Alternatives to Animal Testing:

OPPORTUNITIES AND LIMITATIONS IN THE REGULATORY FRAMEWORK

Prof. Coenraad Hendriksen, Netherlands Centre for Alternatives to Animal Use, Utrecht University.

Highlights:

- Professor Hendriksen demonstrated that although there have been some successes in the implementation of alternatives to animal testing, it has been a difficult and time-heavy task.
- To speed up the process, he recommended that the 3Rs (reduction, refinement and replacement) be higher on the regulatory agenda and more importantly that conflicting regulation at the EU level need to be harmonised, emphasising that the 3Rs should be considered as equally important in reducing the numbers of animal used but also pain caused to animals.
- Finally, in light of the limited results obtained so far with the fragmented efforts taking place over the last 20 years, Professor Hendriksen underlined the need for new approaches in the development and acceptance, involving all stakeholders.
- In general, the assembly expressed the need for increased support for this important field of research to match the demands of new regulations.

Summary:
The inaugural AllChemE seminar was well attended with over 40 people enjoying the presentation and debate. The seminar was hosted and introduced by Bob van den Bos, MEP, who was master of ceremonies for the meeting. A brief introduction to the AllChemE organisation was given by Prof. Claudine Buess-Herman of Université Libre de Bruxelles as a representative of FECS - one of the AllChemE partners.

Bob van den Bos then introduced Prof. Hendriksen, a European expert on Alternatives to Animal Experimentation. Prof Hendriksen gave an overview of animal testing including the purposes for which animals are used, the nature of regulatory testing, what alternative testing is and why it is needed, the results of his personal experience of developing alternatives and where the barriers to progress in this area lie.

Around 10 million laboratory animals are consumed in testing each year in Europe, the vast majority being rodents. Regulatory testing forms approximately ten per cent of the testing carried out. In some cases such testing leads to relatively high levels of pain and stress for the animals. Animal testing has, of course, been beneficial - without animal models successive advances in medicine over the past 100 years would have been almost impossible. Professor Hendriksen presented the different reasons why animal testing is still needed to protect human safety and wildlife. He also showed there has been a significant downward trend in the use of animals over the last decades. However, there are a number of intrinsic problems with animal testing ranging from economic (time and cost), through scientific (issues of reproducibility, standardisation and extrapolation) to the more ethical ones.

The concept of the 3R's (Replacement, Refinement and Reduction) in animal testing is codified in the EU by Council Directive 86/609/EEC and supported by the scientific and regulatory community, however advancements in this area has been relatively limited. In certain areas, for example cosmetic testing, progress has been particularly frustrating although there have been notable successes. A major problem cited by Professor Hendriksen is the time taken to develop and validate alternatives. He gave the example of a new test for tetanus vaccine potency which will have taken from 1986 to 2004 to proceed from development to regulatory approval and implementation.

Major obstacles, he says, are a lack of common scientific tools, funding issues, a relatively low priority assigned to this activity and negative cost-benefit analysis. The cost of validation studies, communicating with regulatory bodies and the perceived status of animal studies as a 'gold standard' - despite clear scientific evidence to the contrary - all frustrated the development of new techniques. Greater support is needed to make sure 3Rs development is given higher priority. Prof. Hendriksen called for Directive 86/609 to be fully implemented and for greater harmonisation between international testing regimes to reduce duplicate testing. He said there was a need to support new testing strategies for testing of chemicals and biologicals that are more intelligent, more flexible and less bureaucratic. Finally it is important to consider all three R's equally, as replacement is not necessarily possible or advisable in some cases. Prof Hendriksen concluded by stating that "Less animals makes more science. And more science makes better regulations."

Debate
Following the presentation there was a lively debate with contributions from a wide range of interests. Overall, there was strong support for the concept of the seminars, and bringing together science and parliamentarians. With regards to animal testing, an issue raised was the perceived lacking availability of commercially important test data derived by industry. Comments were also made about the strict deadlines being faced for the elimination of animal testing (taking as an example the cosmetics industry) and whether these deadlines are realistic. There was also a general feeling that alternatives to animal testing needed to be funded at a higher level and given greater priority and a more systematic approach. Though the FP6 programme dedicates funding to this area of research, more emphasis on cooperation and harmonisation is required. Both the chemical industry and cosmetic industry talked about their commitment in the field, through research which has contributed to some of the successes described by Professor Hendriksen.