FOREWORD

For EPAA, which is one of the pioneering public-private partnerships on 3Rs in animal testing, the widening interest in alternative approaches is particularly welcome. The European Union has been setting the pace for more than fifty years, since Russell and Burch developed the 3Rs principles, and it remains at the forefront in promoting alternatives. With the implementation of Directive 2010/63/EU and by the creation of the EU Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM), Europe has consolidated its place as one of the leading actors worldwide on the 3Rs.

The EU is now recognised as a trusted advocate of the 3Rs by the principal international organisations: ICH for Pharmaceuticals (The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use), VICH for Veterinary Drugs (Veterinary International Conference on Harmonisation), ICCR for Cosmetics (International Conference on Cosmetic Regulation), OECD (Organisation for Economic Cooperation and Development) for chemicals, and ICATM (International Cooperation on Alternative Test Methods), which brings together five governmental organisations from EU, Asia and North America to coordinate international validation studies on alternative methods. Over the past decade, a clear recognition has emerged of the need for greater international cooperation, to maximise the cross-fertilization, synergies and economies of scale that can lead to a significant reduction of animal testing throughout the world.

EPAA’s membership now comprises 35 companies and seven European federations among various sectors of activity, as well the European Commission. The EPAA acts as a hub between them, and closer international cooperation is addressed by many of its projects – such as the EPAA vaccines consistency approach, which has established a solid network with representatives of EU, US, Canadian and Indian vaccines manufacturers and regulators. To underline the importance of working together across frontiers, the EPAA selected “Global development and implementation of 3Rs methodologies through international cooperation” as the lead theme in 2012.

This year, the EPAA has signed a Memorandum of Understanding with the US-based Institute for In Vitro Science (IIVS), with its impressive network and educational activities. This partnership will further advance 3Rs implementation right across the globe. In addition, the EPAA is currently exploring opportunities for synergies on the 3Rs with the US Food and Drug Administration as well as with the US Pharmaceutical IQ consortium.

2012 has seen real progress on global cooperation on the 3Rs, and we look forward to further cooperation prospects in the future.

Julia Scheel
Co-Chair of the Steering Committee for industry

Gwenole Cozigou
Co-Chair of the Steering Committee for the European Commission

WHAT IS THE EPAA?

The European Partnership for Alternative Approaches to Animal Testing (EPAA) is a Public-Private Partnership between the European Commission, European industry federations and major companies from seven industry sectors.

It is a structure in which knowledge, research and resources are pooled to accelerate the development, validation and acceptance of alternative approaches for regulatory use, and in which best practice is shared to promote the use of 3Rs methods.

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2012 has been a year of big progress for the European Partnership on Alternative Approaches to Animal Testing: brand new projects (Advancing 3Rs in Regulatory Toxicology, Harmonization of 3Rs in biologics) emerged on the agenda, a new Commission Co-chair has been appointed (Gwenole Cozigou) and new members joined the partnership (Symrise and IFRA).

Echoing the year’s lead theme on International cooperation on 3Rs, the EPAA also launched various initiatives addressing the international aspects of alternative approaches to animal testing. Meetings with US FDA have been organized, the EPAA has been sponsoring international conferences promoting 3Rs (ESTIV conference, HET-CAM workshop) and a Memorandum of Understanding has been signed with the US-based Institute for In Vitro Sciences for future collaboration in educational activities. This year, EPAA granted its 100,000€ Science award to Dr Nils Klüver for his proposal on improved use of fish embryo in acute toxicity testing.

In addition, flagship projects such as the Vaccines consistency approach have been very active in 2012, with three workshops on DTaP vaccines, Human and Veterinary rabies vaccines. Meanwhile, the computational chemistry project delivered solid recommendations that were published in the prestigious journal Toxicology. The stem cells project, one of the backbones of the EPAA platform on Science, defined new objectives and guidelines for the coming years.

Other projects addressing science and regulatory requirements (Acute Toxicity, Thematic review on reproductive toxicity, skin sensitization, etc.) complete the range of issues addressed by the EPAA partners to better implement 3Rs (Replacement, Reduction and Refinement) in regulatory testing in Europe and beyond.
NEW PERSPECTIVES ON SAFETY – FOLLOW-UP: STEM CELLS

Earlier work in EPAA and elsewhere has suggested that the development of a new, evidence-based, risk assessment paradigm can use information from toxicity pathways, systems biology and a range of cellular models covering different target cells and tissues. EPAA believe that systems biology approaches could lead to the development of evidence-based tools for screening and, possibly, for regulatory purposes.

The availability of human pluripotent stem cells and their derivatives opens up a new avenue to overcome the scientific shortcomings in current human-derived cell models. Stem cell-based models can support new methods for safety assessment.

Following the EPAA workshop on stem cells in Ispra in 2011, three small groups of experts were established to work on the three identified clusters of recommendations using “Expression of interest” papers as a starting point. The groups are led by members of the EPAA stem cell project team.

Groups of experts:

i) Fundamental research
The group agreed that the EPAA project should tackle issues of interest to groups and consortia beyond Europe – such as the dose-exposure relationship, which was identified as a possible first topic. In fact, mainly fixed concentrations have been tested in vitro systems so far.

A stepwise approach is planned:

1. Focus on identifying one or two models where dosing dynamics could be analysed in single systems, i.e. find the best way to incubate cells
2. Identify methods to generate highly specific organ-like 3D cultures and to assess toxicity
3. Connect these organ models, attempting to mimic human exposure in a stem-cell-based complex system

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Group leaders are identifying and contacting important players that should be involved and will explore the possibilities of cooperation among other groups doing this type of work. One possible approach is to organise a workshop/round table on such pharmacodynamics so as to develop a “research prospectus” offering advice on research needs.

II) Communication
The principal activity will be the creation of an “International Stem Cell Forum”. At present there is no platform for cross-consortia contacts and communication. Establishing a permanent international forum – co-ordinated by EPAA - on (all types of) stem cells used in toxicology will allow for knowledge exchange, harmonisation, closer collaboration and the avoidance of duplication.

To enable a more lively exchange, personal contacts are preferred to online activities. Meetings/events will be organised in conjunction with other meetings likely to be attended by stem cell experts. A first event will be planned for spring 2013. Envisaged forum members are key experts representing the various consortia. The forum will deal with issues on which everyone has an idea but not THE solution. The “solution”/clarification should be useful to the largest possible number of consortia.

iii) Prediction of long-term toxicity
The group started to look at the issue of “Development of in vitro methodologies by analysing long-term toxic effects on stem cells”. There is room for optimisation regarding the type of cells scientists are working on. Full phenotypes are not yet available.

The major obstacle is defining the mode of action of a toxicant. So far not one toxicity-related pathway has been fully elucidated. Until now only a number of signatures from gene expression, circa 100 of disturbed pathways, are known, and experts are also increasing their knowledge of the full metabolism profile. These biological signatures are guiding knowledge in this area.

NEW PERSPECTIVES ON SAFETY – FOLLOW-UP: COMPUTATIONAL CHEMISTRY

Report on the workshop
A scientific workshop entitled «Revolutionising toxicology: Developing a research prospectus» was held in Brussels on 3 – 4 April 2012.

Participants from Europe and the United States discussed a new approach to toxicological modelling. Reflecting the 2012 EPAA theme of «Development and implementation of 3R methodologies through international cooperation», this workshop highlighted the EPAA’s potential and ambition to establish constructive international collaboration amongst academia, regulators (such as the US EPA and the Hamner Institute), and end-users in global companies.

The workshop was built around the theme of liver mitochondrial toxicity, and agreed key elements for a research prospectus to develop predictive and quantitative models.

A short publication (or «research prospectus») entitled «Characterising Hepatic Mitochondrial Function as a Model for Systemic Toxicity: A Commentary» was published by the project team in the journal Toxicology. It offered recommendations and guidance to applicants to a FP7 call dealing with the same issue. >>>

The team proposed that such a programme of research should:

- Consider transport and interactions from molecular to cellular/organelle levels (liver mitochondria speci-
clusively)
- Be tightly integrated with in vitro experimentation designed specifically to inform this modelling activity
- Be coupled directly to systems modelling from cellular to organ level
- Take account of mechanistic understandings of toxic responses in the liver
- Build on the existing appropriate infrastructure for computation data basing and sharing.

The essence would be to investigate multiple modelling approaches so as to encourage closer links between disciplines that have until now usually operated in isolation.

With this publication the group completed the action of advising on research needs and on the structure for an integrated research programme making use of computational chemistry. The work on this project was thus concluded.

ABSORPTION, DISTRIBUTION, METABOLISM, EXCRETION / PHYSIOLOGICALLY BASED TOXICO KINETICS (ADME/ PBTK)

Following the ECVAM-DG SANCO effort, EPAA and ECVAM co-organised an ADME workshop entitled: “Potential for further integration of toxicokinetic modeling (TK) into the prediction of in vivo dose-response curves without animal experiments”. At the workshop 55 international experts in TK modeling and in vitro and in silico input parameters participated.

The ADME 2011 ECVAM/EPAA Workshop flash report was published in late 2011 on the EPAA website.

The full report and a detailed publication are under final discussion by the Scientific Committee of this project. A synopsis document will also be published subsequently.

The main aspects that will be detailed in the report are related to:
- Identification of Gaps in non-animal test methodology for the assessment of ADME
- Collection of models allocated to three stages of development
- Addressing the issues surrounding user-friendly PBTK software tools and free-to-use web applications
- Try to understand the requirements for wider and increased take up and use of PBTK modeling by regulators, risk assessors and toxicologists in general.

ADVANCING THE 3RS IN REGULATORY TOXICOLOGY

The EPAA has been assessing opportunities for improved regulatory testing of substances and chemicals through advancing the application of the 3Rs. The human medicines, veterinary medicines and crop protection sectors are currently involved in this project.

The central principle has been to examine how each sector approaches regulatory toxicology. The aim is to identify opportunities for cross-sector alignment on best practice and on the introduction of new methodologies that can advance the 3Rs. Alignment has two facets: industry alignment on testing methodologies, and regulatory harmonisation (both across sectors and globally). Thus the project needs not only to identify possibilities but also to consider how these can be translated into regulatory practice.

- An initial survey of the regulatory requirements for each sector was undertaken to identify the most promising areas for future work, with a focus on the interests and priorities of the participating industry sectors, the opportunities for 3Rs benefits, and the possibilities for cross-sector working. Four areas were identified: repeat dose toxicity, carcinogenicity, toxicokinetics and genotoxicity.

- A further questionnaire sought more detailed information from sector experts and member companies of the relevant EPAA member associations (EFPIA, IFAH-Europe and ECPA), covering the scope for variation in study design within the existing guidelines, regional variations in regulatory requirements, individual company practice, and the development of alternatives that would advance the 3Rs.

- The responses were analysed and discussed within the Project Team, and a comprehensive matrix was developed summarising the findings.

The team selected carcinogenicity testing as the most promising area: sector practice is quite divergent, the scientific va-
The Ex Vivo Eye Irritation Test (EVEIT), which won the 2010 Science Award, was partially transferred to a BASF laboratory in July. The winner, Dr Felix Spoeler, acknowledged BASF for the excellent on-site organisation, the assignment of a skilled laboratory technician for the period required, and the insight into GLP compliant implementation of in vitro test systems.

The training of the technician was completed in four days, and for a further four days the technician worked on her own, with Dr Spoeler available to deal with questions and IT issues.

The major findings and achievements were:
- The equipment to perform the EVEIT test is potentially transferable and can be set up in a laboratory within one day.
- Corneal cultures prepared at the awardee’s laboratory are transportable and hence can be potentially delivered to testing laboratories.
- The culturing system was further improved through the expertise provided by the trainee.
- Handling of corneal cultures and substance application were significantly simplified, and can be implemented by skilled laboratory technicians after a short training.
- An applicable protocol for performance of the EVEIT test has now been prepared.

Subsequently, Dr Spoeler tested in his own laboratory in Aachen the same set of substances as tested at the BASF laboratory. In the next months, to finalise the EPAA Science Award project Dr Spoeler will prepare a manuscript summarizing the achievements of the project during the funding period, including the data comparison among both laboratories.

Science Award 2012

Further to the call for proposals, sixteen applications were received, from Germany, France, Austria, Switzerland, the Netherlands and Sweden. In line with the formal requirements, the applicants were mainly PhD students and post docs.

The proposals were evaluated by a scientific panel drawn from EPAA members (both industry and the European Commission) and from the EPAA Mirror Group, according to the following criteria:

1. Potential/expected impact on regulatory acceptance of the method/approach
2. Potential/expected impact on the 3Rs
3. Proximity to “market” (availability of protocol/Standard Operating Procedure, prevalidation, readiness to be applied for regulatory purposes)
4. Potential for collaboration with industry (EPAA companies) and Commission (EURL ECVAM or other bodies)
5. Innovativeness/contribution to meeting an urgent unmet scientific need
6. Cross-sector industrial applicability
7. Potential applicability to other methods and endpoints
8. Technical challenges (for transferability etc.)

Four short-listed finalists with excellent proposals were invited to present them in person to the panel in Brussels on 26 September. The final decision was taken by the EPAA Steering Committee based on the recommendations of the scientific panel.

The 2012 award winner is Dr Nils Klüver from the Department of Bio-analytical Eco-toxicology at the Helmholtz Centre for Environmental Research (UFZ) in Leipzig, Germany, for his proposal “Increasing the predictive capacity of the fish embryo test”.

In the scientific panel’s opinion, Dr Klüver’s proposal is realistic, and concrete progress and 3Rs impact can be expected from it. The results of this “post-validation” project could better define the applicability of the Zebra Fish Embryo Test (ZFET) as a replacement test for acute fish toxicity. In addition to replacement and/or reduction in numbers of fish used for acute toxicity testing for environmental risk assessment globally, the project could result in an amended OECD test guideline that provides more mechanistic information useful also for detecting other types of toxicity beyond environmental risk assessment (e.g. bio-concentration, endocrine disruption and developmental toxicity). It is therefore expected to contribute to the 3Rs and to have an impact on testing in the chemical, agrochemical, cosmetic and pharmaceutical industries.

Dr Klüver’s group has collaborated already with scientists from EPAA partners in studying the application of the Zebra Fish embryo as an alternative model in toxicology and teratology.

His project is expected to be carried out during 2013.
ACUTE TOXICITY

Workstream 1 “Reducing animal use in dermal safety evaluation of substances”

There have been substantial improvements recently in welfare of animals that are used in safety testing of chemical substances and mixtures in line with legal requirements for the purposes of CLP (classification, labelling and packaging). This has occurred through technical progress and recently established 3Rs best practices for acute toxicity testing. An EPAA technical expert group is assessing how similar improvements could be implemented in other relevant EU legislation, specifically REACH, as this would provide additional improvements in animal welfare and facilitate a reduction in the number of animals required in the safety evaluation of each substance.

The group concluded that it is inappropriate to perform an acute dermal toxicity study on a substance that is not classified for acute oral toxicity. The group also considered that there is a mismatch between the wording of the REACH testing annexes (which indicates that testing via a second route is an unconditional requirement) and the detailed guidance published by the European Chemicals Agency (ECHA), which clearly acknowledges situations where testing by a route that is additional to the oral route would not be required.

A document has been compiled that provides information on areas where there has been technical progress that is relevant to REACH Annex VIII. Adaptation of legislation to these areas of technical progress would facilitate change to the chemical sector data requirements and would align these with the “3Rs best practices” for acute systemic toxicity that have recently been established in other EU regulatory schemes. The suggested changes focus on specific data requirements in animal studies. All the recommendations are supported by detailed scientific justification.

Workstream 2 “How could C&L decisions in the agrochemical and chemical sectors be made if stand-alone acute toxicity testing were prohibited?”

The classification and labelling of substances provides vital information in many situations in which exposure to chemicals may occur, including emergency response to spillages and assessment of risks in use of contaminated areas. This information includes hazards from acute human exposure; the assessment of acute toxicity is therefore essential safety information. However, the absolute need for acute toxicity testing in animals for pharmaceuticals has been removed: (Please see http://www.emea.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002720.pdf P. 8, section 4) because in many circumstances the same information can be obtained from other sources.

An industry-government working group is assessing whether a similar approach is plausible for acute toxicity assessments in the agrochemical and chemical sectors, where the differences in risk-benefit assessments are obvious compared with pharmaceuticals. Working group members initially gathered information through their expert networks and produced a comprehensive analysis. Subsequently, a Round Table was organised on 28 September, which aimed to:

- Explore whether an approach similar to that used in the pharmaceutical industry can be achieved in the agrochemical and chemical sectors
- Assess the possibility of establishing a framework for animal studies in which traditional data requirements are replaced with those that are more acceptable ethically for animal welfare. (For example, when safety evaluation without data on acute toxicity was not plausible such as may be essential for evaluating hazards that may arise from major spillages of highly toxic substances).
- Develop a strategy to obtain harmonised approaches by regulators in all major world regions, and ultimately remove the requirement for lethality testing as a de facto absolute data requirement for safety evaluation of new substances in the chemical and agrochemical sectors.

Possible 3Rs alternatives and the potential impact on current classification and labelling approaches across the chemical and agrochemical sectors were assessed. A lively round table discussion included an examination of how animal studies might be reduced and refined where these cannot be fully replaced. Practical application of approaches with multidisciplinary analysis including structure activity relationships, weight of evidence and read-across were recommended. Such 3Rs approaches are increasingly being used.

Eighteen experts from Europe and North America took part and the conclusions will be published.

Workstream 3 “Minimising the requirements for inhalation testing”

Information on toxicity is essential to assess the hazards of substances and mixtures which may be inhaled either accidentally or as an occupational hazard. For example, such information enables evaluation of risks, appropriate precautions, and
The consistency approach for batch release of vaccines avoids the need for in vivo testing of a final production lot for potency by comparing it with previous batches of proven potency in man using validated in-process controls and in vitro tests. The consistency approach for batch release (which enables a 100% in vitro process) is currently being applied only to a limited number of vaccines.

Modern vaccines based on defined antigens do not depend on animal tests for batch release – the consistency approach is often sufficient.

Animal tests are however used for final quality control checks for old-style vaccines (diphtheria, tetanus, pertussis, rabies) and for many veterinary vaccines that use crude antigens plus adjuvants. These areas offer significant opportunities for reduction as they represent 10-15% of all animals used in research in Europe.

In vaccine manufacture, in-process quality control is an essential framework for acceptance of in vitro tests for batch release. Differences in international acceptance of the consistency approach are not yet resolved, but observers from Canada, US, Brazil and India are attending the meetings organised by the project team. The intention is to design consistency approaches for a small number of vaccines (DTaP, rabies, clostridials) and then present them to the authorities on these specific vaccines.

Several workshops have been organised, on:
- DTaP (diphtheria, tetanus and acellular pertussis combination vaccine) on 30-31 August in the Netherlands
- Human rabies on 8-9 October in France
- Veterinary rabies on 5-6 November in Belgium

**Next Step**
Clostridial vaccines workshop, to assess how to progress a collaborative study on clostridial antigen cell line assays as alternatives to animal tests, in light of interest from four manufacturers and four Official Medicines Control Laboratories (early 2013).
OPTIMISED STRATEGIES FOR SKIN SENSITISATION

A report from the October 2011 EPAA-Cefic LRI Workshop was published in July in the Journal of Regulatory Toxicology and Pharmacology under the title: “Optimised testing strategies for skin sensitisation - the LLNA and beyond. Report from a EPAA/Cefic LRI cross sector workshop”. It is available online at: http://dx.doi.org/10.1016/j.yrtph.2012.06.003.

The project team is currently planning an EPAA-Cefic LRI Round Table in early 2013, in Helsinki. It will partly be designed as a “training session” on skin sensitisation methods and data. The aim is to discuss the conclusions from the 2011 workshop, to bring experts together, and develop a strategy framework for skin sensitisation hazard identification promoting the use of non-animal testing (LLNA and in vitro, in silico or “weight-of-evidence”(WoE) approaches). This could also include discussion on opportunities for collaboration related to the OECD Toolbox.

Examples will be presented of testing strategies used by companies for hazard identification, classification and labelling, which can be used to reduce animal testing in dossiers required by REACH. Regulators will be asked what information might be needed to win acceptance of such strategies.

EOGRTS (EXTENDED ONE GENERATION REPRODUCTIVE TOXICITY STUDY)

Following adoption of this test method by the OECD (Test Guideline 443) in July 2011, an expert sub-group under CARACAL (Competent Authorities for REACH and CLP) was tasked with considering all the options to apply it and to explore how it could be used in the context of REACH. CARACAL is the expert group which advises the European Commission and ECHA on questions related to REACH and CLP.

Through the EPAA, industry was invited to contribute to this discussion with information on costs and practical issues related to applying the Test Guideline. Cefic has been coordinating the industry response. A joint scientific publication on the feasibility of the current EOGRTS, including studies conducted on behalf of EPAA member companies (BASF, Bayer, Dow and Syngenta), was published by Fegert et al. (2012) in a peer reviewed journal1.

Practical questions related to the use of EOGRTS have been discussed at CARACAL meetings. The Commission is, in addition, examining the inclusion of the EOGRTS in the 5th adaptation to technical progress of the Test Method Regulation, and subsequent adaptation of REACH Annexes if necessary.


NEW PROJECT: HARMONISATION OF 3RS IN BIOLOGICALS

A new project has recently been initiated related to the international harmonisation of 3Rs requirements for Biologicals.

The project will be led by the EC in conjunction with the European Vaccine Manufacturers, and plans to address the disparity between regulations around the world in requirements for safety and efficacy evaluation of vaccines and other biologicals, such as blood products. The project complements and broadens the already extensive work being conducted on four specific vaccines under the project on vaccines consistency approach.
THE MARKET PLACE

The EPAA continued working on its “market place” concept, aiming to provide regulators, industry and other stakeholders with concise, comprehensive and peer-reviewed information as Thematic Reviews of existing 3Rs methods for regulatory safety testing.

In 2012 the review of reproductive toxicity methods was completed in collaboration with EURL ECVAM. After an extensive bibliographic review performed in 2010 and leading to the description of 39, predominantly in vitro methods, and an overall review document that includes the results of a first industry survey with EPAA member companies on the use of non-animal approaches applied in reproductive toxicology, a second survey was carried out in 2012 on the use of in vivo reduction and refinement methods for reproductive toxicity. The final report is in preparation. The results will be made publically available in the EURL ECVAM’s “DataBase service on ALternative Methods to animal experimentation” (DB-ALM)

Online access (last access 30 October 2012)
http://ecvam-dbalm.jrc.ec.europa.eu

EPAA SPONSORED EVENTS

EPAA shares with other organisations its commitment to the development and promotion of alternatives. In 2012, the EPAA supported the following external activities:

**International Workshop on the HET-CAM** (Hen’s Egg Test on the Chorio-Allantoic Membrane) for eye irritation.
The BfR (German Federal Institute for risk assessment) and SeCAM (Services & Consultation on Alternative Methods) organised this International workshop on 29-30 October 2012 in Berlin. The EPAA co-sponsored the workshop together with the BfR. The aim of the workshop was to make recommendations on the most relevant HET-CAM protocol(s) and prediction model(s) for the different purposes and uses of this test method.

**2012 Conference of the European Society of Toxicology In Vitro (ESTIV)**
16-20 October 2012, Lisbon, Portugal
The Conference covered a broad range of topics on systemic, local and developmental toxicity, with an emphasis on physiologically relevant markers, marker profiles, molecular mechanisms and pathways.

**International Conference of Alternatives to Animal Experimentation (ICAAE)** (EXPECTED)
26 - 27 January 2013, Almada, Portugal
In October 2012 the EPAA agreed to provide financial support to this conference, because of its international character and its plans to promote debate and sharing of information regarding 3Rs policies and alternative approaches.

**Institute for In Vitro Sciences - Education and Outreach Projects** (EXPECTED)
In view of its 2012 theme of international cooperation, EPAA has decided to support selected regulatory-oriented education and outreach projects of IIVS in key regions over the next two years. These relate mainly to in vitro skin and eye irritation methods, are relevant to multiple sectors, and are expected to facilitate global adoption and use of these OECD-accepted methods.
THE EPAA 3Rs ACHIEVEMENTS FACTSHEETS

Further to the recommendations of the EPAA Communication Group, a first batch of three factsheets on the EPAA flagship projects has been published on the EPAA website. These highlight the EPAA Science Award 2012 (Ex Vivo Eye Irritation Test), the Vaccines Consistency Approach, and the Extended One Generation Reproductive Toxicity Study. New factsheets will be further developed and released on the EPAA website.

NEWSLETTERS & INTERVIEWS

EPAA Newsletters summarising the latest breakthroughs in projects have been released in 2012, highlighting the latest workshops on computational chemistry and on vaccines. An interview with Henkel’s Dr Thomas Förster has also been published, focusing on the EPAA lead theme for 2012.

DIGITAL PRESENCE

The EPAA has taken tentative steps to establish an enhanced digital presence with a view to exploring how various social tools can help advance any of EPAA’s activities and broaden the understanding of the role of alternatives.
EPAA MEMBERSHIP

EUROPEAN COMMISSION
DG Enterprise and Industry
DG Research and Innovation
DG Environment
DG Joint Research Centre
DG Health and Consumer Protection
DG Research and Innovation
DG Environment
DG Joint Research Centre
DG Health and Consumer Protection

COMPUANIES
Abbott
Avon
BASF
Bayer
Beiersdorf
Boehringer Ingelheim
Chanel
Colgate-Palmolive
Dow
DSM
Elizabeth Arden
Estée Lauder
Evonik
GlaxoSmithKline
Henkel
Johnson & Johnson
Kanebo
Kimberly-Clark
L’Oréal
LVMH
Merck Serono
Merck Sharp and Dohme - MSD Animal Health
Novartis
Novo Nordisk
Novozymes
Pfizer
Procter & Gamble
Reckitt Benckiser
Roche (F Hoffmann-La Roche)
Sanofi-Aventis
Shiseido
Symrise (since 2012)
Syngenta
Unilever

FEDERATIONS
Soaps and detergents (AISE)
Chemicals (Cefic)
Cosmetics (Cosmetics Europe)
Crop Protection (ECPA)
Fragrances (IFRA) (since 2012)
Pharmaceuticals (EFPIA)
Animal Health Europe (IFAH-Europe)

COMPANIES
Abbott
Avon
BASF
Bayer
Beiersdorf
Boehringer Ingelheim
Chanel
Colgate-Palmolive
Dow
DSM
Elizabeth Arden
Estée Lauder
Evonik
GlaxoSmithKline
Henkel
Johnson & Johnson
Kanebo
Kimberly-Clark
L’Oréal
LVMH
Merck Serono
Merck Sharp and Dohme - MSD Animal Health
Novartis
Novo Nordisk
Novozymes
Pfizer
Procter & Gamble
Reckitt Benckiser
Roche (F Hoffmann-La Roche)
Sanofi-Aventis
Shiseido
Symrise (since 2012)
Syngenta
Unilever

EPAA PROJECTS UNDERWAY
> NEW : Advancing 3Rs in Regulatory Toxicology
> NEW : Harmonisation of 3Rs in Biologicals
> New perspectives on safety – follow-up: Stem cells
> ADME (PBTK)
> Science award
> Acute toxicity testing
> Consistency of production approach in Vaccines (veterinary and human)
> Follow up to the OECD acceptance of Extended One-Generation Reproductive Toxicity Study (EOGRTS)
> Skin sensitisation optimised strategies (the LLNA and beyond)
> Enhance dissemination of 3Rs information to target audiences (thematic review on the topic of Reproductive Toxicity)
> External communication
> Internal communication

GOVERNANCE

In 2012, the EPAA Steering Committee met on 7 February, 27 April, 3 July and 7 September. A fifth meeting is scheduled for December 2012.

The Mirror Group, EPAA’s consultation forum, met on 7 February, 27 April and 7 September. This group is composed of experts from academia, risk assessors, animal welfare and other organisations with an interest in regulatory toxicological testing. Members are proposed by the stakeholders but act in their personal capacity. They provide a critical look at the work of EPAA and valuable advice for on-going and future EPAA projects.

Minutes of the Steering Committee and the Mirror Group meetings are available on the EPAA website.

Work in EPAA projects continues to attract participants from non-governmental organisations both in the EU and globally.

Further info is available at www.epaa.eu.com