EUROPEAN COALITION TO END ANIMAL EXPERIMENTS

testing TIMES

Monthly Update on Animal Experimentation Issues in the EU from the ECEAE

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Welcome to the first Testing Times of 2007.

2007 promises to be a busy year for animal protection organisations working at the EU level. The Commission Proposal for the revision of Directive 86/609/EEC on 'the Protection of Animals used for Experimental and other Scientific Purposes' is due out in the spring, the revision of Directive 91/414/EEC on Plant Protection Products is at the Parliament First Reading stage and concerns such as Nanotechnology and Endocrine Disruptors continue to be worked on.

The REACH Chemicals Legislation was finally adopted after prolonged wrangling between all three EU institutions. While we aren't happy with legislation that will result in the deaths of millions of animals, when we look at how far it has come from the original Commission Proposal it is clear that much has been achieved. We are now working hard within the REACH Implementation Projects (RIPs) to ensure that animal use will be further eradicated.

I hope you enjoy this edition of Testing Times. If you have any questions regarding laboratory animal issues in the EU, please feel free to contact me.

Warm regards,

Michelle Thew
European Coalition to End Animal Experiments

This Issue

REACH Animal Testing Overview

The ECEAE fully supports the idea that we should ensure the safety of chemicals we use. To demonstrate our support, in conjunction with the BUAV, the ECEAE published a report entitled 'The Way Forward: A Non-Animal Testing Strategy for Chemicals', which demonstrated how chemicals could be safety-tested without using animals.

However, the European Union decided to require outdated and unreliable animal methods in spite of the wealth of alternatives and data available. Consequently, REACH will mean the suffering and death of a massive number of animals to test the safety of chemicals. Initially it was estimated that around 45 million animals would be used in these experiments. However, due to our work this number has been substantially reduced and the present estimate is around 8-12 million animals – still a catastrophe for animal welfare and the individuals involved.

One of the reasons for this large reduction is the now mandatory sharing of animal test data. Often a number of companies are developing the same or similar chemicals. This results in much duplication of testing, with each battery of tests potentially involving hundreds of animals. There was initial reluctance among big business to share data but due to intense political pressure it is now accepted that

not sharing data causes unacceptable suffering to animals. Data sharing is now a central feature of the legislation and there are penalties for companies that refuse to comply with their obligations.

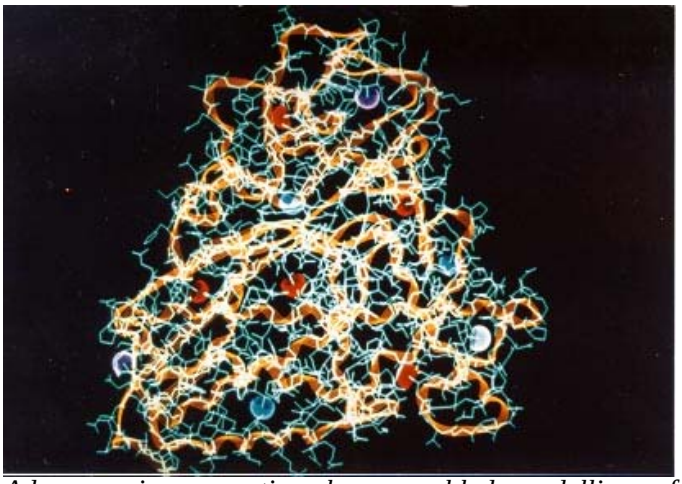
A positive aspect of the whole REACH process is that the promotion of alternatives to animal testing has now been placed firmly on the political agenda. When this process started over five years ago, alternatives to animal testing were not even mentioned. However, due to intensive lobbying and outrage at the horrendous number of animals estimated to be used, the development and use of alternatives has been placed centrally in the legislation. Indeed, Article 1 now states specifically that one of the aims of REACH is the 'promotion of alternative methods for assessment of hazards of substances'. It also states that research on alternatives should be prioritised in future European Union research programmes.

Another success for which we fought hard was the inclusion of a 45-day window for public scrutiny of any tests that companies are planning to carry out for REACH. Evidence from a similar programme in the United States, the HPV Challenge Program, has shown that many tests conducted by companies are indeed duplicated. This can be the case for several reasons: the information is available elsewhere, there is an alternative test available, or simply by redesigning tests animal use could have been significantly reduced. Therefore, the public scrutiny option has the potential to reduce the numbers of animals involved in REACH.

The ECEAE will continue to press for the best possible outcome for animals through the REACH Implementation Projects (RIPs) currently underway.

86/609 Public Consultation Results

In December, the results of the European Commission's public consultation on the revision of Directive 86/609/EEC on the 'Protection of Animals used for Experimental and other Scientific Purposes' were finally published. The results



Advances in computing have enabled modelling of chemicals on computers to yield accurate and informative results.

demonstrate overwhelming public opposition to primate experimentation and animal experimentation in general, and support for tougher regulation of experiments across the EU:

- 50% of respondents believe that the level of welfare and protection of animals used in experiments within the EU is very poor.

- Over 70% of respondents believe the use of non-human primates in experiments is 'certainly not' acceptable.

- Almost 50% (48.9) of respondents believe there is 'certainly not' enough public funding at European level into the development and validation of alternative methods to replace animal experiments.

This sends a clear message from the people of the European Union to the Commission that they wish to see a ban on non-human primate experiments, a strong tightening up of laboratory animal protection and a major increase in funding of non-animal alternative test methods in the forthcoming revision of Directive 86/609. As a public body created to serve the interests of the people of the EU, we call for the Commission to incorporate these findings into the Proposal.

Michelle Thew of the ECEAE attended the Competent Authorities meeting on the Directive on 18th January to discuss the animal protection position directly with the authorities.

7th Research Framework Programme Adopted

The EU's Seventh Framework Programme for Research and Technological Development (FP7) entered into force on 1st January 2007 following its adoption by the Environment Council. This was as expected following a compromise between the Parliament and Council in November. The total budget of 50.521 Billion Euros and will run for seven years, split between four programmes:

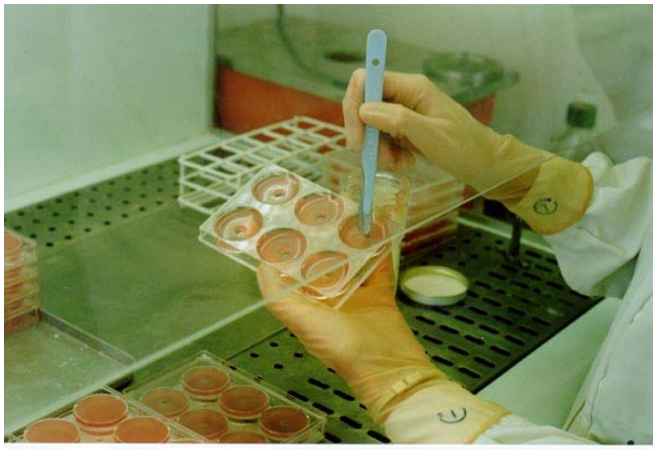
- Cooperation - collaborative research;
- Ideas - the establishment of a European Research Council (ERC) to support frontier research;
- People - human resources;
- Capacities - research infrastructure and potential research capacity.

There will also be 2.7 Billion Euros for the Euratom Programme on nuclear research and 1.75 Billion Euros for the Joint Research Centre (JRC).
Although FP7 states its desire to see a reduction in animal use in research and testing with 'a view to ultimately replacing animal use', the extent to which the European Union is serious about replacing animal testing remains to be seen.

Report into Clinical Drug Trial for TGN1412 published

The Duff report has published its findings into the implications for human drug trials of the disaster at Northwick Park Hospital in the UK last March, in which six young men nearly lost their lives. TGN1412 was touted as a potential treatment for leukaemia and rheumatoid arthritis. The severity of the reaction that the men suffered, within minutes of the drug being administered, was both unprecedented and unanticipated. Non-human primates given a dose 500 times greater had shown no ill effects.

The report, extremely technical for the most part, discusses mostly how to prevent recurrences of this disaster and its analysis and recommendations are quite specific to the type of drug administered. Although it doesn't call for additional animal testing before trials, it does make an explicit statement in support of the value of animal work in drug testing and development.



Cell and tissue culture techniques are making rapid advances as a humane alternative to the use of animals.

The ECEAE is disappointed that the report does not take this invaluable opportunity to look at the big picture of the unreliability of the animal model, and merely illustrates how wedded to this model the scientific community is. Worse still, scientists are now actually attempting to replicate what happened in the volunteers in animals to figure out what went wrong.

Of course, what happened was an almost unprecedented event. However, it neatly illustrates the limitations of using animals as a model for humans and it appears that non-animal tests could have predicted what happened where the use of primates failed.

Although the exact nature of what happened at Northwick Park is very rare, drugs failing in human trials are extremely common – over 90% do so, though mostly they fail because they don't work rather than because they prove dangerous.