

**Dear ecopa messenger subscriber,**

The end of the year 2007 saw a series of substantial meetings on alternatives: the epaa Annual Meeting, addressing "Regulatory Acceptance", and our own *ecopa* Annual Meeting, where the workshop presented a check on what has been achieved in alternative test methods, funding of these, Europe-wide, and what can, resp. cannot be expected.

 [8th Annual ecopa Workshop - Presentations](#)

 [8th Annual ecopa Workshop - Photographs](#)

A further highlight was the welcoming of two new member platforms, i.e. the Plateforme Nationale of France, and Norecopa from Norway. *ecopa* covers now 13 countries on the European continent (see minutes).

The theme of the Annual meeting "Potential improvement in the development of alternative methods: Needs in risk assessment of new technologies and their products vs use of alternatives" provided also the groundwork for the new *ecopa* EU 7th FP-project [START-UP](#) (support-action). This project "Scientific and Technological issues in the 3Rs Alternatives Research in The process of drug development and Union Politics" was a major topic that fits into that overall subject, and which *ecopa* is following with its member NCPs.

The minutes of the Annual Meeting can be found in the next news letter edition.

During the Annual Meeting there was also the election of the Board of *ecopa* for the years to come.


The Executive Board and most of the NCP-delegates as well as 3R-experts were re-elected: Flavia Zucco left the Board (thanks a lot for her valuable service in the past years), and a new Italian 3R-expert has been elected: Isabella de Angelis. Congratulations!

Please also note that the next eSi (*ecopa* Science Initiative) – Workshop in Alicante/Spain initially scheduled for end of September 2008 has been moved to October 16-19 or 2-5, 2008, due to conflicting dates.

With the best wishes for a Merry Christmas and a Healthy, Prosperous and Challenging Year 2008!

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](mailto:bgarthoff@t-online.de)). If you know other people or institutions interested, have them visit our website and [subscribe to this newsletter](#).

 **Issue # 14 (December 2007)**

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## I.1. General News

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### I.1.1. Recent News on REACH

Most of the facts and the implementation aspects of REACH are found in the 60-page-report "Impact of REACH", first edition of a new series of *ecopa*-publications (electronic version). A print-version is available on request. Copies on CD also available, contact the *ecopa* secretariate.



[Impact of REACH \(804 kb\)](#)

In the meantime, the new executive director of EChA has been selected, and is taking office. His name is Geert Dancet, and he has been, already temporarily, in charge. He has been with the ranks of the EU Commission ([see CV](#)) before, and was involved in some of the preparatory work for REACH and the set-up of EChA in Helsinki.

Meanwhile, the race is on to compare the regulatory systems for chemicals: the US Government Accountability Office (a Congress institution) assessed in their August-report the "Chemical Regulation: Comparison of US and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals", concluding that a system modeled after REACH could amend some of the perceived deficiencies in TSCA (the US Toxic Substances Control Act, enacted 1976, with the authorized agency EPA).

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

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



[www.epaa.eu.com](http://www.epaa.eu.com)

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

The EU Commission under lead of Commissioners Verheugen and Potocnik, had initiated a partnership program with the industry and industry associations resp. individual companies. A first kick off meeting was held on November 7, 2005 – a follow-up on this approach "**Europe goes alternative**" will be held each year.

This year's conference focused on regulatory acceptance:

**Workshop on "Regulatory acceptance of 3 Rs methods and strategies"** held November 5, 2007,

in Brussels, Belgium, European Commission/DG Enterprise and Industry.

Further information on the website:

 <http://ec.europa.eu/enterprise/epaa/conf.htm>

Progress report 2007 published:

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

The EPAA has agreed for 21 activities to be carried out over the next 5 years. Current co-chairs are: Mme Lalis, Mr Charles Laroche (DG ENT, Unilever).

As co-chair representing industry in the EPAA, the *ecopa*-Board-member and treasurer Dr. Bernward Garthoff, DMV, was elected in September. Serving in his function during 2008 together with Dir. Georgette Lalis of DG ENT, representing the Commission in the partnership, the important phase of the REACH-implementation will be addressed.

A mirror group of stakeholders including animal welfare bodies and patient groups will again have the chance to give input into a future Mirror Group Meeting end of January, most likely January 30, 2008. *ecopa* is represented here by three of its members.

 <http://ec.europa.eu/enterprise/epaa/uc.htm>

For the 4th EPAA-newsletter, see the website:

 <http://ec.europa.eu/enterprise/epaa/news.htm>

## I.2. Other News

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### I.2.1. Nanotech

Besides of the discussions on the [ecopa Annual Workshop 2005](#) on new technologies, several partners have worked and discussed on nanotechnology, e.g. [at the last eSI-workshop](#).

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.

The European Scientific Committee on Consumer Products (SCCP) has just finished a position paper regarding an opinion on the safety of nanoparticles used in cosmetics. It will appear on the SCCP website, beginning of January 2008.

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

### I.2.2. Review of Directive 86/609

On June 25, 2007, Green MEP Satu Hassi tabled an oral question for the Commission on the review of the Directive 86/609 on animal testing, asking about the timeline for the publication of the proposal and reasons for the delay:

Committee on Environment, Public Health and Food Safety oral question from Satu Hassi (Verts/ALE, FI) to the Commission:

 [http://www.europarl.europa.eu/meetdocs/2004\\_2009/documents/cm/672/672183/672183en.pdf](http://www.europarl.europa.eu/meetdocs/2004_2009/documents/cm/672/672183/672183en.pdf)

## 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

The recent *ecopa*-Board meeting was held on September 27, 2007 in Linz, Austria, before the 14th Congress on Alternatives to Animal Testing. Next Board meeting will be held in spring: March 4, 2008, venue to be determined.

Representatives of *ecopa* in EU projects 6th Framework Programme:

- *SSA project ForInViTox* (Forum for researchers and regulators to meet manufacturers of toxicology test methods) - *ecopa* is represented by Dr. Odile De Silva.
- *BioSim* - Flavia Zucco represents *ecopa* in this EU Project.
- *CarcinoGENOMICS* - Bernward Garthoff is the *ecopa* representative in this IP FP6 project. *ecopa* has taken over the Work Package of dissemination of results of the consortium.  
[A questionnaire of the WP 11 regulatory group](#) can be found on the *carcinoGENOMICS* website for

consultation and input.

Input is requested and welcome from representatives of regulators, authorities, agencies and especially from toxicologists in industry and academia.

- *ACute Tox* – Peter Maier is the representative in the Advisory Board.
- *Sens-it-iv* – Vera Rogiers (represented by the *ecopa* secretariate) is the representative in the Advisory Board, and *ecopa* is seconding in the dissemination of results.
- *PREDICTOMICS* – Bernward Garthoff is the representative in the Advisory Board.
- *Liintop* – Horst Spielmann is the representative in the Advisory Board.
- *ReProTect* – Karin Gabrielson, Vera Rogiers and Bernward Garthoff (Chair) are representatives on the Supervising Board, and *ecopa* is seconding in the dissemination of results.
- *CONAM* – The last CONAM and Board review meeting was held on March 6, 2007 in Paris. The CONAM-project has, thus, successfully been finalized by submitting the final report.
- *ecopa* – The Board of *ecopa* was re-elected with the following changes: Flavia Zucco left the Board (thanks a lot for her valuable service in the past years), and a new Italian 3R-expert has been elected: Isabella de Angelis.

Actual composition of *ecopa*-Board

<b>Executive</b>	<b>Board Persons involved</b>	<b>Function</b>
Daily follow-up, elected by General Assembly	Vera Rogiers (B, Ac)	Chairperson
	José Castell (E, Ac)	Vice-Chairperson
	Bernward Garthoff (D, I)	Treasurer
Board		
Elected NCP members by General Assembly	Peter Maier (CH, AnW/I)	
	Roman Kolar(D, AnW)	
	Walter Pfaller (A, Ac)	
	Jan van der Valk (NL, Ac)	
3R-experts		
Elected by General Assembly	Odile de Silva(F, I)	
	Horst Spielmann (D, G)	
	Isabella De Angelis (I, Ac)	

Ac: Academic; I: Industry; AnW: Animal Welfare; G: Governmental.

## **II.1.1.2. Platforms**

### **II.1.1.2.1. Austrian Platform**

» [z e t – Austrian Centre for Alternative and Complementary Methods to Animal Testing](#)

- The Linz-congress has taken place on September 28-30, 2007, the “14th Congress on Alternatives to Animal Testing & 11th Annual Meeting of MEGAT - Middle European Society for Alternatives to Animal Testing”, Linz, Austria.

### **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

- DACOPA has decided to postpone the Opening Symposium initially scheduled for November 9, 2007. The new date will be sometime during 2008; exact date has not yet been decided upon.

### **II.1.1.2.5. Dutch Platform**

» [NCA - The Netherlands Centre Alternatives to Animal User](#)

### **II.1.1.2.6. Finnish Platform**

» [Fincopa](#)

- A short report of the meeting of Fincopa board (Helsinki, August 17, 2007).

The meeting was the first meeting of the board elected in the business meeting in May 2007. Professor Hanna Tähti stepped down as chairman (2003-2007) of Fincopa, and is now followed by Dr Eila Kaliste.

The new board is:

Dr. Eila Kaliste (President), Dr. Paula Vesa (Secretary), Dr. Marianna Norring (Treasurer), Prof. Kirsi Vähäkangas (Vice- President), Dr. Christina Björklund, Dr. Helinä Ylisirniö, Prof. Hanna Tähti (Past President) and Dr. Kimmo Louekari. The members represent the four parties as follows: research (2), administration (2), animal protection (2) and industry (2). In addition there are nominated vice members for each board member. The complete list can be found at the web page of Fincopa:

 <http://www.uta.fi/jarjestot/fincopa/index-suomi.htm>

- The coming activities of Fincopa were discussed. Fincopa will organize in connection of the annual meeting on Spring 2008 a seminar. In this seminar, state of the development of alternative methods will be presented. The follow-up of the alternatives applied in REACH will be another important topic.
- The board discussed the strategy and coordination of the cowork in the development of alternative methods in Finland. The process should follow the proposals presented in the Memorandum of the working group of the Ministry of Agriculture and Forestry, published in 2006. One of the proposals was that " A national Centre for Alternative Methods should be founded to promote, organizes and coordinate research, communication and education on alternative methods".
- The contacts with Estonian colleagues and the possibility to organize the Finnish–Estonian coowork in *ecopa* were discussed.
- Prof. Kirsi Vähäkangas was elected to represent Fincopa at the *ecopa* meeting November 24/25, 2007.
- Five new members were elected.
- The last board meeting took place on December 04, 2007.

 [PDF: Fincopa Activity Report 2006 \(21 kb\)](#)

#### **II.1.1.2.7. Latest news on the creation of the French platform**

- The set up of the French platform has been finalized. [The official inauguration meeting](#) of the "Plateforme Nationale pour le développement des Méthodes alternatives à l' experimentation animale" took place on November 16, 2007, Paris, France. [Isabelle Fabre presented the French platform](#) at the annual *ecopa* meeting on November 24/25, 2007.

It has been presented that the French platform is constituted of a Steering Committee and 2 Technical Scientific Committee (TSC), one dedicated to health products, secretariate associated with Afssaps, the other one dedicated to chemicals, secretariate associated with Ineris.

In the framework of the TSC for chemicals, Ineris is setting up a big project involving up to 125 french researchers; the project named ANTIOPES, the title being "Integrated Analysis of predictive toxicity for environmental health". This project includes alternative methods to animal testing as recommended by REACH.

Ineris plans to organize a meeting to present this project on February 8, 2008 in Paris, France.

Ineris is going to invite personalities from national and international organisms involved in the environmental field and in alternative to animal testing.

Horst Spielmann and Vera Rogiers have been invited to represent *ecopa* in that project initiated by Ineris.

#### **• Présentations GIS**

 [PDF: GIS Introduction \(32 kb\)](#)

 [PDF: Le médicament Stratégie 3R \(1.1 MB\)](#)

 [PDF: Grandes orientations possibles des activités du GIS sur les substances chimiques \(724 kb\)](#)

 [PDF: Grandes orientations \(748 kb\)](#)

 [PDF: La plate-forme nationale Méthodes alternatives \(684 kb\)](#)

 [PDF: Methodes alternatives\(884 kb\)](#)

 [PDF: Groupement d'Intérêt Scientifique \(1 MB\)](#)

 [PDF: Que fait-on en France pour le développement des « méthodes alternatives »? \(664 kb\)](#)

#### **II.1.1.2.8. German Platform**

» [Stiftung set](#)

- The Annual Report for 2006 has been approved by the council on June 28, 2007 and is to be found on

the website.

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

 [PDF: set Activity Report \(76 kb\)](#)

#### **II.1.1.2.9. Hungarian Platform**

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

#### **II.1.1.2.10. Italian Platform**

» [IPAM - Italian Platform on Alternative Methods](#)

-  [PDF: IPAM annual report 2006 \(5 kb\)](#)

#### **II.1.1.2.11. Irish Platform**

#### **II.1.1.2.12. Norwegian Platform**

» [Norwegian School of Veterinary Science](#)

- With the assistance of the Norwegian Ministries , a permanent, *ecopa*-style, National Consensus Platform in Norway was established. The official opening ceremony took place on October 10, 2007, in Oslo/Norway, at the Norwegian School of Veterinary Science. Our treasurer Bernward Garthoff was present and introduced the work and support of *ecopa*.

 [PDF: Presentation by Dr. Bernward Garthoff \(1,8 MB\)](#)

 <http://oslovet.veths.no/fag.aspx?faq=56>

 [PDF: Presentation Norecopa at the recent \*ecopa\* Annual meeting \(204 kb\)](#)

#### **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](#)

- The REMA activities can be found can at (Spanish version):

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

#### **II.1.1.2.15. Swedish Platform**

» [Stiftelsen Forskning utan djurförsök](#)

- Karin Gabrielson had been replaced by [Cecilia Clemedson](#) due to her maternity leave, who was the official contact for Swecopa until recently. Karin Gabrielson Morton is back as the chair person and contact of Swecopa as of August. [Staffan Jakobsson](#), deputy chair of Swecopa, passed away after having been severely ill for a very short time only. Our sincere condolences.
- **Government support for 3Rs research**  
The Swedish Animal Welfare Agency was closed down in July of 2007. The National Board of Agriculture has taken over the responsibility for all tasks regarding laboratory animals and research into 3R's alternatives, from the Animal Welfare Agency. A total of 9,9 million SEK has been allocated to 3R's research in 2007, to be compared to 18,6 millions in 2006. The funding for 2008 has not yet been decided, but it is likely to be less than in 2007.

Also, it is still not known if there will be future funding for Patric Amcoff's position at the OECD.

- References/links to the Swecopa website should be changed to:

 <http://www.swecopa.se>

#### **II.1.1.2.16. Swiss Platform**

» [3R Research Foundation Switzerland](#)

- Update on Activities:

Latest bulletin of May 2007 to be found here:

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

### **Meeting to mark the 20th anniversary of the 3R Research Foundation and the 20th anniversary of the Swiss Laboratory Animal Science Association (May 2007).**

This meeting was held on September 3-4, 2007 at the Zurich-Irchel University in Zurich. On both days more than 400 persons attended the conference, The focus on day 1 was on „Humane Endpoints“. 39 speakers from Germany, Netherlands and Switzerland presented their results and shared their experience with the audience in two parallel sessions and 4 workshops.

On day two, the focus was on the 3Rs in all his facets (see program). More than 260 persons attended the 3R sessions. 14 invited speakers showed how the 3Rs improve animal welfare, experimental design and results (see photos). The summaries of the papers given have been collated in a 70 page brochure.

 [PDF: 3R-Brochure \(1,8 MB\)](#)

 <http://www.forschung3r.ch/en/news/index.html>

On March 26, 2007 the Administrative Board approved the Annual Report for 2006. Direct link:

 <http://www.forschung3r.ch/en/information/jb06.html>

#### **II.1.1.2.17. UK Platform**

» [The Boyd Group](#), founding member of *ecopa*, decided to withdraw from the *ecopa*-umbrella-activity, effective November 2007.

- Further information and reports are available at the Group's web-site:
  - » <http://www.boyd-group.demon.co.uk>

#### **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\* \(200 kb\)](#)

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**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](http://www.reprotect.eu)

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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 last Supervising Board Meeting was held on June 28/29, 2007 in Madrid, Spain

The Annual Research Area meeting and the Meeting of the Executive Committee was held in Ispra, Italy November 26/27, 2007. A brochure on the ongoing activities is available.

 [PDF: ReProTect Brochure](#)

 [PDF: Executive Summary \(224 kb\)](#)

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

 [PDF: ReProTect Flyer \(320 kb\)](#)

ecopa is involved in the Board and the results dissemination.

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

### II.1.3.1. Recent News

Find the non-confidential information on the First Annual Report of the PREDICTOMICS project here:

 [PDF: Publishable Executive Summary](#)

The consortium has launched a new website with several improvements to facilitate the dissemination of the research done. In the public accessible part, clear and easy to understand information is provided to a general reader, as well links to contact the individual groups through the webmaster.

The 6th meeting took place on December 10-11, 2007 in Valencia/Spain.

Websites: [www.predictomics.com](http://www.predictomics.com) or [www.predictomics.org](http://www.predictomics.org)

 [PDF: PREDICTOMICS - Specific Target Research Project \(268 kb\)](#)

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



### II.1.4.1. Recent News

 [PDF: ACuteTox Summary Report \(80 kb\)](#)

 [PDF: ACuteTox - Optimisation and pre-validation of an \*in vitro\* test strategy \(44 kb\)](#)

 [PDF: ACuteTox - Integrated Project \(324 kb\)](#)

 [PDF: ACuteTox - Integrated Project \(136 kb\)](#)

The first ACute Tox newsletter appeared in December 2006 with amongst others a summary of the project results accomplished during the first project year. The last ACuteTox newsletter appeared in July 2007 and the next newsletter will be available and distributed by next month.

The main results achieved in 2006 are summarized in a press release which you can download from the website

 [http://www.acutetox.org/docs/Press\\_release ACuteTox Augt 07 english.pdf](http://www.acutetox.org/docs/Press_release_ACuteTox_Augt_07_english.pdf)

A mid-term report on the project has been submitted by end of September 2007.

 [PDF: ACuteTox Mid-term report \(92 kb\)](#)

You can subscribe to it by sending an email to [ACuteTox@expertradet.se](mailto:ACuteTox@expertradet.se) and in the mean while, it can be consulted on the website:

 <http://www.acutetox.org>





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

#### II.1.5.1. Recent News

*ecopa* 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](http://www.sens-it-iv.eu), section press material.

*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* released a brochure covering the activities on behalf of Sens-it-iv, and supported the website creation

The twelfth newsletter will appear mid December. Subscription possibility on the website.

The General Assembly Sens-it-iv and Meeting of Sens-it-iv Management Team, Steering Committee took place on October 22-26, 2007 in Ispra, Italy.

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

#### II.1.6.1. Recent News

The third scientific conference for the BioSim Network took place in Potsdam, Germany, from October 10-13, 2007.

The BioSim network of excellence, now in the third year of activity, has accomplished already many tasks. The first and most important one is that very coherent sub-networks assembled around specific topics. This is the case of diabetes, cancer and circadian rhythms, hypertension and cardiovascular diseases.

In those areas, mathematical simulation has been proven to be possible from gene expression to whole-body metabolism, covering, in between, also cell signalling, metabolic regulation and intracellular fluxes of molecules. The pathway of collaboration is still scattered, but the trials performed are very promising and, for some of them, is already possible to forecast clinical outcomes. The area of mental disorders and neuronal system is still in search of optimal interfaces among different possible collaborators, being competences still a bit far from each other: therapeutic effects of desynchronizing brain simulation goes together with models for sleep-wake cycles or energy metabolism related to inclusion formation in neuronal disease. However a fruitful dialogue is started and integrated possible tasks are explored.

Some application has been shown concerning computer simulation in the design of clinical trials and in predicting human metabolic clearance, by incorporating population variability. More in general the aspect of the contribution of modelling and biosimulation to health care has been discussed and a relevant approach has been presented, consisting in the Innovative Medicine Initiative (IMI) which will be eventually approved by the end of the year ([www.imi-europe.org](http://www.imi-europe.org)). It is a joint initiative between the EU Commission and EFPIA, to launch a research project aimed at improving the drug efficacy and minimising the counter effects. An increased collaboration among industries and academia is at the basis of this effort.

Being biosimulation in the phase of blooming, the methodological aspects are of great interest: challenges of modelling cell synchronisation, the role of noise in cellular processes or mapping the sensitivity of regulatory networks are met with success, with the aim of applying them to other organisms or pathway in the search perhaps (again!) of the universal fundamental formula!

For more information the home page of the project is the following:

 <http://www.biosim-network.net>

### II.1.7.1. Recent News

*ecopa* - Representative in Liintop is Horst Spielmann.

 [PDF: Liintop Summary \(22 kb\)](#)

The Kick-off meeting of Liintop was organized on January 12-13, 2007 in Rome, Italy. The agenda of the last Management Team Meeting, held June 18, 2007 in Manchester, UK, can be found on the website.

The next meeting of all Working groups will take place in Rennes on 24-25 Jan 2008.

 <http://www.liintop.cnr.it/img3/MTMeetingSchedule.doc>



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

### II.1.8.1. Recent News

The Kick-off meeting of CarcinoGENOMICS took place November 5-7, 2006 in Maastricht, the Netherlands.

 [PDF: CarcinoGENOMICS Press Release \(24 kb\)](#)

The 1st Consortium & General Assembly Meeting was held on Nov. 6-8, 2007 in Valencia/Spain. A questionnaire of the WP 11 (the workpackage directed by *ecopa*) regulatory group is available on the carcinoGENOMICS website: [www.carcinogenomics.eu](http://www.carcinogenomics.eu) for consultation and input. It was also distributed at the last EPAA-meeting which was covering regulatory aspects (Nov. 5, 2007/Brussels/Belgium).

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

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

The EU-Parliament decided on the initiatives of industry and science enforcing European competitiveness by Dec. 11. For the so-called "4 Flagship"-programs, a total of 2.67 billion € will be expended, Under these, the allocation of funds for Innovative Medicine (1.0 bn), and Nanotechnology (0.45 bn) are prominent!

**SusChem**

### 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 5th Stakeholder Meeting took place on March 8, 2007 at the Concert Noble in Brussels.

Presentations available on suschem website

 <http://www.suschem.org/content.php?pageId=3428>

The next event listed on the SusChem calendar is the 6th Stakeholder and brokerage event on **January 29-30, 2008** - in Berlin, Germany. On the second day panel-led discussions on major issues of sustainable chemistry cover the nanosciences and the climate change. Both panels will involve representatives from industry, academia and the NGO community. The afternoon is devoted to a workshop, which will explain how to prepare a good proposal for collaborative research in FP 7.

### II.2.2. Preparation 7th Framework Programme Projects

The objective of a workshop **"EU funded research on alternatives to animal experimentation: stocktaking from FP6 and views for the future"** that took place on June 13-14, 2006 was to identify gaps in research in the area of development of alternatives to animal testing, to explore ways to close this gap, and to identify opportunities for strategic research activities to be formulated and implemented under FP7.

Additional info on this workshop with the official report and the new topics that were discussed for future projects can be found here:

 [PDF: Group A Report \(Contribution of QSAR/QSPR to alternatives\) \(960 kb\)](#)

 [PDF: Group B Report \(Nanotechnology and alternatives\) \(36 kb\)](#)

 [PDF: Group C Report \(Alternatives and Drug Discovery / Development\) \(88 kb\)](#)

Given *ecopa's* follow up-project START-UP (see topic II.2.4) the Group C report will be a basics for discussion.

### II.2.3. Regulations of the 7th Framework Programme

Update 7th EU RTD- Framework Programme

#### 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](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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*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, if approved accordingly and negotiated with the Commission.

### II.2.4. 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 \(1,2 MB\)](#)

## II.2.5. 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.

## Miscellaneous

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### III.1.1. *ecopa* events

#### III.1.1.1. 9th Annual *ecopa* Workshop

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

The future *ecopa* Annual Meetings will be:

10th: November 28-29, 2009

11th: end of November 2010

#### III.1.1.2. *ecopa* Board meeting

 [PDF: Minutes of the \*ecopa\* Board Meeting: September 27, 2007, Linz, Austria \(32 kb\)](#)

The next *ecopa* Board meetings:

March 4, 2008

September 23, 2008

March 3, 2009

September 16, 2009

#### 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](#).

The next workshop is to take place in October 2008 in Pueblo Acantilado; Alicante, Spain; either October 16-19 or October 2-5, 2008 will be the date. It will focus on "Scientific and technological progress in 3 Rs alternatives in the pharmaceutical and cosmetic area: current and in future".

### **III.1.2. other events**

#### **III.1.2.1. The 6th SusChem Stakeholder Meeting and 2nd Brokerage Event**

to be held on **29 and 30 January 2008** at the Hotel Concorde in Berlin.

For more information:

» <http://www.suschem.org>

#### **III.1.2.2. EUROTOX 2008**

to be held in Rhodes, Greece from October 5–8, 2008. The theme of the Congress is "FROM TOXINS TO OMICS : HEALTH, SAFETY AND WELL-BEING". Its scientific programme comprises symposia and workshops accordingly whereas distinguished and renowned speakers will address the participants, presenting the current and latest scientific innovations, discoveries and practices on important subjects in the multidisciplinary field of Toxicology.

For more information visit:

» <http://www.eurotox2008.org/>

#### **III.1.2.3. Recombinant Antibodies Annual Conference 2008**

##### **New approaches and opportunities for faster antibody development**

to be held in London on the **23rd – 25th January 2008**.

For more information:

» <http://biotechnology-europe.com/events/>

#### **III.1.2.4. International Congress on *In Vitro* Toxicology, ESTIV2008**

to be held at Djurönäset in Stockholm 25–28 Sept, 2008.

For more information:

» <http://www.estiv2008.org>

### **III.2. Awards and Publications**

#### **III.2.1. Announcement of the Doerenkamp-Zbinden-Prize 2008**

The Doerenkamp-Zbinden Foundation for Animal-Free Research will again award a prize for outstanding achievements in scientific animal protection in 2008. Suggestions for the prize may be made by members of the Foundation Board or the Scientific Advisory Committee of the Doerenkamp-Zbinden Foundation as well as by recognized institutions of science and animal protection (e.g. universities, scientific societies, private research institutions, interregional animal protection organisations). Direct applications for the prize are not possible. Suggestions may be made by December 15, 2007.

If no convincing suggestions for a laureate are made to the Foundation Board, the prize will not be awarded in 2008. According to the deed of the foundation scientific methods which can replace or reduce animal experiments that cause pain and suffering, especially to non-human primates, dogs, rabbits and cats as well as pigs, horses and ruminants are worth funding. Work in basic research will be considered preferentially according to the new deed of the foundation.

The prize is endowed with 25 000 CHF and can be shared.

For more info see website:

» <http://www.doerenkamp.ch/en/default.html?id=64>

#### **III.2.2. Dieter Luetticken Award**

##### **Announcement of the Intervet's award 2008**

Intervet offers the Dieter Lütticken award to promote scientists or life science research institutions working in research areas that serve the 3R-concept i.e. reducing, refining or replacing the use of animals in testing for development and production of veterinary medicines. The total funding for the award is 20,000 Euro.

Intervet actively screens at country level for suitable applications. However, Intervet welcomes

submissions for the Dieter Lütticken Award from all scientists and life-science research institutions, excluding commercial organizations.

### **III.2.3. EPAA Newsletter, October 2007**

The 4th edition of the EPAA-newsletter is available now.

» <http://ec.europa.eu/enterprise/epaa/news.htm>

### **III.2.4. New ECVAM Workshop Reports no's 60 and 63 - now available online**

ECVAM wishes to inform, that the new ECVAM Workshop Reports no. 60 "[Chemical Respiratory Allergy: Opportunities for Hazard Identification and Characterisation](#)" and no. 63 "[Physiologically-based Kinetic Modelling \(PBK Modelling\): Meeting the 3Rs Agenda](#)" are now online.

The Workshop Report can be downloaded from the [ECVAM Website](#). Please select inside the section "Publications / Workshop Reports."

### **III.2.5. Biographics Laboratory 3R-newsletter (fall 2007)**

The VirtualToxLab has been launched on the internet. It claims to estimate the toxic potential of drugs and environmental chemicals towards a total of currently nine receptor models completely *in silico*.

<http://www.biograf.ch/downloads/newsletter.pdf>

### **III.2.6. DG SANCO Newsletter**

The second issue of the newsletter of DG SANCO concerning the activities of the Commission Scientific Committees SCHER (Scientific Committee on Health and Environmental Risks), SCCP (Scientific Committee on Consumer Products) and SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks) has been published. This Newsletter is also available on DG SANCO website.

» [SANCO-c7-newsletter@ec.europa.eu](mailto:SANCO-c7-newsletter@ec.europa.eu)

### **III.2.7. SCAW's 2007 Rowsell Award and New Publication**

SCAW (Scientists Center For Animal Welfare) announces the recipients of the annual Harry C. Rowsell Award:

Steven P. Pakes, DVM, PhD, the Award will be presented at SCAW's 2007 Winter conference in San Antonio.

### **III.2.8. EU animal statistics**

The 5th report on the statistics and number of animals used in research is published by the EU Commission.

» [http://ec.europa.eu/environment/chemicals/lab\\_animals/pdf/staff\\_work\\_doc\\_sec1455.pdf](http://ec.europa.eu/environment/chemicals/lab_animals/pdf/staff_work_doc_sec1455.pdf)

### **III.2.9. 26. Tierschutzforschungspreis / 26th Research Award for Animal Welfare**

of the German Ministry for Agriculture associated with € 15,000 was given to Dr. Ellen Fritsche, The University of Duesseldorf, Germany and Dr. Christoph Giese, ProBioGen, Berlin, Germany on December 11, 2007.

### **III.2.10. Research Expenditure for 3R Alternatives: A Review of National Public Funding Programmes in European Countries**

*ecopa*, in cooperation with P+G and Eurogroup for Animals has finalized a survey of funding Alternatives; [as presented at the ecopa Annual](#), [and here is the report](#). Cumulative data on Germany and EU FP 5,6,7 funding was given in [Garthoff's presentation](#).

### **III.2.11. Swiss Laboratory Animal Science Association announces newsletter**

## **III.3. Calls**

### **III.3.1. The call for experts for the seventh framework programme has been launched**

The personal data collected in the context of the present call will be processed in accordance with the Regulation (EC) n° 45/2001 of the European Parliament and of the Council of December 18, 2000 on

the protection of individuals with regard to the processing of personal data by the Community institutions and bodies on the free movement of such data.

» <https://cordis.europa.eu/emmp7/index.cfm?fuseaction=wel.welcome>

### **III.3.2. The ECLAM ESLAV Foundation is now accepting applications for funding in 2008-2009**

It is a charitable organisation that funds studies for the discovery, validation and implementation of refinement of the care and use of animals in research.

In particular the Foundation funds small studies, up to 20000 euros in the following areas:

- Refinement in experimental techniques, anaesthesia and analgesia to reduce pain and distress
- Objective measures of animal welfare.
- Studies to ensure scientific basis for housing and husbandry standards
- Validation of environmental enrichment to improve behavioural well being

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

The Foundation's website can be found at:

» <http://www.eclameslavfoundation.org>

with a grant application form at:

» <http://www.eclameslavfoundation.org/applications.htm>

A leaflet describing the Foundation is available at:

» <http://www.eclameslavfoundation.org/promotion/2007Flyer.pdf>

## **III.4 VARIA**

### **III.4.1 Public Consultation on the Green Paper 'European Research Area: New Perspectives'**

The European Commission invites citizens and stakeholders to participate in the debate on the European Research Area (ERA), in particular by putting forward their views in this public consultation. The consultation is based on the questions raised in the Green Paper 'The European Research Area: New Perspectives'.

The results of the debate will be used by the Commission to prepare initiatives that will be proposed in 2008.

More detailed information can be found on:

» [http://ec.europa.eu/research/era/consultation-era\\_en.html](http://ec.europa.eu/research/era/consultation-era_en.html)

For more information and to participate in the consultation please visit the consultation web site.

» <http://ec.europa.eu/yourvoice/ipm/forms/dispatch?form=ERAGreenPaper>

### **III.4.2. The NC3Rs - Information Portal - Species selection**

The British NC3Rs has an extensive Information Portal where to find a wide range of references and links for guidance on implementing the 3Rs.

A new section on [species selection](#) has recently been added. Where animal use is necessary in research or testing, the choice of species (and breed/strain) should always be carefully considered and justified. This page sets out some of the factors to consider, particularly in relation to the 3Rs.

### **III.4.3. Training Course on metabolism:**

ADME, PK/TK, and Drug Metabolism in Drug Discovery and Development, January 22nd and 23rd 2008, Brussels, Belgium.

For more information:

» <http://www.mondialresearchgroup.com>

### **III.4.4. An Innovative Website on Non-Animal Methods of Toxicity Testing**

AltTox.org offers three ways to help accelerate progress on *in vitro* and *in silico* approaches to toxicity testing.

For more information:

» <http://www.alttox.org/>

### **III.4.5. Open Call for Traineeship at ECVAM**

The Institute for Health and Consumer Protection (IHCP) has launched an open call for traineeship as

part of a scientific trainees programme within the framework of the traineeship scheme of the [Joint Research Centre \(JRC\)](#). ECVAM as part of the IHCP offers one of the positions, with a duration of 12 months, to work on alternative methods to animal testing in the field of topical toxicity for individuals who have just finished their University, Master's degree or PhD.

More information: [General conditions \(IHCP website\)](#), specific information on the ECVAM traineeship: [Project n° 023/TR/IHCP/ECVAM/2007](#).

First cut-off: 18 January 2008.

Contact for applications: Elena Moneta, Tel.: +39 0332 786204, e-mail: [jrc-pns-recruitment-ihcp@ec.europa.eu](mailto:jrc-pns-recruitment-ihcp@ec.europa.eu).

For more information:

» <http://ecvam.jrc.ec.europa.eu/index.htm>