSI Meeting

III.1.2. other events

III.1.2.1. Reduced Animal Testing, July 23/24, 2009 Zurich, Switzerland

July 23-34, 2009 in Zurich, Switzerland

For more information:
» http://www.nc3rs.org.uk/event.asp?id=984

III.1.2.2. Workshop: Genomics in Cancer Risk Assessment

August 27-28, 2009 in Venice, Italy

Abstract submission and registration by July 17, 2009 – latest!
This workshop is 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 (August 20-25, 2009) and the "7th World Congress on alternatives and animal use in the life sciences" Rome, August 30 - September 3, 2009.

For more information:
» http://www.hesiglobal.org/i4a/pages/index.cfm?pageID=3432

Potentially, student awards can be given. For information check here:

» http://www.hesiglobal.org/files/public/Committees/Genomics/Meetings%20and%20Workshops/2009/CRA%20Workhshop/GenomicsWorkshop_StudentAwards.pdf

III.1.2.3. VII World Congress on Alternatives & Animal Use in the Life Sciences

August 30 – September 3, 2009 in Rome, Italy

For more information:
» http://www.aimgroup.eu/2009/WC7

III.1.2.4. Course in Philosophy of Risk in Health Risk Assessment

October 12-16, 2009 at the Royal Institute of Technology, Stockholm, Sweden

The objective of the course is to provide an overview of important aspects of interactions between science and policy in health risk assessment with a focus on strategies to handle scientific uncertainty. The course is intended for PhD students, post docs, senior scientists and other professionals. Funding for travel, subsistence and course fee is available for PhD students and post docs. The course is organised by RA-COURSES, a project funded by European Union Marie Curie Actions in collaboration with the Postgraduate programme in Environmental Factors and Health at Karolinska Institutet and CASCADE Network of Excellence.

Application deadline is August 14, 2009.

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

III.1.2.5. Predictive Toxicology 2009: Understand New Developments in Predictive Toxicology and Their Impact on Business Development for Pharmaceutical Companies
September 3 - 4, 2009 in Prague, Czech Republic

Predictive toxicology is considered as one of the most important steps in the drug discovery process. The current trend of including toxicology earlier in the discovery phase permits to identify harmful toxins in the preclinical phase and thus allows for early withdrawal of harmful compounds or can help turn a potentially dangerous compound into a successful one.
Companies that actively engage in predictive toxicology avoid late-stage development failures and save costs.
This conference is supposed to provide participants with answers for shaping successful strategies and will supply global overview of predictive toxicology. The event combines both scientific and business development point of view.

For more information:
» http://www.marcusevans.com/html/eventdetail.asp?eventID=15664&SectorID=31

III.1.2.6. Safety Biomarkers in Drug Development
September 14 – 15, 2009 Bratislava, Slovak Republic

Integrate biomarkers into clinical research to predict, diagnose and avoid adverse events. The ability to accurately predict adverse events related to areas like cardiology, nephrology, neurology, haematology and hepatology is extremely exciting. Validated safety biomarkers provide the opportunity for smarter and earlier decision making in R&D, meaning project kill decisions are made quicker, later-stage projects become less risky and hundreds of millions of dollars can be saved.

For more information:
» http://www.nextlevelpharma.com/events/view/safety_biomarkers_in_drug_development

III.1.2.7. Norecopa's 3rd International Consensus Meeting: Harmonisation of the Care and Use of Fish in Research
September 22 – 24, 2009 at the Clarion Hotel Oslo Airport in Oslo, Norway

Among the topics being addressed are: Welfare indicators for fish, Environmental enrichment, Health monitoring, Telemetry, Global update on guidelines for fish research, Update on neurophysiological and behavioural research, Humane endpoints; methods of humane killing, Best practice when bleeding and administrating compounds to fish and Update on European legislation Speakers include recognised international experts in these fields.

For more information:
» http://www.norecopa.no/sider/tekst.asp?side=53

III.1.2.8. Organotypic Tissue Culture for Substance Evaluation
September 22 – 25, 2009 at the Kongresshotel Potsdam am Templiner See, Potsdam, Germany

For more information:
» http://events.dechema.de/tissue09.html

III.1.2.9. EuroNanoMedicine 2009
September 28 - 30, 2009 in Bled, Slovenia

The programme of this conference will cover current topics and recent progress in the field of nanotechnology for medical care areas and its advantages. In detail all aspects of targeted nanomedicine and therapeutic concepts, overcoming biological barriers, medical diagnostics and sensor devices, nanomedicine and regenerative medicine, nanomedicines for gene delivery, and safety aspects of nanomaterials for medical applications will be addressed.

Registration, information here:
» http://events.dechema.de/euronanomedicine2009.html

III.1.2.10. 2nd International Conference on Drug Discovery and Therapy
February 1 – 4, 2010 in Dubai, UAE

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

For more information:

» http://www.icddt-dd.com

III.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. Dieter Lütticken Award 2008 recognizes development of new vaccine quality control assay

On April 7, 2009 Intervet/Schering-Plough Animal Health announced that the Dieter Lütticken Award 2008 for alternatives in animal testing goes to Dr. Ivo Claassen for a project that he has managed at the Central Veterinary Institute (CVI), Lelystad (the Netherlands). The announcement was made by Prof. Coenraad Hendriksen, chairperson of an independent expert jury panel and Professor of Alternatives to Animal Testing at Utrecht University (the Netherlands).

For more information:
» http://www.intervet.com/news/2009-04-07-dieter-luetticken-award-announced.aspx

III.2.3. Dieter Lütticken Award 2009

Candidates should give full contact details, co-operation partners, an executive summary of the studies and an argumentation why they should be taken into consideration, a publications list related to the studies and a selection of copies of those publications which give a good overview of the work.

For application forms please contact:
Intervet Global Communications Animal Health, Boxmeer, The Netherlands
(communications@intervet.com.
This year's deadline is November 15, 2009

The document is available here:
» http://www.intervet.com/news/2009-04-07-dieter-luetticken-award-announced.aspx

III.2.4. NC3Rs e-Newsletter Issue 21

NC3Rs-e-newsletter #21 is available now. You can read it online here:
» http://www.nc3rs.org.uk/news.asp?id=1064

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. 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.2.6. 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.2.7. 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.

» http://www.altex.ch/en/index.html?id=50&iid=101

III.2.8. Stem cells online journal

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

III.3. Calls and Vacancies

III.3.1. Call for applications 2009 – Second Programme of Community action in the field of Health (2008-2013)

Deadline for submissions of the proposals under each call was 20 May 2009.

Priorities of the EU Health Programme 2008-13 and WP2009:
- 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 several financing instruments:

- projects, (~50% of the budget) : maximum EC contribution: 60 % for the following topics:
http://ec.europa.eu/eahc/documents/health/calls/2009_CALL_PROJECTS.pdf

- conferences: maximum EC contribution: 50 %
http://ec.europa.eu/eahc/documents/health/calls/2009_CALL_CONFERENCES.pdf

- operating grants to the functioning of non governmental bodies and specialised networks
http://ec.europa.eu/eahc/documents/health/calls/2009_CALL_OPERATING_GRANTS.pdf

- joint actions financed by the EC and the Member States and participating countries (Norway, Iceland, Liechtenstein, Croatia),…
http://ec.europa.eu/eahc/health/actions.html

Further information
All relevant 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

III.4 VARIA

III.4.1. Countries Unite to Reduce Animal Use in Product Toxicity Testing Worldwide

U.S., Canada, Japan and European Union Sign International Agreement
Representatives from four international agencies, including the director of the U.S. National Toxicology Program (NTP), today signed a memorandum of cooperation that could reduce the number of animals required for consumer product safety testing worldwide. The agreement between the United States, Canada, Japan and the European Union will yield globally coordinated scientific recommendations on alternative toxicity testing methods that should speed their adoption in each of these countries, thus reducing the number of animals needed for product safety testing.

The memorandum is available at:
» http://iccvam.niehs.nih.gov/docs/about_docs/ICATM-MOC.pdf

The press release can be found here:
» http://www.niehs.nih.gov/news/releases/2009/pttw.cfm

III.4.2. Skin irritation test validated

EU regulators have accepted new *in vitro* skin irritation methods that use reconstructed human epidermis, to replace tests on rabbits. This is the first time that the EU has accepted a replacement safety test ahead of OECD approval.
The replacement methods, which are both cheaper and faster than the previous animal test, will now be used in the REACH (Registration, Evaluation, Authorisation and Restriction of Chemical substances) programme. The replacement methods make the animal tests completely redundant, which will save thousands of animals that were due to be used in REACH and other skin irritation tests.

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