

Report of the Animal Procedures Committee for 2004

Laid before Parliament by the Secretary of State for the Home Department pursuant to Section 20(5) of the Animals (Scientific Procedures) Act 1986, and on behalf of the Northern Ireland Minister of Health, Social Services and Public Safety pursuant to Section 20(5), as modified by Section 29, of the same Act.

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ANIMAL PROCEDURES COMMITTEE

Membership as at 31 December 2004

Michael BANNER, MA DPhil (Chairman) – Director, ESRC Genomics Policy and Research Forum and Professor of Public Policy in the Life Sciences, School of Clinical and Molecular Medicine, University of Edinburgh

Christopher ATTERWILL BPharm PhD FRCPATH FRPharmS FIBiol – Director: Prognus Ltd. Drug Safety Consultancy

Donald BROOM MA ScD Hon DSc – Professor of Animal Welfare, Department of Clinical Veterinary Medicine, University of Cambridge

Grahame BULFIELD CBE BSc Dip An Gen PhD Hon DSc FIBiol CBiol FRSA Hon FRASE FRSE – Vice-Principal and Head of the College of Science and Engineering, University of Edinburgh; Professor of Animal Genetics, University of Edinburgh

David CLARK OBE BSc PhD CBiol FIBiol – Honorary Senior Research Fellow, University of Kent

Stephen CLARK MA DPhil – Professor of Philosophy, University of Liverpool

Robin DUNBAR BA PhD FBA – Professor of Psychology, University of Liverpool.

Michael FESTING MSc PhD DSc FIBiol CStat – Research Scientist, MRC Toxicology Unit and Honorary Lecturer, Department of Genetics, University of Leicester

John GREGORY FIAT CBiol MIBiol RANtech – Imperial College of Science, Technology and Medicine

Alan HOLLAND MA BPhil – Professor of Applied Philosophy, University of Lancaster

Robert HUBRECHT BSc PhD – Deputy Director, Universities Federation for Animal Welfare

Maggy JENNINGS BSc PhD – Head of Research Animals Department, Royal Society for the Prevention of Cruelty to Animals

Gill LANGLEY MA PhD MIBiol CBiol – Scientific Adviser, Dr Hadwen Trust for Humane Research

John MARTIN MBChB, MD, FRCP, FESC, FMedSci – Professor of Cardiovascular Medicine, University College, London

Alan McNEILLY BSc PhD DSc FRSE – Deputy Director, Medical Research Council Human Reproductive Sciences Unit, Edinburgh; Honorary Professor, University of Edinburgh

Graham MOORE BVM&S, MRCVS, CBiol, MIBiol, FRSH – Veterinary Consultant, Science Policy & Scientific Affairs, Pfizer Global Research & Development.

Timothy MORRIS BVetMed PhD CertLAS DipACLAm DipECLAM CBiol FIBiol MRCVS – Head of Animal Welfare and Ethics, GlaxoSmithKline

Dawn OLIVER BA MA PhD Barrister – Professor of Constitutional Law, University College, London

Genevra RICHARDSON LLB LLM – Professor of Public Law, Queen Mary, University of London

Secretariat

Richard West

Gary Earle (until 27 August 2004)

Nadine Hall (until 12 March 2004)

Anna Paterson (from 13 September 2004)

Philip Brenner

CHAIRMAN'S LETTER TO THE RT HON CHARLES CLARKE MP, SECRETARY OF STATE FOR THE HOME DEPARTMENT AND TO SHAUN WOODWARD MP, THE NORTHERN IRELAND MINISTER OF HEALTH, SOCIAL SERVICES AND PUBLIC SAFETY

I have pleasure in submitting to you the Animal Procedures Committee's Annual Report for 2004.

The debate about the use of animals in scientific research and testing is not new, but the circumstances within which that debate occurs are ones which change over time. In our current context, three particular factors seem noteworthy.

First, there is evidence to believe that a number of pressures exist which may lead to an increase in the use of animals in scientific procedures in the near future. For example, heightened concerns for human safety may lead to tougher regimes for the testing of chemicals, and new understandings in biology may suggest promising lines of enquiry in the search for cures or treatments of the diseases of old age. Second, an increasing realisation of the genetic similarity between humans and animals has, amongst other things, heightened sensibilities about the use and treatment of animals. Third, many observers of the social scene have noted over the last fifty years, a quite general questioning of authorities, and of the authority of government and science in particular.

In such a context, the task of regulating the use of animals is a challenging one. Of course the Animal Procedures Committee is not a regulatory authority; the Committee believes, however, that in advising the Home Secretary on matters relating to the Animals (Scientific Procedures) Act 1986 it plays an important part in offering a critical and independent assessment of developments and initiatives in this area. It is a key feature of the Committee's composition and operation, that members give their time and expertise as individuals and not as representatives of particular organisations, and I know that Ministers have welcomed and continue to welcome the perspectives which the Committee offers.

MICHAEL BANNER

INTRODUCTION

This report describes the work carried out during the year 2004 by the Animal Procedures Committee.

2. The Committee is established by the Animals (Scientific Procedures) Act 1986 (the 1986 Act) to give advice to the Secretary of State on the use of animals in scientific procedures. Two important requirements of the 1986 Act are:

- that the Committee can look at matters of its own devising, but must give advice to the Secretary of State on any matter; and
- when considering such advice the Committee must have regard both to the legitimate requirements of science and industry and to the protection of animals.

3. Annex A to this report sets out some information about the Committee, including its legislative background, the Ministers it reports to and its membership. On joining the Committee, members agree to be bound by a Code of Conduct which appears at Annex B. Among other things this requires them to *'declare any personal or business interest which may, or may be perceived (by a reasonable member of the public) to influence their judgement'*. The register of members' interests appears on the APC website.

4. The full Committee met three times during 2004, and in addition there were numerous sub-committee and working group meetings. As in previous years we also held a weekend conference which provides an additional and useful forum for learning and discussion. Annex C sets out members' attendance at main meetings of the Committee during 2004. Annex D details the membership of the Committee's sub-committees and working groups.

The highlights and main points of the Committee's work in 2004 were as follows:

- The advice we offered on licence applications, and changes to the types of applications that are referred to the Committee;
- On-going work carried out by our permanent sub-committees – Primates, Research and Alternatives, Education and Training and Housing and Husbandry;
- The Home Office's responses to some of the Committee's completed reports – on the use of Primates and on "Overbreeding";
- Progress on the work of the Committee that the Home Office has commissioned – on the Statistics of animal use, on Suffering and Severity, and on the revision of "Schedule 1" (methods of euthanasia);
- Progress on subjects that the Committee itself has identified as deserving study – on cephalopods; the lessons to be learnt from the BUAV allegations about primate use at Cambridge University; and on the batch testing of Botulinum toxin;
- The report concludes with the Committee's work plan for 2005.

¹ The use of primates under the Animals (Scientific Procedures) Act (1986), Analysis of current trends with particular reference to regulatory toxicity; Animal Procedures Committee December 2002. The Control of Surplus Laboratory Animals (Overbreeding) can be found at Annex G of the Report of the Animal Procedures Committee for 2003 (Stationery Office, London 2004).

THE COMMITTEE'S WORK DURING 2004

Applications

1. The Home Office refers a small number of project licence applications to the Committee for advice. Until recently, the categories of applications referred included:

- wild-caught non-human primates
- non-human primates in procedures of substantial severity
- microsurgery
- the testing of tobacco and tobacco products

In our last annual report we described how we had reviewed the categories of application that the Committee would be best employed examining. We considered that some categories of application that we had hitherto seen were relatively non-contentious applications, and as a result the Minister had agreed to cease the automatic referral of applications of licences to use animals for microsurgery training and those involving tobacco products, and she had announced the changes to Parliament in October 2003.

2. We considered that there were some applications that might raise novel policy issues or other concerns that were not automatically referred to the Committee for consideration, but that the public might reasonably expect us to see. We had seen very few applications of this kind, and we believed that sight of a wider range of such applications would enable us to take a more informed and strategic view in relation to some of the more contentious areas of the use of animals. The Minister agreed in principle that the Committee might see additional types of application, and agreed that her officials would discuss a way forward with us. Early in 2004 the Chairman met the Chief Inspector to discuss this, after which the Chairman wrote to the Minister on 28 June identifying three additional categories of project licence applications that the Committee wished to see in future:

A. Applications involving specially protected species in procedures of substantial severity²

3. Section 5(6) of the 1986 Act provides that the Secretary of State shall not authorise a project licence involving the use of cats, dogs, non-human primates or equidae, if there is a suitable alternative for the programme of work. By means of this section, the 1986 Act makes special provision for these species, and we believed that it would therefore be appropriate for the Committee to review all applications that involve these species in procedures of substantial severity as we considered that these applications are likely to be of greater public concern. Based on the numbers of project licences of this type issued in the last five years, we considered that this would lead to a manageable number of applications being referred to the Committee each year.

B. Applications giving rise to societal concerns

4. We also considered that applications that are of the greatest concern to the general public should be referred to the Committee, as raising "societal concerns". We consider that societal concerns will vary over time and as new techniques are developed. However, for the present, we identify them as applications involving animals of any protected species in protocols with a substantial severity limit or major animal welfare or ethical implications involving, for example:

² Licences are given an overall severity assessment of mild, moderate or substantial severity.

- xenotransplantation of whole organs;
- genetic modification of non-human primates (even without substantial severity protocols);
- chronic pain models;
- study of the central nervous system; and
- embryo aggregation chimaeras.

C. Applications that raise novel or contentious issues

5. The equine nuclear transfer application that the Home Office had referred to the Committee in June 2003 was the first application in this category that the Committee had seen for at least five years. We considered that public opinion would expect the Home Office to use this mechanism for referring cases to the Committee liberally. For example, animal work involving human embryo stem cells might be included in this category.

6. We also advised the Minister that in order to meet the likely increase in the numbers of applications referred to the Committee as a result of the change in approach, and to deal with them expeditiously, we proposed to establish an “Applications” Sub-Committee which would meet regularly, as required. The Sub-Committee’s commitment would be to complete consideration of any application within 30 calendar days of its referral.

7. The Minister replied on 1 December 2004 with a final response to our proposals confirming that the following categories of application would be referred to the Committee:

- any involving the proposed use of wild-caught non-human primates;
- any involving the proposed use of cats, dogs, equidae or non-human primates in protocols of substantial severity;
- any projects with a substantial severity banding, or major animal welfare or ethical implications, involving (a) xenotransplantation of whole organs, or (b) chronic pain models, or (c) study of the central nervous system;
- applications of any kind raising novel or contentious issues, or giving rise to serious societal concerns. (As an example, she said that this would include any application involving the genetic modification of non-human primates or embryo aggregation chimaeras involving dissimilar species.)

8. Finally the Minister welcomed our commitment to ensure that referred applications would not be unduly delayed, as she attached particular importance to that. She welcomed our intention to review the effectiveness of the new arrangements after two years, but added that an earlier review might be necessary should handling problems become apparent before then. The Minister said that the new arrangements would come into effect from the beginning of 2005. On 21 December she made a statement to Parliament announcing these changes.

Specific project licence applications referred to the Committee for advice

9. In 2004 no applications were referred to the Committee. However, we report here further events involving one of the applications that we advised on in 2003, and the receipt of two new applications in late 2004.

10. As our report for 2003 describes, in that year we had given advice on an application to amend an existing licence in order to allow two experiments: one involving cross-embryo transfer to examine placental development in horses, and the other involving the use of cloning as a production method for sport horses. We had advised that the amendment to allow the first experiment should be licensed, but not the second. The Minister also received advice on the applications from the Animals Scientific Procedures Inspectorate and two

external assessors. In April 2004 the Home Office informed the licensee of its intention to refuse the request to amend the licence for either experiment. In June we were told that the applicant had decided to make representations against the Minister's intention, and that under Section 12 of the 1986 Act the Minister would appoint a suitably qualified person to hear the appeal. That person would then have to report his or her conclusions to the Minister, and the Minister would then take that report into account in deciding whether to grant the amendment. An oral hearing of the appeal took place in December.³

11. Two licence applications, both involving the use of non-human primates in procedures of substantial severity, were referred to the Committee in late November 2004. One was to carry out research on pedunculopontine nucleus (PPN) and stem cell therapy in Parkinson's disease. The other was to study the efficacy of antibiotics for the treatment of anthrax. There was insufficient time to discuss these applications before the end of 2004. We will report our detailed conclusions in our next annual report.

The APC's Primates report and the stakeholder forum

12. The APC's report "The use of primates under the Animals (Scientific Procedures) Act 1986 – analysis of current trends with particular reference to regulatory toxicology" was published at the end of 2002. Recommendation 1 of that report stated "We recommend that the Home Secretary convene an appropriately resourced forum for all interested stakeholders to address the issues and questions this report contains, to review the recommendations, and to progress these." The Home Office accepted this recommendation and held a stakeholders' forum to consider the content of the report and the remaining recommendations on 9 January 2004.

13. The aim of the forum was to promote discussion and debate that the Minister could take into account in her response to the APC's report. It was agreed that a report of the proceedings of the forum would be posted on the Home Office website for further comment by stakeholders.⁴

Other work of the Primates Sub-Committee

14. The role of the Primates Sub-Committee is to advise the Committee on issues relating to the acquisition, housing, care and use of non-human primates in scientific procedures. In 2004 the membership of the Primates Sub-Committee was Professor Dunbar (chair), Professor Atterwill, Dr Hubrecht, Dr Jennings, Dr Langley and Professor McNeilly. The Home Office consults the Sub-Committee for advice on overseas breeding establishments seeking approval to supply primates to the UK for use under 1986 Act. It also carries out a preliminary assessment of non-human primate licence applications referred to the Committee for advice. In 2004 the Sub-Committee continued work on formalising existing criteria for its consideration of these establishments. We will report on the outcome in our next annual report.

The Research and Alternatives Sub-Committee and the establishment of the NC3Rs

15. This Sub-Committee comprises Professor D Clark (chair), Dr Festing, Dr Jennings and Mr Moore. The sub-committee's function has been to advise the Home Office about the allocation of the grants which it makes available to sponsor scientific work in one or more of the following areas:

- i the replacement, reduction or refinement of scientific procedures on animals (the "three Rs"), or refinement of laboratory animal husbandry;

³ The Home Office published the result of the representations on its website in March 2005. <http://www.homeoffice.gov.uk/comrace/animals/index.html>

⁴ The report on the forum was published in March 2005. <http://www.homeoffice.gov.uk/comrace/animals/index.html>

- ii the development and promotion of awareness and use of alternatives to animal procedures;
- iii aspects of interest or concern relating to the operation and/or effectiveness of the Animals (Scientific Procedures) Act 1986.

16. For the financial year 2004/2005, the Home Office made available a budget of £280,000 for this purpose, the same as in the three previous financial years.

17. On 21 May 2004, Caroline Flint, Home Office Parliamentary Under-Secretary of State, announced the establishment of a National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) in a Written Ministerial Statement to the House of Commons. Lord Sainsbury, Parliamentary Under-Secretary of State for Science and Innovation at the Department of Trade and Industry, made a parallel statement to the House of Lords on the same day. This implemented a recommendation of the House of Lords Select Committee on Animals in Scientific Procedures on establishing a National Centre for the 3Rs.

18. The aim of the new Centre is to provide a focus for the promotion, development and implementation of the 3Rs in animal research, and replaces and builds upon the Medical Research Council's Centre for Best Practice for Animals in Research (CBPAR). The Centre aims to bring together stakeholders in the 3Rs in government, academia, industry and animal welfare organisations to facilitate the exchange of information and ideas, and the translation of research findings into practice that will benefit both animals and research. The NC3Rs will fund high-quality 3Rs research, develop a range of 3Rs information resources and guidelines, and organise workshops and symposia to disseminate and advance the 3Rs.

19. The NC3Rs Board is comprised of experts across the spectrum of animal research, care and welfare. Its purpose is to develop the NC3Rs strategy and work plan, and monitor its performance. The Chair of the Board is Lord Leslie Turnberg, Scientific Adviser to the Association of Medical Research Charities. The Deputy Chair is Professor Paul Flecknell, Professor of Laboratory Animal Science at the University of Newcastle upon Tyne and a former member of the APC. Two other current APC members are on the board on personal merit – Dr Michael Festing and Dr Maggy Jennings – as is the head of the Home Office's Animal Scientific Procedures Division.

20. In June 2004, Caroline Flint wrote to our Chairman informing him that as part of the arrangements for the creation of the NC3Rs £250,000 of the Home Office research budget administered by the APC on the Home Office's behalf would be transferred to the new centre, once current commitments had been honoured. Our Minister sincerely thanked the APC for the very significant contribution it had made through its sponsorship of research. She particularly thanked past and present members of the Research and Alternatives Sub-Committee for their commitment and hard work in identifying and selecting suitable projects for funding that had contributed to valuable progress with the three Rs.

21. Our Chairman wrote to the Minister in September saying that the Committee welcomed the establishment of the new centre and wished it every success. He also welcomed the retention of a budget of £30,000 by the Home Office for research related to Home Office and APC functions under the Animals (Scientific Procedures) Act 1986. Although one remit of our research work – promoting three Rs research – had gone, the sub-committee was pleased to continue with its two other stated remits; promoting research into the development and promotion of awareness and use of alternatives to animal procedures; and aspects of interest or concern relating to the operation and/or effectiveness of the Animals (Scientific Procedures) Act 1986. We also noted that the Sub-Committee needed to continue to monitor its existing research projects.

22. The Chairman had informal meetings with the Chair, Deputy Chair and Chief Executive of the NC3Rs. Whilst the Committee would continue to have informal liaison through common membership of the advisory board, it was agreed that it would be appropriate for the Committee's contacts with the Centre to be put on a more formal basis through the sort of annual meeting which the Committee had with other bodies such as the Farm Animal Welfare Council.

23. There are several existing projects that the Home Office is funding. Those which were still in progress at the beginning of 2004 were as follows:

- Professor Dawkins (University of Oxford): *The effects of cage cleaning regimes in laboratory rat welfare.*
- Mr Hardwick (Higher Education Staff Development Agency): *To review, develop and merge the Multiple Choice Questions databases used by the two existing accrediting bodies.*
- Dr Main (University of Bristol): *Welfare benchmarking of laboratory mice in animal units.*
- Dr Mendl (University of Bristol): *Developing recommendations for rat housing using scientific assessment of welfare: interactions between cage size, space allowance and enrichment provision.*
- Professor Nicol (University of Bristol): *A targeted approach to environmental enrichment for laboratory mice.*
- Professor Price (Central Science Laboratory): *Investigation of the potential of QSAR to predict the acute toxicity of anticholinesterase pesticides to birds.*
- Professor Wall (University of Bristol): *Development of an in vitro rearing system for parasitic Psoroptes mites, to minimise the experimental use of infected vertebrate hosts.*
- Dr Williamson (Defence Science and Technology Laboratory): *Remote telemetry to identify humane end-points in vaccine efficacy testing for regulatory purposes.*
- Dr Xing (National Institute for Biological Standards and Control): *Development of an alternative test to the histamine challenge test based on in vitro enzymatic-HPLC coupled assay for pertussis vaccines.*

24. Before the establishment of NC3Rs in May 2004, the Home Office had accepted the sub-committee's advice to offer grants to the following three new projects that were started in 2004:

- Professor Adams (University of Stirling): *Vaccine efficacy testing in fish – replacement of disease challenges with serological testing.*
- Mrs Harris (Central Science Laboratory): *Evaluation and validation of electrochemiluminescent method for detection of Clostridium botulinum toxins A, B, E and F in foodstuffs.*
- Dr Irving (Centre for Environment, Fisheries and Aquaculture Science): *Use of the cockroach as an alternative to the mouse as a bioassay animal for the statutory testing of shellfish toxin.*

Projects completed in 2004:

25. The projects being conducted by Dr Main, Professor Price, and Dr Williamson concluded during the year, and reports on them are provided below. (A report on Mr Kemp's project: *Up date of "With Care" videos and their conversion to CD-ROM* which was completed in 2003 is also included, as it was not reported in the 2003 Annual Report.)

Dr Main (University of Bristol): *Welfare benchmarking of laboratory mice in animal units.*

26. Dr. Main and his collaborators have developed a welfare assessment protocol for quantifying welfare-related provisions and outcomes associated with husbandry conditions of laboratory mice. Using this protocol they conducted welfare assessments in several animal facilities in the United Kingdom. They have made available the information obtained in a rolling database that enables the participating animal facilities to benchmark their own welfare performance and thereby aid in improving and maintaining high standards of laboratory mouse welfare.

Publications:

RSPCA/UFAW Rodent Welfare Meeting: *Harlow, Essex* (2004): Spoken presentation entitled: 'Development of welfare benchmarking scheme for laboratory mice'.

Animal Science Group/Home Office/ UK licence holders meeting: *London* (2004): Spoken presentation entitled: 'Welfare benchmarking of laboratory mice in the UK'.

Development of a welfare-benchmarking scheme for laboratory mice. Leach M. C., Thornton, P. D. & Main, D.C.J (2004) *Laboratory Animals* (submitted)

Identification of appropriate measures for the assessment of laboratory mouse welfare. Leach M. C., Thornton, P. D. & Main, D.C.J (2005). *Animal Welfare* (submitted)

An assessment of laboratory mouse welfare in UK animal units. Leach M. C. & Main, D.C.J (2004) *Animal Welfare* (submitted)

Welfare-benchmarking scheme for laboratory mice Leach M.E. (2004). *AWSELVA Newsletter*, April Edition.

Conference presentations and seminars:

UFAW Symposium: Science in Service of Animal Welfare: *Edinburgh, UK* (2003): Poster entitled: 'The development of a mouse welfare benchmarking system'.

IAT Annual Congress 2003: *Coral Bay, Cyprus* (2003): Spoken presentation entitled: 'Welfare benchmarking of laboratory mice in the UK'.

IAT/ NACWO Advanced Course: *Storrington, UK* (2003): Spoken presentation entitled: 'Development of a welfare benchmarking scheme for laboratory mice.'

University of Glasgow, Veterinary Services (2003): Seminar entitled: 'Aversion of rats and mice to gaseous agents used for anaesthesia and euthanasia' and 'Development of a welfare benchmarking scheme for laboratory mice'.

Astra Zeneca, *Alderley Edge* (2003): Seminar entitled: 'Aversion of rats and mice to gaseous agents used for anaesthesia and euthanasia' and 'Development of a welfare benchmarking scheme for laboratory mice'.

University of Bristol, Department of Clinical Veterinary Science (2003): Seminar entitled: 'Development of a welfare benchmarking scheme for laboratory mice'.

APC Research and Alternatives Sub-committee: *London*, (2004): Spoken presentation entitled: 'Welfare benchmarking of laboratory mice'.

APC Housing and Husbandry Steering Committee Workshop: *London*, (2004): Spoken presentation entitled: 'Welfare benchmarking of laboratory mice'.

9th FELESA Symposium on Internationalization and Harmonization in Laboratory Animal Care and Use Issues: *Nantes, France* (2004): Spoken presentation entitled: 'Welfare benchmarking of laboratory mice in the UK'.

Professor Price (Central Science Laboratory): *Investigation of the potential of QSAR to predict the acute toxicity of anticholinesterase pesticides to birds.*

27. Professor N. Price and his collaborators designed and tested the feasibility of in vitro Quantitative Structure-Activity Relationship (QSAR) models to predict acute toxicity of organophosphates and carbamate insecticides to birds, and to extrapolate between species using toxicity datasets already available in different bird

species. QSAR models were successfully built for the 130 pesticides included in the study and were subjected to a variety of validation process. The most successful models, based on linear-regression methods, were against carbamate compounds but they were not as conclusive for organophosphate pesticides. They concluded that more work was needed to develop robust QSARs to predict the acute toxicity of anticholinesterase in birds.

Publications:

Quantitative structure-activity relationships (QSAR) in predicting the environmental safety of pesticides. Price, N. R., Watkins, R. W. (2003) *Pesticides Outlook*, June 2003: 127-129.

Linear and non Linear QSAR models for the preparation of toxicity of anticholinesterase pesticides to birds – manuscript in preparation.

Poster presentation:

11th International QSAR Workshop 9-13 May 2004, *Liverpool, UK*. Poster: Development of QSAR models for the prediction of avian toxicity of anticholinesterase pesticides.

Dr Williamson (Defence, Science and Technology Laboratory): *Remote telemetry to identify humane end-points in vaccine efficacy testing for regulatory purposes.*

28. The key objective for Dr. E. D. Williamson and her team was to develop remote telemetry devices to identify certain physiological changes in animals on study, prior to clinical symptoms so that early humane endpoints could be implemented. To this end the team has developed and successfully tested miniaturised transponder devices and demonstrated the feasibility of monitoring core body temperature in multiple animals in a single arena using such devices. The application such remote monitoring of animals on vaccine trials and other studies would allow the objective identification and implementation of humane endpoints and would be particularly useful in situations where such studies need to be carried out under biocontainment conditions.

Publications and presentations:

Application of remote monitoring in efficacy studies within biocontainment – manuscript in preparation.

LASA Winter Meeting 2004, Presentation: Remote monitoring in biocontainment.

Mr Kemp (*Institute of Animal Technology*): *Up date of “With Care” videos and their conversion to CD-ROM.*

29. Mr. R. Kemp on behalf of the Institute of Animal Technology (IAT) was responsible for updating the IAT audio-visual teaching aid ‘Handle with Care’ that was first produced in 1986 on VHS format. The new format is a CD-ROM with interactive facility which allows for a flexible approach to learning. The CD-ROM has been updated to take into account of current best practice in the care and welfare of laboratory animals. New species of laboratory animals also feature in the CD-ROM. Although this CD-ROM is primarily aimed at the education of scientific and technical staff in the United Kingdom it would be made available for use in other countries.

Publications:

IAT Handle with Care, interactive DVD, www.iat.org.uk

Education and Training Sub-Committee

30. This Sub-Committee comprises Dr Jennings (chair), Mr Gregory, Dr Festing and Mr Moore. Last year we reported that the Sub-Committee had decided that a thorough review of the modular system was merited since it had been in operation for 10 years. The review would include consideration of the intended outcomes of licensee training, the content and structure of modules, methods of assessment and the course accreditation system. We also recognised the need to take account of the different categories of staff who might require

training. We learnt that the Minister had accepted that introductory training for NACWOs, using the syllabus recommended by the Committee, should be mandatory from 1 January 2004. The Home Office granted accreditor status to the Institute of Animal Technology (IAT) and the Universities Accreditation Group (UAG), in line with our recommendations.

31. During the year the Sub-Committee also considered the question raised in the House of Lords report as to whether visiting scientists and students should be allowed to work under the licences of established licence holders. After extensive review and consultation, our conclusions were passed to the Home Office in March 2004. We agreed with the Government's response to the House of Lords' recommendation, ie that there should be no further exemptions in training requirements for visiting scientists and students, whether from the UK or overseas. We recognised that the track record of experienced visiting scientists would stand as evidence of their technical expertise, but believed that training specifically in UK law and its implementation in practice was nevertheless essential. While supporting the need to reduce bureaucracy, we considered that any unjustified exemptions from training requirements might lead to breaches of the Act and adverse effects on animal welfare.

32. During 2004 the Sub-Committee carried forward its review of modules 1 to 4 of personal licensee training. We held a well-attended forum for trainers and representatives of the accrediting bodies in January, to discuss the expected outcomes of this training, and a further meeting in October to consolidate the outcomes, and discuss whether the modules needed revision to take these into account and provide more easily deliverable training packages for different categories of staff such as certificate holders or visiting workers. This part of the work will be completed in 2005.

33. Late in 2003 we received a request from the Home Office to comment on the acceptability of the Scottish Accreditation Board as an accreditor for personal and project licence training courses. This would be in addition to the two existing training course accreditation bodies, the IOB and UAG. The questions that the Sub-Committee considered needed to be addressed with regard to the application, applied to the accreditation system as a whole, rather than just the SAB, and it was therefore difficult to assess in isolation from the Sub-Committee's overall review. However, the Sub-Committee understood the Home Office's need to consider this application immediately, and we therefore met with the SAB steering group and assessed the application using the original criteria set out in the APC's annual report for 1993.

34. The Sub-Committee concluded that the application met these criteria but advised the Home Office that it should satisfy itself that the proposed composition of SAB would provide enough independence from the course providers (ScotPIL) and that SAB had the resources to provide effective monitoring and sufficient site visits for courses throughout the UK. The Sub-Committee was also concerned about the proposed "open book" policy for candidate assessment in that this might not be appropriate for tests employing multiple choice questions. Lastly, the Sub-Committee was concerned that it might be difficult to ensure consistent UK-wide standards with an increase in the number of accrediting bodies.

35. In August the Home Office informed us that it had decided to approve the application of SAB as an accreditor for personal and project licence training courses and considered that the concerns that we had expressed had been satisfactorily addressed. In response to our specific concerns:

- there would be sufficiently clear separation of roles, responsibilities and personnel between SAB and ScotPil for there to be trust in the integrity and independence of the SAB;
- resources would be provided proportionate to the level and location of the necessary site visits. The SAB business plan required this; and
- the open-book policy had been adequately defended as an assessment method.

Housing and Husbandry Sub-Committee

36. The APC attaches great importance to the housing and husbandry of animals used in research, due to its importance for the lifetime welfare of the animals involved. The Housing and Husbandry Sub-Committee comprises Dr Hubrecht (Chair), Professor Broom, Mr Gregory, Dr Jennings and Dr Morris, and has the following terms of reference:

- The Sub Committee will deal with housing and husbandry issues on a case by case basis as requested by the APC Committee or where issues are determined as being important by the sub-committee.
- Where housing and husbandry issues overlap with those of other committees, the housing and husbandry sub-committee will seek advice from those sub-committees.

37. The Sub-Committee's main task in 2004 was to host a meeting with ethologists⁵ and laboratory animal scientists on implementing good practice in housing and husbandry of mice and rats (the two most widely used species used in experiments). Besides sharing information on good practice, its aim was to identify barriers to progress, for example, by working with other Government organisations on issues that are partially within their provenance. The forum on housing and husbandry of rats and mice was held on 2 March 2004 and was attended by 50 representatives, including breeders, technicians, academic and regulatory scientists, veterinarians, funders and members of the Animal (Scientific Procedures) Inspectorate. Experts gave lectures covering rodent welfare needs, current practice and future legislative changes. Following this, attendees took part in workshop sessions to identify areas that the APC could pursue to advance good practice in rodent housing and husbandry.

38. As a result of this meeting and its own discussions, the sub-committee identified a number of areas for further work which have included:

- 1) Discussions with The Laboratory Animal Veterinary Association (LAVA) with respect to the role of the Named Veterinary Surgeon. This has become more complex, with increasing pressure to add managerial roles to the animal-care responsibilities. In addition, the sub-committee has noted that the traditional medical skills of the veterinarian have increasingly needed to be supplemented by a degree of expertise in ethology and applied animal behavioural science that traditionally have not been part of the veterinary curriculum. The sub-committee is continuing its dialogue with LAVA on these issues.
- 2) The Forum identified a possible lack of understanding amongst research grant applicants of the policies of funding bodies with respect to funding improvements either to animal facilities or to the caging or of the internal environment of cages. The sub-committee has been discussing this issue with funding bodies to identify means of improving awareness amongst researchers of their policies. We have concluded that while there are divisions of financial responsibilities between funding bodies and research institutions, funding bodies should make clear that they expect basic standards to be met and should indicate to what extent they can help to achieve these standards. The committee is now working with the funding bodies on practical ways to advance this issue.
- 3) The Sub-Committee has identified that the balancing of the requirements of human health and safety with those of housing and husbandry is an area where animal welfare could potentially be compromised. For example, the introduction of individually ventilated cages (IVCs) is perceived to be a means of ensuring a safe working environment for humans, by reducing human/animal contact to a minimum. However, there is also a concern that without careful planning of issues such as cage cleaning and environmental enrichment, the introduction of IVCs might have a negative effect on animal welfare. We shall explore this in the coming year with Home Office officials.

⁵ Ethology - the study of the behaviour of animals in their normal environment. Applied ethology is an important aspect of animal welfare, and includes experiments to determine animals' preferences and also their reactions to farming and other practices.

The Committee's review of the statistics of animal use

39. Last year we reported that we had established a working group to take forward the Home Office's request that the Committee should carry out a review of the statistics of animal use under the 1986 Act, published annually by the Home Office. The working group comprised Professor Bulfield (Chairman), Dr Festing, Dr Langley, Mr Moore and Professor Oliver. A consultation letter to stakeholders and other interested parties was sent out on 30 October 2003, asking for responses by 31 January 2004.

40. The working group made significant progress in 2004 and met several times. Two consultants, Dr Jane Smith and Dr Janice Pearce, were engaged to assist the working group. They completed a comprehensive analysis of the responses received, attended the working group's meetings and helped to draft the report. We wish to record our thanks to them for their careful work, carried out to tight deadlines.

41. Towards the end of the 2004, the Minister agreed to extend the deadline for delivery of our recommendations to the end of March 2005 to enable analysis and discussion of the responses to our consultation letter to be completed. We will report our conclusions in our next annual report.

Suffering and Severity

42. Last year we reported that the Minister had asked the Committee to take on – as a discrete work programme item which she did not see as necessarily linked to our review of statistics – the development of practical recommendations about a new system of classifying severity. She asked that we consult widely with stakeholders and interested parties. Professor Oliver agreed to the Chairman's request that she chair a working group to consider the issue. The membership of the working group was Professor Oliver (chair), Mr Gregory, Professor Holland, Dr Hubrecht and Mr Moore.

43. The terms of reference of the working group was to address the following topics:

- the strengths and any weaknesses of the current system of severity limits and bands as a way of prospectively assessing suffering and severity. If significant weaknesses were perceived, what alternative system could be proposed; and
- How suffering and severity might be assessed retrospectively.

44. Our Cost/Benefit report had examined the identification and assessments of costs and benefits and commented in particular on the issue of severity limits and bands.⁶ Our report on biotechnology also contained discussion of welfare assessment, for example about cageside scoresheets.⁷ The House of Lords Report suggested that a scoring system might be developed to record animal suffering.⁸ Further work was carried out by the Boyd Group and the RSPCA, which produced a report "Categorising the severity of scientific procedures on animals"⁹. This report provided essential background for our discussions. As indicated above, because of time constraints the working group on statistics could not delay its review while consideration was given to the desirability and form of a pilot study of retrospective reporting of severity.

45. The working group concluded that the current prospective assessment system should be regarded as part of the regulatory and monitoring system rather than as an element of a system for imposing accountability for animal experiments. The group's provisional conclusion was that as part of a regulatory/monitoring system the prospective system functioned satisfactorily, though it might be fine tuned. They thought that it would be helpful if the information and explanation of the system given in the annual Statistics publication made clearer

⁶ Animal Procedures Committee. 2003. Review of Cost-Benefit Assessment in the Use of Animals in Research. Home Office, London.

⁷ See Annex E. The Report of the Animal Procedures Committee for 2001. The Stationery Office, London 2002.

⁸ House of Lords. Report of the Select Committee on Animals in Scientific Procedures. 2002. The Stationery Office, London 2002.

⁹ "Categorising the severity of scientific procedures on animals", RSPCA Research Animals Department, 2004

the precise function of the prospective system. The group felt that public accountability for animal experimentation could best be furthered by a system of retrospective assessment, the results of which could be published in the Statistics publication.

46. The working group was considering advising the transformation of the current prospective system of severity assessment into a retrospective system, possibly based on a prospective model by Professor Mellor of Massey University, New Zealand. A pilot study could be conducted when the proposal had been finalised. It was noted that the Laboratory Animals Science Association (LASA) was already proposing a feasibility study for a pilot study of a retrospective system to measure substantial severity.

47. At its meeting in October, the working group invited a small group of licensees to discuss and advise on the feasibility of converting Professor Mellor's system for prospective assessment into a retrospective assessment system. The group concluded that Professor Mellor's system might feasibly be converted into a retrospective system, and resolved to liaise with LASA in order jointly to carry out a pilot study of the proposed system. After the report on the pilot study a stakeholders' forum would be convened to discuss the results and whether and how a retrospective system might be adopted more widely. It would then be necessary to consider whether the prospective assessment system should be amended to secure 'fit' with any retrospective system.

The Committee's review of Schedule 1 of the Act

48. The humane killing of a protected animal is not a regulated procedure requiring authorisation by a project or personal licence, if it is undertaken at a designated place for a scientific purpose, and if it is performed by a method listed in Schedule 1 as appropriate to the type of animal. As described in our annual report for 2001, in June of that year the Home Office asked the Committee to carry out a review of Schedule 1 of the 1986 Act, which sets out the appropriate methods of humane killing for different animal species. In 2004 our "Schedule 1" working group continued its work. Its membership comprised Mr Gregory (Chair), Professor Broom and Dr Morris with the additional help of an animal facilities manager from the University of Manchester. At the end of 2003 the Committee recommended to the Home Office that the decapitation of non-precocial, neonatal rodents up to the age of seven days should be included in Schedule 1 of the 1986 Act as a method of euthanasia. This is explained in further detail in our report for 2003.

49. The Minister responded in March thanking the Committee for that recommendation. She said that she had decided to postpone further consideration of our recommendation until we had completed our work reviewing other Schedule 1 issues. That was because she wished to carry out consultation with stakeholders on all recommendations that the Committee might make. She also said that delaying consideration might also mean that the position at European level might be clearer. (Methods of humane killing and whether they should be regulated are being considered as part of the current review of European Directive 86/609.)

50. During the year the working group continued its review of Schedule 1, examining the following topics:

- Reviewing current information and research into inert gases as a potential improvement over the use of CO₂ for euthanasia of rodents;
- Monitoring the progress of an ongoing academic project into the aversiveness of CO₂ for rodents, with a view to using its information to finalise advice on the acceptability of CO₂ for euthanasing rodents under Schedule 1;
- Assessing CO₂ acceptability as a Schedule 1 method for birds;
- Assessing whether to widen Schedule 1 methods for birds, such as (a) argon, nitrogen or other inert gases, or any mixture of these gases in atmospheric air with a maximum of 2% oxygen by volume; or (b) any mixture of argon, nitrogen, or other inert gases with atmospheric air and carbon dioxide provided that the carbon dioxide concentration does not exceed 30% by volume and the oxygen concentration does not exceed 2% by volume;

- Acceptability of CO₂ as a Schedule 1 method for rabbits;
- The maximum weight threshold for rats and guinea pigs at which the dislocation of the neck should be permissible;
- The acceptability of refrigeration, carbon dioxide exposure and disruption of membranes for the euthanasia of embryonic chicks and reptiles in eggs in the final 20% of development before hatch;
- Reviewing the presentation and effective explanation of Schedule 1 and advising good practice in euthanasia.

51. The working group will complete its examination of these topics and present its final report to the main Committee in 2005.

The control of surplus laboratory animals (“Overbreeding”)

52. The Chairman wrote to the Home Office Minister on 8 July 2004 enclosing the Committee’s report on the control of surplus laboratory animals (Overbreeding). The text of our report was published as Annex G of our annual report for 2003. Our conclusions were that there are strong pressures on breeders not to produce surpluses of animals, and that at the time of the review there was no evidence that a surplus of cats, dogs and non-human primates did occur. The report also concluded that more could be done to reduce surpluses of rodents by, for example, increased co-ordination in academia. We also identified ways in which the numbers of surplus animals might be reduced, and recommended that more information should be provided to the public about how laboratory animal breeding is managed and regulated.

53. Caroline Flint replied to this report in November 2004. She welcomed and endorsed the Committee’s report as providing valuable insights and helpful clarification, as well as constructive recommendations on best practice. Her reply, which is attached at Annex E, also contained a briefing note about the management and regulation of laboratory animal breeding which has been posted on the Home Office website.

Biotechnology issues

54. We published our report on Biotechnology in 2001, and in 2004 we reconvened our Biotechnology Working Group in order to assess the progress that had been made with the Committee’s recommendations. We decided to postpone further consideration to await the Home Office’s response to our proposals about applications referred to the Committee (see paragraphs 1 to 8 above), and in order to consider the final report of the work on the cageside assessment of genetically altered mice, to be published in “Laboratory Animals” which we anticipate will be relevant to the implementation of several of our recommendations. We will report on further progress in next year’s annual report.

Cephalopods¹⁰

55. Currently the 1986 Act defines a “protected animal” (ie, one to which the protection of the 1986 Act is extended) as any living vertebrate other than human, and one invertebrate species, the cephalopod *Octopus vulgaris*. In our report for 2003, we reported our proposal to the Minister that protection under the Act be extended to all octopus, squid and cuttlefish, rather than, as we had earlier recommended, all species of cephalopod. In response, the Minister suggested that Home Office officials should explore the supporting evidence in discussion with the Committee before the matter was considered in detail. This meeting was held in February 2004.

¹⁰ Cephalopods are invertebrate animals comprising members of the class *Cephalopoda*, including nautilus, cuttlefish, squid and octopus.

56. In the light of the discussion, the Chairman undertook to write again to the Minister with supplementary advice after further consultation with the full Committee.

57. At its meeting in October 2004 the Committee discussed three possible options for taking forward its recommendation on Cephalopods, namely:

- A) removal of *Octopus vulgaris* from the protection of the Act;
- B) extension of the Act to a selective list of those cephalopods most likely to have the ability to feel pain, distress or lasting harm; or
- C) extension of the Act to protect all octopus, squid and cuttlefish

It was suggested that further work on this issue could be postponed until the revision of the EU Directive – particularly conclusion of its deliberations on the species to be protected – was announced. The Home Office understood that the European Commission was consulting and setting up expert groups on a number of issues, including the possible inclusion of certain invertebrates, particularly cephalopods. The APC documents have been fed into the EU review process.

58. The Chairman suggested that a letter could be drafted to the Minister outlining the main points of the discussion and explaining that the Committee considered both options B and C had merit. Option C was seen as the most pragmatic, but option B could be valuable, given the development of convincing criteria for selection of species to be protected. Due to pressure of other work the letter had not been drafted by the end of the year. We will report further progress in next year's annual report.

The “Cambridge/BUAV” Working Group

59. A working group set up in 2003 comprising Professor Holland (chair), Professor Atterwill, Dr Hubrecht and Dr Jennings is assessing the allegations made in 2003 by the British Union for the Abolition of Vivisection (BUAV) about the use of marmosets at Cambridge University in the light of the ensuing report by the then Chief Inspector and the Home Office's response, in order to identify areas of discussion for the APC. The working group is also considering the matters of whistle blowing by established members of staff and clandestine investigations by undercover activists.

60. In 2004, the working group presented early versions of its report at our meetings in June and October, and draft conclusions were discussed at our weekend conference in November. The working group also showed the draft report for comment to those individuals and organisations that it had visited or interviewed. At the end of 2004 the working group hoped to consider these comments and bring a final report to a Committee meeting early in 2005.

Infringements

61. The Home Office classifies breaches of the 1986 Act and of licence or certificate conditions into three classes of infringement, each of which merits different reporting and action systems. The system is designed to match the demands of administrative resources to the gravity of the case, thus enhancing the efficiency and effectiveness of the enforcement system.

- *Class one infringements* involve minor breaches of licence or Certificate conditions, which are not potential criminal offences, have no aggravating circumstances and no disputed facts. Details are recorded on file.
- *Class two infringements* may include potential criminal offences but where admonition alone is judged appropriate; prosecution, or variation or revocation of licences or certificates of designation are clearly

and defensibly not necessary. Admonition letters are sent by the relevant regional office staff and details are recorded on file.

- *Class three infringements* are where training or re-training, variation, revocation or suspension of licences or certificates of designation, or referral for prosecution are options that may be considered. These cases are referred to the Head of the Animal Procedures Licensing Section for consideration. Any issues that may have adverse consequences for animal welfare must be treated as a class 3 infringement.

62. The Home Office provides the Committee with an annual summary of infringements. At our meeting in October 2004 the Home Office presented its 2003 annual infringement report. This reported 21 Class three infringements on which action had been completed in the reporting period. Ten were reported by licensees to the Home Office, 9 were discovered and reported by Inspectors and 2 were discovered by the Home Office following allegations made by an animal protection organisation. A total of 17 establishments had infringements reported. Eleven involved academic establishments, 5 commercial establishments, 4 Non-Departmental Public Bodies and 1 National Health Service establishment.

63. The Home Office also provides us with detailed individual reports of any infringement that impacts negatively on animal welfare once Home Office action on the infringement has been completed. At our April meeting the Home Office informed the Committee that a licensed establishment had reported to the Home Office that two live mice that were intended for use in non-regulated procedures had been left in their cages for five days and there was no confirmation that they had had access to fresh drinking water during that period. The Chief Inspector said that those who had found the mice had reported that the mice had not appeared to be suffering. The Committee expressed surprise that mice could survive for five days without any drinking water. It asked if the Chief Inspector could find out as much further information on whether water might have been available, and for how long. Members said that the infringement would be of much greater concern if there had been a complete absence of water for five days. The Committee was also particularly concerned to learn that in 2002 the Home Office had reported that the same establishment had reported a similar infringement, and that some of the lessons from that infringement appeared not to have been learnt.

64. Further information on this infringement was provided by the Inspectorate at our June 2004 meeting. This confirmed that, although the maximum time that the mice could have suffered water deprivation was five days, there was insufficient evidence to determine whether water was available during four of those five days. It was the practice at the establishment to indicate that cages were empty by turning water bottles around so that the spouts faced away from the cage. When the two mice were discovered, the spout of the bottle was facing away from the cage, but it was not known when the bottle had been turned around. It was the establishment's policy to check each cage daily. The Home Office reported that the Certificate Holder had been formally admonished and had been warned that a further similar infringement could lead to the revocation of the establishment's certificate of designation.

65. At our October meeting a member asked about the revocation of an establishment's Certificate of Designation following its failure to maintain rabbits to the required husbandry standards. There was a suggestion that this had been too harsh a penalty, and that it might raise concerns over consistency. The Home Office explained that this course of action had not been taken lightly. The case in question involved an establishment which had problems of non-compliance and had not been able to provide a clear strategy for dealing with the problems.

66. We also noted that a number of class three infringements involved individuals carrying out procedures in the belief that they had a personal licence when in fact they did not. This apparently occurred when training certificates were confused with personal licences. The absence of a formal requirement for personal licence applications to be signed by establishments appeared to exacerbate this confusion. The Home Office confirmed that this issue had been a source of concern for some years and that two more infringements of this type had already occurred in 2004. They intended to clarify the difference between a training course certificate and a personal licence. However, the Home Office emphasised that each establishment should have checks and balances to avoid such infringements. We suggested that copies of certificates and licences could be publicly

displayed on the premises of an establishment in order to avoid this confusion, but the Home Office informed the Committee that that was not possible, for security reasons. The Education and Training sub-committee intends to take up this issue in future.

Batch testing of botulinum toxin

67. At our meeting in December 2003 one of our members had suggested that the Committee might wish to examine the cosmetic use of botulinum toxin. She was concerned that although botulinum toxin was licensed by the Department of Health as a prescription-only drug for medical purposes, it was widely understood to be increasingly used for purely cosmetic purposes. She was also concerned that routine batch testing of botulinum toxin involved lethal dose tests (LD50), used hundreds of mice and could cause substantial suffering. Our members agreed that it would be useful to have more information about potency testing for botulinum toxin. However, we noted that the use of botulinum toxin was a matter for the Department of Health, and outside of the remit of the Home Office and the Committee.

68. At our meeting in April 2004 the Chief Inspector advised that as far as the Home Office was aware there were no current animal tests being carried out in the UK of botulinum toxin product manufactured specifically for use in cosmetic clinics. He added that current European testing procedures required an LD50 test, but that method was expected to be phased out before the end of 2004. Depending on the purpose of the testing, there were already circumstances where the material could be tested by other methods and (at the batch release stage) by non-animal alternatives. The Chief Inspector also confirmed that the animal testing and production of the botulinum toxin brand “Botox Cosmetic” was not carried out in the UK.

The Committee’s work programme for 2005

69. We discussed the Committee’s work programme for 2005 at our weekend conference in November 2004, and agreed it in early 2005. The work programme is at Annex F.

ANNEX A

Background information about the Committee

This annex sets out some basic information about what the Animal Procedures Committee is and what it does.

The legislation

1. The Committee was first appointed in 1987 and was set up by sections 19 and 20 of the Animals (Scientific Procedures) Act 1986 (“the Act”). The Act replaced the Cruelty to Animals Act 1876. The Act requires the licensing of any experiment or other scientific procedure carried out on living, protected animals which may cause them pain, suffering, distress or lasting harm. The Act regulates scientific procedures carried out on all vertebrate species except humankind – that is mammals, reptiles, birds, amphibians and fish – and one invertebrate species, *Octopus vulgaris*.
2. The Act also requires the licensing of places where certain species of animal are bred for use in regulated procedures. The species whose breeding is regulated in this way are all primates, dogs, cats, all of the most common types of rodent used in scientific procedures, rabbits, ferrets, quail and sheep, and pigs only if genetically modified.
3. The Act applies throughout the United Kingdom. For work taking place in England, Scotland and Wales the Home Office issues licences under the Act on behalf of the Home Secretary. In Northern Ireland, licences are issued by the Department of Health, Social Services and Public Safety. In each department there is an Inspectorate consisting of professional staff with medical or veterinary qualifications which examines and advises on all applications for authorities under the Act. The inspectors also inspect establishments and the licensed work being carried out there.

The Committee

4. The function of the Animal Procedures Committee is to provide the Home Secretary and the Northern Ireland Minister of Health, Social Services and Public Safety with independent advice about the Act and their functions under it. Those two Ministers are responsible for appointing members of the Committee. Members are experts from a wide variety of backgrounds, and the list at the beginning of this report sets out the membership as at the end of 2004. There were no changes to membership in 2004.
5. The Animals (Scientific Procedures) Act 1986 requires
 - that there must be at least 12 people on the Committee (excluding the Chairman) and
 - that: at least two-thirds of the members must have full registration as medical practitioners or veterinary surgeons, or be qualified in a biological subject relevant to the work of the Committee;
 - at least one member must be a barrister, solicitor or advocate;
 - at least half of the members must not have held a licence under the Act during the last six years; and
 - the interests of animal welfare should be adequately represented (this has tended to mean, in practice, the appointment of members associated with animal welfare organisations, but all members pay high regard to animal welfare).
- There is normally a philosopher on the Committee, although this is not a statutory requirement.

6. Members are appointed for terms of up to 4 years and can be re-appointed once. The 1986 Act specifies that payments may be made to the Chairman by way of remuneration, and that other members can receive reimbursement for any expenses incurred by them in the performance of their duties. Apart from the Chairman, members are not paid for their work on the Committee, though they can claim reasonable out of pocket expenses. During the financial year 2004/2005, the Home Office had budgets of £10,000 and £27,500 respectively from which to make such payments.

7. Under section 20 of the 1986 Act, the Committee can devise its own agenda and can offer advice on any issue which it thinks relevant. But it must also deal with any question which Ministers refer to it.

8. Whatever issue the Committee is looking at, the law requires it to take account both of the legitimate requirements of science and industry and of the protection of animals against avoidable suffering and unnecessary use in scientific procedures.

Ministers

9. The Home Secretary in practice delegates his responsibilities under the Act to another Minister in the Home Office, which administers the Act in England, Scotland and Wales. That Minister was Caroline Flint MP. As stated above, in Northern Ireland the administration of the 1986 Act is the responsibility of the Department of Health, Social Services and Public Safety. The responsible Minister in 2004 was Angela Smith MP.

ANNEX B

The Animal Procedures Committee's Code of Conduct

1. The Animal Procedures Committee is an advisory Non-Departmental Public Body (NDPB) established under section 19 of the Animals (Scientific Procedures) Act 1986.

2. Members of the Committee are responsible for ensuring that the Committee fulfils its statutory duty as set out in section 20 of the 1986 Act

“To advise the Secretary of State on such matters concerned with this Act and his functions under it as the Committee may determine or as may be referred to the Committee by the Secretary of State”.

3. The 1986 Act adds that:

- (i) in its consideration of any matter the Committee shall have regard both to the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures;
- (ii) the Committee may perform any of its functions by means of sub-committees and may co-opt as members of any sub-committee any persons considered by the Committee to be able to assist that sub-committee in its work;
- (iii) the Committee may promote research relevant to its functions and may obtain advice or assistance from other persons with knowledge or experience appearing to the Committee to be relevant to those functions;
- (iv) the Committee shall in each year make a report on its activities to the Secretary of State who shall lay copies of the report before Parliament; and
- (v) members of the Committee shall be appointed for such periods as the Secretary of State may determine but no such period shall exceed four years and no person shall be re-appointed more than once.

4. The Secretary of State for the Home Department (or, in Northern Ireland, the Minister of the Department of Health, Social Services and Public Safety) is answerable to Parliament for the performance of the Committee, including the policy framework within which it operates.

5. To ensure its accountability in carrying out its duties, the Committee will seek to work as openly as possible, complying with the Code of Practice on Access to Government Information.

6. Members are required to observe the Seven Principles of Public Life endorsed by the Nolan Committee on Standards in Public Life and to comply with this Code.

7. Each member must at all times act in good faith and observe the highest standards of impartiality, integrity and objectivity in relation to the conduct of the Committee's business. In particular, members should:

- (i) familiarise themselves with the terms of reference of the Committee;
- (ii) undergo any required induction training;
- (iii) declare any personal or business interest which may, or may be perceived (by a reasonable member of the public), to influence their judgement. This should include, as a minimum, personal direct and

indirect pecuniary interests, and should normally also include such interests of close family members and of people living in the same household. A register of interests will be kept up-to-date and will be open to the public;

- (iv) not participate in the discussion or determination of matters in which they have a personal or business interest, and should normally withdraw from the meeting (even if held in public) if their interest is direct and pecuniary;
- (v) make a declaration of interest at any Committee meeting if it relates specifically to a particular issue under consideration, for recording in the minutes (whether or not a Committee member withdraws from the meeting);
- (vi) not misuse information gained in the course of their public service for personal gain or for political purpose, nor seek to use the opportunity of public service to promote their private interests or those of connected persons, firms, businesses or other organisations;
- (vii) not hold any paid, or high profile unpaid, posts in a political party, and not engage in specific party political activities on matters directly affecting the work of the Committee. When engaging in other political activities, members should be conscious of their public role and exercise proper discretion; and
- (viii) understand and accept that they are appointed as individuals and not as representatives of organisations by which they are employed or with which they have significant contacts.

8. The Chair has particular responsibility for providing effective leadership to the Committee and for:

- (i) ensuring that the Committee meets at appropriate intervals, and that the minutes of meetings and any reports to the Secretary of State accurately record the decisions taken, and where appropriate, the views of individual members;
- (ii) representing the views of the Committee to Ministers;
- (iii) representing, where appropriate, the views of the Committee to the general public;
- (iv) ensuring that new members are briefed on appointment;
- (v) sitting on the panel which advises Ministers on new appointments and re-appointments.

9. Notwithstanding 8(ii) above, any Committee member has the right of access to Ministers on any matter which he or she believes raises important issues relating to his or her duties as a Committee member. In such cases, the agreement of the rest of the Committee should normally be sought.

10. Committee members may be personally liable if, in the performance of their Committee duties, they make a fraudulent or negligent statement which results in a loss to a third party. They may also commit:

- (i) an offence under section 24 of the Animals (Scientific Procedures) Act 1986;
- (ii) a breach of confidence under common law; or
- (iii) a criminal offence under insider dealing legislation

if they misuse information gained through their position on the Committee. Individual members who have acted honestly, reasonably, in good faith and without negligence will not, however, have to meet out of their own personal resources any personal civil liability which is incurred in execution or purported execution of their duties.

11. In accepting this Code of Conduct members accept that they will not disclose any information or documents if they are marked “Restricted” and not disclose any subsequent comments about material which has been marked “Restricted”. Members also undertake not to make copies of any such documents, and to follow the advice provided by the Chairman and Secretariat about the handling of such documents.

ANNEX C

Members' attendance at meetings during 2004

The full Committee met on three occasions during 2004: on 14 April, 23 June and 13 October. Attendance at those meetings is shown below.

| | |
|----------------------|---|
| Professor Banner | 3 |
| Professor Atterwill | 3 |
| Professor Broom | 2 |
| Professor Bulfield | 2 |
| Professor D Clark | 3 |
| Professor S Clark | 3 |
| Professor Dunbar | 2 |
| Dr Festing | 3 |
| Mr Gregory | 3 |
| Professor Holland | 2 |
| Dr Hubrecht | 3 |
| Dr Jennings | 3 |
| Dr Langley | 3 |
| Professor Martin | 2 |
| Professor McNeilly | 2 |
| Mr Moore | 3 |
| Dr Morris | 2 |
| Professor Oliver | 3 |
| Professor Richardson | 2 |

ANNEX D

Membership of sub-committees and working groups during 2004

The four sub-committees and five working groups that were in existence in 2004 and their memberships are listed below.

Research and Alternatives Sub-Committee

Professor D Clark (chair)
Dr Jennings
Dr Festing
Mr Moore

Education and Training Sub-Committee

Dr Jennings (chair)
Dr Festing
Mr Gregory
Mr Moore

Primates Sub-Committee

Professor Dunbar (chair)
Professor Atterwill
Dr Hubrecht
Dr Jennings
Dr Langley
Professor McNeilly

Housing and Husbandry Sub-Committee

Dr Hubrecht (chair)
Professor Broom
Mr Gregory
Dr Jennings
Dr Morris

Schedule 1 Working Group

Mr Gregory (chair)
Professor Broom
Dr Morris
One other co-opted member

“Applications” Working Group

Professor Banner (chair)
Dr Hubrecht
Dr Langley
Mr Moore
Professor Richardson

“Cambridge Primates – allegations by BUAV” Working Group

Professor Holland (chair)
Professor Atterwill
Dr Hubrecht
Dr Jennings

Statistics Working Group

Professor Bulfield (chair)

Dr Festing

Dr Langley

Mr Moore

Professor Oliver

Suffering and Severity Working Group

Professor Oliver (chair)

Mr Gregory

Professor Holland

Dr Hubrecht

Mr Moore

ANNEX E

Letter from Caroline Flint to Michael Banner, APC Chairman responding to the APC's Overbreeding Report

Dear Michael

OVERBREEDING REPORT

I would again like to thank the Animal Procedures Committee for its report on the overbreeding of animals for the purposes of animal experimentation. The report provides valuable insights and helpful clarification of what is happening in breeding establishments and academic institutions and constructive recommendations on best practice, for which I am grateful.

I note, in particular, the Committee's conclusion that overbreeding is not a significant problem in designated breeding establishments. This conclusion is supported by the advice I have received from officials based on the observations of Inspectors who visit designated breeding establishments. I also note with regard to the breeding of dogs, cats and non-human primates, that the production of surplus animals was not a problem at the time of the Committee's review. I have been told that due to fluctuations in demand there have occasionally been surpluses and shortages in the supply of these animals at other times and that this is an issue which is monitored carefully by the Inspectorate.

The observations of the Inspectorate also support the Committee's view that economic pressures are providing an incentive to academic institutions to avoid the breeding of surplus animals. We also agree with the Committee that further improvements in co-ordination and longer lead times for studies in academia could be achieved through their local ethical review processes. This is within the defined roles and responsibilities of ethical review processes and part of their existing practices. We will encourage them to focus on this issue through our certificate holders' circulars and propose to help academic institutions with their ethical review processes by ensuring that they are aware of sources of advice on best practice and possible uses for excess animals. We will also raise the issues identified in the report at relevant stakeholder meetings.

I agree with the Committee's recommendation that more information should be given to the public about how laboratory animal breeding is managed and regulated. Accordingly, I attach a draft briefing note which we intend to publish shortly on the Home Office website and use in future correspondence on this issue. We will also ensure that other stakeholder groups are made aware of the APC's recommendations through our certificate holder mailings and encourage others, including the Laboratory Animal Breeders Association, to make them more widely available.

With regard to the re-homing of suitable surplus animals, this is, of course, a practice we will encourage. However, I am sure you recognise that re-homing is not feasible for the vast majority of animals. More than 90% of the animals used are rodents, birds and fish. It may be feasible for some cats, dogs and non-human primates, and some establishments already have experience in this area.

The remaining principles of best practice set out in the report are already reflected in the current Guidance of the Operation of the Animals (Scientific Procedures) Act 1986 (HC321), published in March 2000. We will, however, bring them to the attention of users again along with the Committee's suggestion that they should also be applied to the production of genetically altered animals.

The options for dealing with surplus genetically altered animals are, however, more limited than for conventionally bred animals. Unlike conventional breeding, the breeding of genetically altered animals is a regulated procedure because of the risk of harmful effects. There are also strict regulations on the distribution of

genetically modified organisms. Genetically altered animals cannot, therefore, be re-housed or used as pet food, and excess animals produced that are not used for tissue are destroyed. It is also more difficult to avoid surpluses. Out of a litter of ten mice sometimes only one may meet the specification because the genetic specifications for genetically altered animals are exacting. This means large numbers may have to be bred to meet the needs of some scientific programmes.

Finally, I note the Committee's conclusion that its survey has not provided evidence of a need for formal reporting of figures for breeding in the Home Office annual statistics. For completeness, the Committee may wish to include its thoughts on this issue in its current review of the annual statistics.

I hope these comments cover all of the key points from the APC report. Should you consider that a meeting with officials would be helpful to discuss any of the points in detail and how to progress them further, I would, of course, fully support and encourage it. Please convey my thanks to the Committee for the careful consideration it has given to these issues.

CAROLINE FLINT

ANNEX (to Annex E)

BREEDING AND SUPPLY OF LABORATORY ANIMALS WITHIN THE UK

Summary

- The breeding and supply of animals for use in scientific procedures is regulated in the United Kingdom by the Animals (Scientific Procedures) Act 1986.
- All of the commonly used laboratory species are bred in establishments licensed under the 1986 Act, unless specific exemptions have been granted.
- Animals bred in designated breeding and supplying establishments account for more than 85% of the total used in scientific procedures in the UK each year.
- For ethical and economic reasons, breeders and scientists make great efforts to minimise the production of surplus animals. All are agreed that it is in no-one's interest to produce more animals than are required.
- Recent surveys have confirmed that the production of surplus dogs, cats and non-human primates is not a problem.
- There are sometimes unavoidable surpluses in the smaller laboratory species.
- Animals bred for use in scientific research are provided with high standards of accommodation, with care provided by experienced technical and veterinary staff.
- Licensed breeding and supplying establishments are subject to unannounced inspections by trained Home Office inspectors.

Commonly used laboratory animals

Schedule 2 to the Animals (Scientific Procedures) Act 1986 lists certain types of animals which may usually only be obtained from designated breeding and supplying establishments.

The animals currently listed in Schedule 2 are the mouse, rat, guinea-pig, hamster, rabbit, dog, cat, primate, any bird of the species *Coturnix coturnix* (quail), ferrets, gerbils, pigs (if genetically modified), and sheep (if genetically modified).

Any establishment intending to breed or supply animals specified in Schedule 2 to the 1986 Act for use in regulated procedures must hold a certificate of designation as a breeding and/or supplying establishment.

Exemptions from the requirements of Schedule 2 are granted only where there is specific justification and normally only when suitable animals are not available from designated sources in the United Kingdom.

Housing and Care

Breeding and supplying establishments are required to comply with standards of housing, welfare and care set out in codes of practice issued specifically to address the needs of breeding animals.

The Codes of Practice require that suitable environmental conditions are provided for the species and the stage of development of the animals, including appropriate temperature, ventilation, lighting and noise levels, animal enclosures, and food and water.

Because, typically, breeding animals are kept for longer periods than animals used in scientific procedures, particular attention is required to ensure that the housing and care practices provide for the animals' behavioural as well as physiological needs

For example, many species seek or create a secure place for giving birth and the raising of offspring – typically a nest, or den, in the case of rodents, rabbits, dogs and cats. As such behaviour is strongly motivated, staff ensure that these needs are met by measures such as the provision of nesting material, nest boxes, or a secluded and sheltered area within the animal enclosure.

Animals are usually housed in social groups, and the design and layout of enclosures enable the expression of a wide range of normal behaviours, for example, through the inclusion of shelves or climbing materials appropriate for the species.

For species such as dogs and cats, socialisation and training programmes are now commonly used, with benefits of improved welfare and science.

Suitably trained staff must be available at all times to care for the animals, and each breeding establishment has an animal care and welfare officer and a veterinary surgeon who offer advice on animal breeding, welfare and care issues.

Breeding

A detailed knowledge of species biology and behaviour is necessary to establish and maintain an appropriate breeding programme which takes account of the housing and care requirements of breeding animals and their offspring.

In breeding establishments records must be maintained of the source, use, and final disposal of all animals bred, kept for breeding, or for subsequent supply for use in scientific procedures. These are important for husbandry and planning purposes and as an indicator of the animals' well-being and welfare.

In breeding colonies data are maintained on colony size, individual performance per breeding female, total output of the colony, litter size, number of litters in a given period, pre-weaning and post-weaning mortality.

The data are averaged over appropriate periods so that any change in performance can be rapidly identified. Acceptable performance targets are agreed with the named veterinary surgeon.

Matching Supply and Demand

Although all animals in a breeding establishment are provided with the same high standards of care, it is important that there are systems in place to minimise, as far as is possible, the number of animals not subsequently used either in a scientific programme or in the breeding programme.

There are many reasons why it may not be possible to match exactly supply and demand. For example:

- On the breeding side there are variations in production times and efficiencies. Although a mouse could be specifically bred to meet a scientific requirement in a period of a few weeks, a similar request for a dog would take many months, and a macaque a number of years.

- On the scientific side there can be significant fluctuations in scientific demand – when, for example, a new drug fails midway through a development programme. There may also be variations in scientific requirements. For example some studies only require single sex animals.

Commercial breeding establishments have in place comprehensive management strategies to review and monitor production, and to maintain colonies at a size which is appropriate to meet anticipated demand.

Exemptions from Schedule 2

The 1986 Act sets strict limits on the circumstances in which exemptions may be allowed to the requirement that Schedule 2 animals may only be obtained from designated breeding and supplying establishments. These are:

- cats and dogs: exemptions may be granted only when no animal suitable for the purpose of the programme specified in the licence can be obtained from a designated breeding establishment;
- animals taken from the wild: exemptions may be granted only when no animal suitable for the purpose of the programme specified in the licence can be obtained from a designated breeder or supplier, or another captive-bred source;
- animals of an endangered species: may only be used on projects aimed at their preservation or for essential biomedical purposes where the species in question, exceptionally, proves to be the only one suitable for the purpose.

Applicants seeking permission to obtain animals from non-designated sources are required to demonstrate that no suitable animal can be obtained from a designated source. Suitability may be determined by particular factors including strain, age, weight and health status.

Overseas breeding centres

Where rigorous controls are applied to ensure that there are no surpluses, one adverse consequence is that animals may have to be obtained from overseas breeding centres, with the attendant concerns over welfare during transport and of standards of care and accommodation in overseas breeding establishments.

Approval for the acquisition of non-human primates, cats and dogs from overseas, or from other non-designated sources, will only be given if the conditions at the breeding or supplying centre are acceptable to the Home Office.

Each batch of animals acquired from overseas must be separately authorised, and the transport arrangements must be acceptable to the Home Office. The Home Office must also be supplied with details of the health status of the animals on, and after, arrival at the designated establishment.

Production of surplus animals

The Laboratory Animal Science Association and the Animal Procedures Committee have investigated the issue of animals surplus to scientific requirements, and have concluded that even when well managed some surplus may be inevitable (see APC report on the Control of Surplus Laboratory Animals (Overbreeding): July 2004). However, it is important that breeders and scientists continue to review their breeding and use requirements regularly to minimise numbers of surplus animals.

The following useful principles for minimising the production of surplus animals were recommended in the APC report:

- ensuring that, where scientists have exacting and specific requirements for animals, this is scientifically justified.
- discouraging small, in-house rodent breeding colonies wherever possible (and where this does not add to welfare costs) and particularly for commonly available species and strains.
- encouraging sharing and cryo-preservation of 'tick over' strains.
- ensuring full co-operation between users, both those that use animals under the terms of the 1986 Act and those that use ex vivo tissue or organs.
- finding uses (within or outside the institution) for surplus animals.
- planning projects as far in advance as is reasonably possible so as to enable the optimum management of animal colonies.

Ethical Review Process

Each scientific and breeding establishment is required to maintain an Ethical Review Process. This can be a valuable focus for consideration of the complex issues involved in matching supply and demand, and for promoting strategies to reduce surpluses. It can also improve co-ordination and communication on animal supply and demand issues within and, where practical, between establishments, and with commercial breeding establishments.

Fate of Surplus Animals

Recent surveys carried out by the Laboratory Animal Science Association have confirmed that the production of surplus dogs, cats and non-human primates does not seem to be a problem. All of those involved make every effort to ensure that animals are not killed unnecessarily. However, despite the efforts of the scientific community and breeders, there are sometimes unavoidable surpluses in the smaller laboratory species. Often these are used as food, for example, for raptors or reptiles. Re-homing has also been successfully employed for some laboratory species [see LASA publication available at http://www.lasa.co.uk/position_papers/rehoming.asp].

Home Office
October 2004

ANNEX F

APC WORK PROGRAMME FOR 2005

A: The work of the Sub-Committees and Working Groups

| Objective | Target Date |
|--|---|
| <i>Research & Alternatives sub-committee</i> | |
| In conjunction with the APC, develop relationship with the NC3Rs. | Ongoing |
| On behalf of the APC, commission preliminary study to examine aspects of the 'duplication' or unnecessary repetition of scientific studies/tests involving live animals. | First phase of study to be completed within six months of commissioning |
| Review alternatives to funding-based options, complementary to role of NC3Rs, for Sub-Committee to fulfil its remit and objectives. | Ongoing |
| Review the functions of the Sub-Committee in view of the reduced budget and recommend to the APC a new remit. | For discussion at next Sub-Committee meeting |
| <i>Primates Sub-Committee</i> | |
| Complete questionnaire process and report on open and transparent criteria for the assessment of overseas primate sources. | October 2005 |
| Develop an overview of current situations/trends in the use of primates in medical research and the understanding of diseases, excluding regulatory toxicology. | December 2005 |
| Assess the use of primate models in neurological disease research. | July 2006 |
| <i>Housing and Husbandry Sub-Committee</i> | |
| Continue to progress actions arising from the Housing and Husbandry forum held in March 2004. | Ongoing |
| Explore, with the Home Office, what mechanisms exist for promoting good practice and how these are used. | June 2005 |
| Explore, with the Home Office and users, the mechanisms in place to ensure high standards for overseas breeding sites. | December 2005 |
| Examine the format of the existing users' Code of Practice, with the aim of providing recommendations relating to the format of any future revision resulting from changes in European legislation. | December 2005 |
| <i>Education and Training Sub-Committee</i> | |
| Circulate agreed core competencies document to trainers and accrediting bodies. | March 2005 |
| Consult with accrediting bodies (and through them, their members) on the Sub-Committee's proposed revision of modules 1-4. Receive feedback and discuss, particularly with regard to implementation of the revised system and lead-in times. | Trainers' meeting in September 2005 |
| Discuss and prepare report on supervision of new personal licencees. | December 2005 |
| Consider issues relating to accreditation, including clarification of expectations and roles, assessment of trainees, and auditing of courses. | December 2005 |

| Objective | Target Date |
|---|--------------------|
| Produce report to the APC and thence the Secretary of State, on proposed actions. | December 2005 |
| <i>Applications Sub-Committee</i> | |
| Consider project licence applications referred to the APC by the Home Office. | Ongoing |
| <i>Suffering and Severity Working Group</i> | |
| Consider the strengths and any weaknesses of the current system of severity limits and bands as a way of prospectively assessing suffering and severity. If significant weaknesses are perceived, consider what alternative system could be proposed. | Late 2005 |
| Receive report on LASA/APC pilot study on how suffering and severity might be assessed retrospectively. | September 2005 |
| Submit Working Group's report to the APC, on how suffering and severity might be assessed retrospectively. | Late 2005 |
| <i>Schedule 1 Working Group</i> | |
| Review outstanding questions about the use of CO2 and inert gases on rodents and finalise Working Group's report, for APC review. | June 2005 |
| Present the report to the Home Office, following APC approval, with appropriate recommendations. | September 2005 |
| <i>Statistics Working Group</i> | |
| Submit report on review of statistics to the APC. | April 2005 |
| Present the report to the Minister, following APC approval. | May 2005 |

B: Items for consideration by the APC

| Objective | Target Date |
|---|--------------------|
| Welfare of fish used in experimentation – commission scoping study. | July 2005 |

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