

**Dear ecopa messenger subscriber,**

The recent *ecopa* Board Meeting in Brussels, which was the first attended by the newly elected Board Member Isabella De Angelis of Italy, addressed the plans for 2008 and 2009, especially the START-UP-7th Framework Programme-project of *ecopa* which was the major topic that fits into the overall subject, and which *ecopa* is following with its member NCPs. It started on March 1, 2008.

Actual time schedule of all events: <http://www.ecopa.eu/content/events.php>

 [Minutes \*ecopa\* Board Meeting of March 4, 2008 \(180 kb\)](#)

Regarding the last *ecopa* Annual Meeting of November 2007, the minutes are also available now, as well as some of the presentation which provide a good basic information for START-UP, e.g.:

 ["3Rs in Safety Assessment in Pharmaceutical Industry", Prof. Friedlieb Pfannkuch, MD \(340 kb\)](#)

 [8th Annual \*ecopa\* Workshop - Minutes \(236 kb\)](#)

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

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


*ecopa* now covers 13 countries on the European continent, now including the two new member platforms, i.e. the Plateforme Nationale of France, and Norecopa from Norway.

The theme of the next eSi (*ecopa* Science Initiative)-Workshop in Alicante/Spain will address: "Recent developments and potentially novel approaches of science to alternative testing of cosmetics and pharmaceuticals". Scheduled date is October 16-19, 2008. The European Partnership for Alternative Approaches to Animal Testing, EPAA, will most likely participate in it.

This meeting will also contribute to the groundwork for the new *ecopa* EU 7th FP-project [START-UP](#) (support-action). The project "Scientific and Technological issues in the 3Rs Alternatives Research in The process of drug development and Union Politics" will be "started-up" with the kick-off meeting on April 10, 2008 in Leverkusen, Germany. At this meeting, the management board together with the participating platforms will discuss the strategy of the project for the near future: there will be two preparational meetings in 2008 besides of eSi followed by 3 workshops in 2009. The next *ecopa* Annual Workshop will take place on November 29 and 30, 2008 in Brussels, please note the date. Topic will most likely be: "Cosmetics Directive, REACH legislation and novel Directive 86/609: realistic 2013 - deadlines?"

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](#).

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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* secretariat.



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



## ECHA (European Chemical Agency)

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### The Member State Committee of ECHA starts working

The first meeting of the Member State Committee took place in Helsinki on February 26-27, 2008. This Committee will play a key role in decision making of the Agency. Its essential task will be to aim for unanimous agreements in such cases where Member States of the EU have diverging views on the Agency's draft decisions or proposals for candidates as Substances of Very High Concern. The first meeting set the scene for the Committee's work by putting down the first operating rules, work processes and priorities.

More information here: [http://echa.europa.eu/doc/press/080228\\_PR\\_MSC\\_1-Final%205.pdf](http://echa.europa.eu/doc/press/080228_PR_MSC_1-Final%205.pdf)

### Concerns over some unclear aspects (source: ICIS, February 11, 2008)

Reservations have been expressed about the preparedness of European regulators, and about the REACH-IT, fundamental to the operation of the system. This, and other as - yet unresolved issues such as participation in Substances Information Exchange. Forums (SIEFs), the size of fees and the role of the Only Representative (used by exporters to the EU) are valid concerns.

### Comparison of the systems

Still, the race is on to compare the regulatory systems for chemicals: the US Government Accountability Office (a Congress institution) assessed in their August-2007-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).

### REACH registration is starting on June 1, 2008!

The table below gives an overview on REACH information requirements and timetable reg. chemicals

regulation: (Source/acc. to ICIS, Nov. 4, 2007)

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

#### Important and helpful:

Price Waterhouse Coopers has conducted a global survey on REACH and it turned out that many companies are not yet aware of the consequences of the REACH legislative. The report "Global companies weigh risks and rewards of Europe's newest law on the safe use of chemicals" can be loaded down from the PWC-website (at no cost) here:

 [http://echa.europa.eu/doc/press/080228\\_PR\\_MSC\\_1-Final%20\\_5.pdf](http://echa.europa.eu/doc/press/080228_PR_MSC_1-Final%20_5.pdf)



[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)

News on e.g. the annual conference "**Regulatory acceptance of 3 Rs methods and strategies**" held November 5, 2007, in Brussels see the website:

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

EPAA-newsletter of January 2008 is published and can be read here:

 [http://ec.europa.eu/enterprise/epaa/epaa\\_newsletter\\_200801.pdf](http://ec.europa.eu/enterprise/epaa/epaa_newsletter_200801.pdf)

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 years. 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.

NEWS: The mirror group of stakeholders including the EP, animal welfare organizations, institutions and patient groups will again have the chance to give input into a future Mirror Group Meeting on April 16, 2008. *ecopa* is represented here by three of its members.

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

EPAA welcomes 2 new member companies Evonik and Sanofi-Aventis, bringing it up to a total of 36 member companies in the partnership.

For more information: <http://ec.europa.eu/enterprise/epaa/partners.htm>

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

The next annual meeting is scheduled for the beginning of November 2008 in Brussels. This years interest of EPAA is the topic of "Research".



#### 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.

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

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 can be obtained from the SCCP website, beginning of 2008.

 [http://ec.europa.eu/health/ph\\_risk/committees/04\\_sccp/sccp\\_statements\\_en.htm](http://ec.europa.eu/health/ph_risk/committees/04_sccp/sccp_statements_en.htm)

Also there is a workshop to be held soon, addressing Nanotechnology and the 3Rs (May 28/29, 2008, London/UK).

 [http://www.nano.org.uk/conferences/alt\\_Animals/proq.htm](http://www.nano.org.uk/conferences/alt_Animals/proq.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)

Currently, a new draft is being expected by May 2008.

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

### II.1.1.1. Recent News on FP6 and FP7 projects

#### NEWS:

New Scientific Officer: As of January 1, 2008, Dr. Ing. Juergen Buesing has been appointed as the new Scientific Officer to cover the area of Alternatives to Animal Testing within DG Research at the European Commission.

The recent *ecopa*-Board meeting was held on March 4, 2008 at the VUB, Brussels. It discussed the implementation and starting of START-UP.

Next Board Meetings scheduled:

- September 2008, during/after ESTIV-meeting, to be held on September, 25/26, 2008
- March 3, 2009
- September 16, 2009

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

- *SSA project ForInViTox* (Forum for researchers and regulators to meet manufacturers of toxicology test methods) - *ecopa* is represented by Dr. Odile De Silva.
- *BioSim* - Flavia Zucco represents *ecopa* in this EU Project.
- *CarcinoGENOMICS* - Bernward Garthoff is the *ecopa* representative in this IP FP6 project. *ecopa* has taken over the Work Package of dissemination of results of the consortium. [A questionnaire of the WP 11 regulatory group](#) can be found on the *carcinoGENOMICS* website for consultation and input. Input is requested and welcome from representatives of regulators, authorities, agencies and especially from toxicologists in industry and academia.
- *ACute Tox* - Peter Maier is the representative in the Advisory Board.
- *Sens-it-iv* - Vera Rogiers (represented by the *ecopa* secretariate) is the representative in the Advisory Board, and *ecopa* is seconding in the dissemination of results.
- *PREDICTOMICS* - Bernward Garthoff 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.

- *START-UP* – [START-UP](#) is the *ecopa*-follow-up-project for CONAM.
- *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, who attended her first *ecopa*-Board meeting on March 4, 2008 in Brussels.

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. This year’s 15th Congress on Alternatives is scheduled for September 19-21, 2008, 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 cowork 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.

#### **• 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**

» [norecopa](http://www.norecopa.no)

- The Norwegian Platform has started operation of their new website:

 <http://www.norecopa.no>

#### **II.1.1.2.13. Polish Platform**

» [polcopa](http://www.polcopa.pl)

#### **II.1.1.2.14. Spanish Platform**

» [REMA – Red Española para el Desarrollo de Métodos Alternativos a la Experimentación Animal](http://www.remanet.net/actividades/)

- 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](http://www.swecopa.se)

 <http://www.swecopa.se>

- 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.

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

» [3R Research Foundation Switzerland](http://www.forschung3r.ch/en/publications/bu35.html)

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

**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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#### **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 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.



[www.predictomics.com](http://www.predictomics.com)

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#### **II.1.3. Predictomics**

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 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 \(268 kb\)](#)





[www.acutetox.org](http://www.acutetox.org)

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## II.1.4. ACute Tox

### II.1.4.1. 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/docs/Newsletter/acutetox_newsletter_3.pdf)



<http://www.acutetox.org>

### E-learning program for in vitro methods

The scientific coordinator of the FP6 project ACuteTox, Expertrådet, is producing an e-learning program for the testing strategy and the methods that will be the result of the project. To get a good implementation and a wide use of the in vitro methods it is important to make it convenient for the industry to use them. One way is to produce interactive manuals that make it possible to attain reproducible results with high and equal quality in all laboratories.

Expertrådet has developed a pedagogic model for an interactive manual within the ACuteTox project. The SOP text is supplemented with short video sequences, photos and drawings that clarifies critical phases of the test methods. Each test will be presented in three different levels: 1) an introduction level where the tests are presented briefly to demonstrate the opportunities of the test; 2) a second level with the SOPs of the tests and with video sequences or pictures that demonstrate how to carry through the tests; 3) in the third level the scientific documentation and background of the tests could be found. The second level is the main part of the e-learning program that will consist of the interactive manual.

This model could also be useful for the other FP6 projects within the in vitro area and it would certainly be convenient for the endusers if the e-learning programs from the different projects looked similar and had the same pedagogic model. Expertrådet is willing to assist other in vitro projects to produce similar e-learning programs.

Contact for more information: [www.expertradet.se](http://www.expertradet.se), [www.acutetox.org](http://www.acutetox.org)



[http://www.ecopa.eu/download.php?file=ACuteTox\\_e-learning\\_abstract.pdf](http://www.ecopa.eu/download.php?file=ACuteTox_e-learning_abstract.pdf)

### Consortium meeting held on February, 20-22, 2008 in Konstanz

After the consortium meeting held in February 2008 in Konstanz, the phase of data compilation and generation has been completed. At this meeting, new software (Acusoft) was presented which will facilitate the estimation and comparison of IC50 values from atypical dose-response curves obtained in different test systems and with different compounds. Furthermore the incorporation of chemical properties of a given compound (pH, lipophilicity, protein binding) was shown to be a good indicator of their kinetic behaviour and to be a very efficient corrector factor for the correlation between in vivo and in vitro data.

A new committee within the project was established from members of the advisory board and from ECVAM. Their task is to develop a test strategy, using the best performing assays in the testing of the 57 reference chemicals. This pre-validation phase will start in the second half 2008.



[www.sens-it-iv.eu](http://www.sens-it-iv.eu)

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## II.1.5. Sens-it-iv

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

#### II.1.5.1. 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.

Newsletter Nr. 15 is out:

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

Newsletter-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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#### II.1.6. 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.1.6.1. Recent News

The third scientific conference for the BioSim Network took place in Potsdam, Germany, from October 10-13, 2007. The next (extended) Board Meeting will be on May 22, 2008 in Amsterdam, NL. The 4th BioSim-Conference is scheduled for September 24-27, 2008 in Budapest, Hungary.

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 signaling, 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>

## **Liintop**

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### **II.1.7. Liintop**

#### **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 recent meeting of all Working groups has taken place in Rennes on January 24-25, 2008.

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

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



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### **II.1.8. 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.1.8.1. Recent News**

 [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).

The next carcinoGENOMICS-Project Board is scheduled for April 21/22, 2008 in Cambridge, UK.

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

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

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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 expensed, Under these, the allocation of funds for Innovative Medicine (1.0 bn), and Nanotechnology (0.45 bn) are prominent!



**SusChem**

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### **II.2.1. Sustainable Chemistry (SusChem)**

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

 <http://www.suschem.org/>

The 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>

## 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

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](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.2.4. 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.

### II.2.4.1. The Abstract of the proposal

The **START-UP** project is concerned with the identification and proposals to abolish bottlenecks in the 3Rs approach in pharmaceutical discovery and development. The goal of the project is the organisation

of 3 **Workshops** in order to determine a) the state of the art of each of the 3Rs in the EU, b) to assess European strength and gaps in 3Rs and c) the identification of rate limiting steps on the political, scientific, technological level. As a result, a Consensus Paper containing the concepts and suggestions for a Roadmap for future research will be produced.


Stakeholders (among them European Pharmaceutical Industries (EPI)) have identified bottlenecks in drug development and in the integration of *in vitro* methods. Early identification of wrong candidates for further development and avoiding efforts for under-performing candidates, are essential for the competitiveness of European Industry. Identification of bottlenecks in the implementation of reduction, refinement and replacement of animal experimentation in drug R&D, should assist in identifying the best *in vitro* and *in vivo* systems, and to speed up the drug development process. Existing hurdles in the scientific, technological, political and environmental level (including regulatory), play a substantial role and are rate-limiting in developing new drugs, including biological entities (almost 50% of the currently developed products).

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

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

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

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

 [PDF: Presentation by Prof. Vera Rogiers \(1,2 MB\)](#)

**NEWS:** The Kick-Off will take place on April 10, 2008 in Leverkusen, Germany, when the *ecopa*-Board will meet with the NCPs and the individual organizers of the workshops.

## 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.

**NEWS:** The Kick-Off is scheduled for April 21-23, 2008, in Cologne, Germany, comprising an open public event on April 21, 2008, late afternoon.

## Miscellaneous

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### III.1. Events

#### 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

 [Minutes \*ecopa\* Board Meeting of March 4, 2008 \(180 kb\)](#)

The next *ecopa* Board meetings:  
September 25 or 26, 2008 (during ESTIV-meeting in Stockholm, Sweden)  
March 3, 2009  
September 16, 2009

 *ecopa*  
Science  
Initiative **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](#).

The next workshop is to take place in October 2008 in Pueblo Acanalado; 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".

**NEWS:** The next workshop is to take place in October 2008 in Pueblo Acanalado; Alicante, Spain on October 16-19, 2008. It will focus on "Recent developments and potentially novel approaches of science to alternative testing of cosmetics and pharmaceuticals". It will most likely be held together with the European Partnership for Alternative Approaches to Animal Testing, EPAA.

### III.1.2. other events

#### III.1.2.1. The Stem Cells Congress

to be held from **March 25-28, 2008** at the Moscone North Convention Center, San Francisco, CA.

For more information:

» [http://www.tri-conference.com/08\\_stm.asp](http://www.tri-conference.com/08_stm.asp)

#### III.1.2.2. FP7 - FINANCIAL & PROJECT MANAGEMENT

to be held from **April 3-4, 2008** in Budapest, Hungary.

For more information visit:

» <http://www.eustrainingsite.com>

#### III.1.2.3. Genetics & Pharmacokinetics in Drug Development

Luncheon seminar to be held in different cities on **April 7, 8, 9 and 10, 2008**

For more information:

» <http://www.microarraybulletin.com/pqx2008/>

#### III.1.2.4. "Metabolic Toxicology: From Pathway to Organism"

International Course to be held from **April 9-11, 2008** at the Auditório da Reitoria of the University of Coimbra, Portugal.

For more information:

» <http://cnc.cj.uc.pt/~pauloliv/Course/2008.htm>

#### III.1.2.5. Alternatives to Animal Testing Symposium

Organized by the European Directorate for the Qualities of Medicine & Healthcare to be held from **April 23-24, 2008** in Dubrovnik, Croatia.

For more information:

» <http://www.edqm.eu/site/Alternatives-to-Animal-Testing-Dubrovnik-Croatia-259.html>

### **III.1.2.6. Antibody Production Upstream & Downstream Processing**

to be held from **April 28-29, 2008** in Dubai/Dubai International Exhibition Centre.

For more information and registration:

» <http://www.pabme.com/antibodies>

### **III.1.2.7. "The Phenion® Skin Model Technologies and Their Applications"**

Second Technical workshop to be held from **May 27-28, 2008** in Düsseldorf, Germany.

For more information:

» <http://www.phenion.com/qb/workshops.php>

» [http://www.ecopa.eu/download.php?file=phenion\\_technical\\_workshop\\_registration.pdf](http://www.ecopa.eu/download.php?file=phenion_technical_workshop_registration.pdf)

### **III.1.2.8. Nanotechnology – towards reducing animal testing**

Workshop to be held from **May 28-29, 2008** at the Royal Society in London.

For more information:

» [http://www.nano.org.uk/conferences/alt\\_Animals/prog.htm](http://www.nano.org.uk/conferences/alt_Animals/prog.htm)

### **III.1.2.9. NC3Rs Workshop: 'Toxicokinetics and the 3Rs'**

The workshop will be held on **May 29, 2008** in central London (Zone 1).

For more information:

» <http://www.nc3rs.org.uk/toxicokineticsworkshop>

### **III.1.2.10. "Applying Systems Biology"**

Conference to be held from **June 9-11, 2008** at the The Fairmont Hotel, San Francisco, CA.

For more information:

» <http://www.beyondgenome.com/08sys.asp>

### **III.1.2.11. "21st Century approaches to toxicity testing, biomonitoring and risk Assessment"**

Workshop to be held from **June 16 -17, 2008** in Amsterdam, Netherlands.

For more information:

» <http://www.cefic-lri.org/templates/shwStory.asp?NID=36&HID=508>

» [http://www.ecopa.eu/download.php?file=ICCA\\_LRI\\_workshop\\_June\\_Amsterdam.pdf](http://www.ecopa.eu/download.php?file=ICCA_LRI_workshop_June_Amsterdam.pdf)

### **III.1.2.12. International Congress on In Vitro Toxicology, ESTIV2008**

to be held from **September 25-28, 2008** at Djurönäset in Stockholm.

For more information:

» <http://www.estiv2008.org>

### **III.1.2.13. 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:

» <http://www.eurotox2008.org/>

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

### **III.2.1. Cefic-LRI and EUROTOX 2008 Innovative Science Award**

The €100,000 prize, which aims to promote innovation in the field of toxicology, will be awarded this year by the LRI (Long Range Research Initiative) in conjunction with EUROTOX (Federation of European Toxicologists & European Societies of Toxicology). The application deadline was March 03, 2008.

For more information visit:

» <http://www.cefic-lri.org>

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

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

Boxmeer, March 17, 2008 – Intervet's Dieter Luetticken Award has been granted to Prof. Dr. George Gettinby from the University of Strathclyde, Scotland, United Kingdom. Gettinby's innovative statistical and epidemiological research methods in sea-lice treatments in salmon farming, fully commit to the advancement of the 3R concept - reducing, refining or replacing the use of animals in research, development and production of veterinary medicines.

» [http://www.intervet.com/news/2008-03-17-prof\\_dr\\_george\\_gettinby\\_wins\\_dieter\\_luetticken\\_award.asp](http://www.intervet.com/news/2008-03-17-prof_dr_george_gettinby_wins_dieter_luetticken_award.asp)

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

The newest (5th) edition of the EPAA-newsletter is available now.

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

### **III.3. Calls**

#### **III.3.1. The ECLAM ESLAV Foundation is now accepting applications for funding in 2008-2009**

It is a charitable organization 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 behavioral well being

Funding applications for 2007-2008 are closed. 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: [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.3.2. Call for expression of interest as Members of the Board of Appeal of ECHA**

The European Commission has published a call for expression of interest in the appointment as chairman and as members of the Board of Appeal of the European Chemicals Agency. For further information see the attached notice and the addresses (links) mentioned in the notice.

» [http://echa.europa.eu/doc/press/20080201\\_PR\\_08\\_01RAC.pdf](http://echa.europa.eu/doc/press/20080201_PR_08_01RAC.pdf)

#### **III.3.3. Call for interest for Grantholders for Doctoral and Post-doctoral positions in ECVAM**

The Institute for Health and Consumer Protection (IHCP) has launched a call for interest for Grantholders for Doctoral, Post-doctoral and Senior Research Positions. ECVAM, part of the IHCP, offers two of the Grantholders positions.

For more information:

» [http://ihcp.irc.ec.europa.eu/job/Grantholders\\_open\\_calls.htm](http://ihcp.irc.ec.europa.eu/job/Grantholders_open_calls.htm)

### **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.