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Research animals

Animals are used for many different purposes in research and testing and each area of use raises specific ethical, welfare and scientific issues. The RSPCA adopts a constructive, practical approach, judging every issue individually, critically questioning the necessity and justification for animal use and arguing the need to reduce the conflict between the interests of animals and of science. Our aim is the replacement of animal experiments with humane alternatives worldwide. Until this can be achieved, we work to help ensure that the minimum numbers of animals are used and that they experience the minimum suffering and have the best possible quality of life.

The Society liaises with those involved in animal use in government, industry and academia to promote initiatives that:

- **develop effective processes of ethical review**
- **lead to fuller implementation of the 3Rs***

Andrew Forsyth/RSPCA Photilibary x3

* The 3Rs are: **replacement** of animals with humane alternatives, **reduction** of animal use, and **refinement** of husbandry and procedures to reduce suffering and improve welfare throughout the animals' lives.

New animal experiments law for UK

Since a new European Directive on the Protection of Animals used for Scientific Purposes (2010/63/EU)[1] came into force on 9th November 2010, the UK government has been making preparations to transpose its requirements into UK law. The new EU controls represent a significant advance in the regulation of animal experiments for many Member States and should lead to improvements for tens of thousands of animals across Europe. However, in many areas the standards fall short of what we have had in the UK for a number of years.

Under Article 2 of the Directive, the UK has been given some freedom to maintain current UK standards where they are higher. However, the RSPCA and many other stakeholders, have been concerned that the UK government might simply choose to adopt the new minimum baseline regulations set by Europe. This could have serious implications for the welfare of animals, for the quality of science undertaken, and for public confidence that this use of animals is being appropriately controlled. It would also go against the express declaration of the House of Lords European Union Committee that there should be 'no weakening of standards in the UK'[2].

Home Office Minister, Lynne Featherstone MP, has acknowledged[3] that a number of the provisions in the new European law are 'potentially less stringent' than current UK regulations[4]. In practical terms, it could mean that some animals may be allowed to suffer long-lasting unalleviated 'severe' pain, suffering or distress – something the Lords' committee stated would be 'unacceptable'. Minimum cage and pen sizes for some animals may also be reduced – affecting both the space available to move around and the capacity for caregivers to provide appropriate environmental complexity. In addition, there could be a significant decrease in the number and frequency of visits and inspections of laboratories by a depleted Home Office inspectorate.

Furthermore, some research establishments could be able to opt to water down the role and membership of their local Ethical Review Process (ERP). This is despite the importance of ERPs, as acknowledged by the Minister[5], in 'ensuring no relevant replacement, reduction or refinement measure has been overlooked' and the significant contribution they have made to reducing animal use and improving welfare over the past decade.

The government seems to be aware of the poor public reaction which would greet any move to weaken UK animal welfare standards since, in recent months, it has sought to make some encouraging noises about the desirability of maintaining current provisions. For instance, Home Office Minister Lord Henley said[6] that he could give 'an absolute and categorical assurance that we will not be dropping our standards in any way whatever', whilst Lynne Featherstone announced[7] that 'what we do not want to do is weaken United Kingdom standards of animal welfare and protection'.

However, as in so many cases, the devil is in the detail, and there are conflicting opinions amongst different stakeholders as to what might actually constitute a 'weakening' or 'reduction' of standards. The transposition process comes at a time when economic arguments against the continuation of various regulatory 'burdens' and for a 'level playing field' in Europe are being sympathetically received. The government has stated that it will use the transposition process to review current UK controls in order to reduce bureaucracy – despite there being little convincing evidence in our view to substantiate that this is indeed a significant problem.

The RSPCA has been monitoring events closely, liaising with concerned MPs, members of the public, and the scientific community, taking every opportunity to argue the importance of maintaining current UK standards. We submitted a comprehensive response[8] to the public consultation from the Home Office which ran from July to September, and throughout the year have had various meetings to make our case with Home Office officials, the Minister and others.

It is likely that a formal guidance document to accompany the new legislation, and which will describe how the new UK law should be implemented in practice, will be finalised during the second half of 2012 with the new law itself coming into force on 1st Jan 2013.

Given the plethora of statements made by the current and previous governments and by many in industry and academia that everything in the UK is done 'to the highest possible standards' and that 'animal welfare is a top priority', it would be disingenuous – and in our view completely unacceptable – for measures to be adopted that would see protection and provisions for animals reduced.

FOOTNOTES AND REFERENCES

1 European Directive on the Protection of Animals used for Scientific Purposes -2010/63/EU. Brussels. See: http://ec.europa.eu/environment/chemicals/lab_animals/legislation_en.htm
2 The revision of the EU Directive on the protection of animals used for scientific purposes - Volume 1: Report. House of Lords European Select Committee - 10th November 2009. www.publications.parliament.uk/pa/ld200809/ldselect/ldeucom/164/16402.htm
3 Written answer to Parliamentary Question 38791 - 10th February 2011. www.publications.parliament.uk/pa/cm201011/cmhansrd/cm110210/text/110210w0001.htm#11021062000273
4 The Animals (Scientific Procedures) Act 1986.
5. Written answer to Parliamentary Question 53687 - 18th May 2011. www.publications.parliament.uk/pa/cm201011/cmhansrd/cm110518/text/110518w0002.htm#11051892002921
6. Animals: Experimentation - Question for Short Debate - 24th October2011. www.theyworkforyou.com/lords/?id=2011-10-04a.1013.0&s=scientific+procedures#g1015.4
7. Written answer to Parliamentary Question 82709 - 28th November 2011. www.theyworkforyou.com/wrans/?id=2011-11-28a.82709.h&s=animal+experiments+section%3Awrans
8. Available at: www.rspca.org.uk/getinvolved/campaigns/laboratory/uklabanimallaw

The 'Bateson Review' of primate use

The use of primates in medical research raises profound ethical questions and is a matter of great concern to the RSPCA and the public. Many in the scientific community consistently maintain that primate use is essential for understanding serious human diseases and valuable in discovering treatments for them. However, an enquiry into primate use in medical research reported[1] in 2006 that actual evidence of the value of primate research was 'anecdotal'. The report called on the major organisations funding primate research (the Medical Research Council (MRC), Biotechnology and Biological Sciences Research Council (BBSRC) and the Wellcome Trust) to undertake a systematic review of the outcome of the research they had funded over the preceding decade, to establish how valuable the research actually was.

It seemed astonishing to the RSPCA, given the emphatic nature of statements about the value of primates in medical research, that the supporting evidence was not already available. The RSPCA was also appalled that research funders did not appear to critically review the outcomes of the research they funded – in the case of the MRC and BBSRC, with public money. The review was eventually started in 2009, three years after the original recommendation; during this time the RSPCA wrote several times to the funding bodies asking about the delay. The review panel was chaired by Sir Patrick Bateson and the panel's report was published[2] in July 2011.

The panel admits that 'assessments of medical and other benefits were made with difficulty[1] and often could be no more than 'informed guesses.' However, it would appear that for a number of research projects, a scientific finding might have been achieved but this had not actually led to any particular medical benefit, or that the benefit achieved may not have justified the harms actually caused to the animals involved. Of particular concern were the nine percent of the research projects where it was stated that neither a scientific, medical or social benefit had emerged.

The report identifies many questionable aspects of individual research projects in terms of planning, approval, conduct and exploitation for scientific and medical benefit. It makes recommendations which, if implemented immediately and assiduously, should make a real contribution to ensuring that the potential benefit of proposed research is assessed more rigorously, and that the numbers of primates used in research and the level of suffering they experience are minimised.

The first recommendation, for example, underlines the need for rigorous review of grant applications with regard to scientific value, probability of benefit, availability of alternative approaches and likely animal suffering. The second calls on funders to critically examine the choice of primates as test species, and the possibility of using alternative methods. We have been repeatedly told over many years that such rigorous review is standard practice. It is therefore disturbing – and telling – that the Bateson Panel felt it necessary to restate these requirements.

The RSPCA welcomes the report and believes it should provide a driving force for change – but only if it is taken seriously by the research community. It is important that these issues have been raised and made public in such an authoritative forum. The recommendations must be pursued and implemented without delay, and we will be following this up with the research funders and other appropriate bodies.

FOOTNOTES AND REFERENCES

1 *The use of non-human primates in research. A working group report chaired by Sir David Weatherall FRS FMedSci*. December 2006. The Academy of Medical Sciences/Medical Research Council/The Royal Society/Wellcome Trust. London. http://royalsociety.org/General_WF.aspx?pageid=9115&terms=weatherall

2 *Review of research using non-human primates. Report of a panel chaired by Professor Patrick Bateson FRS*. July 2011. BBSRC/MRC/NC3Rs/Wellcome Trust. London. www.bbsrc.ac.uk/organisation/policies/reviews/funded-science/1107-review-research-using-nhps.aspx

World congress on alternatives

The *8th World Congress on Alternatives and Animal Use in the Life Sciences* took place in Montreal in August 2011. This important event, held every third year, brought together people from 52 countries to discuss progress in the development and implementation of the 3Rs. Over 800 delegates attended, representing governments, regulatory bodies, pharmaceutical and chemicals companies, academia and animal protection organisations. RSPCA scientific staff co-chaired a scientific session on ethical review, and also provided presentations[1] on:

- applying the 3Rs to challenge assays used in vaccine testing
- guidance on the severity classification of procedures involving fish
- ethical review of animal experiments – current practice and future challenges
- facilitating the role of lay members in ethics and animal care and use committees
- openness and public accountability – the why, who, what and how of it.

The 9th World Congress will be held in Prague in 2014.

FOOTNOTES AND REFERENCES

1 The full Congress abstract booklet is available at: http://www.wc8.ccac.ca/files/C17932_LivreCW8Abstract.pdf

Andrew Forsyth/RSPCA Photolibrary; ahwla.org.uk; istockphoto.com/wakila

Reducing severe suffering

Animal experiments are currently classified as mild, moderate or substantial (severe) in the UK depending on the amount of pain or distress that animals experience. The use of animals in procedures that have the potential to cause severe suffering are of particular and major concern. The RSPCA has therefore decided to increase its focus on achieving a reduction in the number of animals who experience severe suffering, within the context of our overall programme of work to promote the fullest implementation of the 3Rs and effective ethical review.

Animals can experience severe suffering when they are used to study conditions that cause severe pain or distress in humans or other animals, for example chronic arthritis, cancer pain, dementia or some infectious diseases. Many vaccine tests also involve severe suffering, as do some acute toxicity (safety) tests. At present, there is no single source of information on which procedures cause severe suffering as this is not reported in annual Home Office statistics on animal use. (The new European Directive regulating animal experiments requires actual suffering to be reported[1], but this will not take effect in the UK until 2013.)

The research animals department is currently researching the use of animals in severe procedures, through consultation, reviewing the scientific literature and project abstracts in the Home Office database[2], and discussion with those who use and care for the animals involved. Further information on the nature and purpose of severe procedures will enable us to identify practical approaches to avoiding and reducing suffering within both industry and academia.

The project aims to help achieve reduced levels of suffering so that it is no longer severe, and to facilitate more effective monitoring of animal suffering. A further objective is for severe procedures and models to be avoided; for example, by using alternative approaches such as use of 'biomarkers' instead of full disease models. As an initial step, the RSPCA research animals department held a workshop in autumn 2011 to explore ways of refining animal models of multiple sclerosis and epilepsy, with a view to producing guidelines for researchers in 2012.

FOOTNOTES AND REFERENCES

1 See Article 54 (2) and Annex VIII of European Directive on the Protection of Animals used for Scientific Purposes -2010/63/EU. Brussels. Available at: http://ec.europa.eu/environment/chemicals/lab_animals/legislation_en.htm

2 Abstracts for 2011 can be viewed at: www.homeoffice.gov.uk/publications/science-research-statistics/769901/animal_abstracts_for_2011/

Ban on the use of animals to test household products

In line with a pledge made by the UK coalition government when it came to power, on 18th July 2011, Home Office Minister Lynne Featherstone announced[1] a 'ban' on the use of animals to test household products. To enact this, the Home Office intends to add a condition to relevant animal experiment licences which will prohibit the testing of products intended primarily for use in the household.

The RSPCA has always campaigned against the use of animals to test products such as cosmetics, toiletries, and household cleaners, believing that there are more than sufficient available, and that there is no justification for causing animals to suffer to develop more. However, as the RSPCA has consistently pointed out, the proposed ban may sound good for the government, but will have very little impact. Out of 3.6 million animals used in experiments in the UK in 2010, just 24 were used for this purpose[2], and zero were used the year before. Furthermore, defining 'household products' will be difficult, and the ban will therefore be easy to circumvent. It may apply only to 'finished' products, and not to their chemical ingredients, so it will still not guarantee that all household products are 'cruelty free'. The ban will therefore impress few people unless it is followed by more substantial progress in other areas of safety testing where tens of thousands of animals continue to suffer.

The RSPCA believes that the current legal requirement to weigh the harms caused to animals against the benefits of testing before granting a licence should be more rigorously applied. The need for each new product should be taken into account regardless of whether they are intended for use in the household or elsewhere.

FOOTNOTES AND REFERENCES

1 www.homeoffice.gov.uk/publications/about-us/parliamentary-business/written-ministerial-statement/testing-animals-reduce-use-wms/

2 www.homeoffice.gov.uk/publications/science-research-statistics/research-statistics/other-science-research/spanimals10/

Rodent welfare

The RSPCA and the Universities Federation for Animal Welfare (UFAW) have jointly organised an annual meeting[1] on rodent welfare for the past 18 years with the aims of providing a discussion forum on new developments in the 3Rs for rodent care and use, and encouraging and promoting advances in rodent welfare.

The 2011 meeting focused on the application of technologies such as imaging (see right), biotelemetry and automated blood sampling in studies involving rodents. There can be both scientific and animal welfare benefits associated with the use of these techniques; for example, with repeated imaging animals can be used as their own controls, numbers can be reduced and endpoints refined. Telemetry facilitates the collection of data from freely-moving animals, and automated blood sampling removes the requirement for repeated capture, handling and needle insertions

However, there can also be additional harms associated with the application of these technologies to rodents. Some, such as automated blood sampling and telemetry, can result in single housing of social animals, which is a major stressor. Repeated anaesthesia and scanning sessions, which can be for long periods, can also affect welfare. This can lead to a dilemma – the numbers of animals can be significantly reduced within projects by using these technologies, but there may be an increased negative impact on individual animals. Despite the perceived pressure to reduce numbers, it may be preferable to use more animals and reduce suffering instead.

The 2011 meeting explored these issues and enabled participants to discuss how these harms and benefits can be weighed against one another when making decisions about techniques and protocols. Over 80 delegates attended, including scientists, animal technologists and veterinarians from a range of establishments within industry and academia. An interactive discussion session enabled all to explore how they, and others, made decisions on the use of new technologies and provided some very useful insights into the range of views on the topic. The report from the meeting will be published in the journal Animal Technology and Welfare during 2012.

MRC Clinical Sciences Centre

FOOTNOTES AND REFERENCES

1 For more information about the RSPCA/UFAW Rodent Welfare Group and for free to download reports from past meetings, see: www.rspca.org.uk/sciencegroup/researchanimals/implementing3rs/rodentwelfaregroup

Genetically altered animals – reduction and refinement

The creation and use of genetically altered (GA) animals continues to escalate worldwide. Mice and zebrafish are the two most common GA species used in research though technical developments published during 2011 mean a surge in the number of GA rats produced is expected over the coming years. Much of the growth in the number of GA animals is driven by a scientific demand for 'new or improved animal models' of disease. Unfortunately, these rarely replace existing ones and in practice become additional models, thus pushing up the number of GA animals further. Implementation of the 3Rs is therefore particularly important in this field and, to this end, the research animals department undertook a number of initiatives in 2011.

- As issues relating to the practical implementation of European Directive 2010/63/EU and its transposition into UK law have been discussed, the RSPCA has aimed to ensure that transparency on the use of GA animals, and opportunities for reduction and refinement are kept at the forefront of people's minds. Some people have suggested a change in the criteria for counting GA animals which could see dramatic reductions in the reporting of these animals in UK annual Home Office statistics[1]. The RSPCA argues for the inclusion of all animals used in the production, breeding and maintenance of GA animals so that meaningful information can be obtained relating to the true costs of applying genetic technologies – both in terms of animals' lives and any suffering experienced.
- In June, the RSPCA was invited to give a presentation on the 3Rs and animal welfare to an audience of senior animal technicians, animal unit managers, scientists and vets from across the UK and Europe. The presentation formed part of a three-day Wellcome Trust advanced training course *Managing mouse colonies: breeding, genetics and welfare*. This course follows on from a 3Rs training initiative organised by the RSPCA in 2010 and will run annually, having been given a regular place within the Wellcome Trust training program.
- In July, a training event *Genetically altered animals and the 3Rs - what's it all about?* was held for scientists and technicians with the aim of highlighting 3Rs opportunities. The meeting included a range of presentations and workshop sessions to illustrate current good practice in the production, breeding and care of GA animals, with the aim of minimising the number of animals created and used and the potential for them to experience pain, suffering or distress.

FOOTNOTES AND REFERENCES

1 Potentially, vast numbers of GA animals created would no longer appear anywhere in the statistics. In addition, some argue that invasive techniques used to genotype animals, such as tail-tipping, ear notching or toe-clipping, should be re-categorised simply as 'husbandry' rather than as a 'scientific procedure'. Were this to happen, then this animal suffering (currently reported) would also be 'lost' from official figures.

2 For more information on the above initiatives, see: www.rspca.org.uk/sciencegroup/researchanimals/implementing3Rs

Ethical review

Ethical Review Process (ERP) Lay Members' Forum 2011

Delegates from over 40 establishments, representing both academia and industry, attended the meeting which focused on *Making difficult decisions* within the ERP.

An underlying theme was recent progress in the assessment of pain, suffering and distress in laboratory animals. Delegates heard about clinical signs and monitoring systems used to assess suffering in a number of animal 'models', including autoimmune disease and ageing studies. Questions that ERP members could raise about the severity of procedures and the scientific approaches to particular projects were also discussed.

The difficulty, at times, of balancing reduction and refinement was then highlighted through consideration of the application of new technologies, such as imaging (e.g. MRI scanning), biotelemetry and automated blood sampling, to animal research and testing. This led on to discussion of the concept of 'cumulative suffering' which aims to recognise and reduce suffering at every stage of the animals' life experience. Individual 'case studies' typical of industry and academia were provided.

The harms and potential benefits of research in behavioural pharmacology were then presented and the ERP's role in reviewing projects in this field was discussed. This touched on some current controversies about the benefits of medicines that emerge from such research and whether or not it is appropriate to use medication to manipulate human behaviour.

Ethical review from a global perspective was then explored. This is increasingly important – both for multinational companies and for the academic community. To be effective and improve standards, the local ethical review process has to consider differences around the world in culture and legislation, along with standards of, and consideration for, animal welfare.

FOOTNOTES AND REFERENCES

1 For more information regarding our work to promote effective ethical review, see: www.rspca.org.uk/sciencegroup/researchanimals/ethicalreview/eventsandnewsletters

Influencing decision makers

Scientific staff from the RSPCA's research animals department promote the Society's policies, aims and objectives through advocacy to statutory bodies, industry, academia and other organisations. They are members of many national and international committees and working groups, and also have expert input into a range of consultations, both to government and non-governmental bodies, on a wide range of laboratory animal issues. Staff have also produced papers on a variety of topics that have been published in peer reviewed scientific journals.

Membership during 2011 included the following

- European Commission – expert working groups on statistical reporting, and retrospective severity assessment.
- European Partnership for Alternative Approaches to Animal Testing – Mirror Group.
- UK OECD Shadow Group.
- Animal Procedures Committee (APC) – including member of the sub-committee on Housing and Husbandry of laboratory animals; and member of the working group reviewing the revision of the European Directive on animals in scientific procedures.
- Laboratory Animal Science Association – Co-convener of section on Education, Training and Ethics.
- BVA(AWF)/FRAME/RSPCA/UFAW Joint Working Group on Refinement (the research animals department provides the secretariat for this initiative).
- The Boyd Group.
- UFAW 3Rs Liaison Group.
- Various ethical review processes in industry and academia.

Examples of meetings/events participated in during 2011

- 8th World Congress on Alternatives and Animal Use in the Life Sciences.
- Joint CAAT Europe/ECOPA Workshop on *Implementation of the new EU Directive 2010/63/EU*.
- Home Office/Animal Welfare and Alternatives Stakeholder Group meetings on transposition of the European Directive.
- British Society of Toxicology and Pathology/Laboratory Animal Veterinary Association joint meeting: *All about the mouse – health and disease*.
- Fondazione Guido Bernardini International Scientific Conference on *Pain and Distress – Prevention, Assessment and Alleviation in Laboratory Animals*.
- Institute of Animal Technicians (IAT) Congress 2011.
- British Association for Zebrafish Husbandry (BAZH) – May Seminar.
- 3rd East Mediterranean ICLAS Symposium.
- British Association for Psychopharmacology – training course.
- Novo Nordisk 3Rs Award 2011.
- Laboratory Animal Science Association (UK) Winter Meeting.
- Society of Biology/Universities UK/Home Office (Animals in Science Regulation Unit) Workshop.
- Various NC3Rs events (e.g. Annual Science Review 2011; Joint NC3Rs/Society of Biology meeting; CRACK-IT funding scheme launch).

Responses to consultations included the following:

- Home Office – Consultation on options for the transposition of European Directive 2010/63/EU on the protection of animals used for scientific procedures (August 2011).
- Home Office – Consultation on issues relating to the delivery of the coalition agreement commitment to end the testing of household products on animals (November 2011).