



Project Reference: LSSB-CT-2004-504776

CONAM

CONSENSUS NETWORKING ON ALTERNATIVES WITHIN EUROPE

Instrument: Specific Support Action

Thematic Priority: Life sciences, genomics and biotechnology for health

PERIODIC ACTIVITY REPORT # 3

Period covered: from 01-03-2006 to 31-03-2007 Date of preparation: 22-04-2007

Start date of project: 01-03-2004

Duration: 37 months

Project coordinator: Prof. Dr. Vera Rogiers

Project coordinator organisation: Vrije Universiteit Brussel

EXECUTIVE PUBLISHABLE SUMMARY

Contract Nr:	504776	Reporting period:	From 01-03-2006 to 31-03-2007
Title:	CONSENSUS NETWORKING ON ALTERNATIVES WITHIN EUROPE		

SECTION 1: PROJECT OBJECTIVES AND MAJOR ACHIEVEMENTS DURING REPORTING PERIOD 3**Overview of general project objectives, and the project's current relation to state-of-the-art:**

Overall, the general objectives of CONAM must be considered within a context where the development and implementation (after their official validation in the EU by ECVAM) of new 3R-alternative methods are on the rise in the EU, but where in contrast, the need for testing (in vivo respectively in vitro) is increasing.

This will especially be the case after implementation of the new EU Policy on chemicals, REACH. Moreover, the EU legislative climate on cosmetics is changing substantially since the implementation of the 7th Amendment, that imposes a progressive testing and marketing ban for cosmetic ingredients and cosmetics tested on animals, with specific deadlines. In this context, CONAM is important for the construction of an extensive consensus network for 3R-alternatives that ideally could cover all European countries (existing and new EU countries and candidate countries).

Summary of the objectives, the work performed, the contractors involved and main achievements in the second reporting period (please refer to SECTION 2 for more in depth reporting):

The objectives to be reached in the first, second and third reporting periods were met by the different Work Packages, all running under the sole contractor VUB- *ecopa*:

* Implementation of a management tool and develop final network plan: The management updated the Gantt chart for both reporting periods and allocated all tasks.

* Expansion of the *ecopa* website: The website (design, content) was thoroughly expanded throughout the reporting periods by Mr. Stephan Belitz.

* Creation of a newsletter: Already eleven issues of the *ecopa* newsletter were distributed.

* Starting up of contact building in order to create new platforms: New platforms were started up in Norway, Denmark, Poland, Hungary and Ireland resulting in a total number of 16 NCP's. Denmark and Hungary have been accepted as full *ecopa* members at the 6th Annual Meeting. DACOPA is holding its first DACOPA-Day in November 2007.

In 2007, the draft statutes for the permanent Norwegian platform were sent to the Ministry for approval and the chair of Norecopa, Prof. A. Smith is waiting for their reply (04-07).

France is in the process of starting up their national platform. The official inauguration in France for the national platform is foreseen for 2007.

* CONAM/*ecopa* Board participation in FP6 projects: A number of *ecopa* Board Members participate in FP6 projects that are involved in alternative methods e.g. in PREDICTOMICS, ReProTect, A-CUTE-TOX, Sens-it-iv, Biosim, ForInViTox, CarcinoGENOMICS and Liintop.

* CONAM/ecopa Board participation in FP7 projects: the *ecopa* Executive Board handed in a proposal for a Support Action in the HEALTH Call-2007-1.3-2, called START-UP. Different NCPs are involved.

ecopa Board Members are also participating in FP7 proposals that are involved in alternative methods e.g. ESNATS, Alterscreen and ZF-Altox.

* Organization of a Workshop: The seventh edition of the Annual *ecopa* Workshop was organized in Brussels on 25-26 November 2006. All stakeholders were present.

Also, the second edition of the *ecopa* Science Initiative (eSI) took place on 29-30 September 2006 in Pueblo Acantilado, Spain. In this event young scientists met established senior top scientists.

* Contact building with relevant bodies: Contacts with IVTIP have been further elaborated through collaboration within the FP6 Project Sens-it-iv.

* Information collection on chemicals and publication of report: After having the data collection finalized, a detailed calculation model for animal use in chemical testing was developed during 2005, namely the "*ecopa* calculator" and finally presented at the public at the Chemical Workshop, held on 01.02.06 in Brussels.

The final report has been realized in March 2007 and sent to the Commission.

* Start of the organization of an educational program: Following the example of the Spanish platform REMA, the Italian platform IPAM organised a course on alternatives in February 2007 for governmental people and scientists.

* Ethics working group organized a second international workshop on the 24th of November 2006 at the Sheraton, Brussels with the topic "Human tissues as alternatives for animal experiments" and conducted a survey by means of internet and telephone to update the information about the progress of the 3 R's (Replacement, Reduction and Refinement of the use of animals in scientific research).

Most important problems during the period including corrective actions undertaken:

No major problems were encountered during the reporting period.

SECTION 2 - WORK PACKAGE PROGRESS OF THE PERIOD**Progress of WP 0: MANAGEMENT in reporting period 2 (01-03-2006 - 31-03-2007)**

Progress towards objectives - tasks worked on and achievements made referring to planned objectives:

1. Review meetings: A first CONAM Review meeting took place in Den Hague, on 17-03-2005. A second review meeting was held in Brussels, on 16-12-2005. The minutes of these meetings are available at the *ecopa* website <http://www.ecopa.eu/>. The 3rd Board meeting took place in Basel on 16-03-06. The fourth meeting was held on 20-10-06 in Brussels and the final review meeting was organised in Paris, on 6-03-2007. Since the final Board Meeting took place in March, a prolongation with one month of the CONAM contract was asked to the Commission officials.

Deviations from the projects work programme, and corrective actions taken + nature and reason for the problem and contractors involved: A change in the date for the fourth review meeting took place, 20 October 2006 instead of 01 September 2006 and the final fifth review meeting was organised in Paris, on 6-03-2007 instead of 01-03-2007.

List of deliverables, including due date and actual/foreseen submission date

Del. no	Deliverable name	WP	Date due	Actual/ Forecast delivery date	Estimated Indicative Person-months	Used indic. person-months	Lead contractor	Status
9	Review 3	0	Month 23	Month 25 (16-03-2006)	2	2	VUB (<i>ecopa</i>)	Done
12	Review 4	0	Month 29	Month 32 (20-10-2006)	2	2	VUB (<i>ecopa</i>)	Done
20	Review5	0	Month 35	Month 37 (6-03-07)	2	2	VUB (<i>ecopa</i>)	Done

Table 1: Deliverables List

List of milestones (MS), include due date and actual/foreseen achievement date

MS.	Milestone name	WP.	Date due	Actual/ Forecast delivery date	Lead contractor	Status
2	Organization of interim meetings of the Management Board with report	0	16-03-2006	1-03-2006	VUB (<i>ecopa</i>)	done
3	Organization of interim meetings of the Management Board with report	0	20-10-2006	01-09-2006	VUB (<i>ecopa</i>)	done
4	Organization of 1 final meeting with end report	0	06-03-2007	06-03-2007	VUB (<i>ecopa</i>)	done

Table 2: Milestones List

Progress of WP 1: NETWORKING IN ALTERNATIVE METHODS AND FP6 in Reporting Period 2 (01-03-2006 to 31-03-2007)

Work Package objectives and starting point of work at beginning of reporting period:

The objective of this Work Package is to establish and organize the functioning and managing of a European network that aims to involve all potential National Consensus Platforms on 3R-alternative methods with emphasis on non-EU Candidate Countries, making sure that the four invited parties, being animal welfare, academia, industry and government, are represented adequately.

Progress towards objectives - tasks worked on and achievements made with ref. to planned objectives:

Please note that this period covers activities that are a continuation of those of the first period, mentioned in activity report 1.

a) A newsletter, called "*ecopa messenger*", was launched during the first reporting period. The goal was to send out a newsletter twice a year.

There is an overachievement as until now, 11 newsletters have been sent out and are published on the website: #07 (on 15-03-2006), #8 (05-07-2006), #9 (31-10-2006) and #10 on 16-12-2006, respectively the Xmas Xpress edition. #11 appeared 31 March 2007.

The content and structure of the newsletter is now standardized and provides detailed information on the different FP6-EU projects on 3R-alternatives: such as PREDICTOMICS, ReProTect, ACUTE-TOX, Sens-it-iv, Biosim, Liintop and CarcinoGENOMICS.

b) The website is functional as described in the previous report and was repeatedly updated.

A new statistic tool is running since June 2006, so figures are available for the last 11 months. The statistics for the last 11 months indicate that the *ecopa* website had 5299 visitors and 19452 hits.

The *ecopa* calculator was downloaded 119 times, so far (de datum 26/04/07).

The statistics also show a particular interest in the *ecopa* workshops, as the *ecopa* annual workshop and eSI workshop, more particularly the *ecopa* annual workshop of 2006 with 183 hits.

The visitors in 2007 were from the following countries: US (18%), Belgium (14%), Germany (12%), France (7%), Norway (5%) and other countries (45%).

c) Ongoing efforts were done in 2006 to induce new and future National Consensus Platforms.

Poland: The most active person of Polcopa, Dr. Maciej Stepnik, plans in the first trimester of 2006 a meeting of the Founding Committee. As a result of the meeting a Founding Document will be prepared and submitted to the National Court Register. He has, however, difficulties to get the four parties actively involved.

He also prepared the Polcopa questionnaire on alternative methods which is available in Poland and the Polcopa website (polish/English version: <http://www.imp.lodz.pl/polcopa>) is fully operational.

Hungary: *hucopa* has been accepted as a full member at the 6th Annual *ecopa* Meeting. The new Executive Board has been elected and the responsibilities of the chair are being handled by Dr. Lajos Balogh, Eva Hercsuth, heading the Animal welfare platform, Prof Tibor Bartha, heading the Academy, Laszlo Pallos, Authority and Zsuzsa Somfai, Industry. An action-plan has been made for 2007 in order to rejuvenate the Hungarian NCP, and a meeting is planned for June, 2007.

Denmark: Prof. Ove Svendsen stepped down as chairman of DACOPA and is followed -up by Prof. Jann Hau. DACOPA planned a first DACOPA-day in November 2007 and the *ecopa* chair is a guest of honour.

Norway: The Norwegian Platform can be formally established, within short, as the structure is ready. Draft statutes for the permanent Norwegian platform were sent to the Ministry for approval and they are waiting for their reply (de datum April 2007).
The acceptance of the Norwegian associated platform as a full *ecopa* member is therefore foreseen for the 8th Annual *ecopa* Workshop.

d) Dissemination info on other FP6 projects: to induce effective participation of candidate countries into joint projects on 3R-alternative methods: This ongoing activity is mainly done through the *ecopa* website and newsletter. Available leaflets are also spread during the annual *ecopa* meeting.

e) Participation in EU Projects: Some CONAM project-members effectively participate within the stakeholders Boards or Advisory Committees of some FP6 research projects in order to assist and support these on 3R-alternative methods:

Reprotect is an IP which *ecopa* has co-initiated and in which *ecopa* is represented with 3 members in the Supervising Board including the Chairperson. The project started in 2003 with 21 partners.

Predictomics is a STREP, co-initiated by *ecopa*, which started in 2003 with 14 partners. *ecopa* is represented in the Board by Dr. B. Garthoff.

A-CUTE-TOX is an IP of FP6. Prof. P. Maier is present in the Advisory Board.

Sens-it-iv is another IP in the 6th Framework Programme-project which started in 2005 with 31 partners. Prof. V. Rogiers is present for *ecopa* as a partner. Folders and posters for this EU project have been designed and produced.

Dr. F. Zucco, (*ecopa* board member) is present in the Advisory Board of Biosim, which was initiated December 2004, and has 40 partners involved.

ecopa is represented by Dr. Odile De Silva in the SSA project **ForInViTox** (Forum for researchers and regulators to meet manufacturers of toxicology test methods).

CarcinoGENOMICS is an IP of FP6. Dr. B. Garthoff is the *ecopa* representative and is Work Package leader for the dissemination of the project results.

This information spreading goes mainly through the *ecopa* website and the newsletter.

Liintop is a STREP. *ecopa*'s Board Member Prof. H. Spielmann is present in the Management Board. Dr. Zucco (3R-expert of *ecopa*) is the coordinator of this project.

-Preparation for CONAM/*ecopa* Board participation in FP7 projects. The *ecopa* Executive Board 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 as acronym: START-UP. Several NCPs are collaborating in this project. Several *ecopa* Board Members are participating in other FP7 proposals that are involved in alternative methods e.g. ESNATS, Alterscreen and ZF-Altox.

f) The organisation of workshops: The 7th Annual *ecopa* Workshop was organized at the Sheraton Airport Hotel in Brussels on 25 and 26 November 2006, and was dedicated to REACH: "REACH for help: science back up?". All stakeholders were present and again lectures were held by experts, being representatives of the four stakeholders. A round table discussion was held. The event was seen as informative and interesting to the participants of the different parties. The minutes of this event are published on the *ecopa* website.

The date for the 8th *ecopa* Annual Workshop is already set and foreseen for 24-25 November 2007.

Also, the second edition of the *ecopa* Science Initiative (eSI) took place on 29-30 September 2006, at Pueblo Acantilado, Spain. The event focused again on providing a forum for young scientists where they can establish contacts with senior scientists and experts involved in new science and technologies.

The theme of the eSI workshop was “*in vitro/in vivo* in Experimental Research, Pharmacology and Screening: validated versus valid?”

The eSI event was funded by the P&G/ Eurotox/ Humane Society Award alternative award that Prof. Rogiers won, earlier in 2005, by Bayer AG/RC, DE, the Vrije Universiteit Brussel, Dept. Toxicology, BE and SET (Stiftung zur Förderung der Erforschung von Ersatz- und Ergänzungsmethoden zur Einschränkung von Tierversuchen), DE.

The next eSI Workshop is planned on 25-27 September 2008.

g) Contacts with relevant third parties:

-Good contacts were established with relevant third parties in 3R-alternatives: During the 7th Annual *ecopa* Workshop, speakers were invited from DG Enterprise, DG Research, COLIPA, epaa, ECVAM and the Eurogroup for Animal Welfare.

-There is a good collaboration with ECVAM: the head of the unit, Prof. Dr. Hartung is always willing to give a lecture at *ecopa* Workshops. He was present at the 7th one.

Prof. Rogiers also represents *ecopa* as an ESAC member.

-There is a good interaction with Zebet as Prof. Horst Spielmann, the previous head of ZEBET is 3R-expert in the *ecopa* Board and his successor Dr. Manfred Liebsch is also an ESAC member.

Prof. V. Rogiers participated at the 4th Stakeholder SusChem Meeting, Budapest, Hungary on 27 August 2006.

-Prof Rogiers was invited to give a lecture in France for GIRCOR(Groupe Interprofessionnel de Réflexion et de Communication sur la Recherche) (31/1/2007 on REACH: Use of animals or alternative methods) and in Belgium for FEDICHEM (9/3/2007) on alternative methods applicable for REACH. There was also an advisory interaction with the Belgian Senate on a proposal for toxicogenomics.

Good contacts exist with Colipa and IVTIP. *ecopa* is regularly invited at IVTIP meetings and there is the collaboration in the EU project, Sens-it-iv.

Deviations from the projects work programme, and corrective actions taken + nature and reason for the problem and contractors involved: none

List of milestones, include due date and actual/foreseen achievement date:

MS no.	Milestone name	WP	Date due	Actual/ Forecast delivery date	Lead contractor	Status
1	Newsletter on website/by e-mail twice/year	1	02-12-2006	16-12-2006	VUB (<i>ecopa</i>)	Done
2	Expansion website to receive info coming from the four WP	1	01-11-2006	01-11-2006	VUB (<i>ecopa</i>)	done
3	Establishing good contacts with relevant bodies in non-EU Candidate Countries for building NCP's	1	16-04-2006	16-04-2006	VUB (<i>ecopa</i>)	done
4	Establish good contacts with relevant third parties	1	01-03-2007	31-03-2007	VUB (<i>ecopa</i>)	done
5	Workshop 7 th annual <i>ecopa</i> meeting	1	25-26-11-2006	25-26-11-2006	VUB (<i>ecopa</i>)	done

Table 2: Milestones List

Other activities

-Expansion of the website into the ethical area is foreseen and was discussed with the team leader of WP 4, Prof. T. De Cock Buning. Under supervision of Prof. De Cock Buning, the process of updating the database has started and a link to the database will be provided. See WP 4.

The establishment of new NCP's continues: France was mentioned as a potential new associate platform candidate.

-An international study was initiated in 2006 and finalized in 2007 by *ecopa* in collaboration with P&G and the Eurogroup for Animal Welfare on the availability of funding of alternative methods within the Member States. This study provides a comprehensive picture of the structure and amount of the funding of 3R's research at the national level. It will be of assistance in the further planning of EU coordinated research. The results will be placed in the public domain and a poster is submitted at the World Congress 2007 in Tokyo, Japan. Also *ecopa*'s chair gives a lecture at the WC5 and is responsible for a scientific session on new 3R-technology.

-Representation in relevant bodies: Workgroup 2 representatives K. Gabrielson, (Animal Welfare) V. Rogiers, (Academia) and H. Spielmann (Government) were invited members in the Steering Committee of the Partnership Commission/Industry, epaa.

Progress of WP 2: EU Policy Chemicals in reporting period 2 (01-03-2006 to 31-03-2007)**Work Package objectives and starting point of work at beginning of reporting period:**

The tasks at the beginning of the reporting period are listed. Note that they mostly run over the 3 year contract period.

The objectives for WP2 are:

- The information collection on chemicals/follow-up.
- The organisation of a workshop.
- The generation of a consensus report aiming to advice EU bodies.

Progress towards objectives - tasks worked on and achievements made with ref. to planned objectives:

-The Working Group has been re-modulated. Members are of Mrs. Karin Gabrielson (Animal Welfare) replaced by Dr. Barry Phillips, Dr. Bernward Garthoff (Industry), Dr. Karsten Müller (Industry), Dr. Simon Webb (Industry), Prof. Horst Spielmann, representative of the governmental institution ZEBET and Prof. Vera Rogiers (Academia).

-The data collection for animal use/testing of chemicals was finalized. Part of the data were previously presented at the Annual *ecopa* Workshop 2004 by Dr. Garthoff, reported in several *ecopa* newsletters and placed on the FORUM of the *ecopa* website. Regularly updated info was taken up.

-Initially, the REACH workshop was planned end of 2005, but due to, the delay of the final REACH text, it took place on 01/2/2006 at the Sheraton Airport Brussels hotel. The REACH Workshop was a reality check and formed a good basis for the consensus report delivered at the end of the project.

As an extra effort, a computer programme was made for the calculation of animal use within the actual testing schemes described in REACH. This was in particular done by the intensive collaboration of *ecopa* with P&G (S. Webb), BASF (M. Kayser and K. Mueller) and Bayer (B. Garthoff). This "Animal Use Calculator" has been presented at the *ecopa* Chemical Workshop on 01.02.06. The tool is present on the *ecopa* website, and for free download.

-Statement: Chemical Policy Working Group Statement in regard to proposed amendments to REACH, July 2005, which led to the consensus procedure for "sensitive" articles or publications.

- The main task in the 3rd reporting period for this working group was to deliver a publishable consensus paper on EU policy of chemicals. The paper was distributed at the end of March 2007, via the *ecopa* newsletter. It is now available on the *ecopa* website and is actually being sent around to all interested parties.

Deviations from the projects work programme, and corrective actions taken + nature and reason for the problem and contractors involved:

The initial foreseen consensus paper became a paper with major contributions of industry, academia and government, and only a minor contribution of animal welfare. Therefore, it was decided not to call it a consensus paper, although, animal welfare considerations were taken up at the end of the report.

List of deliverables, including due date and actual/foreseen submission date:

Del. no	Deliverable name	WP	Date due	Actual/ Forecast delivery date	Estimated Indicative Person-months	Used indicative person-months	Lead contractor	status
18	Generation of a paper on EU policy of chemicals	2)	Month 35	Month 37	4	4	VUB (<i>ecopa</i>)	done

Table1: Deliverables List

List of milestones, include due date and actual/foreseen achievement date:

MS no.	Milestone name	WP no.	Date due	Actual/ Forecast delivery date	Lead contractor	Status
2	Publication of a paper on EU policy of chemicals	2	Month 36 (01-02-2007)	Month 37 30/03/2007	VUB (<i>ecopa</i>)	done

Table 2: Milestones List

Progress of WP 3: "Education" in Reporting Period 3 (01-03-2006 to 31-03-2007)**Given the Work Package objectives and starting point of work at beginning of reporting period:**

The aim of this working group is to support activities in the area of training and education on 3Rs methods, and to provide effective means of communication between members of national consensus platforms on 3R-alternatives to animal experiments.

The tasks to start off with at the beginning of the project:

- a) Creation of a database on national legislation within Europe on animal experimentation and implementation of the 3Rs principle in the legislation.
- b) Centralisation of information on education/formation/training courses within Europe and outside with respect to 3R-alternative methods and diffusion of this information by modern approaches.

c)

Progress towards objectives - tasks worked on and achievements made with reference to planned objectives:

* In the reporting period 3, three different information pages, made available through the *ecopa* website, were prepared entitled "Education", "Databases" and "Legislation". These were regularly updated.

* Lectures given in this reporting period.

Following lectures were given on education and training in 3Rs methods and on the activities of *ecopa*:

- Role of National Platforms and *ecopa*. Status & visjoner for en norsk platform og et pengefond for alternativer til dyreforsøk. Oslo, Norway, 17 October 2006
- Symposium '3Rs centres' Baltimore, USA, 1 November 2006
- 'Alternatieven voor dierproeven in het bedrijf: Betrokken - Bewust - Beleid', Organon minisymposium Alternatives, 11 November 2006, Organon, Oss (Alternatives to animal experimentation in the organization: Involvement – Consciousness – Policy)
- *Ecopa* "Human tissue workshop", 24 November, 2006, Brussels, Belgium
- Invitroheart kick-off meeting, Copenhagen, Denmark, 19 January 2007

* Course given in reporting period 3:

Following the Spanish example: in 2006, a formative workshop on Alternative Methods to Animal Experimentation was held at the university of Rome, in Italy on 15/16 February, 2007. The course on alternative methods to animal experiments and on related bioethical issues was organised by the Italian Platform, IPAM, and it addressed experts in bioethics and civil servants in public and governmental institutions.

* Future plans: The board of the Spanish platform, REMA has organized two meetings dated on 30th May and 12th of December 2006 in order to define the programme of the 2nd Course on alternatives in Research, Testing and Teaching addressed to members of Ethical Committees from Universities, Industry, Hospitals and Research institutes REMA/UAM (Córdoba 20th November 2007). The course will be held at the University of Córdoba, bearing the title "Workshop on Reduction, Refinement and Replacement of animals in research, development and education." Various 3Rs experts will participate during the whole program, consisting of an introduction about the 3Rs concept and the new legislative scenario, talks about refinement and reduction followed by a practical session in which the participants will learn to use the internet to retrieve relevant data. Next, replacement methods will be discussed by different speakers and after a round table discussion about practical cases of experiences of 3Rs application in Bioethical Committees, conclusions will be made from the course. A cd-rom containing the lectures and significant works and documents in the 3Rs field will be edited and distributed to the participants.

Deviations from the projects work programme, and corrective actions taken (if applicable). Identify nature and reason for the problem.

None

List of deliverables including due date and actual/foreseen submission date:

Del. no	Deliverable name	WP	Date due	Actual/ Forecast delivery date	Estimated Indicative Person-months	Used indicative person-months	Lead contractor	status
13	Website enlargement	3	Month 18	Month 18	5	5	VUB (<i>ecopa</i>)	done
19	Educational programmes	3	Month 34	Month 36	5	5	VUB (<i>ecopa</i>)	done

List of milestones, include due date and actual/foreseen achievement date:

MS no.	Milestone name	WP	Date due	Actual/ Forecast delivery date	Lead contractor	Status
1	Website enlargement and increasing of accessibility for different existing NCP's and <i>ecopa</i> members	3	01-08-2005	01-08-2005	VUB (<i>ecopa</i>)	done
2	3 rd National training course on 3R-alternatives Implement and launch other countries	3	01-11-2006 until 16-02-2007	16-02-2007	VUB (<i>ecopa</i>)	done

Table 2: Milestones List

Progress of WP 4: "Harmonization ethical investment" in Reporting Period 1 (01-03-2006 to 30-03-2007)

Work Package objectives and starting point of work at beginning of reporting period:

The objective of this work package was to provide a flanking activity within the Consensus Networking on Alternative Methods within Europe. While other Work Packages directly focus on the development and application of alternatives, this Work Package emphasizes the need for consensus processes within the network.

Progress towards objectives - tasks worked on and achievements made with reference to planned objectives:

The current composition of WP4 is now as follows:

Chair: Tj. De Cock Buning, Vrije Universiteit Amsterdam, NL

Academia::	E.Vilanova (Spain),	M. Stepnik (Poland)
Industry:	R. Remie (The Netherlands),	H. Jones (UK)
Governmental:	H. Spielman (Germany),	K. Pelkone (Finland)
Animal Welfare:	P. Beaufays (Belgium)	J. Smith (Boyd group UK)

The second international workshop of WP4 was organized in autumn 2006 and took place at the Sheraton Airport hotel Brussels on 24 November. The topic "Human tissues as alternatives for animal experiments" was chosen during the work package leaders meeting March 16, 2006 out of a list of subjects that were suggested during the annual meeting of the Ethics working group of *ecopa* (November 2005). The topic is an intrigued mix of legal and ethical aspects which seem to differ from country to country in the EU. The meeting was organized as a closed expert meeting and was attended by 13 participants from 6 countries (NL, D, It, UK, B, P). The report summary is published on the *ecopa* website and discussed during the plenary session of the *ecopa* annual meeting November 2006.¹

As Europe is expanding, while the development of research into 3R-alternatives to animal experiments continues, a survey by means of internet and telephone has been conducted to update the information about the progress of the 3 R's (Replacement, Reduction and Refinement of the use of animals in scientific research). The following issues were mapped:

- The level of implementation of the 3R's in the legislation.
(Internet link to the text of this particular legislation; Internet link to this authority)
- Educational courses provided of laboratory animal science and instruction about the 3 R's
(Internet link of this educational programme).
- Updated internet link to a national consensus platform for alternatives which combines the four concerned parties: animal welfare, industry, scientific and governmental institutions.

¹ See Annex B

- Updated internet link to an Information Centre for Alternatives to animal experimentation.
- Whether scientific research is performed concerning the ethics of animal experimentation. (Internet link of the University conducting this research).²

The information is now available for Austria, Belgium, Bulgaria, Cyprus Denmark, Estonia, Finland, Germany, Ireland, Italy, Lithuania, Poland, Portugal, Slovakia, Spain, Sweden, UK, Norway, and Switzerland. This information is made available by the *ecopa* website and is enclosed as annex in this report.

Deviations from the projects work programme, and corrective actions taken + nature and reason for the problem and contractors involved:

none

List of deliverables, including due date and actual/foreseen submission date:

Del. no	Deliverable name	WP	Date due	Actual/ Forecast delivery date	Estimated Indicative Person-months	Used indicative person-months	Lead Contractor or	status
3	Ethics working group :	4	Month 5	report, delivered jointly with periodic report 2	4	4	VUB (<i>ecopa</i>)	done
14	database	4	Month 32	01-01-2007	4	4	VUB (<i>ecopa</i>)	done
15	Website enlargement	4	Month 32	01-03-2007	5	5	VUB (<i>ecopa</i>)	done

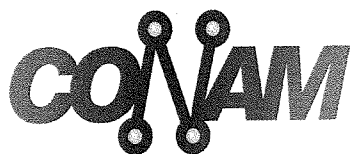
Table 1: Deliverables List

List of milestones, include due date and actual/foreseen achievement date:

MS no.	Milestone name	WP	Date due	Actual/ Forecast delivery date	Lead contract or	status
1	Preparation of database on ethical committees at universities, research institutes and industry	4	01-05-2006 until 30-11-2006	01-01-2007	VUB (<i>ecopa</i>)	Done
2	Enlargement of <i>ecopa</i> website towards ethical issues in 3R-alternatives and animal use	4	01-05-2006 until 05-03-2007	01-03-2007	VUB (<i>ecopa</i>)	done

Table 2: Milestones List

² see Annex C



Project Reference: LSSB-CT-2004-504776

CONAM

CONSENSUS NETWORKING ON ALTERNATIVES WITHIN EUROPE

Instrument: Specific Support Action

Thematic Priority: Life sciences, genomics and biotechnology for health

FINAL REPORT

Period covered: from 01-03-2004 to 31-03-2007 Date of preparation: 22-04-2007

Duration: 37 months

Project coordinator: Prof. Dr. Vera Rogiers

Project coordinator organisation: Vrije Universiteit Brussel

EXECUTIVE PUBLISHABLE SUMMARY

Contract Nr:	504776	Reporting period:	From 01-03-2004 to 31-03-2007
Title:	CONSENSUS NETWORKING ON ALTERNATIVES WITHIN EUROPE		

**Objectives:**

The objective of CONAM is to build a solid consensus network on 3R-alternatives, ideally including all European countries and with links to 3R-relevant organisations and institutes, including the European Parliament. CONAM will deliver critical consensus expert opinions on 3R-issues and strategies. Furthermore, in this project, special attention will go to potential new alternatives and emerging new technologies, and what their value is in the development of new 3R-methods. This information will be disseminated over the CONAM network and will be at the basis of active collaboration between the 4 parties with interest in 3R- alternatives within the different European countries with special emphasis on the new EU member states and non-EU candidate countries. As such CONAM will play, throughout FP6, a key role in the networking capacity and information exchanging role of scientific, socio-political and technological matters in relation to the development and validation of 3R-alternatives.

More specific, the major objectives are situated in the field of consensus networking on 3R-alternatives:

- Support of existing and new national consensus platforms with special attention to new EU member states and non-EU candidate countries. As a start, Poland and Hungary will be focused on.
- Collaboration and linking with the new EU member states and non-EU countries will be stimulated through the organisation of workshops and meetings. Contacts will be made with key persons of the existing pharmaceutical, cosmetic and chemical industry, with major governmental people, animal welfare groups and academia.
- Establishment of a newsletter on 3R-alternatives, including website expansion.
- Links with other FP6 projects on 3R-methodology will be established and reporting will be done on the latest developments. The above mentioned FP6 projects should reach us, through the commission, on regular times and major developments and progress will be taken up in the *ecopa* newsletter on the website. Activities that will support the major objectives will address ethics on harmonisation and consensus, education in the field of 3Rs and legislative follow-up.

SECTION 1: PROJECT OBJECTIVES AND MAJOR ACHIEVEMENTS

The objectives to be reached in the first, second and third reporting periods were met by the different Work Packages, all running under the sole contractor VUB- *ecopa*:

WP0

* Implementation of a management tool and develop final network plan: The management updated the Gantt chart for all the reporting periods and allocated all tasks.

* Review Meetings: The Management Work package organised the Review Meetings foreseen and produced the four Review reports of the 6-month meetings, 3 EU Reviews were made and or final review report at the end of the project, as foreseen in the project plan.

WP1

* The appointment of a scientific collaborator - secretary: Mr. Koenraad Ghys, biologist, appointed from 01-02-2005 was substituted from 01-09-2005 onwards by Mrs. Tonia Devolder, master in law.

* Creation of a newsletter: A newsletter, called "*ecopa messenger*", was launched during the first reporting period. The goal was to send out a newsletter twice a year. An overachievement can be noted as already eleven issues of the *ecopa* newsletter were distributed during the CONAM project.

* Expansion of the existing *ecopa* website: The website (design, content) was thoroughly expanded throughout the reporting period by Mr. Stephan Belitz, DE. The "News section" contains a variety of information such as *ecopa*'s statements or information on future calls in FP6 and FP7. In the "Events section", upcoming events are announced and their programs or minutes are published. Older documents are stored in the "Archives section". The pages "Education", "Databases" and "Legislation" were prepared by Work Package 3.

On the website the member countries (NCPs) are marked on a map of Europe, with their respective contact information.

Also all past newsletters remain available on the website in a specially designed section. Besides the classic links and contact sections, a "Forum section" is now also included on the website. If registered, users get access to discussion forums where they can comment on *ecopa*, inform about events and activities or make proposals and make remarks. There are also discussion forums present for each EUproject in which *ecopa* is involved, and the same possibility exists for each Work Package.

However, the use of the forum needed some encouragement.

Statistics indicated in which topics the interests of the visitors are situated.

* Starting up of contact building in order to create new platforms: Fruitful efforts were done to induce new and future National Consensus Platforms. A Stakeholder Workshop was jointly organized by ECVAM and *ecopa* in Prague on 5 and 6 June 2004, in order to inform stakeholders in the new EU Member States about 3R-alternatives and to stimulate formation of NCPs in these countries.

New platforms were started up in Norway, Denmark, Poland, Hungary and Ireland resulting in a total number of 16 NCP's. Denmark and Hungary have been accepted as full *ecopa* members at the 6th Annual Meeting.

France is in the process of starting up their national platform. The official inauguration in France for the national platform is foreseen for 2007.

* Dissemination info of other FP6 projects to induce effective participation of candidate countries into joint projects on 3R-alternative methods: This is mainly done through the *ecopa* website and newsletter, and the spreading of available leaflets at *ecopa* meetings.

* CONAM/*ecopa* Board participation in FP6 projects: A number of *ecopa* Board Members participate in FP6 projects that are involved in 3R-alternative methods e.g. PREDICTOMICS, ReProTect, A-CUTE-TOX, Sens-it-iv, Biosim, ForInViTox, CarcinoGENOMICS and Liintop.

* CONAM/*ecopa* Board participation in FP7 projects: the *ecopa* Executive Board handed in a proposal for a Support Action in the HEALTH Call-2007-1.3-2, called START-UP.
ecopa Board Members participate also in FP7 proposals that are involved in alternative methods e.g. in ESNATS, Alterscreen and ZF-Altox.

* Organization of Workshops:

ecopa held a session "Regulatory toxicology: safety of substances & products" at the 10th ICTX congress (11 to 15-07-2004, Tampere, FIN).

3 Annual *ecopa* Workshops were organized in Brussels during the CONAM project. The 5th *ecopa* Annual Workshop was organized on 27 and 28 November 2004, and was dedicated to SCALE and its consequences for the development of alternative methods respectively animal use. REACH was also addressed. The 6th Annual *ecopa* Workshop was held on 17 and 18 December 2005, and was dedicated to nano- and biotechnology and the use of alternative methods. The topic of the 7th Annual *ecopa* Workshop, held on 25 and 26 November 2006, was dedicated to REACH: "REACH for help: science back up?"

All stakeholders were present, and apart from talks given by expert representatives from the stakeholders, there was also a round table discussion. The events were seen as informative and interesting to the participants of the diverse parties. The minutes of the events are published on the *ecopa* website.

Also, during the CONAM Period a new Workshop to be repeated on a regular basis was launched: the *ecopa* Science Initiative (eSI). The first Workshop was organized on 29-31 October at Pueblo Acantilado, Spain and the second on 29-30 September 2006. The event provided a base where young scientists could establish contact with senior scientists and experts with respect to developing new science and technologies.

* Contact building with relevant bodies and third parties :

- Good contacts were established with relevant third parties in 3R-alternatives: during the Annual *ecopa* Workshops, speakers were invited from DG Sanco, DG Enterprise, DG Research, OECD, COLIPA, epaa, ECVAM and the Eurogroup for Animal Welfare.

- There is a good collaboration with ECVAM: the head of the unit, Prof. Dr. Hartung is always willing to give a lecture at *ecopa* Workshops. He was present at the 6th and 7th Annual Workshops. Prof. Rogiers represents *ecopa* as a full member at ESAC, ECVAM Scientific Advisory Committee.

- There is a good interaction with Zebet as Prof. Horst Spielmann, the previous head of ZEBET is 3R-expert in the *ecopa* Board and his successor, Dr. Manfred Liebsch also is an ESAC member.

- There is a good interaction with Zebet as Prof. Horst Spielmann, the previous head of ZEBET is 3R-expert in the *ecopa* Board and his successor, Dr. Manfred Liebsch also is an ESAC member.
- Prof. Rogiers participated at the round table discussions at the CEFIC LRI Workshop of 16-17/11/2005 in Brussels and in several SusChem meetings: "horizontal issues" and Stakeholder Meetings.
- Contacts with IVTIP have been further elaborated through collaboration within the FP6 Project Sens-it-iv.
- Representation in relevant bodies: Workgroup 2 representatives K. Gabrielson, (Animal Welfare) V. Rogiers, (Academia) and H. Spielmann (Government) are members of the Steering Committee of Partnership Commission/Industry, epaa.

WP2

* Remodulation of the Working group: The Working Group consisted of Mrs. Karin Gabrielson (Animal Welfare), who was replaced by Barry Phillips during her maternity leave in 2007, Dr. Bernward Garthoff (Industry), Dr. Martin Kayser (Industry) replaced by Dr. Karsten Müller, Dr. Simon Webb (Industry), Prof. Horst Spielmann, (representative of the governmental institution ZEBET) and Prof. Vera Rogiers (Academia).

* Information collection on chemicals and publication of report:

- After having the data collection finalized, a detailed calculation model for animal use in chemical testing was developed during 2005 and finally presented at the public at the Chemical Workshop, which was held on 01.02.06 in Brussels.

The computer programme, deals with the use of animals within the actual testing schemes described in REACH. This project was in particularly realised by the intensive collaboration of *ecopa* with P&G (S. Webb), BASF (M. Kayser and K. Mueller) and Bayer (B. Garthoff). This "*ecopa* Animal Use Calculator" was presented at the *ecopa* Chemical Workshop on 01.02.06. The tool was placed on the *ecopa* website, and can be freely downloaded.

- Statement: Chemical Policy Working Group Statement in regard to proposed amendments to REACH, July 2005, which led to the consensus procedure for "sensitive" articles or publications.

- The final report of this Working Group has been realized in March 2007. The paper was distributed at the end of March 2007 through the *ecopa* newsletter and placed on the *ecopa* website.

WP3

* Website enlargement: Three different information pages, made available through the *ecopa* website, were prepared.

Information page 1, entitled "Education", gives a list and description of websites related to Laboratory Animal Science Courses. The aim is to provide organizations that are in the process of developing laboratory animal science courses, the opportunity to contact those in the field who have already experience with this activity.

Information page 2, entitled "Databases", covers those websites that provide databases with information on 3Rs models. This information facilitates the search for 3Rs models and contribute to a reduction of animal use.

Information page 3, entitled "Legislation", lists the websites where information can be found on national legislation with respect to the use of laboratory animals. These examples may help other countries to develop their own national legislation

* Start of the organization of the educational programme: The Spanish platform REMA organized 2 courses on alternatives.

1) The course “Alternative Methods in Toxicology” was organised at the University of Navarra, Pamplona, Spain on 27/5/2005. The target group was postgraduate students in life sciences. The programme consisted of the 3R’s concept; *in vitro* methods; validation procedures of ECVAM, ICCVAM and OECD; validated methods; strategy irritation/corrosion.

2) A Course on “The 3R’s in Research, Testing and Education” was addressed to members of Ethical Committees from Universities, Industry, Hospitals and Research institutes REMA/UAM (Madrid 23 November 2005). The course was held at the Faculty of Medicine, Autonomous University of Madrid, bearing the title “The 3Rs in research, development and education.”

3) Following the example of the Spanish platform REMA, the Italian platform IPAM organised a formative workshop on Alternative Methods to Animal Experimentation at the university of Rome, in Italy on 15/16 February, 2007.

WP4

* Ethics working group with an operational programme: An ethics group was formed, and it organized a “consensus training course between stakeholder platforms in Europe in the context of *ecopa*/CONAM” on 10-12 June 2005 in Ljubljana.

* A consensus Report was produced between the different Stakeholders which appeared on 12-4-2006. (The report is included in the report of the 2nd reporting period).

* The ethics working group organized a second international workshop on the 24th of November at the Sheraton Airport hotel Brussels with the topic “Human tissues as alternatives for animal experiments”. The report is present in annex and is also available on the *ecopa* website.

* A database for ethics and committees on the themes mentioned above has been developed.

* Enlargement of the *ecopa* website towards ethical issues in 3R-alternatives and animal use:

A survey by means of internet and telephone has been conducted to update the information about the progress of the 3 R’s (Replacement, Reduction and Refinement of the use of animals in scientific research). The report is present in annex and is also available on the *ecopa* website.

SECTION 3 - CONSORTIUM MANAGEMENT

Status of the project, management and follow-up activities:

Consortium Management tasks and achievements, problems and solutions: All management is done within WP0 as there is only 1 partner (*ecopa*).

Contractors: There is only one contractor: (VUB - *ecopa*).

Project timetable and status + clarify changes and impact on the milestones:

Project timetable: see Gantt chart in Attachment 1 to this Periodic Activity Report

Short comment and information on coordination activities between partners, project meetings, possible cooperation with other projects/programmes etc:

- All Work Packages within CONAM have carried out their tasks as foreseen. A good collaboration exists within each group but the coherence among the Work Packages still could be improved.
- There is a good cooperation with other EU projects, (Predictomics, ReProTect, A-CUTE-TOX, Sens-it-iv, carcinoGENOMICS, Liintop) on 3R-alternative methods and all relevant news and results are reported on the *ecopa* website and in the newsletter (*ecopa messenger*) under separate headings.
- CONAM Work Package group meetings and CONAM Board meetings took place as foreseen in the project. No problems occurred. There was a creative and constructive atmosphere.
- During the course of the project, all CONAM and associated workshop reports were ready as foreseen and were made available on the *ecopa* website. All papers can be consulted by the public and all interested parties.

SECTION 4 - OTHER ISSUES

Projects which were subject to requirements and /or recommendations regarding ethical issues: not applicable to CONAM.

ANNEX - PLAN FOR USING AND DISSEMINATING THE KNOWLEDGE

Section 1 - exploitable knowledge and its use

The project is concerned with the information on other projects, and 3R-initiatives and disseminates this information through CONAM via the website, newsletters, leaflets, congresses and regular meetings.

Section 2- dissemination of knowledge

Information on the CONAM project and of other FP6 projects on 3R-alternatives are disseminated through the *ecopa* website, newsletters, leaflets, congresses, and regular meetings. Also the reports of the latter two types of events appear on a regular basis on the *ecopa* website and in the newsletters. Distribution is done to all NCPs having the 4 stakeholders involved in the respective countries. Also separate e-mailing is done to individuals, associations, etc. that have expressed their interest in 3R-alternatives.

The chair of *ecopa* also spread information on the use of alternative methods in interviews as e.g. Rogiers V. Replacement, reduction, refinement. Chair of *ecopa* Professor Vera Rogiers advocates sound science and the use of alternative methods to animal testing in Europe ... Public Service issue: *European Union Issue 13* (Health section), A PSCA International Publication, 2007, pp 262-263

Section 3 -publishable results

A computer programme, the "Animal Use Calculator", on the realistic number of animals used within the context of REACH, was developed and is ready for free download from the *ecopa* website since 1/2/2006.

The paper on chemicals produced by Work Group 2 on Chemicals and the paper on Ethics by Work Group 3 are available on the *ecopa* website.

ANNEX

CONAM WG 2: EU POLICY CHEMICALS WORKING GROUP

A. The impact of REACH

CONAM WG 4: ETHICAL WORKING GROUP

B. Summary Human Tissue workshop *ecopa*, November 24 2006, Brussels

C. CONAM Survey 3Rs implementation in Europe