Report of the Animal Procedures Committee for 2000

Laid before Parliament by the Secretary of State for the Home Department pursuant to Section 20(5) of the Animals (Scientific Procedures) Act 1986

Ordered to be printed by the House of Commons 19 July 2001

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ANIMAL PROCEDURES COMMITTEE

Membership as at 31 December 2000

Reverend Michael BANNER, MA DPhil (Chairman)—FD Maurice Professor of Moral and Social Theology, King's College, London.

Ronald ANDERSON, BVMS PhD MRCVS—Honorary Professor, University of Liverpool.

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Mike BAKER BA—UK Director, International Fund for Animal Welfare

Donald BROOM MA PhD—Professor of Animal Welfare, Department of Clinical Veterinary Medicine, University of Cambridge

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David CLARK BSc PhD FIBiol—Honorary Professor, University of Kent

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

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

Paul FLECKNELL MA VetMB PhD DLAS DiplECVA DipECLAM MRCVS—Professor of Laboratory Animal Science and Director, Comparative Biology Centre, the Medical School, University of Newcastle.

John GREGORY FIAT CBiol MIBiol RAnTech—Imperial College of Science, Technology and Medicine

Alan HOLLAND MA BPhil—Professor of Applied Philosophy, University of Lancaster.

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

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Robert McCRACKEN—Barrister

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

Iain PURCHASE OBE BVSc PhD MRCVS FRCPath FIBiol—Professor, School of Biological Sciences, University of Manchester

Genevra RICHARDSON LLB LLM—Professor of Public Law, Queen Mary & Westfield College, University of London

John TURNER BSc DPhil DSc FRSA—Professor of Evolutionary Genetics, University of Leeds.

Secretariat

Mr Chris Bone (until March 2000)
Mr Richard West (from March 2000)
Ms Sara Bacon
Mr Philip Brenner

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CHAIRMAN'S LETTER TO THE RT HON DAVID BLUNKETT MP, SECRETARY OF STATE FOR HOME AFFAIRS

During the year 2000 the Committee made significant progress on the agenda which emerged from our review of the Act, completed in 1998. We concluded consultation exercises on openness and biotechnology. Using the results of those exercises, two working groups of the Committee worked hard at analysing the difficult issues involved and formulating practical recommendations. That work enabled us to offer our considered advice on openness to the Home Office at the end of the year, and our report on biotechnology is also close to finalisation. We also started a wide-ranging consultation exercise about the cost-benefit assessment, and made encouraging progress on other areas of our review of the Act. This report also includes a work programme for the coming year, which gives details of how we intend to take these and other issues forward.

The Committee also carried on with its regular duties. For example, our Research and Alternatives sub-committee continued to identify suitable projects for funding to identify practical alternatives to the use of animals. The Committee also gave advice on certain applications, such as those involving microsurgery training using animals.

The Committee prides itself on bringing an independent and critical scrutiny to the use of animals in scientific procedures. In pursuit of its general duties and particular enquiries it finds itself asking whether the current regulatory regime is adequate, effective and efficient in meeting the objectives of the legislation, and it is concerned to make practical proposals for improvement where appropriate.

Perhaps inevitably, the Committee is criticised as either complacent towards current practice or as unduly hostile. A better appreciation of the Committee's function and work would be assisted by recognition of two key points. In the first place, there is widespread misunderstanding of current practice, as recent controversies have revealed. For example, it is plainly not commonly understood that most scientific procedures do not cause grave suffering to animals, and that even the taking of a blood sample constitutes a procedure under the Act. In the second place however, even supposing a better understanding of the use of animals in scientific procedures, the Committee's programme of critical appraisal of the Act and its working is fully warranted. In no sense can it be characterised as anti science or industry. Rather, it should be recognised that the continuing investigation of the use of animals in scientific procedures by the Committee is a key element in ensuring confidence in the regulation of what is and is likely to remain a highly contentious area.

Michael Banner
Chairman

INTRODUCTION

To begin our report it will help to set out some basic information about what the Animal Procedures Committee is and what it does.

The legislation

2. The Committee was first appointed in 1987 and was set up by sections 19 and 20 of the Animals (Scientific Procedures) Act 1986 ("the 1986 Act"). The 1986 Act replaced the Cruelty to Animals Act 1876. The 1986 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 1986 Act regulates scientific procedures carried out on all vertebrate species except man – that is mammals, reptiles, birds, amphibians and fish – and one invertebrate species, *Octopus vulgaris.*

3. 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 primates, dogs, cats, all of the most common types of rodent used in scientific procedures, rabbits, ferrets, quail and sheep and pigs 'if genetically modified'.

4. 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. Both departments have an Inspectorate consisting of professional staff with medical or veterinary qualifications who examine and advise on all applications for authorities under the 1986 Act. They also inspect establishments and the licensed work being carried out there.

The Committee

5. The function of the Animal Procedures Committee is to provide the Home Secretary with independent advice about the Act and his functions under it. The members are experts from a wide variety of backgrounds, appointed by the Home Secretary. The list at the beginning of this report sets out the membership as at the end of 2000.

6. 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 the Home Secretary refers to it. Through its Research and Alternatives sub-Committee, it advises the Home Office on the expenditure of an annual budget for sponsoring scientific and other research work connected with the 1986 Act.

7. 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. On joining the Committee, members agree to be bound by a Code of Conduct which appears at Annex A. 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 at Annex B.

Ministers

8. The Home Secretary in practice delegates his responsibilities under the 1986 Act to another Minister in the Home Office. Throughout 2000 that Minister was Mike O'Brien MP. The Chairman met Mr O'Brien twice in 2000.

Changes in membership of the Committee

9. Three members left the Committee during 2000. Two of these resignations were for personal reasons: Mr Ward resigned in May, and Dr Southee resigned in June. At the end of the year Professor Turner left the Committee after coming to the end of his four year term of membership. We would like to express our thanks to Mr Ward, Dr Southee and Professor Turner for the work they did for the Committee. The Home Office is currently engaged in a recruitment exercise to identify new members of the Committee.

Members' attendance, and honours received

10. Annex C sets out members' attendance at main meetings of the Committee during 2000. The Committee wishes to express its congratulations to two members who received honours in the 2001 New Year Honours list. Professor Bulfield received a CBE, and Mr Ward received an MBE.

PART 1—THE COMMITTEE'S WORK DURING 2000

Application for microsurgery training

11. The Home Office routinely refers to the Committee licence applications for training in microsurgery. The pre-1986 legislation prohibited the use of animals for training in surgical techniques. The 1986 Act can allow such training under licence, but the then Government promised that all such applications would be sent to the Committee for advice before a licence could be granted, and the present government is maintaining that commitment.

12. The application which the Committee considered at its February meeting was to renew one of the small number of such licences which are in existence. The proposal was to allow training on anaesthetised rats. At the end of the procedure the rats would be humanely killed without recovering from the anaesthetic ("terminally anaesthetised"). The training would form the second part of a two-part microsurgery course approved by the Royal College of Surgeons. In the first part, candidates – all experienced surgeons – would study theory and do in vitro work using tissues from dead animals. They would move on to the second part of the course and work on terminally anaesthetised rats only if they had successfully completed the first part and had demonstrated the necessary aptitude for microsurgery. Not all surgeons have this aptitude.

13. In its discussions the Committee established that the Royal College of Surgeons had previously reviewed these courses and had concluded that the use of anaesthetised rats remained the only way for surgeons to perfect micro techniques. Adult rats are apparently ideally sized animals for work of this kind – their blood vessels are closely similar to those which surgeons would encounter in their human patients. Non-animal alternatives such as the PVC rat model or the Solvay Practice Rat do not fully mimic all the features of living tissue, such as clotting or the effects of surgical error. Each trainee would use no more than one rat per day during the 5-day course. There is considerable demand for microsurgery courses nationally. It was suggested that the consequence of a refusal of the application might be that waiting lists for plastic surgery would get longer, or that there might be movement overseas: by patients for treatment or intending microsurgeons to receive training. The Committee agreed that the need to elicit basic information of this kind at its meeting indicated that the adequacy of the Home Office's project licence application documents needed to be examined. (The Committee later made a detailed recommendation to the Home Office in connection with its recommendations about openness about how the project licence application form might be improved – see Annex H, paragraph 4.)

14. On the basis of the assurances given, and in particular that no alternative was available for training in the techniques in question, the Chairman wrote to the Minister suggesting that he approve the application. The Minister accepted the Committee's advice.

Home Office investigation of Harlan-Hillcrest

15. At the end of June 1999 the Home Office received a report from BUAV making serious allegations about Harlan-Hillcrest, a breeding establishment licensed under the Act. The allegations related to the welfare and treatment of dogs, pigs and rodents. The Minister commissioned an investigation by the Inspectorate. The investigation was carried out by Inspectors who had not previously been involved in Harlan-Hillcrest. In a Parliamentary reply in July 1999 the Minister said that the Home Office would inform the Committee of the outcome of the Inspectorate's investigation. But the Minister went further than that by providing the Inspectorate's report to members and eventually publicising it more generally.

16. The report by the Inspectorate concluded that the majority of the BUAV's allegations were not substantiated. There had been one infringement meriting admonition, and a formal letter of admonition had been sent to the company. That related to the daily checks of a rodent room on two separate days. The records kept by Harlan-Hillcrest for those days did not confirm that the daily checks had been carried out.

No welfare problem caused by this infringement was detected. In addition, the company had given the Home Office assurances about staffing levels at the establishment. That was because of occasional acute staffing problems, which had led to operational duties essential for the proper care of animals being delivered only at the expense of other tasks.

17. The Committee welcomed the Home Office's decision to make the report public. The Committee also considered that it was right that the Inspectorate were asked, in the first instance, to carry out an investigation of the charges made, even though one of the BUAV allegations related to an Inspector. The Committee recognised that it was not in possession of the information to take a view of the rights and wrongs of the various allegations made against Harlan-Hillcrest. However, it was felt by a majority of members that the Inspectorate's report left a number of outstanding questions. Some members even felt that that the report gave the impression of seeking to exonerate Harlan-Hillcrest.

18. In its discussions the Committee was concerned to draw constructive, practical lessons for the future. It had, and continues to have confidence in the professionalism of the Inspectorate and in its concern to ensure the rigorous application of the legislation. However, a majority of the Committee thought it likely that public confidence in any future investigations of allegations which touched on the performance of the Inspectorate would be enhanced by the inclusion of an unquestionably independent element. The Chairman wrote to the Minister on 11 May passing on the Committee's conclusions. After further discussions with the Chairman, the Minister proposed that the Committee should provide an audit team to carry out a quality assurance check of future Inspectorate investigations. The proposal envisaged a small panel, drawn from members of the Committee. The panel would meet towards the end of the evidence-gathering phase of any Inspectorate investigation to check that the investigation team had fulfilled its remit. The panel could advise Ministers accordingly, and make recommendations for further work that might be required.

19. The report by the Inspectorate also suggested that the Committee might be asked to advise on the appropriateness of requiring animal care staff at designated establishments to undertake mandatory training. That was a matter which the Education and Training sub-committee already had under consideration and is dealt with in section 2. The Committee also took the view that the report raised the general issue of the effectiveness of the monitoring and enforcement of the Act. That is obviously a matter of great importance and it is now part of the Committee's work plan (Annex D).

Allegations by "Uncaged" about xenotransplantation work at Imutran and Huntingdon Life Sciences

20. In September 2000 the Daily Express carried a news feature based on serious allegations which the animal rights group "Uncaged" had made about conditions under which licensed xenotransplantation procedures had been conducted. The allegations related to work which had been commissioned by Imutran, a biotechnology company, and had been carried out by Huntingdon Life Sciences. It involved transplanting genetically modified organs from pigs to macaque monkeys and baboons. Allegations included suggestions that the agreed levels of severity of the procedures had been breached and that Imutran's interpretation of the progress with xenotransplantation had been more optimistic than was warranted by the results. "Uncaged" had obtained copies of a large number of documents relating to the experiments, and called for the Home Secretary to institute an independent judicial review of their allegations. The Committee's Secretariat was provided with copies of all the documentation by "Uncaged". An injunction against "Uncaged" obtained by Imutran prohibited public discussion of the papers, but the Home Office and the Committee were excluded from that injunction to the extent that the matters could be discussed in the course of business.

21. In November 2000 the Secretary of State announced in a reply to a Parliamentary Question how the allegations made were to be investigated. He stated that he had no plans to institute an independent judicial review. He said that he had decided instead to ask the Chief Inspector to examine, as part of the Inspectorate's normal statutory inspection and reporting function, the available evidence relating to compliance with the authorities granted to Imutran for its xenotransplantation work between 1995 and 2000.

22. There was some surprise in the Committee at the Home Secretary's decision, because his response to the allegations about Harlan-Hillcrest had been to commission an Inspectorate investigation. The Chairman therefore asked the Minister if he could provide some background on why a special investigation by the Inspectorate, as had occurred with the allegations about Harlan-Hillcrest, had not been commissioned. This would also have involved the Committee in providing a quality assurance panel. The Committee intends to discuss this and the other issues raised by the allegations when the Chief Inspector has concluded his examination, and an account of this will be given in the Committee's next annual report.

Meetings and Visits

23. The Committee sees an important and continuing need to liaise with animal welfare groups and representative bodies. During the year, besides meeting the Home Office Minister on several occasions the Chairman and/or the Secretariat had meetings with the British Union for the Abolition of Vivisection, the United Kingdom Xenotransplantation Interim Authority (UKXIRA) and the Agriculture and Environment Biotechnology Commission (AEBC). Two members of the Committee attended a Ministerial forum on Freedom of Information. The forum was chaired by Mike O'Brien, and was attended by several interest groups from animal welfare organisations and from industry.

24. The meeting with UKXIRA was noteworthy in that it identified two areas where closer liaison was essential. The Committee's Primates sub-committee examines licence applications for work involving primates, and would find it helpful to have someone from UKXIRA with knowledge of xenotransplantation issues to attend as a co-opted member as a source of expert advice. The Committee is grateful for UKXIRA's agreement to nominate members for this purpose. In turn UKXIRA stated that they would find it useful to have information from the Home Office of the details of current xenotransplantation licensed procedures. The information held by the Home Office about these projects is given in confidence, and could not be passed to UKXIRA without the consent of the relevant licence holder. Consequently, the Committee advised the Home Office to take this forward by approaching past and present xenotransplantation licence holders for such consent.

25. The Committee tries to make regular visits to establishments licensed under the Act. Some members have little experience of scientific procedures involving animals, and the Committee finds these visits very helpful in familiarising members with the practical issues. The visits are by invitation, and are not inspections. It is also agreed that the Committee makes no public comment about visits. During the year the Committee visited five establishments. The Committee is very grateful to those five organisations for their invitations, and found the visits both interesting and informative.

Infringements

26. The Committee is provided annually with a report by the Home Office of infringements against the Act. The Home Office informed the Committee that a new three-tier policy on dealing with infringements had been adopted from 1 July 2000. Some minor technical infringements which had no effect on animal welfare were to be dealt with at local and regional level. More serious infringements would, as before, be seen by the Chief Inspector and the head of the Animal Procedures section of the Home Office. At the Committee's December meeting the Home Office made a report of the 25 infringement cases dealt with centrally in the current year. The infringements ranged from errors in cage labelling to infringements such as failure to check whether particular procedures had been authorised under the project licence. Many of the infringements were self-reported, or had come to light by internal monitoring by the designated establishment. Besides dealing with each individual case, the Home Office stated that they also sought to identify trends and to disseminate appropriate remedial advice. It was explained that current practice was to take strong action where unnecessary suffering had been caused; where the licence holder did not appear to realise the gravity of the infringement; or in the case of repeated offences.

27. Some members of the Committee expressed the wish that the report of infringements should include information about the effects on animal welfare of each infringement, and which infringements had been self-reported. Information about whether the infringement had been caused by an individual's error or by a management failure would also be important, as would the incidence of repeated offences. The Committee recognised that naming the establishments concerned might have the negative effect of discouraging self-reporting, but felt that it was important to know whether there were establishments which repeatedly committed infringements. Lastly, members suggested that the report should comment about trends and numbers of cases. The Home Office agreed to consider those suggestions, and its response will be covered in next year's report.

PART 2—SUB-COMMITTEES AND WORKING GROUPS

28. This part of the report covers the activities of the Committee's sub-Committees and working groups. There are three sub-Committees, which have been set up on a permanent basis to advise the Committee about issues of continuing interest and concern. These are the Research and Alternatives sub-Committee, the Education and Training sub-Committee, and the Primate sub-committee.

29. The Committee also has currently five working groups, which have been set up to give the Committee advice on particular issues and which will disband when they have completed their work. Four of them are considering biotechnology issues, the cost-benefit assessment, openness, and overbreeding. Between them, these sub-Committees and working groups take in most of the major issues which were earmarked for further investigation as a result of the Committee's overall review of the operation of the 1986 Act. There are also a number of other issues – collected together in chapter 9 of the report of the review as it appears in the Committee's 1997 annual report – which are being taken forward by a further Miscellaneous working group.

30. The Committee's work programme, at Annex D, summarises the future plans of the sub-Committees and working groups. The rest of this part of the report describes progress during 2000 in more detail.

Research and Alternatives sub-Committee

31. At the beginning of the year the Research and Alternatives sub-Committee comprised Professor Anderson (chair), Professor D Clark, Dr Southee and Dr Langley. In May, Dr Southee resigned from the Committee. In September, Dr Langley offered her resignation from the sub-committee due to other commitments. There was therefore a need to identify new members, and the Committee was grateful to Dr Jennings for her agreement to join the sub-committee on a temporary basis, pending her replacement by one or more of the new members who are to be recruited.

32. The sub-committee's function is 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, or refinement of laboratory animal husbandry;

(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.

The sub-committee's research strategy recognises that 60% of the money should still go to traditionally defined research projects in the area under point (i) above, but the plan is to use the rest of it to support work which will fall under points (ii) and (iii).

33. For the financial year 2000/2001, the Home Office made available a budget of £265,500 for this purpose. This was a modest but welcome increase on the amount of £259,000 made available for the previous year, 1999/2000. This budget allows the Committee to make only a relatively small contribution to sponsorship of the above three categories, particularly since many projects have a three-year span. In view of the importance to the public and scientific and industrial communities of finding and promoting alternatives to the use of experimental animals, the Committee strongly believes that the Government should not only maintain, but also substantially increase its financial support for these initiatives.

34. As in past years, the sub-committee has experienced difficulties because funds unspent at the end of one year cannot be carried forward to the next year. That has implications for projects whose start and finish times do not coincide with the financial year. This is a factor of Government accounting procedures which is unlikely to change. The sub-committee tries to address this problem by commissioning interim reports and staging payments. Each project has a member of the sub-committee as assessor, and the assessor's consideration of interim reports helps the Home Office to decide whether further payments can be made.

35. Notwithstanding these difficulties, the sub-committee believes that the projects currently being supported and that have been identified for future support will contribute to reducing the numbers of experimental animals used, the substitution of non-animal alternatives and the reduced suffering of animals which are still necessarily required for experimental reasons.

36. Existing projects which were still in progress at the beginning of the year were as follows:

Dr Bendig (Public Health Laboratory)—*evaluation of PCR-based diagnosis to replace suckling mouse innoculation for detection and typing of cocksackie viruses*

Dr Denning (University of Manchester) – *non-invasive body temperature measurements in rodents*

Dr Dewhurst (University of Edinburgh)—*development of an interactive, computer assisted learning (CAL) programme to teach experimental design to users of laboratory animals*

Dr Greenman (University of Hull)—*exploitation and dissemination of bacteriophage antibody-display library technology*

Dr Heard (University of Wales)—*biometric polymer antibody substitutes in immunoassays*

Dr Orphanides (a project formerly conducted by Dr Brooks) (Zeneca)—*in vitro gene profiling*

Dr Porter (University of Aberdeen)—*novel biosensors in the UK's paralytic shellfish toxin monitoring programme*

Mrs Wolfensohn (University of Oxford)—*environmental conditions during transportation of non-human primates*

Dr Xing (NIBSC)—*alternative potency test to the intracerebral mouse protection test for pertussis vaccines*

37. The projects being conducted by Dr Bendig, Dr Denning, Dr Dewhurst and Dr Greenman concluded during the year. There follows brief details of the results of the projects.

Evaluation of PCR-based diagnosis to replace suckling mouse inoculation for the detection and typing of coxsackie vuruses.

38. Dr Bendig, from the Public Health Laboratory Services Coxsackie Reference Unit, carried out a study to investigate molecular methods, especially an in-house generic enterovirus polymerase chain reaction (PCR) assay for its ability to detect coxsackie viruses. His results have shown that the PCR-based in vitro test for the detection and typing of Coxsackievirus was as sensitive as the present suckling mouse inoculation test, and that such animal tests were no longer needed for the routine detection and typing of coxsackie virus.

Development of non-invasive body temperature measurements in rodents.

39. Dr Denning, at the University of Manchester, has validated a non-invasive method for measuring the surface body temperature in mice using infra-red telemetry. He correlated infra-red measurement of body temperature with temperature measurement by implantable microchip in mice. (The mice had already been implanted with the microchips in connection with a separate licensed experiment for the evaluation of new antifungal agents.) The study was conducted over a 10-day period and it was concluded that this new non-invasive method was accurate and rapid, and caused little stress to the mice. Dr. Denning proposes to validate this new method for measuring body temperature in other species of animals.

Experimental design – A guide to using fewer experimental animals and getting the most out of your experiments.

40. Dr Dewhurst, at the University of Edinburgh, has completed in a CD ROM format, a computer assisted learning program for teaching experimental design to users of laboratory animals with the aim of refining the experiments and reducing the number of animals used. During the making of this program account was taken of the comments made by individuals from the pharmaceutical industry and FRAME. The APC Education subcommittee has now been invited to consider effective ways for the dissemination of this programme.

Exploitation and dissemination of bacteriophage antibody-display library technology.

41. Dr Greenman, from the University of Hull, proposed to exploit the potential of phage-antibody libraries as an alternative to hybridomas for the generation of monoclonal antibody reagents against parasites of clinical relevance and various human tumors. He has established standard protocols and has generated many phage antibody display libraries with the aim of replacing animals for the production of monoclonal antibodies. He has also compiled useful information and antibody panels for use by other research groups. He has since attracted substantial external funding to continue and expand this project. In addition to the presentation of his research findings at conferences, Dr. Greenman and his colleagues have published the following manuscripts:

Topping, KP., Hough, VC., Monson, JRT., Greenman, J. (2000) Isolation of colorectal tumor reactive antibodies using phage display technology. Int. J. Oncol. 16: 187-95.

Khan, N., Greenman, J., Topping, K., Hough, V., Temple, GS., Paget, T. (2000) Isolation of Acanthamoeba-specific antibodies from bacteriophage display library. J. Clin. Micro. 38: 2374-7.

Khan, N., Jarroll,EL., Panjwani.N., Cao. ZY., Paget, T. (2000) Proteases as markers for the differentiation of pathogenic and non-pathogenic species of Acanthamoeba. J. Clin. Micro. 38 2858-61.

42. In January 2000 the sub-committee placed an advertisement in the New Scientist to seek further applications for funding. The sub-committee received 27 preliminary applications, and decided to ask eight of those for full applications. After receiving their full applications the sub-committee interviewed those applicants, and decided to offer grants to the following:

Mr Atkins (DERA)—*using nematode worms as models of bacterial disease instead of mammals*

Dr Judson (LHASA Ltd)—*international toxicology information centre*

Dr Mendl (University of Bristol)—*disruptive effects of common husbandry procedures on social recognition and social stability in laboratory rats*

Dr Sells (University of Liverpool)—*testing the efficacy of anti-venoms using fertilised hens' eggs instead of mice*

Professor Shah (Central Public Health Laboratory)—*using mass spectroscopy instead of mice to test for botulism*

43. The Committee's next annual report will contain reports on those projects which end in 2001.

Education and Training sub-Committee

44. This sub-Committee comprises Professor Flecknell (chair), Mr Gregory and Dr Jennings. Its work programme is set out at Annex D. The sub-committee's major action during 2000 was its work on training for Named Care and Welfare Officers (NACWOs). The sub-committee proposed that training for newly appointed NACWOs should be made compulsory, and examined a syllabus drawn up by the Institute for Animal Technicians (IAT) for an introductory course, which would be designed for professional animal technicians. In discussion by the main Committee at its December meeting, the proposal was accepted, but

it was suggested that the course might need to be expanded to include more detail about welfare observations as well as a general introduction to ethics training. In the meantime the Chairman wrote to the Minister to give him early notice of the Committee's proposals. A copy of his letter, which includes the proposed syllabus as an annex, is at Annex E.

The Primates sub-Committee

45. Originally the Primates sub-Committee comprised Professor Dunbar (chair), Professor Atterwill, Dr Langley, Professor McNeilly and Mr Ward. After Mr Ward's resignation (paragraph 9), Dr Jennings joined the sub-committee. As with the other sub-Committees and groups, its work programme is set out at Annex D.

46. At the Committee's meeting in June the sub-committee presented a paper which addressed two of the five issues which the Committee's review of the 1986 Act had identified as being for the Primates sub-committee to take forward. Those were: the minimisation and eventually elimination of primate use and suffering; and the use of primates in regulatory toxicology.

47. The paper showed that current use of primates was not as high as had been feared by some. However, as far as future use was concerned, increasing human longevity was making the development of solutions to diseases of old age more pressing than current diseases causing concern, such as heart disease and cancer. That might lead to an increase in the use of primates for research into neuro-degenerative diseases.

48. Most of the conclusions in the part of the report which discussed primate use in regulatory toxicology related to contract research organisations. First, there was much uncertainty about regulatory requirements, which might lead to an overuse of primates. Secondly, there was a need to improve licence applications so that the justification for primate use was more transparent. This could be assisted by a central exchange data base. Thirdly, a mechanism for licensing individual projects within the framework of a blanket licence could reduce public fears and speed up the licensing process. Fourthly, the sub-committee had concerns that in some projects primates might be being used prematurely in a sequence of experiments in order to save time. The sub-committee was clear that there had to be firm evidence for the use of primates.

49. The Committee has not yet offered any advice on these matters to the Minister. This is because it considers that further work is needed. The Committee wishes to focus on the practical implications of how any recommendations might be implemented. The sub-committee will be urgently examining these issues in 2001, and progress will be reported in the Committee's next annual report.

Biotechnology working group

50. The biotechnology working group comprises Professor Richardson (chair), Professor Broom, Professor Bulfield, Professor S Clark and Professor Purchase. Its aim, following the main Committee's conclusions in its review of the operation of the Act is to provide advice on the adequacy and appropriateness of the 1986 Act in regard to the production and use of transgenic and cloned animals in laboratory work and other procedures regulated by the 1986 Act.

51. The working group issued a public consultation document in November 1999, and a copy was included in that year's annual report at Annex F. During 2000 the working group held 10 meetings. A diversity of views was expressed in the responses to the consultation exercise. For example, one area of extensive discussion has been the measurement of the welfare needs of genetically modified animals.

52. The working group intends to present its report to the Committee at its first meeting in 2001. Both the Royal Society and the AEBC are also currently examining biotechnology issues, and the Committee intends sharing its report on Biotechnology with those bodies once it has been agreed.

Cost benefit working group

53. The Cost Benefit working group is chaired by Professor Banner, and its other members are Professor D Clark, Professor Holland, Dr Jennings and Professor Martin. The Committee's report of its review of the 1986 Act said that the cost/benefit assessment provided a workable and flexible framework in which to decide whether the use of animals is justified. But the Committee felt that there were some areas where further consideration and discussion is necessary to clarify, and make more transparent, aspects of the cost/benefit assessment which appear obscure and thus to promote better understanding of it.

54. The working group's terms of reference are to

- compare the way the cost/benefit assessment is currently carried out with other cost/benefit models;
- investigate the factors that are, or should be, taken into account in the assessment of costs and benefits, and the relative weights applied to each, taking into account not only the individual project but how that project contributes to wider programmes of research and to the development of technology and human knowledge; and
- examine the nature of the judgement required when weighing costs and benefits, and how this judgement can be made more transparent and objective.

55. The working group's objectives remain as set by the main Committee. But it also plans to produce an authoritative statement on the validity of animal experiments and to address the question of whether and how the present cost-benefit assessment process might be improved. Improvement could be in a range of areas – for instance, in terms of transparency or in terms of the process of weighing cost and benefit.

56. The working group issued a public consultation paper in December 2000. A copy is at Annex F. The working group hopes to produce its report on the cost/benefit assessment in 2001.

The openness working group

57. At present, section 24 of the 1986 Act imposes a confidentiality requirement on all those who receive information about animal procedures under the Act (including this Committee). It makes it a criminal offence for a person to disclose that information '*otherwise than for the purpose of discharging his functions under this Act*' if he or she knows or has reasonable grounds for believing that the information was given in confidence.

58. There are strong arguments in favour of increasing the amount of official information about animal procedures which is available to the public. There is a strong public interest in knowing what is going on, either to cast light on what is perceived by some as a secretive world, or on the grounds that greater public knowledge would lead to greater public acceptance and understanding and that ignorance plays into the hands of those who oppose experiments. There are also arguments against an unfettered increase in openness, such as the personal security of individuals and commercial confidentiality.

59. The openness working group was established in order to explore this subject more thoroughly. The working group first met in November 1999 and decided as a first step to seek the views of interested individuals and bodies on the issues. A copy of the consultation letter, sent out on 13 January 2000, is at Annex G.

60. Initially, three members of the Committee comprised the working group: Professor Christopher Atterwill (chair), Mr Mike Baker and Mr Robert McCracken. The consultation period ended on 10 March 2000. Because of the very large number of responses which had been received (a total of 2,320) it was decided to increase the membership of the working group by two further members of the APC: consequently Professor Grahame Bulfield and Professor David Clark joined the working group on 17 March 2000. During 2000 the working group met seven times.

61. At some of its meetings the working group was assisted by visiting specialists from industry, the Home Office and elsewhere. The working group was grateful to them for their helpful contributions to the understanding of the issues.

62. At the Committee's meeting in December the working group submitted two reports to the main Committee – a majority report, supported by three of the members of the working group, and a minority report, supported by the other two members of the working group. In discussion the Committee noted the continuing disagreements on various matters, in particular in relation to revisions to the project licence application form and the publication of results. The Committee agreed that the Chairman should write to the Minister reflecting the discussion which had taken place and presenting the Committee's recommendations whilst noting the continuing disagreements. It was agreed that the Chairman would submit a revised report agreed by the Committee as a whole to the Minister in due course. A copy of the Chairman's letter to the Minister is at Annex H.

The overbreeding working group

63. Last year's report referred to work carried out by the Laboratory Animal Science Association (LASA) about the "overbreeding" of laboratory rodents. LASA were reporting on a survey they had conducted of the breeding of rats and mice which revealed that *'up to half the animals bred for scientific procedures become surplus to requirements'*. As the next paragraph demonstrates, there are specific reasons why animals bred for scientific procedures are not used for that purpose. However the breeding of laboratory animals which become surplus to requirements is plainly a serious issue and LASA's report suggested some causes and possible remedies. To take the matter forward the Committee set up a small working group to liaise with LASA and complement their work with a study of its own. The group comprises Professor McNeilly (chair), Mr Baker and Mr Gregory.

64. The working group had an informative meeting with representatives of LASA. Large commercial breeders licensed under the Act dispose of the rodents they breed in one of four ways. The first group comprises animals which are sold for use in scientific procedures. The second group comprise animals which are not sold, but are kept by the breeder for further breeding. The third group comprises animals which do not meet the requirements of the first two categories. For example, this might be because they do not meet the criteria of sex, age or weight required in a particular procedure, or they might not be suitable for breeding. The fourth and final group comprises surplus animals, that is animals which are suitable for sale for use in scientific procedures but for which there is no demand. Animals in the third and fourth categories are killed and then sold or given away to zoos or private pet keepers as feed for carnivorous birds and reptiles. Demand exceeds supply; for example captive herons will consume around 5,000 rodents a year. While animals used for feed are not "surplus" in that they are put to a use, the working group intends to explore the ethical issues that this practice exposes.

65. The working group discussed some possible solutions to the problem, and decided to ask LASA to carry out a similar survey of overbreeding of cats, dogs and primates. This second survey is nearing completion.

The "Miscellaneous" working group

66. The group comprises Professor Broom (chair) and Mr Gregory. Its purpose is to investigate the issues discussed in the final "other issues" chapter of the Committee's 10 year review of the 1986 Act (published in the Committee's annual report for 1997). The working group presented its initial conclusions at the Committee's meeting in June. Topics covered included:-

- fees and resources;
- the level of regulation and its effect on the export of animal use;

- the scope of the 1986 Act in regard to the inclusion of further invertbrate species and to the 50% gestation stage limit;
- the retrospective assessment of severity;
- humane methods of killing;
- re-use of animals; and
- acquisition of animals.

67. The working group is currently examining its report in the light of the Committee's discussions. The Committee intends to present its advice to the Home Office in September 2001.

ANNEX A

The Animal Procedures Committee's Code of Conduct

CODE OF CONDUCT FOR MEMBERS

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, for the Department of Health and Social Services for Northern Ireland) 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:

- an offence under section 24 of the Animals (Scientific Procedures) Act 1986;
- a breach of confidence under common law; or
- 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.

ANNEX B

REGISTER OF MEMBER'S INTERESTS

Name	*Occupation*	*Organisation*	*Nature of interest*
Professor Michael Banner	Professor of Moral & Social Theology, King's College, London	Royal Commission on Environmental Pollution. Agriculture and Environment Biotechnology Commission Department of Health Committee on variant CJD	Member Member Chairman
Professor Ronald Anderson	Honorary Senior Fellow, University of Liverpool	Universities Federation For Animal Welfare Humane Slaughter Association Society for Animal Welfare in Israel Society for Companion Animal Studies	Chairman of Council & Trustees Chairman of Council & Trustees Chairman of Council & Trustees President
Professor Chris Atterwill	Director of Biosciences Huntingdon Life Sciences	University of West of England & University of Hertfordshire	Visiting Professor
Mr Michael Baker	UK Director, International Fund for Animal Welfare	The British Union for the Abolition of Vivisection	Member
Professor Donald Broom	Professor of Animal Welfare Department of Clinical Veterinary MedicineUniversity of Cambridge	EU Scientific Committee on Animal Health and Animal Welfare Huntingdon Life Sciences	Member and Deputy Chair of Animal Welfare sub-group Member of Ethical Review Procedure committee
Professor Grahame Bulfield CBE	Director & Chief Executive, Roslin Institute	Roslin Institute Roslin Nutrition Ltd Roslin Biocentre Ltd Rosgen Ltd B & K Universal British Biotech plc University of Edinburgh	Holder of Certificate of Designation Chairman Chairman Non Executive Director Non-executive Director Shareholder Honorary Professor
Professor David Clark	Senior Research Fellow, University of Kent	Unilever plc European Centre for the Validation of Alternative Methods European Cosmetics Trade Association University of Surrey	Shareholder UK representative on Scientific Committee Chairman of Steering Committee Visiting Professor

Name	*Occupation*	*Organisation*	*Nature of interest*
Professor Stephen Clark	Professor of Philosophy, University of Liverpool	Liverpool University	Member, animal use ethical review Committee
		Farm Animal Welfare Council	Member
		Boyd Group	Member
		RSPCA	Member
		UFAW	Member
		Animal Aid	Member
		BUAV	Member
Professor Robin Dunbar	Professor of Psychology, University of Liverpool	Cameroon Wildlife Aid	Trustee
		University of Liverpool	Member, animal use ethical review Committee
Professor Paul Flecknell	Director, Comparative Biology Centre, University of Newcastle	Pharmaceutical companies, Universities	Home Office PPL and PIL holder Named Veterinary Surgeon, Lecturing and Consultancy
		British Laboratory Animal Veterinary Association	Member
		Association of Veterinary Anaesthetists	President
		Grant awarding bodies (e.g. Wellcome Trust Leverhulme, Animal welfare charities)	Research grants to Department
		Laboratory Animals Ltd,	Director & trustee
Mr John Gregory	Facility Manager, Central Biomedical Services, Imperial College of Science, Technology and Medicine, Hammersmith Hospital	Imperial College	Home Office PPL and PIL holder
		Institute of Animal Technology	Chairman of Council
		Institute of Biology	Member of Accreditation Board
		Royal Veterinary College	Visiting lecturer
		Boyd Group	Member
		Laboratory Animal Science Association	Member
		Research Defence Society	Member
Mr Alan Holland	Senior lecturer in Philosophy, University of Lancaster	None	
Dr Maggy Jennings	Head of Research Animals Department, RSPCA	RSPCA	Employee
		UKXIRA	Member
		Animal Health Trust	Member of ethics committee
		Boyd Group	Member
Dr Gill Langley	Scientific Adviser and Consultant, Dr Hadwen Trust	British Union for the abolition of Vivisection	Consultancy payments
		International Fund for Animal Welfare	Consultancy payments
		Animal Aid	Consultancy payments
		Uncaged	Consultancy work
		GAIA	Consultancy payments
		Vegan Society	Book royalties

Name	*Occupation*	*Organisation*	*Nature of interest*
Professor John Martin	University College and British Heart Foundation: Chair of Cardiovascular Science	European Society of Cardiology European Vascular Biology Association Research Defence Society Eurogene Lacer plc (Spain) British Heart Foundation European Commission	Vice President Vice President Member Director Consultant Research grants received Research grants received
Mr Robert McCracken	Barrister		
Professor Alan McNeilly	Deputy Director, Medical Research Council Edinburgh	JNCC Parkes Trust Medical Research Council University of Edinburgh Society for the Study of Fertility	Consultant Trustee PPL & PIL Holder, Certificate holder Member of Faculty of Medicine Animal Resources Committee Chairman
Professor Iain Purchase	Visiting Professor, University of Manchester and Consultant	AstraZeneca plc Bayer AG Celltech UK Interdepartmental Group on Health Risks from Chemicals Expert Group on Efficient Regulation International Council for Science: Preparation of a monograph on Genetically Modified Food for Development, Health and Nutrition	Shareholder and Consultant Consultant Shareholder Chairman Chairman Honorary project leader on behalf of the International Union of Toxicology
Professor Genevra Richardson	Professor of Law, University of London Queen Mary and Westfield	Medical Research Council	Member
Dr Jacqueline Southee	Consultant, non-animal alternative methods	Hill Top Globe Crown International	Contract laboratory offering non-animal Testing
Professor John Turner	Professor of Evolutionary Biology University of Leeds	AstraZeneca plc	Power of attorney over shares
Mr Les Ward	Director, Advocates for Animals	St Andrew Animal Fund World Society for the Protection of Animals Marchig Animal Welfare Trust Houghton Memorial Fund The Boyd Group Felix Cat Rescue	Company Secretary Advisory Director Trustee Trustee Member Patron

ANNEX C

Members' attendance at meetings during 2000

The full Committee met on five occasions during 2000. Attendance at those meetings is shown below. The number of asterisks by a name indicates the number of sub-committees and working groups to which an individual belongs. The number of meetings of sub-committees and working groups varies from one or two per year to as many as ten.

Professor Banner*	5
Professor Anderson*	4
Professor Atterwill**	5
Mr Baker**	2
Professor Broom**	4
Professor Bulfield**	4
Professor D Clark***	4
Professor S Clark*	2
Professor Dunbar*	4
Professor Flecknell*	4
Mr John Gregory***	5
Professor Holland*	4
Dr Jennings****	5
Dr Langley**	5
Professor Martin*	4
Mr McCracken*	3
Professor McNeilly**	5
Professor Purchase*	2
Professor Richardson*	5
Dr Southee[1]*	1
Professor Turner	3
Mr Ward[2]*	1

[1] Dr Southee resigned from the Committee in June 2000
[2] Mr Ward resigned from the Committee in May 2000

ANNEX D

The Committee's work programme for 2001

This work plan is in three parts:

- part one deals with the work of the existing three sub-committees and five working groups;
- part two deals with other tasks; and
- part three lists the topics suggested for in depth discussion at Committee meetings through the year.

Part 1: the work programme of the Committee's sub-committees and working groups

Objective	*Target date(s)*
Research Sub-Committee	
Advertise for new research proposals	January 2001
Identify new members of RASC	June 2001
Regular work on monitoring existing projects and identifying new ones	As necessary
Education & Training Sub-Committee	
Report to main APC on	
* *changes to the modular system of training*	
* *mandatory training for NACWO's and certificate of designation holders*	
* *ethics training*	
* *training of personnel with limited grasp of English*	
* *training in humane killing*	
* *minimum training standards*	
* *refresher training courses*	April 2001
APC to report to Ministers on these issues	June 2001
Primates Sub-Commttee	
Main APC to advise Home Secretary	
* how to minimise or eliminate primate use & suffering	
* primate use in regulatory toxicology	March 2001
Sub-committee to advise APC on remaining primate topics:	
* acquisition of primates	
* housing & care	
* use of wild-caught primates	September 2001
Openness Working Group	
Final version of openness paper to APC	[December 2000]
Report to Home Secretary	January 2001
Biotechnology Working Group	
Report to main Committee	February 2001
Report to Home Secretary	March 2001
Cost-Benefit Working Group	
Circulate consultation	[December 2000]
Report to APC	September 2001
Report to Home Secretary	December 2001

Objective	*Target date(s)*
Overbreeding working group	
Review LASA report on overbreeding of dogs, cats and non-human primates	February 2001
Report to APC	October 2001
Report to Home Secretary	December 2001
Miscellaneous issues working group	
Present revised Miscellaneous issues report to APC	April 2001
Report to Home Secretary on miscellaneous issues coming out of review of the 1986 Act	September 2001

Part 2: other tasks to be carried out

Objective	*Target date(s)*
Annual report	
Publish Annual report	April 2001
Recruitment of new members of APC by the Home Office	
Trawl interested bodies for nominations	January 2001
Selection process completed	April 2001
New members appointed	June 2001
Regular tasks	
Advise Home Secretary on applications for licences involving non-human primates; tobacco; and microsurgical training Review infringements Liaise with other relevant bodies Visits	As necessary

Part 3: topics for discussion through the year

- Working methods, responsibilities and staffing of the Animal Procedures Committee;
- ASPA 1986: enforcement and compliance;
- Accommodation and care of animals;
- ASPA 1986: consideration of the effectiveness of the legislation in the light of reports by DTI and group of experts

APC Secretariat
December 2000

ANNEX E

The Committee's letter about training for NACWOs

Animal Procedures Committee
Room 978, 50 Queen Anne's Gate
London SW1H 9AT

020 7273 2915 or 2770

From the Chairman
Reverend Professor Michael Banner MA DPhil

Mike O'Brien MP
Parliamentary Under-Secretary of State
Home Office
50 Queen Anne's Gate
London SW1H 9AT

11 January 2001

Dear Mr O'Brien

ANIMAL PROCEDURES COMMITTEE (APC): TRAINING FOR NAMED ANIMAL CARE AND WELFARE OFFICERS (NACWOs)

At its meeting on 13 December the APC accepted a recommendation of its Education and Training sub-committee that training for newly-appointed NACWOs should be made compulsory. I attach a copy of the sub-committee's paper, which includes a draft syllabus.

During the discussion by the full Committee on 13 December it was suggested that the syllabus could be improved if it included more detail about welfare observations and a general introduction to ethics training. I have asked for further work to be carried out on the additional elements which might be incorporated into the syllabus, which I will pass on to you after further discussion by the Committee. In the meantime, I hope that sight of the sub-committee's paper will enable your officials to start their consideration of the Committee's advice.

Yours sincerely

MICHAEL BANNER

Animal Procedures Committee
Education and Training sub-Committee

Recommendation to the APC:-

"The Education & Training sub-Committee recommends to the APC for acceptance, that training for newly appointed NACWO's should become mandatory."

After extensive discussions, the sub-committee further recommends:

1. That such training should not be retrospective

2. That the training provided should follow the models established for mandatory training of other named persons:

One or more course accrediting bodies should be recognised by the Home Office.

These accrediting bodies would accredit courses, and the course providers would issue certificates of successful completion of the course to participants.

Training should generally be undertaken as soon as practicable, but in any event no longer than one year should elapse between appointment as a NACWO and successful completion of a training course.

The content and nature of the training would be determined by the accrediting body, and approved by the Home Office. The Institute of Animal Technology had indicated that it would be prepared to act as an accrediting body. A draft syllabus and proposals for accreditation had been provided, and after discussions between the sub-committee and the Institute, these had been amended. The amended versions are attached to this recommendation, and provide a syllabus that, in the opinion of the sub-committee, would be appropriate for NACWOs.

The sub-committee also wished to recommend that all NACWOs (and Certificate holders) should be advised that continuous professional development of NACWOs should be encouraged.

Draft Syllabus for an Introductory Course for Named Animal Care & Welfare Officers (prepared by the Institute of Animal Technology)

RATIONALE

The course has been designed to provide information and some of the basic skills required by an individual who is to take on the role of Named Animal Care and Welfare Officer (NACWO). The course is intended to build on existing academic and professional qualifications. Completion of the course will enable participants to understand and begin to fulfil the responsibilities of the NACWO as detailed in the Guidance on the Operation of the Animals (Scientific Procedures) Act 1986. They will, however, need to supplement the information and learning derived during the course with experience from within their working environment, in addition to assistance and guidance gained by networking with others in similar positions in their own or other establishments.

OBJECTIVES OF THE COURSE

1. Develop an appreciation of the important role of the NACWO as an acknowledged expert in the care and welfare of laboratory animals and the management of designated establishments.

2. Provide a clear understanding of the scope of the Animals (Scientific Procedures) Act 1986 and an appreciation of other legislation and guidelines appertaining to the care and use of laboratory animals.

3. Develop an understanding of the regulation, administration and spirit of the Act.

4. Develop an appreciation of the roles, responsibilities and interactions of those working within the Act, namely the HO Inspectorate, Named People, project and personal licence holders.

5. Develop an awareness of the Ethical Review Process and the role of the NACWO.

6. Provide a forum to discuss the concept of the Three Rs and to explore ways in which the NACWO is able to contribute towards their introduction.

7. Develop a process for assessing levels of pain or suffering in animals and create an awareness of the courses of action that may need to be taken.

8. Promote the exchange of ideas and experiences during the course but also later by networking with others in a similar position.

9. Develop an awareness of continuing developments within the field of laboratory animal science and the need to keep up to date with scientific advances.

10. Promote the concept of continuing professional development and life time learning.

Course Content

On completion of the course the trainee should be able to:

1. Demonstrate a sound knowledge of the legislation appertaining to the care and use of laboratory animals.

Animals (Scientific Procedures) Act 1986:

- Scope of the Act
- Regulation via Certificate of Designation, Project & Personal licences

- Roles, Responsibilities and interactions of those working under the Act—the Home Office Inspectorate, Animal Procedures Committee, named people, project and personal licensees
- Role and constitution of the Animal Procedures Committee
- Schedules to the Act and guidelines.

Other legislation impinging on laboratory animal work:

- Protection of Animals Act, 1911
- Protection of Animals Act (Anaesthetics) 1954, 1964
- Veterinary Surgeons Act, 1948, 1966
- Rabies Act 1974
- Balai Directive 92/65

2. Be fully conversant with the NACWO role:

- legal and ethical responsibilities
- Codes of Practice
- interactions with others, to include potential confrontational situations
- promoting a culture of care
- infringements and how to deal with them

3. Demonstrate an understanding of the project licensing system to include:

- design of the licence
- the mechanism for performing a cost benefit analysis

4. Demonstrate an understanding of the three Rs:

- their inception
- examples of reduction, refinement and replacement
- the role of the NACWO particularly in the fields of refinement and reduction

5. Describe the Ethical Review Process:

- the aims of the review
- membership and operation of the Ethical Review Group/Committee
- participating in the review, the likely role of the NACWO

6. Recognise and quantify pain, suffering and distress in animals:

- signs to look for
- scoring systems
- severity limits/bands, constraints upon adverse effects, humane endpoints

DURATION

It is expected the course will take a minimum of twelve hours to deliver. Some of this time may be allocated to private study and take the form of published or specially prepared material to be read before attendance on the course. Prior learning eg attendance on Home Office modules 1—3 may also be taken into consideration. Assessment time, see later notes, is in addition to the twelve hours previously mentioned.

TEACHING AND LEARNING STRATEGY

Whilst much of the course material may be delivered by overview lectures other methods may be incorporated including:

- directed reading
- discussions
- case studies
- syndicate exercises

ASSESSMENT STRATEGY

A tutor marked end of course assignment will be used to assess and reinforce the knowledge base. This will be expected to be of no less than forty-five minutes duration. Delegates who achieve a 50% or higher mark will be issued with a Certificate of Successful Achievement.

ANNEX F

The Committee's consultation letter on the Cost/Benefit assessment

Animal Procedures Committee
Room 978, 50 Queen Anne's Gate
London SW1 9AT

Tel: 020 7273 2915 or 2770

Apc.secretariat@homeoffice.gsi.gov.uk

6 December 2000

Dear Reader

CONSULTATION PAPER ON THE COST/BENEFIT ASSESSMENT AND THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986

Introduction

1. This letter seeks your views on the cost/benefit assessment used in the consideration of applications to carry out animal experiments under the Animals (Scientific Procedures) Act 1986.

2. The role of the Animal Procedures Committee (APC) is to provide the Home Secretary with advice, independent from the Home Office and its Inspectorate, about the legislation and his functions under it. Our membership consists of experts from a wide variety of backgrounds. By law, we must take account of both the legitimate requirements of science and industry and the protection of animals against avoidable suffering and unnecessary use in scientific procedures.

We have previously undertaken an overall review of the Animals (Scientific Procedures) Act 1986, the conclusions of which appear in our annual report for 1997. As that report explains, we received during the course of the review a large number of comments about the cost-benefit assessment. These comments showed that many believe that the cost-benefit assessment has made a contribution to animal welfare since the 1986 Act first brought it into law, but that some thought that the law was not applied with sufficient rigour. More generally there was some uncertainty about how the cost/benefit assessment operates in practice – uncertainty, regarding the factors that are taken into account and how these are put together in coming to a judgement. We concluded then that we should "produce and publish an extended statement on the assessment of costs and benefits required by the Act". We hoped that this would make an important contribution to the effective operation and public understanding of the principles and functioning of this significant piece of legislation. This consultation document is our first step towards doing that.

Section 5(1) of the Act describes a project licence as a licence granted by the Secretary of State specifying a programme of work and authorising the application, as part of that programme, of specified regulated procedures to animals of specified descriptions at a specified place or places. Section 5(3) of the Act states that a project licence shall not be granted unless the Secretary of State is satisfied that it is undertaken for one or more of the following purposes-

- The prevention (whether by the testing of any product or otherwise) or the diagnosis or treatment of disease, ill-health or abnormality, or their effects, in man, animals or plants;
- The assessment, detection, regulation or modification of physiological conditions in man, animals or plants;

- The protection of the natural environment in the interests of the health or welfare of man or animals;
- The advancement of knowledge in biological or behavioural sciences;
- Education or training otherwise than in primary or secondary schools;
- Forensic enquiries;
- The breeding of animals for experimental or other scientific use.

Section 5(4) of the Act provides that "in determining whether and on what basis to grant a project licence the Secretary of State shall weigh the likely adverse effects on the animals concerned against the benefit likely to accrue as a result of the programme to be specified in the licence". The Committee intends to offer the Government its considered advice on the assessment of adverse effects and benefits, and in particular hopes to be able to offer views on how to ensure that the assessment is sensitive to all relevant considerations, accords them proper significance, and is as transparent and open as possible.

5. We are seeking views chiefly on three areas of concern: the scientific validity of experimentation on animals; the identification and weighing of harms and benefits; and the development of good practice and processes in carrying out the Cost/Benefit assessment.

The scientific validity of Animal Experiments

6. A(SP)A 1986 requires the Home Secretary to weigh the likely adverse effects on animals of the programme of work, against the benefits likely to accrue. Those people, however, who believe that animal experiments are scientifically invalid (i.e. are scientifically misleading, yielding no worthwhile or reliable knowledge) consider that this assessment is very straightforward. They would argue that experiments on animals yield no benefits and therefore no licences should be granted.

7. Clearly, the argument regarding the validity of animal experiments is integral to any review of the cost-benefit assessment. Those at either end of the spectrum of views on this issue argue about 'validity' as if it were an all or nothing affair. The arguments used to support these opposing positions focus on the specific failures or successes of animal experiments and then extrapolate to a general position—animal experiments as a whole are either invalid or valid science. A question in the debate is whether or not animals provide a good model for humans based on their physical and physiological similarities and differences[3]. However, animals are used for many different purposes, and to obtain many different types of information which is subsequently used in a variety of ways. They are not used only as models of humans. The research goals can be study of the animals themselves, or the acquisition of general biological knowledge. Basing the validity argument solely on the relevance of animal models to humans therefore seems unsustainable.

8. A more considered review of the issue of validity in relation to the cost-benefit assessment seems necessary which would need to take into account at least:

- the purpose and experimental design of the research/testing programme;
- the reasons for believing the animal model will give insight into a problem;
- what the individual experiments are designed to achieve;
- the potential and/or limitations of other approaches;
- how the results will be used; and
- the benefit of fortuitous discovery.

[3] *An annex to this letter provides a discussion of such similarities and differences in the heart and blood of humans and animals*

9. We would welcome your views on the following two questions:

Can the validity of experiments on animals be argued in absolute terms as set out in paragraph 7 or should this be considered on a case by case basis taking into account the factors such as those in para 8 above? It would be helpful if you could explain the criteria you believe should be used to assess the scientific validity of animal experiments.

Do you consider that the cost-benefit assessment adequately addresses the scientific validity of projects and individual experiments within these? Who do you consider has/should have responsibility for assessing validity (e.g. the researcher, the funding body, the Animal Scientific Procedures Inspectorate, Ethical Review Process, regulators, other)?

The Identification and Weighing Of Harms And Benefits

10. Section 5(4) of the Animals (Scientific Procedures) Act 1986 requires that "in determining whether and on what basis to grant a project licence, the Secretary of State shall weigh the likely adverse effects on the animals concerned against the benefit likely to accrue as a result of the programme to be specified in the licence".

11. The way costs and benefits are currently determined by the HO Inspectorate, together with a guide to how decisions are made with respect to the weighing of these—the justification of each project – is set out in Chapter 2 Annex 1 of the review of ASPA contained in the APC report for 1997.

12. The ASPA also sets out in Section 5(3) the broad purposes for which animals can be used (see paragraph 4). In recent years, the Secretary of State has introduced restrictions on work for which licence authorities can be obtained. There are some types of animal experiment – to test offensive weapons, alcohol, cosmetics and tobacco products, and use of some species (the Great Apes) – which the Home Office has ruled out in principle, on the grounds that the Government considers the costs are unjustified, or alternatives are available or they are "morally objectionable". The number of licensed procedures involving the use of genetically modified animals is increasing, and there may be costs and benefits specific to this expanding area that should be given separate consideration. We would therefore be grateful for your views on these issues.

13.The APC would welcome views on the following questions:

- *Are there additional categories of uses of animals, or particular types of procedure, which should be viewed as unacceptable either in terms of the level of suffering involved or the species of animal that is used regardless of the benefit that comes from such use or procedures?*
- *Are there some types of benefit (the overall purpose of the experiment) that might be held as not justifying the use of animals or justifying it only in exceptional circumstances regardless of whether or not the animals would suffer?*
- *Are all relevant harms and benefits identified by current HO practice? Even if, by its nature, the weighing of costs and benefits always has to be a matter of opinion, is there need for further clarification of the criteria which have been or should be employed in particular cases?*
- *Are costs other than those involved in, or consequent upon, the actual procedures given their due weight? These include the physical and psychological harms/sufferings associated with capture, confinement, transportation, social isolation, husbandry systems and general handling of animals. Should death in itself be considered a harm and what weight should be given to this in the cost-benefit assessment?*
- *Are there costs to animals, for example, aspects of poor welfare or undesirable changes in animals, which could be specific to transgenic animals or animals treated with products from genetically modified organisms? Do you consider that any of these costs could never be justified by benefits?*

- *Please give detailed examples of benefits specific to the use of transgenic animals, or to the treatment of animals with products from genetically modified organisms, which are likely to be very great. Are there, or will there be, benefits whose magnitude is too small, or whose likelihood of accruing is too remote or too distant in time, to outweigh the costs?*

14. Research is increasingly a multinational process and UK researchers often collaborate with scientists abroad who are operating under different regulatory regimes which may have much less regard for animals and their welfare.

- *Do you believe that this is a significant problem? If so, what might be done to address it?*

The Development Of Good Practice And Processes In Carrying Out The Cost/Benefit Assessment

15. We are aware that there is experience of assessing and weighing adverse effects and benefits outside the sphere of animal experimentation from which we might be able to learn. Comparisons analogous to the one which is at the centre of ASPA have a part in the work of the HSE for example, and also the Environment Agency. Similarly, those considering the acceptability of clinical trials in human subjects have to make careful appraisals of the likely adverse effects and the likely benefits. The APC would welcome contributions regarding the questions in this paper from those involved in these fields.

16. We are keen to be informed of good practice with regard to the evaluation of costs and benefits, and of judgements made in weighing these, amongst researchers themselves and also in the work of the ethical review process. We hope to hear from those involved at all levels, from those funding and/or regulating the work to those carrying it out. We hope to learn how they ensure that decisions in this area are fully and carefully considered in the light of all relevant concerns, and are furthermore, transparent and open in setting out the path which has been followed in reaching them.

17. We are particularly keen to learn how ERPs are addressing the sort of questions set out in this paper. We will especially welcome submissions describing procedures aimed at ensuring thorough consideration and appraisal of the costs and benefits of experimental programmes, and of how judgements on their scientific and ethical justification are made.

Conclusion

Please let us have your comments by 28 February 2001. Reply to the postal address above or to *apc.secretariat@homeoffice.gsi.gov.uk*

I will of course be happy to deal with any queries you may have. We will, if asked, disclose the contents of responses to this letter and the identities of respondents. Please let us know if you would prefer us not to do either or both of these things in your case.

We have placed this letter on the APC's website at *http://www.apc.gov.uk*

RICHARD WEST
Secretary

ANNEX

The use of animals in medical research – an example

1. Whatever one thinks of the ethics and validity of animal experiments it is clear that some aspects of animals are at least similar to man. For instance the heart of all mammals is a pump that contains four chambers and the exit from each chamber has a valve. Blood is brought into the heart by veins and carried away by arteries. The pressure maintained by the heart in all mammals – man included – is about 100 mm mercury.

2. The hearts of other orders of animal are distinct. For example those of crabs only have one chamber. Therefore it appears more useful to use the heart of any mammal to model the heart of a human being as a pump than that of a crab. Some elements of particular mammals are more specialised than the same elements in man. For example the ears of rabbits are extremely efficient organs for temperature control whereas in man the ears do not have that function. Some elements of animal structure and function are more directly equivalent to those elements in human beings, while others are less directly equivalent.

3. There are fundamental similarities between all living things which are made up of cells. Each cell has a nucleus. A nucleus controls protein production, the cell is controlled by receptors on the surface and the cell releases agents into the surrounding environment. In order to understand whether the cell or tissue or organ is comparable in the structure or function between species, detailed analysis of the exact function and structure in both man and the lower species must be made. Each case must be judged on its own merits.

4. The biological structure and function of organisms is determined by genes within chromosomes in the nucleus of the cell. An analysis of the similarity or difference of genetic make up of two organisms gives us some idea whether an organism might be a more or less appropriate model for understanding the human structure and function. The gene determines particular aspects of the animal, for example the structure of a protein. A gene in one species can give rise to a protein which is exactly similar to that in another species. Even if that protein has a slightly different structure it may have the same function in the two species.

5. It can be said that in terms of their genes apes are 99% equivalent to human beings. Even a worm shares 36% of its genes with human beings. This implies that as long as the differences between animals and humans are understood they might give useful information about the structure and function of the human body. As one moves towards worms more care in extrapolation is required, but a recent study of the genome of the worm C. elegans has produced extensive information about how the genomes of all species might function.

6. An example of how the study of cells in different species of mammals might help understand disease in man is found in a study of the platelet. The platelet is a small cell that circulates in the blood whose job is to stop bleeding when an artery or a vein is punctured. Inappropriate activation of this system of stopping bleeding can lead to thrombosis of a vessel and its consequent occlusion. This leads to heart attack or stroke. As often in medicine one finds that an inappropriate activation of an important function (like stopping bleeding) leads to a human disease (like thrombosis). Platelet volume distribution is an important physiological parameter in that it is similar in all mammals from the mouse to man and that it is unlike any other cellular volume distribution found in any cell in any species.

7. Animal studies have shown that larger platelets are more "sticky" and therefore more likely to produce thrombosis. This led to the finding that in men with heart attack the volume distribution curve is shifted to higher values. The understanding that the nature of the shift in the human platelet volume distribution curve can be analysed in animals brought about an advance in our understanding of the events that might precede a heart attack. The reiterative experimental process in animal experiments produced results that allowed new human experimentation to be performed. Those human experiments again gave rise to new animal experiments.

8. This process of reiteration between animals and man in understanding platelet physiology and pathophysiology was only possible because of the similarity on many parameters in the nature of platelets in all mammals.

ANNEX G

The Committee's consultation letter on Openness

Animal Procedures Committee
Room 978, 50 Queen Anne's Gate
London SW1H 9AT

0207 273 2915 or 2770

apc.secretariat@homeoffice.gsi.gov.uk

13 January 2000

Dear reader

CONSULTATION PAPER ON OPENNESS AND ANIMAL PROCEDURES

This paper seeks your views on the application of openness to the use of animals in scientific experiments or other procedures. We will use the responses which we receive to advise the Government on this issue as the current Freedom of Information Bill goes through Parliament and thereafter.

2. The paper begins with some background information. We then set out the issues, and some options for change. We welcome comment on all of this. But you may find it helpful to focus on the alternatives which are set out in paragraph 21.

Background – Government policy on openness

3. The Government is committed to a radical change in people's ability to participate in public decision making and the exercise of the State's powers. Its policy is based on:

The assumption that information should be released except where disclosure would not be in the public interest

Government Background Paper to the Freedom of Information Bill

Background – the legislation

4. The Animals (Scientific Procedures) Act 1986 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.

5. Licences under the Act are issued by the Home Office on behalf of the Home Secretary. They may only be issued if the benefits outweigh the likely adverse effects to the animals concerned. No reasonably practicable alternative not involving animals must be available. The Home Office's Animals (Scientific Procedures) Inspectorate examines all applications and provides professional advice on them.

6. Section 24 of the 1986 Act relates specifically to the release of confidential information about animal procedures. It makes it an offence for anybody *'otherwise than for the purpose of discharging his functions under the Act'* to disclose information about animal procedures which the person who provided it has given in confidence. The future of this section of the Act is a key consideration in the debate on openness in animal procedures.

Background – the Animal Procedures Committee

7. The Animal Procedures Committee (APC) provides the Home Secretary with advice, independent from the Home Office and its Inspectorate, about the legislation and his functions under it. The Committee consists of experts from a wide variety of backgrounds.

8. By law, the APC must take account of both the legitimate requirements of science and industry and the protection of animals against avoidable suffering and unnecessary use in scientific procedures.

Applying the Government's new approach on openness to animal procedures

9. Much public concern has been expressed about what is perceived as the secrecy of the procedures for the licensing and conduct of animal procedures.

The reasons for animal procedures

10. Many people believe that animal experimentation is necessary to benefit mankind

- by researching causes and treatments for diseases
- by performing risk assessments on new medicines
- by testing new and existing products to minimize harm to humans.
- and cannot be replaced by non-animal alternatives.

11. It is nonetheless agreed that animal welfare is a matter of very great concern, and the Animals (Scientific Procedures) Act seeks to ensure that, as well as being justified by the balance of benefits and burdens, all experimentation is subject to principles of reduction, refinement and replacement.

The Case for Greater Openness

12. Some feel, however, that

- repetitive or otherwise unjustifiable work is authorised
- licensing conditions do not ensure that animals live as far as possible in conditions which respect their nature
- licensing conditions do not ensure that the procedures involve the minimum of suffering
- compliance with licensing conditions, such as those relating to living conditions and conduct of procedures, is not adequately enforced
- such breaches of conditions as do come to light are not viewed by the authorities sufficiently seriously
- no effective mechanism exists to ensure that the potential benefits derived from the harm inflicted are actually realised.

13. Those who have the above concerns tend to feel that greater public access to information about the operation of the system and treatment of animals would make possible more effective public scrutiny. Such scrutiny would lead to worthwhile improvements for affected animals. At present even members of the APC have access only to the most limited amounts of information.

14. Others who argue in favour of greater openness take a different line. Their argument is that there are no serious defects in the current arrangements for the welfare of animals used in experiments, and that the problem lies in the public's (mistaken) perception that there are. Every reassurance from or about the Home Office's Inspectorate is met with the response that 21 Inspectors cannot begin adequately to protect the animals involved in two million procedures a year. Those who support this argument are, however, unable to present the information which would justify their position because of the current restrictions on access to information about animal procedures.

The Case against Greater Openness

15. An argument against greater openness would be that, whatever criticisms may have been justified in the past, the present system and culture ensures that the welfare of laboratory animals is properly attended to in contemporary scientific practice.

16. Researchers and toxicologists should not have to face public criticism or even physical assault just for doing their important jobs. Commercial organisations should not have to make available information which might cause them patent problems or would save their competitors from the trouble of doing research for themselves.

17. The public has no need to know more because there is nothing to which any reasonable person would object if he or she became aware of it.

The Animal Procedures Committee

18. The Animal Procedures Committee indicated in its Annual Report for 1997 that it would be considering the practical implications of a balanced application of *"the principle of openness concerning the use of animals in scientific procedures"*. The Committee advised the Home Office's Freedom of Information Unit in 1999 that *"the overall presumption should be that information provided to the Home Office in the course of licensing scientific procedures on animals is disclosable on demand"*

19. It is important that it advise the Home Secretary early in 2000 as new legislation is being considered by Parliament. The APC Openness Working Group seeks the views of interested individuals and bodies on the issues.

20. We invite respondents to consider particularly the practical issues involved in a balanced application of the principle of openness in relation to:

- details of licence applications
- contents of the Inspectorate files
- Inspectorate advice to the Home Secretary
- results of research
- compliance monitoring and enforcement
- proceedings of the Animal Procedures Committee
- Local Ethical Review Processes (LERPs)
- application of alternative methodologies and compliance with principles of reduction, refinement and replacement

21. Respondents may find it convenient to express views on the following possibilities:

OPTION A: Full information is made available about all the above matters

This would provide the fullest benefits which access to information can offer. It might, however, expose individuals to risk of public criticism or attack. It might also prejudice the financial interests of commercial organisations whose trade secrets were revealed.

OPTION B: Full information is made available about all the above matters with the exception (on demonstration by affected persons of prejudice from disclosure outweighing public interest in disclosure) of information revealing:

the identity and addresses of individuals

This would protect individuals from attack but would otherwise have the same benefits and disadvantages as Option A.

OPTION C: Full information is made available about all the above matters with the exception of information (on demonstration by affected persons of prejudice from disclosure outweighing public interest in disclosure) revealing:

the identity and addresses of individuals or
potentially patentable material before it is made public through the patent process or
information about investigations into non compliance before completion thereof.

This would protect individuals from public criticism or attack and commercial organisations from financial loss through exposure of trade secrets but achieve only some of the benefits of openness.

OPTION D: Full information is made available about all the above matters with the exception of information (on demonstration by affected persons of prejudice from disclosure outweighing public interest in disclosure) revealing:

the identity and addresses of individuals or
potentially patentable material before it is made public through the patent process, and any other strategic research and development information of commercial value to competitors; or
compliance monitoring and enforcement

This would avoid emotive exploitation for publicity of unusual occurrences but would provide fewer of the benefits of openness than Option C.

OPTION E: Full information is made available except in relation to matters which have been the subject of a requirement from affected persons for confidentiality

This would provide maximum protection for individuals and commercial organisations. It would provide few, if any, of the benefits of openness.

22. We suggest that in replying to us you focus on what is desirable *in principle*. We are considering the legal feasibility of, and mechanisms for achieving, these objectives separately.

Your reply

23. Comments on the above issues and options should be sent to APC 'Openness', Room 978, Home Office, 50 Queen Anne's Gate, London SW1H 9AT so as to arrive by Friday 10 March 2000. Or you can if you prefer e-mail us by that date at *apc.secretariat@homeoffice.gsi.gov.uk*. Again please mark your e-mail reply 'openness'.

24. We attach a *pro-forma sheet* which you might wish to use for your reply. You do not need to use this sheet to reply to us, but if you do please briefly fill out the information at the top of the form and tick off which of the options A to E (as described in paragraph 21) you prefer.

25. We will, if asked, disclose the content of responses to this letter and the identities of respondents. Please let us know if you would prefer us not to disclose your name and address.

CHRIS BONE
Secretary

Proforma reply (optional)

Your name _____

Your address _____

e-mail (if applicable) _____

Representing (if applicable) _____

My preference is for Option A

Option B

Option C

Option D

Option E

ANNEX H

The Committee's letter of advice to the Home Office about Openness

ANIMAL PROCEDURES COMMITTEE
ROOM 978, 50 QUEEN ANNE'S GATE
LONDON SW1H 9AT
020 7273 2915 or 2770

From the Chairman
Reverend Professor Michael Banner MA DPhil

Mike O'Brien MP
Parliamentary Under-Secretary of State
Home Office
50 Queen Anne's Gate
London SW1H 9AT

3 January 2001

Dear Mr O'Brien

ANIMAL PROCEDURES COMMITTEE: RECOMMENDATIONS ON OPENNESS

As you know, the Animal Procedures Committee has been carrying out a consultation exercise on openness in relation to the use of animals in scientific experiments. This letter presents you with the Committee's advice on this important subject. Because of the tight timetable I know you are working under, I am not presenting you with the Committee's full report at this stage. However the Committee will in due course publish a full report setting out the basis of our reasoning.

2. The consultation letter was sent out on 13 January 2000 and 2,320 responses were received. A working group of five APC members had eight meetings between March and November to consider the advice which should be offered. The working group submitted two reports to the main Committee at a meeting on 13 December – a majority report, supported by three of the members of the working group, and a minority report, supported by the other two members of the working group.

3. At the meeting on 13 December, I sought a consensus of views. After discussion, the Committee agreed that I should write to you presenting recommendations for Home Office action. After careful consideration, we have concluded that total openness, as supported by a number of individuals' and animal protection organisations' responses, is not practical chiefly because of concerns in relation to personal security, but also because of issues of commercial confidentiality. Our aim however, has been to recommend measures which will lead to the greatest degree of openness compatible with those concerns. The two most important recommendations are those relating to the revisions to project licence applications, and to the publication of results of experiments.

RECOMMENDATION 1: THE PROJECT LICENCE APPLICATION FORM

4. We recommend that the Project Licence Application form should require a summary of the procedures to be undertaken, and that this summary should be comprehensive and detailed enough to provide a reader with a clear indication of the costs and benefits of the project. Such a summary would be perhaps a maximum of two pages, and would be written in language appropriate to the general reader. We recommend that such a summary should include:-

- Key objectives and possible benefits of the project;
- Reasons for the need to use animals; what alternatives have been considered; and why these are not appropriate;
- Reasons for the choice of species and strains;
- Numbers of animals to be used and kept for the specific project;
- What will happen to the animals as a result of the project – a synopsis of the main adverse effects covering the lifetime experience of the animal; including factors such as source, husbandry, procedures and their effects, and eventual fate of the animal;
- Estimated level of the severity of the project;
- Specific measures to minimise adverse effects and improve welfare, including both husbandry and procedures; and
- How the applicant has weighed the costs against the benefits to judge whether the use of animals is justified.

The Committee recognised that there were advantages and disadvantages to whether a summary of a licence application should be made public at the stage when an application was received by the Home Office, or later, at the stage when a licence was granted. If the application were made public at the earlier stage:

- it would give members of the public time to comment before a licence was granted, so that they could seek to influence the decision making process;
- animal protection organisations might be able to refer to possible alternative procedures which had not been considered;
- sight of applications which were ultimately turned down would allow the public to see that the licensing process was sufficiently rigorous.

6. On the other hand, it was also suggested that making an application public before the licence had been granted:

- would hamper the iterative process of discussion which goes on between the Home Office and applicants;
- as applications are progressively developed by that iterative process, more than one version of a changing application would have to be made public;
- until a licence is granted, the procedure has not been subject to an exercise of governmental judgement, and therefore should not be made public.

7. I hope that when the Home Office considers the stage at which a summary of a project licence application should be made public, the advantages and disadvantages of both options will be taken into consideration.

RECOMMENDATION 2: PUBLICATION OF RESULTS

8. Positive outcomes of experiments are usually published in open scientific literature, but projects which yield no useful results, or fail to prove a project or principle ("negative results") are seldom written up –

this is true, in particular, of basic medical research. Failure to publish such results could lead to unnecessary repetition of animal experimentation.

9. Mechanisms for making available information on both positive and negative research outcomes would differ depending on whether the research was basic medical research or commercial research. One possible mechanism for basic medical research could be to record on the ABCU website the results achieved or an explanation of why the project was abandoned. The effort this would entail should not be underestimated and would contribute little to academic progress. Another possibility would be to publish interim reports on grant-funded research. In the commercial sector, the position is not simple. Negative results are rarely published, and for reasons of commercial secrecy even positive results are not published until a patent application has been lodged. If a new medicine fails to reach the market neither positive nor negative results may ever be published. In such circumstances the process of assessing the release of any information will involve commercial lawyers more than scientists, and it will be a lengthy, complex and iterative procedure. Because of these problems, we recommend that a more detailed investigation of a workable process should be undertaken.

10. The Committee recognised that this was a particularly difficult and complicated area. However, the Committee urges you to commission further examination of possible mechanisms for publishing negative results, as the development of a satisfactory system could result in a reduction of nugatory experiments.

RECOMMENDATION 3: NO RETROSPECTIVE AMENDMENT TO SECTION 24

11. Any change relating to animal experimentation should not be retrospective. We recognised that because a Project Licence lasts only five years, changes to the disclosure of project licence information would be fully achieved in that time scale.

RECOMMENDATION 4: INCREASED OPENNESS REGARDING INFRINGEMENTS

12. Summaries of major infringements are considered in an anonymised form by the APC, and discussed at Committee meetings. In the case of a more serious infringement a detailed anonymised account is supplied. We believe that information of this kind should be more widely available and we would be willing to publish this material as an appendix to our annual report.

RECOMMENDATION 5: INCREASED OPENNESS IN STATISTICAL REPORTING

13. Annually, a statistical report on animal experimentation is published, available from HMSO. We recommend that the usefulness of the information in that report should be improved. For example, it should include numbers of animals kept for experimentation in addition to the existing statistics, which detail only numbers of animals actually used in experiments. We also recommend that the report should include details of the severity of experiments. This would assist the public to come to an informed view.

14. Although an annual statistical report is produced, there is no annual report of other areas of the work of the Inspectors. We recommend that there should be such an annual report, which might cover areas such as visits to establishments; the results, number and type of licences processed; and the outcome of research renewal applications.

OTHER RECOMMENDATIONS

15. You will also wish to be aware of other recommendations which the Committee agreed, although they are for the Committee itself to pursue, rather than the Home Office.

RECOMMENDATION 6: ADDITIONAL VOLUNTARY OPENNESS

16. To assist public debate the Life Science institutions should be encouraged to open their facilities to the responsible public.

RECOMMENDATION 7: APC INVOLVEMENT IN SPECIAL INVESTIGATIONS

17. We note that APC minutes are placed on the APC website. In the same way, where the APC discusses a report by an APC working group carrying out a "quality assurance audit" of an investigation by the Inspectorate, that discussion, the report of the audit working group and the Inspectorate report should all be made available on the web, suitably anonymised.

RECOMMENDATION 8: APC INTERACTION WITH OTHER BODIES

18. The APC should have a programme of regular interaction with other committees, representative bodies and pressure groups in the UK and overseas. This would be for two purposes: to educate and inform members of the APC; and to achieve a mutual and reciprocal educational and information process with other relevant influential bodies. In the UK this would include bodies such as the House of Lords select committee on animal experimentation, the Agriculture and Environment Biotechnology Commission (AEBC), the United Kingdom Xenotransplantation Interim Regulatory Authority (UKXIRA), and representatives of users and animal protection organisations. The aim of international co-operation would be to contribute towards the development of international Freedom of Information legislation relating to animal experimentation, especially within the European Union.

19. On behalf of the Committee I commend these recommendations to you. I hope that our advice will prove helpful to your consideration of this difficult subject.

Yours sincerely

MICHAEL BANNER

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