Date: 23.12.2004, 02:50:44

Subject: ecopa messenger - #02-2004 X-mas/X-press,

This newsletter, the "ecopa-messenger", is part of our EU 6th Framework Programme-project CONAM, and it details information of other projects within that EU programme (such as PREDICTOMICS, ReProTect etc.) which were co-initiated and are supported by ecopa. It also addresses recent activites of ecopa and its working groups.

In this regard, it might be of interest to you that our Annual ecopa-Workshop in November covering SCALE and environmental testing, was seen as informative and interesting to the participants of the diverse parties as the former workshops in the years before.

just two quotes:

- "Many thanks again for the very good and informative ecopa meeting this weekend." Marlou Heinen, Eurogroup for Animal Welfare, Brussels, Belgium.
- "Thank you for the nice ecopa meeting." Hanna Tähti, Univ. Tampere, Finland.

The ecopa-Annual is apparently the DISCUSSION FORUM for alternative methods development. Results and details of the ecopa Workshop of November will be given by the "messenger" in Qu. 1/2005. For those participating resp. interested, please find photos of both the October/ November ecopa events (Photos 5th ecopa Workshop) & (Photos eSI Meeting). An update of ecopa status and activities you will find in the NEWS section on the ecopa website or here: Initiatives & Platform Formation, 2 MB

By the way, regarding the usage of our website 3520 total hits in November 2004 were performed by 940 visitors of more than 40 countries.

During the Annual Workshop addressing the general theme SCALE, environmental testing and impact of numbers of animal used, there were also discussions in regard to the impact of REACH, see GENERAL NEWS.

Even though this is already "messenger no. 2" appearing, and even though recipients seemed to have been content up to now with what they see, any proposal or recommendation regarding style, content or distribution of the newsletter is highly welcome and appreciated (bgarthoff@t-online.de)

FINALLY, after a very industrious and successful year for ecopa, let me wish you, on behalf of the Board a

Merry X-mas and a Happy New Year.

Bernward Garthoff Treasurer ecopa on behalf of the ecopa Management Board

P. S. If you know other people or institutions interested, have them visit our website and subscribe to this newsletter.

Issue # 02 (December 2004)

ecopa:

- General News
- Statement regarding SCALE
- Technical Info to use the Forum of ecopa

EU 6th Framework Programme Projects / ecopa Working Groups:

- CONAM
- ReProTect
- PREDICTOMICS
- eSI: ecopa Science Initiative
- Sens-it-iv

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- EU NEST Calls



ecopa had initiated this year several conferences and workshops which were either part of its general activities within the scope of its past mission, but also part of its now extended spectrum "to re-vitalize the alternative method-scene".

- The major decision at the Annual ecopa Workshop end of November was to start another sign-in action by ecopa for the European citizens to get heard. Before SCALE and testing regulations on that basis are being brought on their way into the EU parliament or being even finalized, we would like to direct you to the NEWS section, and the ecopa statement and sign-in.
- One other interesting aspect at the Workshop was the controversial EU wide discussion in regard to the impact of the REACH programme on expected total animal numbers to be used due to the regulations to come.

- Please find an updating information
 - a) regarding the discussed figures as outlined in a slide presentation by Bernward Garthoff at the workshop, and
 - b) a recent publication on this topic sent to us by Kees van Leeuwen (Head of the Institute for Health and Consumer Protection, DG JRC, Ispra, Italy) for information, in the FORUM section. (discussion in the ecopa forum)
- Also, at the Annual Workshop there was the updating on potentially new member platforms – see in the CONAM section of this X-press newsletter.

Statement regarding SCALE

During the ecopa Annual Workshop, the proposal of a new ecopa Statement regarding SCALE was agreed to.

Please find the full text below and sign-in on our website <u>ecopa statement in regard to SCALE (with sign-in)</u>.

STATEMENT OF THE ecopa - WORKING GROUP IN REGARD TO SCALE ON BEHALF OF THE ecopa ANNUAL ASSEMBLY

ecopa, the quadripartite umbrella organisation of National Consensus Platforms for Alternatives to Animal Experiments, has voiced, in the past, concern over the potentially extensive use of laboratory animals due to the new EU Chemicals Policy regulations based on the resp. White Paper and REACH-programme. Due to the intervention of ecopa and other organisations, there has been an appropriate adaptation of the request for testing and funding of the EU for alternative method development in that context.

With the EU environmental initiatives such as SCALE expanding the testing for and evaluation of safety resp. hazard and risk assessment, it is to be expected that once more lab animal testing will increase due to lack of existing adequate alternative methods within the foreseen time frame.

In fact, the current documents of the EU Commission and Technical Working Groups already indicate that exactly that is going to happen: they require the development of further animal models, instead of the respective alternatives.

ecopa demands that for the SCALE programmes, different fromt the REACH case, alternative method development is requested and funded from the very beginning, and is taken up as a guiding principle in the future regulations.

ecopa requests that for the estimate of lab animal testing required due to the future regulations, unbiased analysis is performed and reports are supplied to the European citizens and the Parliament.

This should be supervised and ensured by an independant organisation such as ecopa.

Also, ecopa asks the Commission, the Member States and the Members of the European Parliament to carefully balance the justified concerns for human health and the environment with the ethical concerns over additionally required testing, and lacking alternative methods for it.
The SCALE programme should be diligently screened for unnecessary testing activities that do not offer additional safety for human health nor environmental protection.
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Technical Info to use the Forum of ecopa
The Forum Section is now available via the ecopa page or the direct link (http://ecopa.vub.ac.be/forum/) .
 In regard to EU Project/ecopa Working Groups: to read and post messages in the Forum-section of the ecopa website, the users need to register themselves. After registration (and authorization by Board and Webmaster), each user-address has to be activated for this section. In regard to the General Discussion Section: the users need to be registered to post messages in this section, but they can read all posts in here. The Forum itself is quite self-explanatory, here's just a short introduction – and in addition you will find a detailed Q+A Section there as well: (forum FAQ) After you have registered yourself, click on a section to view or post a message.
 To post a message, click in a section on "new topic". When there already is a message in

- To post a message, click in a section on "new topic". When there already is a message in a section, you can click on "new reply" to directly reply to that message. You can click the button "pm" under a message, to write a private message to the author.
- Go to learn-by-doing, for any other questions or problems you can have a look at the forum-FAQ Section (forum FAQ) or sent a mail to the Webmaster.

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EU 6th Framework Programme Projects / ecopa Working Groups
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*Details, Minutes, Contract numbers and alike will be dispatched on the FORUM pages in future, once activated by the individual teams.



Abstract of the project

The CONAM project is proposed by ecopa. This is the only quadripartite not-for-profit organisation that promotes a consensus strategy for 3R-alternative methods in the EU. Innovative is that the 4 parties having a major interest, animal welfare, industry, government and academia, are equally represented and reach consensus. Actually, national consensus platforms of 10 Member States, 2 Associate States and 2 Associate Candidate Countries are involved.

The objective of CONAM is to build a solid network on 3R-alternatives, ideally including all European countries and with the aim to deliver critical consensus expert opinions on 3R-issues, to draw attention on new alternatives and technologies, to disseminate this information and to initiate collaboration.

Identified priorities are:

- Consensus networking on 3R-alternatives with focus on website expansion, to support existing and new national consensus platforms, to stimulate collaboration and linking in particular with non-EU candidate countries.
- Ethics with emphasis on harmonisation and consensus by analysing and proclaiming shared ethical, legal and societal values, to continue dialogue where others failed and to develop consensus documents with focus on "omics" technology, access to human data and samples.
- Education activities to support (inter)national training and education of 3R-methods with focus on non-EU candidate countries.
- Legislative issues with emphasis on the EU Chemicals Policy: to harvest relevant information on the translation of the EU White Paper into legislation, to disseminate and discuss among the 4 parties, to come with a consensus paper to advice the EU decision making process. ecopas networking offers equilibrated, scientifically-sound and technically-relevant expertise and experience. The opportunities of emerging "omics" technologies should be fully explored, including ethical, educational and socio-political impact.

Recent News

Still Open: the vacancy!

Open vacancy for secretary of ecopa. Candidatures to be sent to Vera Rogiers, position immediately available, full-time position at the Vrije Universiteit Brussel for at least 3 years, university diploma requested (politics, PR, Sciences,...) and language and writer skills (vacancy notice)

Platforms

- Polish Platform:
 Polish_Platform_Brussels.pdf (155 kb)
- Norwegian Platform: <u>PlatformNO.pdf (95 kb)</u>
- Hungarian Platform
 Hungarian_Platform_for_Alternatives-Ecopa_annual_assembly.pdf (55 kb)
- Slovenian Platform

ecopa_Bruxelles_Nov04_SLOVENIA.pdf (265 kb)

- Danish Platform
 Danish_Consensus_Platform_for_Alternatives_(dacopa).pdf (37 kb)
- Czech Platform
 CZECOPA_2004_Brusel.pdf (227 kb)

In future, the FORUM page for CONAM will also be activated – see above for technical details.

Also, there will be in that place more general information in that place on the CONAM project available, which will not necessarily be referred to by this newsletter – so, check it out (ecopa forum).

As part of the CONAM project and in response to the request of the EU, we will give any news, minutes of project (as far as they are non-confidential and non-proprietary) or post relevant info in the respective Forum Section. We will refer to it by use of the Newsletter. Also, as part of ecopa extended mission, we will refer to up coming events such as local workshop, conferences, meetings of the NCPs or ecopa working group etc. on our Website EVENT page, and if appropriate, in this newsletter.

Please supply us with the relevant info whenever deemed useful in your own interest.

Interested to form a new national platform in your country, if not existing? Please contact us under the CONTACT page.

For an upfront info how to create a platform in your country, and which criteria apply to be official recognized by ecopa, refer to the presentation of José Castell at the Stakeholder Workshop in Prague (ECVAM/ecopa Stakeholder Workshop)



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 €, resp. 13.5 mio €. Contract with the EU was signed on July 1, 2004; the administration is performed by Prof. Michael Schwarz, University of Tübingen.

Abstract of the Project

ReProTect is an Integrated Project of the EU (IP) funded within the 6th Framework Programme. This Integrated Project, putting together 35 different European partners from Academia, SMEs,

Governmental Institutes and others intends to explore the most complicate and delicate field of toxicology, the reproductive toxicity. The investigation in this field currently requires substantial number of animals and the main objective of this IP is to reduce this number. The project will drive the R&D toward alternatives to animal tests according to the needs identified, with the main intention to pre-validate and validate the most promising ones.

This represents the ambition of developing a novel approach in hazard and risk assessment of reproductive toxicity, by a combination and application of in vitro, tissue and sensor technologies.

The project will run over 5 years.

Recent News

The kick off meeting and the Supervisory Board-meeting took place in Ispra/Italy at the ECVAM-Location on July 18-21, 2004. (Links to the Minutes not open to the public yet!) A discussion on chemicals selection and metabolic activation was held at Ispra on November 29th and 30th, 2004 (link to the Minutes not open to the public yet).

Next meetings for the project partners (Area Research Meeting) is scheduled for January 18th and 19th, 2005, in Copenhagen and next Meeting of the Supervising Board for January 24, 2005 in Brussels.

For contact: reprotect@jrc.it

PREDICTOMICS

The ecopa-induced 6th Framework Programme project has been started in 2003, with 14 partners, all in all.

The overall funding is scheduled to be 2.3 mio €. Contract with the EU was signed on September 1, 2004; the administration is done by REMA.

Abstract of the project

The development of new pharmaceutical compounds will be more efficient if human relevant toxicology information early in the selection process is available. While acute toxicity can be reasonably detected during the early preclinical stages of drug development, long-term toxicity is more difficult to predict, relying almost exclusively on animal experiments. Animal experimentation of this kind is expensive and time consuming, raises ethical issues and does not necessarily represent best toxicological relevance to man. This project addresses the urgent need to develop in vitro based systems which are capable of predicting long term toxicity in humans.

The major objectives of this project are:

 1) To develop advanced cell culture systems which as best possible represent the human liver and kidney in vivo. This will be achieved using combined strategies namely: cocultures of resident cell types, targeted cell transformation, stem cell technology and new developments in organotypic cell culture (i.e. perfusion cultures and 3D cultures).

- 2) To identify specific early mechanistic markers of toxin induced cell alterations by using integrated genomic, proteomic and cytomic analysis.
- 3) To establish and prevalidate a screening platform (cell systems together with analysis tools) which is unambiguously predictive of toxin induced chronic renal and hepatic disease.

This proposal is unique in it's mechanistic integration of the three levels of cellular dynamics (genome, proteome and cytome) together with advanced cell culture technology to detect early events of cellular injury. Only with such an integrated approach will in vitro techniques ever be applicable to predicting chronic toxicity in man.

This project, if successful will (1) contribute to the replacement of animal testing in drug development, (2) increase the speed and decrease the cost of bringing new pharmaceutical compounds to the patient and (3) increase our understanding of toxin induced chronic disease development.

Recent News

The kick-off meeting was held on September 24 and 25 close to Valencia (Minutes of the Predictomics Kick-Off meeting)



The ecopaScienceInitiative is a project ecopa had initiated at its last Annual Workshop in November 2003 in Brussels (Minutes of the Fourth ecopa Workshop). The ecopa Management Board members had campaigned for it on different occasions and had also talks with representatives of the Cabinet of DG RTD of the EU Commission in that respect.

With substantial support of s e t , the German National Platform, Procter and Gamble, as well as Bayer CropScience, the Department of Toxicology at the VUB, the Dep.de Bioquímica Hospital Universitario La Fe of Valencia, this essential activity could be performed, and the workshop could be organized near Alicante, Spain (http://www.uv.es/~jcastell/indexESI.htm)

Abstract of the project

The eSI Conference under the heading: "Reaching the young scientist" was 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.

ecopa had invited some renowned European scientists, i.e. "doyens" in their field of research such as proteomics, genomics, pharmaco- and toxicogenomics, but also of other areas that might have relevance to the development of alternative methods. It was not asked for immediate proposals for alternatives application from these key note speakers in their state of

the art-presentation, but this had to be back in their mind, of course. In addition, ecopa has asked experts of technology applications to give their input as well. Also, ecopa invited some young research scientists and postdocs who might have some application for their current reseach projects.

The Workshop took place with 52 participants representing 14 European countries, 6 companies, thereof 1 SME.

Recent News

Pictures of the eSi-workshop

Quotes of eSi participants & speakers

eSi Report (PDF-File)

Sens-it-iv

This 6th Framework Programme-project is in statu nascendi and will be covered with some more detail in one of our next info ecopa-newsletters.

Other Projects



The European Commissio, DG Research, Directorate B (Structuring the European Research Area) has initiated NEST (New and Emerging Science and Technology) calls on the 10th of December 2004 (NEST_Calls.pdf).

The deadline for the submission of proposals, in total 65 mio €, is April 30th, 2005.