Workshop 3.3
Forum of national and international institutions funding

Lecture

ECVAM and its collaborative efforts to ensure a better co-ordination and funding of research, development and validation of alternative methods for regulatory purposes

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One of the past bottle-necks in the funding schemes was the lack of global European co-ordination of the identification and validation of alternative methods for regulatory purposes. The European Commission and its relevant DGs have recognised this and many initiatives were taken.

ECVAM closely collaborates with national, international and industrial research funding bodies to make the missing alternatives available. On European Commission level, ECVAM offers to play a proactive role in this process by encouraging development activities and being involved in several FP6 projects, which deliverables will hopefully feed into ECVAM's validation studies.

ECVAM funds directly and manages feasibility and pre(validation) studies which could reduce, refine and replace the use of animals for cosmetics, chemicals and other products testing, thus meeting the legislative requirements.

ECVAM funds and organises on a regular basis workshops and taskforce meetings, which help to identify promising alternative methods and testing strategies and feedback to research programmes or validation activities.

Although the commitment and willingness of the European Commission to contribute to co-ordination and funding of 3Rs efforts through its own research and validation funding, significant results can only be obtained if there is a joint effort between scientists, the Member States, industry and NGOs.

Lecture

FRAME – A scientific charity working for better science and animal welfare

Robert D. Combes
FRAME, Nottingham, UK

FRAME (Fund for the Replacement of Animals in Medical Research) was founded as a scientific charity in 1969 in London with the objective of promoting the development and validation of alternatives to animal experimentation. Since the early 1980s, FRAME funds a research programme focused on laboratory research at the University of Nottingham Medical School and at its offices nearby. This research has encompassed all the Three Rs (replacement, refinement and reduction) of Russell and Burch. Substantial contributions have been made by FRAME scientists in many areas, including skin and eye toxicity using human cell models, embryotoxicity, genetically modified animals, endocrine disruption, genotoxicity, carcinogenicity, toxicogenomics, the use of non-human primates, testing legislation, the non-invasive use of volunteers and animal welfare. FRAME also has two scientific committees, on reduction and toxicity respectively, and a comprehensive web site which provides a useful resource on information on alternatives and how to search for it in the literature. FRAME works closely with industry, regulatory agencies and governments at national and international levels and is active in campaigning for legislative reform worldwide. FRAME receives funding from a variety of sources, including the general public, charitable trusts, industry and research grants to enable it to pursue its ultimate goal of replacing all animal experiments with advanced, scientifically justified and robust non-animal methods.

Lecture

Research in *in vitro* toxicology funded under the 6th Framework Programme. Review and opportunities for the forthcoming 4th call

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The development of novel, alternative *in vitro* tests has been a priority for the various European Community research programmes since the 80s. The current Framework Programme (FP6) funds research on non animal testing methods mostly under thematic priority 1.

In the first three years of the programme, 55.5 million € have been invested in developing robust and effective *in vitro* methods that will withstand the requirements of international validation. The funding instruments used are: Integrated Projects (IP), Specific Targeted Research Projects (STREP) and Specific Support Actions (SSA).

Research topics currently supported by the EC encompass the application of *in vitro* cell and sensor technologies to replace *in vivo* animal studies, *in vitro* test strategies predicting human acute, chronic and reproductive toxicity. Hepatotoxicity, cellular (this includes research on human embryonic stem cells) and organ toxicity and specific types of toxicity such as allergies are also included.

Funding is also devoted to pharmacotoxicity and kinetic studies applied to product screening and the development of pharmaceutically relevant lead compounds. SSAs range from activities to raise awareness on the use of alternative methods in New Member States and Candidate Countries, to the promotion of new biosensor-based technologies for the Three Rs, and the analysis of the mechanisms of nuclear hormone receptors to potentially bridge the gaps between *in vitro* and *in silico*.

This presentation will provide a review of currently available funding under FP6 relevant to Three Rs research, with detailed information on forthcoming possibilities offered by the 4th call (deadline November 2005).

Lecture

Funding opportunities through the Johns Hopkins Center for Alternatives to Animal Testing (CAAT)

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The Johns Hopkins Center for Alternatives to Animal Testing, Baltimore, USA

CAAT established its Research Grants Program shortly after the Center's creation in 1981. The program originally was intended to provide critical seed money for scientists to develop new *in vitro* methods for risk assessment. As the need for more research in the refinement area became apparent, CAAT expanded its grants program, starting in 2001, to include refinement projects as well.

For the 2006-2007 funding period, CAAT solicited projects in the following areas:

- Refinement ($25,000 maximum): grants focused specifically on the issues of alleviating pain and/or distress in laboratory protocols.
- Developmental Toxicology and Developmental Neurotoxicology ($50,000 maximum): projects using *in vitro* methods, embryonic stem cells, or species such as *c. elegans* or zebrafish to address these areas.
- Immunotoxicology ($50,000 maximum): grants focused on basic mechanisms as they relate to toxicity.

We follow a stringent, peer-reviewed process for selecting grant recipients. To date, CAAT has funded nearly 300 grants for a total of about $5.5 million.

In 2004, CAAT further expanded the refinement program, adding the Animal Welfare Enhancement Awards. These awards ($6,000 each) are aimed at the people who work directly with the animals, such as lab technicians, animal technicians, and veterinarians. The focus of the awards is to improve housing, handling and/or experimental situations for laboratory animals.

For more information about CAAT grants, please see http://caat.jhsph.edu/programs /grants/grants.htm.

Lecture

"Three Rs" R&D in the European Union: Funding tools and opportunities of Framework Programme 7

Beatrice Lucaroni and Maria Dusinska
European Commission, Research Directorate General, Brussels, Belgium

The Seventh Framework Programme, FP7, refers to the next research programme in a series of multi-annual Framework Programmes that have been the European Union's main instrument for funding research and technological development since 1984.

The Commission's proposals for FP7, published on April 6, 2005, will cover the period 2007-2013.

The total budget for FP7, as proposed, is of 73 billion Euro, with a yearly average of around 10 billion Euro.

The adoption of the research framework programme will be subject to a co-decision procedure, in which the Commission, Council and the Parliament play an equally important role. The new proposal is based on a year-long process of consultations with interested parties. The debate on FP7 continues throughout 2005 and 2006 and includes negotiations among the European institutions, Member States and stakeholders.

Subtitled "Building the European research area of knowledge for growth", FP7 is designed to respond to the competitiveness and employment needs of the EU through four specific programmes:

1. Co-operation: mainly collaborative research in 9 areas, and joint technology initiatives
2. Ideas: basic research, through the European Research Council
3. People: training, fellowships
4. Capacities: infrastructures, helping SMEs, regions of knowledge, science and society.

Details of these programmes will be set out later in the year.

The presentation will provide an update of FP7 preparations, focussing on scientific areas and funding tools relevant to research in the Three Rs, particularly in the sections devoted to Human Health, Environment as well as Science and Society.

Lecture

The beneficial partnership between the European (ecopa) and the National Consensus Platforms (NCPs) for Alternatives to Animal Experimentation is growing

Peter Maier
3R Research Foundation, Münsingen, Switzerland

Ecopa represents the pan-European umbrella organisation of national consensus platforms (NCP) consisting of those four parties (animal welfare organisations, industries, governmental institutions and academia) interested in fostering research, development and implementation of alternatives to animal experiments. NCPs and ecopa adhere to the 3R concept of refinement, reduction and replacement. They exhibit a type of non-governmental organisations combining the parties involved in an area of interest being diverse in their views and nature, but agreeing to find a consensus.

Members of ecopa are the NCPs in Europe (voting members) but also associate members (individuals, societies, associations, institutions). Ecopa was founded 2002 in Brussels by NCPs from now 15 European states and legally recognised on April 21, 2004 as an international not-for-profit organisation.

Examples will be presented how ecopa strives (see: http://ecopa.vub.ac.be) i) to raise public, government and scientific awareness in Europe for a better acceptance of alternatives in animal experimentation, ii) to facilitate the exchange of scientific information, expertise and experience between National Consensus Platforms, EU, government, industry, animal welfare and science institutions, iii) to organise conferences and seminars, publish documents, collect and circulate information and iv) to support scientific and educative initiatives. The final goal is the further development and implementation of 3R methods in Europe and worldwide. This is driven by the ongoing EU specific-support-action CONAM (Consensus networking on Alternative Methods within Europe). Examples of interactions between the 3R Research Foundation (the NCP of Switzerland) and ecopa demonstrate the beneficial outcome of this networking.

Lecture

Research directions in toxicology at the US National Toxicology Program

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In its more than 25 years of existence, the NTP has been a leader in toxicology testing and research within the United States and contributed significantly to the scientific knowledge used in making public health decisions. Dramatic advances have occurred in computer science and molecular biology during the last decade of the 20th century and beginning of the 21st century. In August 2003, the NTP set forth a vision for the 21st century: to support the evolution of toxicology from a predominantly observational science at the level of disease-specific models to a predominantly predictive science focused upon a broad inclusion of target-specific, mechanism-based, biological observations. The NTP Roadmap, developed with input from leading researchers in academic, industry, government, and advocacy groups, addresses the goals of the NTP vision for the 21st century and provides a framework for setting NTP research priorities to achieve the most efficient and effective research portfolio possible. The NTP Roadmap identifies the challenges and opportunities confronting the program and discusses the directions for the NTP in three main areas: (1) refining traditional toxicological assays, (2) developing rapid, mechanism-based, predictive screens for environmentally induced diseases, and (3) improving the overall utility of toxicology for public health decisions. The NTP Roadmap is posted on its web site (http//ntp.niehs.nih.gov) or available in hardcopy from the NTP Liaison and Scientific Review Office (phone: +1-919-541-0530).

Lecture

An overview of the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs)

Vicky Robinson
National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), London, UK

This presentation provides an overview of the NC3Rs, including background and examples of current activities.

In May 2004, Lord Sainsbury, Parliamentary Under-Secretary of State for Science and Innovation, announced the establishment of the NC3Rs. The NC3Rs became operational after the first meeting of its board in September 2004.

The NC3Rs provides a UK focus for the promotion, development and implementation of the 3Rs in animal research. The Centre brings together stakeholders in the 3Rs in government, academia, industry and animal welfare organisations to facilitate the exchange of information and ideas, and the translation of research findings into practice that will benefit both animals and research.

The NC3Rs funds high-quality 3Rs research, organises workshops and symposia to disseminate and advance the 3Rs and is developing a range of 3Rs information resources and guidelines. Further information on the NC3Rs can be found on the new, comprehensive 3Rs web resource at www.nc3rs.org.uk.

Lecture

ZEBET's funding program for the development of alternatives to testing in animals

Horst Spielmann, Manfred Liebsch, Andrea Seiler and Susanne Boy
ZEBET, National Center for Documentation and Evaluation of Alternative Methods to Animal Experiments, BfR, Federal Institute for Risk Assessment, Berlin, Germany

Since 1990 ZEBET at the BfR has funded research in Germany according to the 3Rs principle in order to reduce testing in animals for scientific and regulatory purposes. An annual budget of 300,000 € allowed ZEBET to support on an average of 10 concurrent projects for 2-3 years. To date 87 projects have been funded; most of them at university laboratories. The program is advertised at the national level and around 20% of the applications have received funding. Several successful projects have initiated international validation studies in the field of regulatory toxicology, e.g. phototoxicity, skin and eye irritation, ecotoxicology, pyrogenicity. ZEBET has also funded biostatistical support for validation studies. Other projects helped to replace the production of monoclonal antibodies in the ascites mouse by culturing ascites cells in advanced bioreactors, the production of polyclonal antibodies in chicken eggs rather than in rabbits, the use of embryonic stem cells in embryotoxicity testing, establishing transgenic cell lines for drug metabolism in humans and quality control and standardisation of commercial human skin models.

Funding by the German government via ZEBET and the BfR has proven remarkably successful, since some of the new methods developed in the program have been accepted for regulatory testing at the international level. Moreover, a considerable number of projects achieved international recognition and were awarded for contributing to refining, reducing or replacing testing in experimental animals.