European Research for Product Safety: reducing Animal Testing through Innovation

Today - World Lab Animal Day - the European Commission is presenting its activities in the area of research for reducing animal testing. Over the past 20 years, Europe has taken the lead in replacing animal experimentation in product development through dedicated research. EU funding for the development and quality assessment of new testing techniques is allocated to cutting-edge research programmes funded through the EU's Research Framework Programmes and coordinated by DG Research and the Joint Research Centre of the European Commission. The research activities with DG RTD focus on developing new ideas and the JRC establishes their quality via its European Centre for the Validation of Alternative Methods (ECVAM). Demand to speed up these processes has been increasing recently due to the EU Cosmetics and Chemicals Legislation and the desire to avoid complications associated with drug development.

Currently, ECVAM is actively involved in a total of 13 projects financed from the 6th Research Framework Programme with a budget of around €80 million and comprising over 260 partners. ECVAM links these development activities with pertinent EU regulations, such as the REACH chemicals legislation. The Commission's intention is to reduce animal testing substantially by investing wisely in high-tech R&D and validation techniques.

The biotechnology revolution of recent years has triggered a wave of innovation creating new solutions to supplant animal testing, not to mention the added turnover it has meant for small- and medium-sized enterprises (SMEs). For example, a recent study jointly undertaken by DG RTD and the JRC has produced four new testing methods and cut validation times in half. These newly discovered assays for bacterial contamination detection (known as pyrogens) have the potential to reduce animal tests in Europe by 200 000 rabbits each year. Most interestingly, they can also be used for new cell therapies, where no appropriate test had previously been available.

These new projects have set very ambitious goals for themselves with the aim of reducing or further possibly even completely eliminating animal testing for acute oral intoxication (for example, how much of a medicine is dangerous), embryotoxicity (negative effects on embryos), allergic reactions, cancer etc. Within the context of these projects, almost every possible health effect provoked by chemicals in industry, consumer products and drugs is addressed. An intelligent combination of various technologies, such as cell and tissue culture, sensor technologies, computer modelling and imaging techniques are employed.

These projects represent a significant contribution to the 'Europe goes alternative' platform. Under the auspices of Vice President of the European Commission Günter Verheugen and Commissioner for Science and Research Janez Potočnik, two Conferences on Alternatives to Animal Testing were held in 2005 and 2006.

Speakers and participants included high-level representatives and experts from industry, animal welfare organisations, academia and national, European as well as international institutions. The first conference was the starting point for a European Partnership (EPAA) between the Commission and industry to promote alternative approaches to animal testing. Through this partnership, the European Chemical Industry Council (CEFIC), the European Federation on Pharmaceutical Industries and Associations (EFPIA), the European Cosmetic Toiletry and Perfumery Association (COLIPA), the European Association for Bioindustries (EuropaBio), the European Crop Protection Association (ECPA), the International Association for Soaps, Detergents and Maintenance Product Industry in Europe (AISE), and the Commission agreed to the "Three Rs Declaration" aiming at **refining**, **reducing or replacing** animal use. Based on the declaration, an action programme with concrete activities was set up designed in the perspective of identifying barriers to progress and propose appropriate solutions in order to promote the development, validation and regulatory acceptance of alternative approaches.

On-going research projects where ECVAM is limiting animal tests cover a wide range of human health issues such as:

- Long-term toxicity of new medicines and pharmaceuticals (Predictomics)
- Assessing the effect of substances and chemicals on human reproduction and genetic makeup (Reprotect, Alterscreen, Comics)
- Effect of chemicals in humans and animals (A-cute-tox)
- Lung disease, which is a major health problem in Europe (Pulmo-net)
- Skin sensitivity and irritation. As testing cosmetics on animal will be largely banned from 2009, it is important to have alternatives in this field to ensure consumer safety
- Cancer, by using alternative methods to asses the cancer-inducing properties of chemicals and cosmetics (Carcinogenomics)

Other projects address the regulatory procedures for chemicals established by REACH, proposing ways in which the tests to ensure the substances are safe for humans can be carried out with the minimum of testing on animals (Osiris, Tox-Drop,

A third area of activity is the production of effective models that can be used to replace animals in industries such as cosmetics, pharmaceuticals and chemicals by mimicking the reaction of certain parts of the body, such as the liver, brain or heart. (Vitrocellomics, Invitroheart, Artemis)

ECVAM also manages a database of alternative methods, where in particular scientists and regulatory authorities can find information about all the tests validated to date, such as descriptions, protocols and evaluation studies.

More information available at: http://ecvam.jrc.cec.eu.int/index.htm