

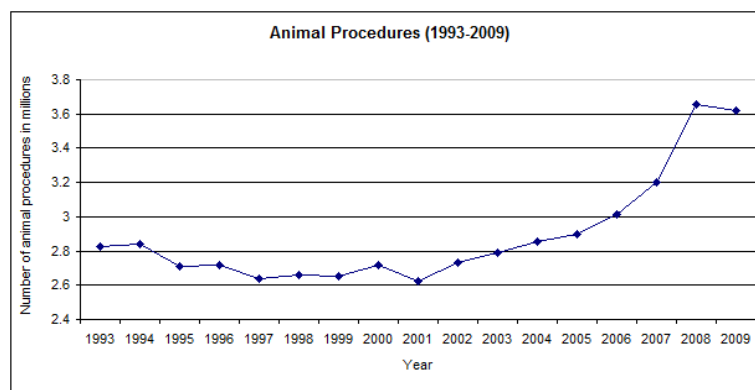
Naturewatch

MP Briefing

In your hands: the future of humane scientific research

Home Office figures confirm, that since 2001, the number of scientific procedures on animals have increased over 7 successive years, reaching just under 3.7 million in 2008.

In 2009, the number of procedures dipped by a mere 1%, to 3.6 million, yet in spite of this 1% drop, the UK's use of animals in research facilities remains inordinately high, making the UK one of the highest users of animals for research purposes in Europe.



Yet this total reliance on animals as research models needn't continue. New hi-tech methods reducing or replacing animals hold the key to humane scientific research. Not only more humane these methods deliver human relevant research data.

This briefing provides an overview of some of the issues surrounding animals in scientific procedures in the UK and outlines practical measures on which progress towards humane scientific research depends. It is intended to provide a balanced and objective précis of the issues, hurdles and potential involved:

- It charts the development of the humane approach to animals in scientific procedures over the past 50 years. Highlighting some of the incredible non-animal research currently underway.
- Considers key issues regarding EU Directive 2010/63/EU adopted September 2010.
- Points to barriers which impede the development and implementation of pioneering non-animal techniques; suggesting measures that remove these barriers.

This briefing is intended to provide the basis on which YOU can help quicken the pace of progress towards humane, human relevant science. We hope that it will help you make the right choice to support humane scientific research. It's in your hands.

Please support all efforts that develop and promote non-animal alternative research methods.

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UK scientists pioneer humane research:

Over 50 years ago, two British scientists William Russell and Rex Burch outlined the principles of humane experimental technique, namely Replacement, Reduction and Refinement.¹ The “3Rs” have since been recognised as a model approach, and indeed underpin the newly revised EU legislation² which protects animals used in scientific research, adopted by the European Union in September 2010.

And yet in spite of this recognition, in the main progress towards developing and implementing non-animal alternatives has over the intervening years been desperately slow.

While pioneering techniques including tissue-engineering, micro-dosing, computer models and hi-tech toxicity testing on bio-chips, are being developed in the UK. Home Office statistics confirm the prevailing trend, towards the use of animals to model human conditions, irrespective of their limitations.

Hi-tech, humane and human relevant:

Tissue engineering and skin models: offer human tissue equivalents which mimic human structures such as human airway or kidney.

Micro-dosing: minute doses given to human subjects, can reduce the number of animal tests required, and replace costly, doubtfully reliable testing regimes. Despite passing the animal tests required by regulatory bodies 92% of all potential new drugs fail in clinical trials³



Computer modelling: uses software to predict toxicity and model human conditions, mimicking virtual human beings.

Bio-chips offer hi-tech toxicity testing. Each micro-size chip holds hundreds of tiny dots of test substance and can analyse biochemical reactions in minutes.

Each new method holds enormous potential; not only more humane, the findings have direct relevance to humans. **So why has progress in this field been so slow?**

While scientific innovation can't be dictated. The conditions which nurture progress lie inside our control. Funding and political will are key. For decades non-animal alternatives were under-funded. Only in recent years has this shortfall in funding been recognised.

Quickening the pace of progress

In 2004, the opening of the National Centre for Replacement, Reduction and Refinement (NC3Rs) provided the much needed catalyst to drive non-animal alternatives forward. Since its inception NC3Rs has delivered innovative programs to help overcome hurdles hampering progress.

Over recent years several expert bodies have noted non-scientific barriers to the development and implementation of alternatives.

In 2005 **The Nuffield Council on Bioethics** questioned why replacements in specific research areas were not available,⁴ and identified shortfalls in funding, the lack of incentives, and the conservatism of some researchers to use alternatives.

*In 2007 **Toxicity testing in the 21st Century: a vision and a strategy***⁵ prepared by the National Research Council at the request of the US Environmental Protection Agency highlighted the enormous potential of modern technologies to replace time-consuming, costly and often questionable animal testing regimes. It noted “far reaching shifts in orientation and perception” will be crucial to achieving this goal.

Early Day Motions: NC3Rs is undoubtedly tackling these barriers head on, working with the scientific community, funding bodies, and other players. Naturewatch recognises the work of the NC3Rs as pivotal, and in the 2009 parliamentary session, over a third of MPs also pledged their support. Early Day Motion 545 tabled on behalf of Naturewatch urged the government to do more to promote pioneering work in the UK, to develop hi-tech methods of research replacing and reducing animals.

¹ Russell, W & Burch, R. 1959, *The Principles of Humane Experimental Technique*.

² European Union. Sept 2010, EU Directive 86/609/EEC.

³ US Food & Drug Administration White Paper: Innovation or Stagnation, 2004

⁴ Nuffield Council on Bioethics. 2005, *The ethics of research involving animals*. p.275

⁵ National Research Council. *Toxicity Testing in the 21st Century*. 2007.

In total 268 MPs signed EDM 545 making it the sixth most highly supported EDM out of 2421 EDMs!

And what would the possible future be if together we weren't to strive for humane research?

On the 8th September 2010, the EU adopted a newly revised Directive intended to protect animals used in scientific procedures. The revised Directive 2010/63/EU is enforceable throughout the 27 member bloc, harmonising regulations throughout the EU. While it recognises the 3Rs approach as good practice, several provisions made in the Directive fall disappointingly short of the long-hoped for reforms, and the Directive remains heavily weighted in favour of animal research.

- Research on non-human primates will not be limited only to that for debilitating or life-threatening diseases, fundamental research is also permitted.
- The seven year phasing out of primates captured from the wild and young born of wild caught parents is postponed pending a feasibility study.
- Only 33% of research facilities are required to undergo inspection.

It has been mooted that the revised EU Directive could dilute the UK's own animal protection regulations⁶. Hence it's crucial that the UK continues the lead of humane technique pioneers Russell and Burch, and presses for a non-animal alternative agenda in Europe.

Under the new EU Directive each country is required to set up a national committee⁷ to provide advice to the relevant authorities. It's foreseen that the Animal Procedures Committee will evolve into this role under the revised Directive.⁸

In January 2010 the NDBP review of the Animal Procedure Committee (APC), suggested extending the role for the APC, to "add leadership across Europe on issues such as animal welfare." Given this remit, Naturewatch hopes the future committee could drive forward the 3Rs agenda in Europe in the same way the NC3Rs has done within the UK

scientific community. Ensuring there is no "dumbing down" of UK regulations to fit EU legislation, and indeed strengthening the animal welfare element of the new EU Directive, which will be subject to a 5 yearly review.

Any other future would be a bleak one, especially for animal welfare. The realities of animal use in scientific procedures come home in the following excerpt from Annex VIII EU Directive 2010/63/EU (Oct 2010) which outlines the 4 categories of severity: Non-recovery, Mild, Moderate and Severe.

How would you classify the following procedures?

- Acute dose-range finding studies, chronic toxicity/carcinogenicity tests, with non-lethal end-points.
- Use of metabolic cages involving moderate restriction of movement over a prolonged period (up to 5 days)⁹

You'd be forgiven if you thought the procedures above were classified as Severe, however they are actually categorised as Moderate.

The Severe classification is reserved for procedures such as the ones below:

- Inescapable electric shock (e.g. to produce learned helplessness)
- Thoracotomy without adequate analgesia
- Use of metabolic cages involving severe restriction of movement over a prolonged period.
- Induction of tumours that are allowed to ulcerate.

For the complete list of procedures classified as Severe see Annex VIII, EU Directive 86/609/EEC.

In 2009, 2% of scientific procedures on animals in the UK were categorised as "Substantial" the highest level of severity designated in the UK. This equates to 72,200 animals!

Wouldn't you rather non-animal alternatives were available? So how can you support hi-tech methods of humane, human relevant research?

⁶ Dr Hadwen Trust website September 2010

⁷ Article 49, EU Directive 2010/63/EU. 20.10.2010

⁸ Report of the 2009/2010 NDBP Review of the Animal Procedures Committee. January 2010

⁹ Annex VIII, EU Directive 2010/63/EU. 20.10.2010

IN YOUR HANDS:

While animal tests won't end in an instant, there are positive and practical things you can do as an MP, whether asking a parliamentary question, casting your vote or voicing your opinion.

1. Support initiatives promoting the 3Rs throughout the scientific community.

Please support the NC3Rs by ensuring the necessary funding and resources are available.

- 2. Equip the body representing UK interests in the European Union with sufficient**
- financial resources, and
 - animal welfare expertise
- In order that it may lobby effectively for a robust 3Rs agenda in Europe, as well as encouraging the far-reaching shifts in perception and orientation required to move towards non-animal alternatives.

3. Ask parliamentary questions

Help to keep the issue of animal experiments and non-animal alternatives high on the political agenda, through highlighting the following:

- Transparency and openness:
While the annual statistics provide an insight into the number of procedures begun on animals in any given year, there is much which isn't included.

For instance, the level of severity in relation to the species of animal. In 2005, the government's own advisory body recommended this be included, to:

- enhance transparency especially welfare implications of using different species.
- identify trends in animal use
- help in the prioritising of 3Rs resources
This recommendation has not yet been implemented.¹⁰

4. Please pledge your support for non-animal alternatives, by signing the following EDMs:

EDM 380 – Availability of human tissue for medical research. Surplus human tissue removed in surgery, presents a valuable resource for use in research. This EDM calls for measures to help make these surplus tissues more widely available for non-animal alternatives research

EDM 475 - Safety of Medicines. For more information on both these important EDM's visit: www.safermedicines.org

To add your voice to calls for more to be done to promote non-animal alternatives, and for more information on how you can help please contact Naturewatch.

Please support all efforts that develop and promote non-animal alternative research methods, and reduce the number of animals used in scientific procedures.



¹⁰ Animal Procedure Committee. APC Statistics Report 2005.