

Report of the Animal Procedures Committee for 2002

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

*Ordered to be printed by the House of Commons
16 October 2003*

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ANIMAL PROCEDURES COMMITTEE

Membership as at 31 December 2002

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

John MARTIN MBChB, MD, FRCP, FESC – Professor of Cardio-Vascular Medicine, University College, London

Robert McCracken – Barrister

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

Graham MOORE BVM&S, MRCVS, CBIOL, MIBIOL, FRSH – Veterinary Consultant, Science Policy & Scientific Affairs, Pfizer Global Research & Development

Timothy MORRIS BVetMed PhD CertLAS DipACLAM DipECLAM CBIOL FIBIOL MRCVS – Head of Comparative Medicine and Investigator Support, Department of Laboratory Animal Science, GlaxoSmithKline

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

Secretariat

Mr Richard West

Ms Sara Bacon (to 9 August 2002)

Mr Gary Earle (from 7 October 2002)

Ms Kate Horrey (from 15 January to 15 July 2002)

Mr Philip Brenner

CHAIRMAN'S LETTER TO THE RT HON DAVID BLUNKETT MP, SECRETARY OF STATE FOR THE HOME DEPARTMENT AND TO ANGELA SMITH MP, THE NORTHERN IRELAND MINISTER OF HEALTH, SOCIAL SERVICES AND PUBLIC SAFETY

I have pleasure in presenting to you the Report of the Animal Procedures Committee for 2002.

The Report provides an account of the Committee's varied activities during the year. Sometimes the Committee finds itself engaged in careful and detailed consideration of specific applications or infringements; at other times (such as in the production of its report, 'The Use of Primates Under the Act'), it attempts to discern wider patterns and trends, and to think strategically about the future. At all times, its concern is to provide a critical review of work in this area and of its regulation.

I hope that the Committee's work will continue to contribute to the thinking of Ministers about the development of policy and practice.

Yours sincerely

Michael Banner

INTRODUCTION

This report describes the work carried out during the year 2002 by the Animal Procedures Committee.

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

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

Besides these statutory sources of our work, like any public body, the Committee also responds to outside events.

3. Our actions during 2002 reflect these different sources. For example, our regular work advising the Government on particular issues referred to us included

- giving advice on particular applications for project licences;
- advising on the suitability of overseas sources of primates; and
- reviewing the legislation relating to permissible means of euthanasia.

4. Some external events which occupied us in 2002 included the report of the House of Lords Select Committee on Animal Experimentation. In addition, we examined the Home Office responses to allegations made by animal protection organisations.

5. Prompted partially by external events, and partly by our members' awareness of the use of animals in scientific procedures, we identified several issues that the Committee wanted to examine. These included the Housing and Husbandry of animals, and how the 1986 Act is enforced and compliance ensured.

6. This report describes our actions through 2002. We achieved much, although not as much as we would have liked.

7. Annex A to this report sets out some background information about the Committee, including its legislative background, the Ministers it reports to and its membership. On joining the Committee, members agree to be bound by a Code of Conduct which appears at Annex B. Among other things this requires them to '*declare any personal or business interest which may, or may be perceived (by a reasonable member of the public) to influence their judgement*'. The register of members' interests for the year 2002 appears at Annex C. The full Committee met five times during 2002, and in addition there were numerous sub-committee and working group meetings. As in previous years we also held a weekend conference. The annual weekend conference is an additional and useful forum for learning and discussion. Annex D sets out members' attendance at main meetings of the Committee during 2002. Annex E details the membership of the Committee's sub-committees and working groups.

THE COMMITTEE'S WORK DURING 2002

Applications

8. By convention, the Secretary of State refers to the Committee applications involving:

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

In addition, any licence application outwith those four categories may be referred to the Committee if it raises novel policy issues or other concerns. During 2002 the Committee considered four applications. One involved non-human primates in procedures of substantial severity, and three involved microsurgery.

9. The aims of the project involving primates were to use marmosets treated with MPTP as a model of Parkinson's Disease (PD), to elucidate the roles of specific brain pathways and neurotransmitter abnormalities in the movement disorders of PD and of L-DOPA induced dyskinesia (uncontrollable movement), and to assess new therapeutic approaches based on those findings. We were told that the new information on the role in PD or dyskinesia of particular drug applications might represent a significant advancement of biological science and make a significant contribution to the scientific literature. Application of that new knowledge to a clinical setting might make a significant contribution to improved management and treatment of PD, which affects about 1% of over 60s and about 3% of over 80s. Some initial studies in humans had already shown potential.

10. The application was discussed at our meeting in April. A preliminary discussion by our Primates sub-committee had identified several initial questions, and we were grateful to the applicants for providing comprehensive answers to them. Nevertheless, the Committee found the application difficult to assess. After a long discussion we decided by a majority vote to recommend that the application should be granted if particular reassurances were obtained. The Chairman wrote to the Minister setting out the Committee's concerns in detail. For example, we suggested that besides assessments of the animals' physical welfare, psychological welfare should also be measured and monitored. Also, we advised that to aid clarity the evaluation and alleviation of psychological and physical harms be shown by means of tables, noting endpoints, harms, and how they might be alleviated. The Minister replied with comments on our concerns. For example, he told us that the applicant had agreed to revise the text describing the psychological and behavioural adverse effects of the experimental procedures, their incidence and proposed methods of prevention or control, and to use a table format. The Minister agreed with our majority recommendation that the application should be granted. Copies of the Chairman's letter and the Minister's reply are at Annex F.

11. The Home Office routinely refers licence applications for microsurgery training to the Committee. Prior to the 1986 legislation, the use of animals for the purpose of attaining manual skill had been prohibited (Cruelty to Animals Act 1876 section 3(6)). Since the 1986 Act microsurgical training can be granted a licence, but in 1986 the then Government advised that all such applications would be sent to the APC for advice before a licence could be granted. The current Government has maintained this policy position.

12. All three microsurgery applications referred to the Committee in 2002 involved the use of anaesthetised rats. At the end of the procedures the rats would be humanely killed without recovering from the anaesthetic (“terminally anaesthetised”). In our annual report for 2000 we reported that we had 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 microsurgical 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, while useful in teaching techniques, do not fully mimic all the features of living tissue, such as clotting or the effects of surgical error. There is considerable demand for microsurgery courses nationally. The techniques taught include training in surgical techniques on blood vessels of less than one millimetre in diameter, and are used in medicine and veterinary science for such purposes as reconstructive surgery. During our consideration of these applications we were reassured to learn that the training courses were structured so that instructors were able to identify poor performers before they commenced working with live animals or human patients. After short discussions in each of the three cases the Committee recommended granting the licence applications.

13. At its meeting in April the Committee had a general discussion about applications. Paragraph 8 lists the categories of application which are currently referred to the Committee. Our discussion stemmed partly from our experience of the applications for microsurgery, where most members considered that the benefits very clearly outweighed the costs to the animals in all three applications. The feeling was that the Committee might be better employed examining other types of application. We asked ourselves whether the types of applications that the APC were expected, by convention, to see were in fact the most important. We also wanted to examine what value was added by the Committee’s involvement. There were a variety of views of this subject. Several members felt that the current practice was flawed and could be improved. There was some debate as to what kind of advice the Committee was expected to provide, and some members felt that a more strategic approach could be taken to specific kinds of project applications rather than looking in isolation at each application referred to the Committee. Questions were also raised about whether the Committee could properly consider the ethical, scientific and technical merits of some applications and whether work by the applicant’s Ethical Review Process, the Home Office and the APC was being duplicated. Some members suggested that the APC should have greater access to a wider range of applications. For example, there was concern that compared with the applications currently referred to the Committee there might be applications that the Committee did not see that could involve more animals, or more suffering, or where the benefits might be more contentious or harder to ascertain. It was also suggested that more information on the Secretary of State’s response to APC recommendations would be useful. We were also aware that referral of an application to the Committee added to the time taken to process the application, and that the Committee did not have the time or the resources to see more than a very small number of applications.

14. We agreed that it was important for the committee to decide both what types of applications it might wish to see and how it would consider them. A working group was set up to consider this issue further in the light of the points made, and to provide a paper for discussion at a future meeting. The membership of the working group was agreed as Professor Purchase (chair), Professor Banner, Dr Hubrecht, Dr Langley and Professor Richardson.

15. The working group met twice during the year, on 26 June and on 3 September. After the first meeting, Professor Purchase resigned from the working group in view of his impending retirement from the APC, and the chairmanship was taken by Professor Banner. At its first meeting, the working group agreed that its remit should be “to advise the APC about what project licences it might wish to see and how it should consider them.”

16. The working group presented a paper at the Committee’s meeting in October. There was some agreement that the Home Office should cease the automatic referral to the APC of some of the types of

applications currently referred to it by convention, especially those involving microsurgery. As paragraph 11 above shows, microsurgery applications are referred to the APC for historical reasons, because the 1986 Act for the first time allowed the acquisition of manual skills on live animals. In all the microsurgical applications the Committee has seen the severity band has been unclassified, because the rats used are not allowed to recover from anaesthetic. Most APC members were satisfied that this work is of vital importance and that the skills could be acquired in no other way. We added little or no value to those applications, and we thought it was not a good use of the Committee's time to review them. There was also agreement that the APC should continue to see applications which raised novel or problematic trends and issues. However, there was no clear consensus about other issues. For example, should the Committee see applications of substantial severity for species other than non-human primates? Were severity levels the best means of identifying applications to be seen by the Committee? In the light of the discussion the working group was asked to consider the issues further and report back to the Committee. We will report on further progress in next year's annual report.

House of Lords Select Committee on Animals in Scientific Procedures

17. In our last report we described how the Chairman and several other members of the Committee had given oral and written evidence to the Select Committee. The Select Committee's report was published in July 2002, and at our October meeting the Committee held a preliminary discussion on some of the recommendations. We noted that the Committee was not obliged to comment on the report, but that any comment would need to be made before November in order to have any chance of influencing the Government's response. The Chairman invited the Committee to comment on two particular recommendations. He suggested that the Committee should put on record:

- as currently constituted the Committee was not equipped to carry out the detailed role of monitoring the Inspectorate that the report appeared to envisage; and
- that the Committee welcomed the recommendation that the Secretariat be strengthened in order to cope with the demands of the Committee's work, but considered that further separation of the Secretariat from the Home Office was not necessary.

18. The Committee agreed that it might wish to comment further after the Government had announced its response to the Select Committee's report. In the meantime, the Committee agreed that the Chairman should comment as suggested on the two recommendations identified (paragraph 17), but there was general agreement that further comment should be made on several other points, as follows:

- The Committee believed that its research budget was well spent, as the Research and Alternatives sub-committee was well placed to identify worthwhile projects. That budget should therefore be retained by the APC, unless the Government also accepted the parallel recommendation that a Centre for the three Rs be introduced. The Committee also welcomed the Select Committee's recommendations relating to initiatives by Government to increase research into alternatives to the use of animals.
- The Home Office should be reminded that the Committee's "miscellaneous" recommendations had included a recommendation that Members should be paid. This mirrored a similar recommendation by the Select Committee.

The Chairman wrote to the Home Office as suggested. A copy of his letter is at Annex G.

19. At our December meeting we noted that the Home Office, in conjunction with other Government departments, was collating the Government's response to the report and hoped to be ready to publish this shortly. During our annual conference, members had expressed views that might be of interest to the Government in preparing its response. The Chairman suggested that the Committee might wish to offer thoughts to the Home Office on two other recommendations of the Select Committee:

- The APC should examine whether farm animals were satisfactorily regulated by the Act.
- Visiting scientists and students should be allowed to work under the licences of established licence-holders.

Although it was understood that it was too late to influence the Government's initial response to the House of Lords recommendations, it was agreed that the Committee should still offer its views on these two recommendations. We will report on this further in our next annual report.

Infringements

20. The Home Office provides us with an annual report of infringements under the 1986 Act. At the April meeting, the Home Office produced its report covering November 2000 to December 2001 and it was noted that there had been 20 "Class Three" (the most serious) infringements during that period. The Home Office agreed to the Committee's request that they could produce more detailed information in future annual reports, including which species were involved in each of the infringements. It was further noted that as a remedial measure, the Home Office had recommended training in several of the cases listed.

21. At our February meeting, the Committee discussed its current practice for monitoring infringements. The Home Office agreed that in addition to the annual report on infringements we would receive individual reports on any infringement that impacted negatively on animal welfare as soon as Home Office action on the infringement had been completed.

22. One such serious infringement was reported to the Committee at its meeting in October. This involved music being played to over 200 mice dosed with metamphetamine. Some of the mice were said to have suffered "seizures" and at least 19 of them died as a result of the procedures. The study arose from a larger programme of work conducted as part of a licensed project concerning Huntington's disease, but it went beyond the procedures covered by the licence authorities. The infringement had come to light through the publication of a scientific paper on the work. As a consequence of the infringement, the project licensee had been admonished and required to undergo training; a personal licence holder had been admonished; and the certificate holder was asked to remedy defects in the record keeping systems in the department concerned. An admonishment is one of a range of sanctions available to the Home Office when an infringement is identified. Often, as in this case, it can include a requirement for further action to correct perceived deficiencies, such as additional training or altered management practices. The Committee is always concerned to learn of any infringement, but was particularly concerned about this case. It asked whether some of the lessons learnt could be more widely disseminated, perhaps in a circular to Certificate Holders, or reported on the Home Office web-site, suggestions which the Home Office agreed to consider.

23. Two further infringements, both of which had compromised animal welfare, were reported at our December meeting. The first involved a review of records at a designated establishment, and had been undertaken by the Inspectorate. This had revealed that two sheep destined for regulated procedures had been found to have problems with abnormal horn growth. This had resulted in both cases in an immediate welfare problem and had prevented the continued use of the sheep under project licence authority. The local Inspector had considered that these problems could have been identified and dealt with at an earlier stage, and that proper provision had not been made for the care of these animals. The matter had been mistakenly categorised as a Class 1 infringement and dealt with locally rather than being referred "up the line" as a Class 3 infringement. Class 1 infringements are dealt with by letters to those involved, requiring that appropriate remedial action be taken and indicating that future similar lapses will be dealt with more severely. In this case written confirmation had also been obtained from the certificate holder of the improved local processes designed to prevent recurrences. Further action was not deemed appropriate, but the Inspector had been reminded of the correct procedure for dealing with infringements that impacted adversely on animal welfare.

24. The second infringement was felt by some members of the Committee to be of extreme concern. A rat scheduled for humane euthanasia had instead inadvertently been left in its home cage, and had remained there for over five days without access to drinking water. The establishment had re-organised its procedures to minimise the likelihood of re-occurrence. The licensees involved received letters of admonition and the Certificate Holder also received a letter of admonition, with conditions attached to the certificate to require further evidence of administrative and procedural improvements within a specified period. Some Committee members expressed surprise at what they considered the relatively mild level of the sanction imposed in this case, and felt that prosecution should have been contemplated. We noted that prosecution would normally result from the Home Office referring a case to the police, who in turn would consider whether to refer it to the Crown Prosecution Service for a decision on whether to proceed. In this case the Home Office view was that there were factors, including evidential problems, militating against such a course.

Enforcement and Compliance

25. At the 2001 APC weekend conference the Committee discussed how enforcement of, and compliance with the 1986 Act is ensured. In 2002 at our February meeting we identified and discussed three key issues. Those were:

- informing the public about existing controls;
- exploring how prosecution decisions were reached; and
- ways to encourage the reporting of infringements.

26. Statements by some members of animal protection societies and by other members of the public and the media reveal a lack of knowledge of the extent and rigour of methods used to enforce the 1986 Act. Although the information is publicly available, the roles of the Home Office Inspector, the Licence holder, the Named Animal Care and Welfare Officer, the Named Veterinary Surgeon and the local Ethical Review Process seem seldom to be appreciated. We consider that there is a need for further information to be promulgated about the controls and regulations for animals used in scientific procedures. When the controls are described to members of the public, their concerns tend to be reduced. We note that some of this information is already available on the Home Office website and that the site has recently been improved to improve ease of information access. Although we agree that there is a need to further improve public information, we consider that industry and academia are better placed to take forward the task than this Committee or the Home Office.

27. The 1986 Act provides for penalties of up to two years imprisonment for certain infringements under the Act. Some members of the public (and some of our members) express concern that penalties for infringements, even those in which animal welfare has been seriously compromised, are too mild. In particular, there seems to be a belief that not enough prosecutions take place, and that this is because of failings by the Home Office. This latter concern is based on a misconception. The Home Office told us that offences that might in their view merit prosecution would be brought to the attention of the police. The police have responsibility for the investigation of possible offences, in co-operation with the Crown Prosecution Service (in England and Wales); by Procurators Fiscal (in Scotland); and by the Public Prosecution Service Northern Ireland. A case so referred will ultimately, if taken to that point by the police, be reviewed by the relevant prosecuting authority. As with any other case, a prosecution for an infringement amounting to a criminal offence under the 1986 Act proceeds only if

- there is enough evidence to provide a realistic prospect of conviction, and
- it is considered to be in the public interest to proceed with the case, based on the seriousness of the offence and the circumstances of the offender.

It is rare for a case to appear to meet the Crown Prosecution Service's criteria for bringing a prosecution in the public interest. The Home Office considers that the lack of prosecutions reflects more the high standard of compliance on the part of the scientific community, rather than defects in the regulatory system.

28. We are aware that many infringements come to light by "self reporting". That is, establishments discover an infringement themselves, and report it to the Inspectorate. When we discussed this, some members of the Committee had concerns. They felt that members of staff might feel inhibited from raising issues within their organisations. However, other members working in organisations using animals in scientific procedures told us that in their experience members of staff felt comfortable about raising any concerns. To assist members of staff who might feel inhibited about raising concerns internally, an establishment may designate a particular member of the Ethical Review Process as the person who may be contacted by a member of staff with such an inhibition.

29. Some of our members considered that enforcement was an area where it could be counter-productive to be too prescriptive. We noted that there were parallels between enforcement and compliance relating to animal scientific procedures and to the enforcement of Health and Safety legislation. As with the Home Office's approach to ensuring compliance with animal experimentation legislation, the Health and Safety Executive seek to improve safety performance through engendering a positive attitude of self-interested compliance. We learnt that the Home Office adopts an approach which seeks to ensure that standards are maintained by self-regulatory behaviour where possible. This follows principles formulated by the Government's Better Regulation Task Force, which developed an Enforcement Concordat, to which enforcement bodies such as the Home Office Animal Procedures and Coroners Unit and the Inspectorate commit themselves.

30. We noted with interest the information we had gathered about enforcement and compliance, but were not persuaded that it would be the best use of our resources to devote further resources to this issue. We hope that the information about enforcement and compliance set out here will inform public opinion.

Biotechnology issues

31. Our annual report for 2001 included our report on Biotechnology as an annex. We sent the report to the Home Office in July 2001. In 2002 the Home Office provided comments on the report. The Minister's letter noted that the majority of the recommendations reflected current policy, and commented specifically on 11 of the 24 recommendations. When we discussed this response at our meeting in October, concern was expressed, particularly from the members of the Biotechnology working group, that the response did not appear adequately to respond to all recommendations put forward in the report. The Chairman wrote to the Minister expressing those concerns. A copy of the Home Office initial response and the Chairman's letter are at Annex H. We will report on the Home Office's response to the Chairman's letter in our next annual report¹.

32. The Committee had recognised that some of the recommendations in the Biotechnology report were not exclusively for the Home Office to take forward, for example, recommendation 8 ("The APC, possibly with others, should consider the commissioning of a project to examine how to assess the welfare of transgenic animals, especially mice."). We wanted to encourage the evaluation of currently available research on genetically modified animals and investigate the possibility of commissioning further research. We therefore contacted the Medical Research Council, the Biotechnology and Biological Services Research Council and the Wellcome Trust and convened a meeting to discuss taking this forward. Two meetings took place, and were chaired by Dr Hubrecht. Representatives from DEFRA and from Cancer Research UK also attended. These discussions resulted in a proposal that a Transgenic Animal Welfare Assessment Committee (TAWAC) be set up. The MRC's Centre for Best Practice in Animal Research confirmed its willingness to take on a co-ordinating role. We were grateful to all the organisations involved for working together to progress these important issues. The terms of reference for TAWAC were agreed as follows.

¹ A further letter from the Minister was received on 4 February 2003. This is discussed in the minutes of APC meetings in 2003, which can be found on the APC website – www.apc.gov.uk.

BOX 1

TERMS OF REFERENCE OF THE TRANSGENIC ANIMAL WELFARE ASSESSMENT COMMITTEE

Objectives

To develop methods, agreed between the principal funding bodies, for practical means of carrying out initial screens of transgenic animal welfare for new strains, and practical cage side assessments of existing strains. The remit covers all transgenic animals*, but will initially concentrate on transgenic mouse welfare.

Terms of Reference

1. To these ends it will establish various working groups to evaluate existing information regarding practical assessment of transgenic animal strains and;
2. If the information is sufficient it will publish guidelines on agreed/appropriate methods for initial screens and scoresheets or similar for continuing assessment of welfare;
3. It will identify gaps in knowledge and if necessary recommend to funding bodies that they commission or invite research to fill these gaps;
4. The committee will investigate the feasibility of establishing a database to record adverse effects and necessary husbandry details;
5. The committee can modify its terms of reference, if required, to reflect welfare concerns brought about by new technologies.

** The committee will consider the welfare of all animals produced by transgenics and mutagenesis and all other animals whose cells have been genetically manipulated.*

Housing and Husbandry of animals

33. Matters relating to the housing and husbandry of laboratory animals arise in a number of contexts during the work of the APC. In recent times, this has included requests for the Committee's comments on Home Office Codes of Practice under development (such as the Codes of Practice for housing and care of ferrets and gerbils, and for transgenic pigs); and discussion of concerns about husbandry and care for certain species at particular establishments. The latter formed part of the substance of recent allegations by animal protection organisations. Several of the Committee's working groups have also identified husbandry and care as an important issue to address, notably within the Primate sub-committee and the Biotechnology working group. In addition, many of the responses to the cost/benefit consultation document that the Committee received emphasised the importance of improving standards of husbandry and care as a means of reducing harms to animals, and this is certainly a point to which the Committee itself gives weight when reviewing project licence applications. Another important consideration is that the Committee has noted variations in standards of husbandry and care at the establishments it has visited. Although none have been operating below the minimum standards in the Home Office Codes of Practice, it is clear that some make more effort to improve upon these basic standards and provide animals with a good quality of environment, than others. It is also the case that the impact of housing and husbandry can have an equal or greater effect on an animal than the scientific procedures carried out.

34. We discussed these issues at our meeting in April. It was agreed that a working group chaired by Dr Hubrecht, with Professor Broom, Dr Jennings and Dr Morris would consider the best way forward and

bring proposals to the main committee. The working group reported to the main Committee at our June meeting, and identified the following housing and husbandry issues:

- the need to improve on current best practice and implement what is already known about animals' husbandry and care requirements more effectively;
- how increased and properly targeted funding of research into animal welfare to define good standards might be stimulated, and research co-ordinated to achieve more;
- the training and motivation of animal care and other staff.

35. The working group suggested that the APC needed a mechanism for developing policy on the above issues, as well as for coping reactively with issues brought to its attention. The working group saw merits in establishing a sub-committee to deal with specific tasks. It was also felt that the group could be immediately convened to develop policy and APC activities on issues such as encouraging best practice. The sub-committee would immediately examine housing and husbandry policy issues, and could then be activated to address any other issue that might arise.

36. The Committee considered it important that the proposed new group should not duplicate work being performed by other working groups. It agreed that the working group, its membership augmented by Mr Gregory, should become a sub-committee, with the following terms of reference:

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

Review of Schedule 1 of the Animal (Scientific Procedures) Act 1986

37. As described in our annual report for 2001, in June of that year the Home Office asked the Committee to carry out a review of Schedule 1 of the 1986 Act, which sets out the appropriate methods of humane killing for different animal species. A working group comprising Mr Gregory (Chair), Professor Broom and Dr Morris was established. An animal facilities manager from the University of Manchester was co-opted onto the working group to provide additional technical input. During 2002 the working group carried out informal consultation with animal technicians. It also commissioned a literature search on the use of CO₂ and other gases; and on the use of decapitation of neo-natal rodents. The literature search was carried out by the Cambridge University Animal Welfare Information Centre. It was funded by a Home Office grant on the recommendation of our Research and Alternatives sub-committee.

38. The working group made a preliminary report to the main Committee at its December meeting. The only emerging recommendation was for an amendment to Schedule 1 to permit the euthanasia of neonatal rodents (up to the age of seven days) by decapitation. The decapitation of foetal rodents was already permitted under Schedule 1. Decapitation of neonatal rodents already takes place, but currently is a procedure which requires a licence. Neonatal rodents are less physically developed, but there are no proven studies to support the theory that they suffer less pain from this method of euthanasia than juvenile or adult rodents. Indications are that immature animals might retain the potential for feeling pain for longer than mature animals, because immature animals have a greater tolerance of hypoxia. On the other hand, at birth rodents have incomplete neural connections to the cerebral cortex, so may not fully experience pain. Although it may appear illogical to take birth as the point at which decapitation ceases to be permitted unless it is licensed, some members were concerned that there was no firm evidence to support the proposal to extend the point to seven days after birth. In conclusion, the working group agreed to re-draft the document for future consideration by the Committee. It was noted that there would need to be wide consultation about this and any other proposal to amend Schedule 1.

The Committee's work following allegations made by animal protection organisations

39. The Committee regularly discusses the allegations which are made from time to time by animal protection organisations. We are interested in how the Home Office responds to allegations and how lessons can be learnt from any infringements or other failings that are identified. The Committee is not however a body which can carry out its own investigations. That is a job for the Home Office. We have agreed with a suggestion that the Home Office made in 2000 that we would be ready to be part of a panel to quality assure reports by the Inspectorate into allegations about establishments. However, the Home Office did not seek to involve the Committee in this way in 2002. In 2002 the Committee looked at two sets of allegations.

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

40. Our report for 2001 described the Committee's reaction to these allegations and to the Home Office's response. The allegations related to work carried out at Imutran and Huntingdon Life Sciences and involved transplanting genetically modified organs from pigs into macaque monkeys and baboons. They were based on a large quantity of correspondence which had been passed to “Uncaged”. The work about which the allegations were made ended in 1999. Our report for 2001 also set out four substantive areas that the Committee had identified to further work on – the Home Office's response to the allegations, enforcement and compliance, primates and xenotransplantation. The report for 2001 reported our conclusions on the Home Office's response to the allegations, and paragraphs 25 to 30 of this report covers our work in 2002 on enforcement and compliance. Our workplan for 2003 shows that the Primates sub-committee's aims include reviewing and reporting on the acquisition and training of primates. Dr Jennings is a member both of the APC and of the UK Xenotransplantation Interim Regulatory Authority (UKXIRA). UKXIRA is currently reviewing the implementation of the Kennedy report on xenotransplantation.

41. In October 2002 the “Uncaged” organisation wrote to the Chairman enclosing a further package of leaked documents. These related to the original allegations it had made in 2000. At our December meeting the letter was noted, and copies of the enclosures were made available to members. The Committee did not wish to take this further, but the Chairman passed copies of the letter and enclosures to the Home Office.

Allegations made by the BUAV about marmoset work at Cambridge

42. In May 2002 the British Union for the Abolition of Vivisection issued a report making a series of allegations about work being carried out at Cambridge University using marmosets to investigate Parkinson's disease and stroke-related disorders. The allegations were the subject of a report on “Newsnight”, and the BUAV sent copies of their report and a video to all our members. The Home Office Minister Bob Ainsworth, who had separately been sent the BUAV material, announced that he would ask the Chief Inspector to look at some of the issues raised in the BUAV's report. The Chief Inspector was, in particular, to review the licensing decisions concerned, the severity limits and bands assigned to the projects, and related compliance issues.

43. At our June meeting the Committee agreed with Professor Banner's proposal to commission a small working group to assess the BUAV's allegations in the light of the BUAV report and the Home Office's response to it, in order to identify areas for further discussion by the Committee. The Committee agreed the membership: Professor Holland (chair), Dr Jennings and Professor Atterwill. The terms of reference for the review were also agreed by the committee;

- “To assess the BUAV's allegations about the use of marmosets at Cambridge University in the light of the Chief Inspector's report and the Home Office's response to that report, in order to identify further areas of discussion by the APC.”

It was later proposed that in addition to these terms of reference, the working group should examine the issues of clandestine investigations and “whistleblowing”. The Chief Inspector’s report had not been published by the end of 2002. We will report on our further consideration of this issue in our next annual report.

Research and Alternatives sub-Committee

44. For most of the year this sub-committee comprised Professor Anderson (chair), Professor D Clark, Dr Festing and Dr Jennings. On Professor Anderson’s retirement from the Committee at the end of November Professor D Clark became chair, and Mr Moore joined the sub-committee. 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.

45. For the financial year 2002/2003, the Home Office made available a budget of £280,000 for this purpose

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

- Mr Atkins (DERA): *Nematode worm models of bacterial disease – Alternatives to mammalian experiments using mice.*
- Dr Bendig (Public Health Laboratory): *Evaluation of PCR –based diagnosis to replace suckling mouse inoculation for detection and typing of coxsackieviruses – a continuation.*
- Dr Berdoy (University of Oxford): *The hidden behaviours of laboratory rats.*
- Dr Main (University of Bristol): *Welfare benchmarking of laboratory mice in animal units.*
- Dr Mendl (University of Bristol): *Disruptive effects of common husbandry procedures on social recognition and social stability in laboratory rats.*
- Dr Mendl (University of Bristol): *Developing recommendations for rat housing using scientific assessment of welfare: interactions between cage size, space allowance and enrichment provision.*
- Professor Price (Central Science Laboratory): *Investigation of the potential of QSAR to predict the acute toxicity of anticholinesterase pesticides to birds.*
- Professor Nicol (University of Bristol): *A targeted approach to environmental enrichment for laboratory mice.*
- Dr Orphanides (Zeneca): *The use of in vitro gene-profiling to reduce/replace the rat uterotrophic assay in endocrine disruption testing.*
- Dr Porter (University of Aberdeen): *Development of novel biosensors as an alternative to the use of animals in the UK’s paralytic shellfish poisons (PSP) monitoring programme.*

- Professor Shah (Central Public Health Laboratory): *Using mass spectroscopy instead of mice to test for botulism.*
- Professor Wall (University of Bristol): *Development of an in vitro rearing system for parasitic Psoroptes mites, to minimise the experimental use of infected vertebrate hosts.*
- Dr Williamson (DERA): *Remote telemetry to identify humane end-points in vaccine efficacy testing for regulatory purposes.*
- Mrs Wolfensohn (University of Oxford): *Environmental conditions during transportation of non-human primates.*
- Dr Xing (NIBSC): *Development of an alternative test to the histamine challenge test based on in vitro enzymatic-HPLC coupled assay for pertussis vaccines.*

47. A DERA project by Dr Titball was listed in the report for 2001 as a new project. That project was discontinued after an unsuccessful pilot study. The projects being conducted by Professor Glover, Dr. Mendl, Dr. Orphanides, Professor Shah and Mrs. Wolfensohn concluded this year. There follow brief details of the results of the projects.

Development of novel biosensors as an alternative to the use of animals in the UK's paralytic shellfish poisons (PSP's) monitoring programme.

Professor Glover at the University of Aberdeen investigated the potential for replacing the currently recognised mouse bioassay used for the detection of paralytic shellfish toxin by an in vitro biosensor method. Bacterial and yeast biosensors that were developed were able to detect pure samples and mixtures of shellfish toxins. However, when the biosensors were used to detect the toxins against a background of shellfish tissue considerable interference was encountered, resulting in wide variation in toxicity values when compared to the mouse bioassay. Future work will concentrate on resolving the issues surrounding the interference of this assay by shellfish tissue. Publications and presentation were as follows:

Poster presentation. 3rd International Conference on Molluscan Shellfish Safety, Long Island, New York, June 2000.

Poster presentation. 9th International Symposium on Microbial Ecology (ISME-9), Amsterdam, Netherlands, August 2001. (VN/RW)

Disruptive effects of standard husbandry practice on laboratory rat social behaviour.

Dr. Mendl at the Department of Veterinary Science, University of Bristol investigated the extent to which handling and related procedures disrupt recognition processes and/or lead to social upheaval in group housed laboratory rats. He found that the effects of handling could influence the social behaviour of group-housed rats. Not only was general social investigation within the group increased, particularly of those rats that had been handled, but there was also an increase in aggression directed towards the handled rats by their group-mates. The following are the titles of the scientific papers resulting from this study:

Burman, OHP; Mendl, M. (2002) Disruptive effects of standard husbandry practice on laboratory rat social behaviour. Submitted to Animal Welfare.

Mendl, M. (2002) An investigation into the effects of separation and reintroduction on the social behaviour of group-housed rats – in preparation.

The use of in vitro gene-profiling to reduce/replace the rat uterotrophic assay in endocrine disruption testing.

Dr. Orphanides at Syngenta Central Toxicology Laboratory examined whether gene profiling of cultured human breast cells can be used to predict the potential for disruption of endocrine activity. Gene expression of cells that were treated with substances with known oestrogenic activity and controls was studied. Although a correlation between gene expression pattern and oestrogenicity was not found, it was demonstrated that transcript profiling and cluster analysis could successfully group treatments that induce similar biological effects.

Development of in vitro methods for identifying Clostridium botulinum using long chain fatty acids and detection of toxic activity using ProteinChip Arrays.

Professor Shah, Head of Molecular Identification Services at the Central Public Health Laboratory Services assessed two potential in vitro methods for the detection of clostridial toxins that could replace animal tests. It was concluded that the use of long-chain cellular fatty acids (LCFA) as a means of discriminating Clostridium botulinum toxin subtypes was unsatisfactory. The detection of clostridial toxins using Surface Enhanced Laser Desorption/Ionisation Time of Flight Mass Spectroscopy was found to be more promising and additional equipment has been purchased to develop this method. The completed work was presented at the following conferences and seminars:

Nasir, P.; Shah, HN. and Brett, M. A system to work with high-risk pathogens for proteome analysis. PHLS 26th Annual Scientific Conference, Warwick, 17–19 September 2001.

Nasir, P. Delineating the Clostridium botulinum neurotoxins using Surface Enhanced Laser Desorption/Ionisation Time Flight Mass Spectrometry. PHLS Seminar 20 September 2001.

Shah, HN.; Culak, R.; Encheva, V. Keys, CJ. Nasir, P.; Brett, M.; Gharbia, SE. and Humber, DP. Differentiation of microbial pathogens at the toxin and serotype level using MALDI-TOF and SELDI-TOF Mass Spectrometry. CIPHERGEN Symposium and User Meeting, 24-25 May, 2002, Brussels.

Culak, R. and Grant, K. Clostridial Pathogens: New developments using Molecular and ProteinChip Technology. Applications of Biomimics in the Research and Diagnostic Laboratory, 102 July 2002, London.

Culak, R.; Nasir, P.; Brett, M. and Shah, HN. Differential analysis of the Clostridium botulinum strains; application of SELDI TOF Mass Spectrometry. International Union of Microbiological Societies Congress, 27 July-1 August 2002, Paris.

Project to examine the environmental conditions experienced by Non-human Primates during transportation.

Mrs. Wolfensohn, Supervisor of Veterinary Services, University of Oxford undertook to develop and validate a device to monitor the environmental conditions that monkeys experience during transport with the view to recommending possible improvements. A prototype monitoring device and a commercially available system were tested in a preliminary study which revealed many technical problems. Problems were also encountered in establishing behavioural and biochemical methods for evaluating stress in monkeys during transport. Presentations of the studies carried out were made at the following meetings:

Animal Welfare and Human-Interactions Group Seminar. 22 June 2000, Cambridge University Veterinary School.

Workshop on faecal steroid analysis in animal welfare studies. 4 September 2000, Wolfson College, Oxford.

3rd International Symposium on Physiology and Ethology of Wild and Zoo Animals. 4-7 October 2000, Berlin.

New grants awarded in 2002

48. The sub-committee agreed to award grants to the following new projects that were started in 2002:

- Dr Bottrill (FRAME): To establish a database on humane endpoints, which will be made available on the Altweb site.
- Mr Kemp (Institute of Animal Technology): Up-date of “With Care” videos and conversion to CD-ROM.
- Dr Mason (University of Oxford): The effects of cage cleaning regimes in laboratory animal welfare.

The sub-committee also agreed to contribute to the sponsorship of the following meetings in 2002:

4th World Congress on Alternatives, New Orleans.- August 2002.

Miss S Vaughan (FRAME): FRAME Reduction Committee Symposium October 2002.

The Committee’s next annual report will contain reports on those projects which end in 2003.

Education and Training sub-Committee

49. For most of the year this sub-committee comprised Professor Flecknell (chair), Mr Gregory and Dr Jennings. On Professor Flecknell’s retirement from the Committee at the end of November, Dr Jennings became chair, and Dr Festing joined the sub-committee. The sub-committee’s principal task in 2002 was to conclude its work on the compulsory training of, and the syllabus for the training of Named Animal Care and Welfare Officers (NACWOs). A NACWO is the person at each designated establishment who is named on the establishment’s certificate of designation as responsible for day-to-day care for the husbandry, care and welfare of the animals protected by the Act. In January 2001 the Chairman wrote to the then Minister Mike O’Brien MP endorsing the proposal by the Education and Training sub-committee, in conjunction with the Institute of Animal Technicians (IAT), that training for NACWOs should be made compulsory. The syllabus was incomplete however, in that we considered that it needed improving by incorporating more detail about welfare observations and a general introduction to ethics training.

50. In March 2002 the then Minister Angela Eagle MP wrote to the Chairman to confirm that she accepted that training for new NACWOs should be made compulsory, and that officials would take this forward as soon as the APC supplied the finally recommended syllabus. After consultation with the Chairman of the IAT the sub-committee agreed a revised syllabus. This was endorsed by the full Committee at our December meeting, and sent to the Home Office. A copy of the syllabus is at Annex I.

The Primates sub-Committee

51. The Primates sub-committee comprises Professor Dunbar (chair), Professor Atterwill, Dr Hubrecht, Dr Langley, Dr Jennings and Professor McNeilly. The main efforts of the sub-committee in 2002 were devoted to finalising its report into the use of primates in regulatory toxicology. Successive drafts were discussed at our meetings in June and October, and the final report, endorsed by the main Committee, was sent to the Minister on 4 December. We reproduce here an Executive Summary.

THE USE OF PRIMATES UNDER THE ANIMALS (SCIENTIFIC PROCEDURES) ACT (1986) – ANALYSIS OF CURRENT TRENDS WITH PARTICULAR REFERENCE TO REGULATORY TOXICOLOGY

EXECUTIVE SUMMARY

This report has been compiled in the context of the Animal Procedures Committee's (APC) remit to review the use and care of non-human primates under the provisions of the Animals (Scientific Procedures) Act 1986 (ASPA). It summarises primate use in scientific procedures in the UK over the eleven year period from 1990 to 2000, and attempts to identify any significant trends during that period and likely changes to patterns of use in the future. Since the majority of primate use is in pharmaceutical research and development, particularly regulatory toxicology and other safety assessment procedures, this issue is examined in detail. Other uses of primates will be reviewed by the Primate Sub-Committee at a future date.

The report contains a number of recommendations aimed at reducing primate use and these are summarised below. However, it must be emphasised that this is a complex issue with a multitude of 'players', and that there were many questions and concerns raised during the preparation of the report that remain unresolved. These require further serious discussion with key stakeholders if further progress is to be made. It is recognised that many of the issues discussed and recommendations made refer to some animals, which are not primates.

Statistics of primate use

In the eleven year period covered by this report, 40,659 primates were used in scientific procedures under the ASPA. Most were either marmosets and tamarins (38.16% – mainly the common marmoset, *Callithrix jacchus*) or macaques (59.07% – mainly long-tailed macaque, *Macaca fascicularis*, and rhesus macaque, *Macaca mulatta*). No baboons have been used since 1999. There is no distinct pattern in macaque use over the period covered, but there is a slight downwards trend in number of marmosets used overall.

The major use of primates (around 72% of the total in recent years) is in toxicology procedures, including those for pharmaceutical safety and efficacy assessment. Most of these procedures are carried out to fulfil legislative requirements. Macaques appear to be the primates most commonly used in toxicology, and a greater percentage of macaque use is for toxicology than is the case for marmoset use. No baboons have been used in toxicological procedures for the last five years.

The majority of project licences using primates, granted in the last 5 years, have been assessed prospectively to be in the moderate severity banding.

The use of primates in regulatory toxicology

The reasons that primates are used in regulatory toxicology and other pharmaceutical safety studies are examined. The main issues discussed include: the requirement for a second species in regulatory toxicology; species selection (including scientific considerations, practical issues, regulatory influences and ethical concerns); study design and timing (particularly the scheduling of rodent and non-rodent studies); alternatives to primate use; and the role of regulatory bodies and their inter-relation with the pharmaceutical industry.

The licensing of regulatory toxicology procedures under ASPA is also discussed. A key question is whether the process of species selection does indeed result in the use of primates 'only when it is fully justified' as required by ASPA, i.e. whether the current system allows an adequate evaluation to be made of the justification for the use of primates in regulatory studies. The use of 'generic' licences for regulatory toxicology studies is identified as a source of concern, and the need to gain a better oversight and monitoring of procedures that involve large numbers of primates is emphasised.

Future use of primates in pharmaceutical development

Since so much of current primate use is for the development and testing of pharmaceuticals, it is clear that the numbers of primates used in the future will be closely linked to developments in the pharmaceutical industry. The industry's view is that its future lies in developing entirely new classes of neuroactive drugs to combat the increasingly important neurological diseases of old age. Developments resulting from, for example, the human genome project may also have an impact, such that the demand for primates as models in basic research, and in drug development and safety assessment, may actually increase over the next decade or so.

However, there are serious ethical and animal welfare concerns regarding the use of primates in experiments, and considerable public disquiet with regard to such use. These concerns are also likely to increase as more is discovered about their advanced cognitive faculties, complex behavioural and social needs, and the difficulties of satisfying these in a laboratory environment.

Summary conclusions and recommendations

The drive to produce pharmaceuticals for human benefit, and the associated primate use that this currently entails, clearly conflicts with the desire to minimise and eliminate the use of primates in experiments, and thus with the APC's stated goal of "minimising, and eventually eliminating primate use and suffering". If the predictions of an increased demand for primate use are realised then this conflict becomes more intense. The APC believes it is extremely important to recognise this conflict, and *absolutely essential* to more determinedly and actively seek ways of resolving it. However, it must be recognised that this is a global issue, which needs to be tackled on an international basis.

If, as seems likely, the vast majority of primate use continues to be in the development and safety assessment of pharmaceuticals, then it is clear that this is where the focus needs to be if major reductions in use are to be achieved. We recognise that progress has already been made in this respect and that some of our recommendations reflect existing practice. However, we believe that significant inroads could still be made in reducing the numbers of primates used in toxicology if there was sufficient international commitment to this goal. We believe it is essential to establish such a commitment, together with a mechanism that will ensure that primates are only used when the objective of ensuring the safety of human subjects cannot be achieved by any other means. In such cases, every effort should be made to ensure that safety evaluation programmes are designed to minimise the numbers of primates used, reduce suffering, and eliminate the possibility of wastage of animals.

The Committee's recommendations are set out in full in Section 5 of the report.

52. In addition to its work on the above report, during 2002 the Primates sub-committee carried out its regular task of advising the Home Office on the suitability of overseas breeding centres as sources of supply of primates for research and testing in the UK. Those centres are not of course subject to the 1986 Act, but UK project licence holders are only permitted to import and use primates from centres that are considered suitable for the purpose by the Home Office. A member of the Animals (Scientific Procedures) Inspectorate carries out site visits, and can ask for improvements to be made. Nevertheless, it has to be recognised that the numbers of primates going to the UK from these centres is relatively small compared

with those going to other countries, and those countries may have lower standards with respect to cage size, stocking densities, environmental enrichment etc. That means that standards abroad may be lower than standards which can be demanded in the UK. For example, we were told that one centre had expressed reservations about the stability of the UK market (in the light of recent animal rights activity) and this might preclude the necessary investment to increase cage heights, as had been requested. We were told that the centre's US clientele preferred smaller cage sizes so that the animals became conditioned to that area (which was comparable to the US cage size they would ultimately be housed in). This illustrates the type of problem encountered. However, wherever practicable the Home Office seeks to ensure that the standards in centres conform as a minimum to guidelines published by the International Primatological Society. During 2002 the sub-committee advised on several overseas centres. There follow examples of the types of improvements the sub-committee sought to encourage.

53. We are always concerned that a high standard of environmental enrichment should be provided. We also seek to ensure that weaning animals should stay with the mother for at least 6 months. However, for the reasons set out in paragraph 52 above it can be difficult to ensure those high standards. One centre we considered compared unfavourably with other centres in these two important areas. However, the Inspector confirmed that the condition of acceptance could stipulate that the weaning age of animals bound for the UK should be not less than 6 months. We also asked the Inspector to indicate to this and other centres that the APC was intending to look at issues relating to the supply and transport of non-human primates. Improvements in the areas of environmental enrichment and also better arrangements for holding primates prior to shipment (in group housing or pairs) would be expected if licences were to be renewed in the future. The Home Office accepted this recommendation.

54. Some centres catch primates from the wild. For example, in Mauritius macaque monkeys, which are not indigenous, are widely considered as an agricultural pest, and trapping is carried out at various locations on the island. The Home Office prohibits the import of wild-caught primates except where exceptional and specific justification can be established. Unless this exceptional and specific justification is accepted, as with all other sources of primate supply the Home Office requires that only captive-bred animals are exported to the UK from Mauritius.

Cost/benefit working group

55. The Cost/Benefit working group is chaired by our Chairman, Professor Banner and its other members are Professor D Clark, Professor Holland, Dr Jennings and Professor Martin. Our report for 2001 related how the working group had issued a public consultation paper on the cost/benefit assessment and the 1986 Act in December 2000. The working group carried out a careful evaluation of all the responses received to the consultation, met on a number of occasions in 2002 and hoped to have produced its report by the end of the year. This is an extensive issue to address, and it did not prove possible, but a draft of the report was discussed at our meeting in October and another draft had been completed and circulated in December. The working group has addressed several areas of the cost/benefit assessment, including

- The scientific validity of animal experiments;
- the factors to be taken into account in the cost/benefit assessment;
- the roles of the people and processes involved in the cost/benefit assessment;
- some difficulties in cost/benefit assessment;
- how to enhance the transparency of the cost/benefit assessments; and
- the role of post hoc and interim review in informing cost/benefit assessments.

The Committee's work programme for 2003

56. The Committee's work programme for 2003 is at Annex J.

ANNEX A

Background information about the Committee

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

The legislation

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

The Committee

4. The function of the Animal Procedures Committee is to provide the Home Secretary and the Northern Ireland Minister of Health, Social Services and Public Safety with independent advice about the Act and their functions under it. Those two Ministers are responsible for appointing members of the Committee. Members are experts from a wide variety of backgrounds, and the list at the beginning of this report sets out the membership as at the end of 2002.
5. The Animals (Scientific Procedures) Act 1986 requires
 - that there must be at least 12 people on the Committee (excluding the Chairman) and
 - that: at least two-thirds of the members must have full registration as medical practitioners or veterinary surgeons, or be qualified in a biological subject relevant to the work of the Committee;
 - at least one member must be a barrister, solicitor or advocate;
 - at least half of the members must not have held a licence under the Act during the last six years; and
 - the interests of animal welfare should be adequately represented (this has tended to mean, in practice, the appointment of members associated with animal welfare organisations, but all members pay high regard to animal welfare).
 - There is normally an academic philosopher on the Committee, although this is not a statutory requirement.

6. Members are appointed for terms of up to 4 years and can be re-appointed once. The 1986 Act specifies that payments may be made to the Chairman by way of remuneration, and that other members can receive reimbursement for any expenses incurred by them in the performance of their duties. Apart from the Chairman, members are not paid for their work on the Committee, though they can claim reasonable out of pocket expenses. During the financial year 2002/2003, the Home Office had budgets of £10,000 and £27,500 respectively from which to make such payments.

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

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

Ministers

9. The Home Secretary in practice delegates his responsibilities under the Act to another Minister in the Home Office, which administers the Act in England, Scotland and Wales. At the beginning of 2002 that Minister was Angela Eagle MP. Following the Ministerial reshuffle in May Bob Ainsworth MP took over responsibility for animal scientific procedures. The Chairman met Mr Ainsworth in July. As stated above, in Northern Ireland the administration of the 1986 Act is the responsibility of the Department of Health, Social Services and Public Safety. Until the suspension of devolution on 14 October the Minister was Bairbre de Brún MLA. Following the resumption of direct rule Des Browne MP took over responsibility for animal scientific procedures.

Changes in membership of the Committee

10. A total of four members left the Committee in 2002. In March, Mr Mike Baker, who had first been appointed to the Committee in 1998, offered his resignation to Angela Eagle because of pressure of work. The Minister accepted his resignation, and thanked him for the positive contribution he had made during his membership. At the Committee's meeting in April members recorded their appreciation for Mr Baker's contribution to the APC. At the end of November three members came to the end of their second and final four year terms of membership. They were Professor Ronald Anderson, Professor Paul Flecknell and Professor Iain Purchase. All three made a considerable contribution to the work of the Committee: Professor Anderson as an emeritus Professor of animal husbandry and as chair of the Research and Alternatives sub-committee; Professor Flecknell as a Professor of laboratory animal science and as chair of the Education and Training sub-committee; and Professor Purchase as a toxicologist with wide industry experience.

11. In October the Home Office informed us of decisions taken by Ministers about the recruitment of members following the departure of the four members. Ministers were mindful that the report of the House of Lords Select Committee had made several recommendations relating to the APC. At that stage, no decisions had been made on those recommendations, but if they were to be accepted the role of the Committee might need to be expanded, and the Committee might require additional expertise that current members did not possess. Because there was at that stage no clearer idea of any new areas the Committee might need to address, Ministers had decided (in consultation with the Chairman) to restrict further appointments to two at that stage: someone with knowledge of laboratory animal science; and a barrister, solicitor or advocate. Further appointments might be made after decisions had been made about any increased role for the APC. The Home Office carried out an exercise to identify someone with knowledge of laboratory animal science using the short list prepared for the recruitment process in 2001, and Ministers appointed Mr Graham Moore to the Committee with effect from 1 December 2002. Mr Moore has valuable expertise as a senior veterinarian at Pfizer UK, which will be extremely useful to the Committee. A parallel recruitment exercise to identify a barrister, solicitor or advocate was in process at the end of the year.

ANNEX B

The Animal Procedures Committee's Code of Conduct

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

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

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

3. The 1986 Act adds that:

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

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

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

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

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

- (i) familiarise themselves with the terms of reference of the Committee;
- (ii) undergo any required induction training;

- (iii) declare any personal or business interest which may, or may be perceived (by a reasonable member of the public), to influence their judgement. This should include, as a minimum, personal direct and indirect pecuniary interests, and should normally also include such interests of close family members and of people living in the same household. A register of interests will be kept up-to-date and will be open to the public;
 - (iv) not participate in the discussion or determination of matters in which they have a personal or business interest, and should normally withdraw from the meeting (even if held in public) if their interest is direct and pecuniary;
 - (v) make a declaration of interest at any Committee meeting if it relates specifically to a particular issue under consideration, for recording in the minutes (whether or not a Committee member withdraws from the meeting);
 - (vi) not misuse information gained in the course of their public service for personal gain or for political purpose, nor seek to use the opportunity of public service to promote their private interests or those of connected persons, firms, businesses or other organisations;
 - (vii) not hold any paid, or high profile unpaid, posts in a political party, and not engage in specific party political activities on matters directly affecting the work of the Committee. When engaging in other political activities, members should be conscious of their public role and exercise proper discretion; and
 - (viii) understand and accept that they are appointed as individuals and not as representatives of organisations by which they are employed or with which they have significant contacts.
8. The Chair has particular responsibility for providing effective leadership to the Committee and for:
- (i) ensuring that the Committee meets at appropriate intervals, and that the minutes of meetings and any reports to the Secretary of State accurately record the decisions taken, and where appropriate, the views of individual members;
 - (ii) representing the views of the Committee to Ministers;
 - (iii) representing, where appropriate, the views of the Committee to the general public;
 - (iv) ensuring that new members are briefed on appointment;
 - (v) sitting on the panel which advises Ministers on new appointments and re-appointments.
9. Notwithstanding 8(ii) above, any Committee member has the right of access to Ministers on any matter which he or she believes raises important issues relating to his or her duties as a Committee member. In such cases, the agreement of the rest of the Committee should normally be sought.
10. Committee members may be personally liable if, in the performance of their Committee duties, they make a fraudulent or negligent statement which results in a loss to a third party. They may also commit:
- (i) an offence under section 24 of the Animals (Scientific Procedures) Act 1986;
 - (ii) a breach of confidence under common law; or
 - (iii) a criminal offence under insider dealing legislation if they misuse information gained through their position on the Committee. Individual members who have acted honestly, reasonably, in good faith and without negligence will not, however, have to meet out of their own personal resources any personal civil liability which is incurred in execution or purported execution of their duties.

ANNEX C

Member's register of Interests in 2002

CURRENT APC MEMBERS AND REGISTER OF INTERESTS

At the end of 2002 there were 19 members of the Committee (including the Chairman). 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, and to declare any personal or business interest which may, or may be perceived (by a reasonable member of the public), to influence their judgement. This includes, as a minimum, personal direct and indirect pecuniary interests, and will normally also include such interests of close family members and of people living in the same household. All members are appointed as individuals and not as representatives of organisations by which they are employed or with which they have significant contacts. This Register of Interests includes information about Professor Anderson, Mr Baker, Professor Flecknell and Professor Purchase, all of whom left the Committee during the year.

REGISTER OF INTERESTS

Name	Occupation	Organisation	Nature of interest
Professor Michael Banner	Professor of Moral & Social Theology, Kings College, London	Royal Commission on Environmental Pollution	Member
		Agriculture and Environment Biotechnology Commission	Member
		Department of Health Committee on variant CJD	Chairman
		Shell	Chair of Animal Testing Review Panel
Professor Ronald Anderson	Professor Emeritus of Animal Husbandry, University of Liverpool	Universities Federation For Animal Welfare	Chairman of Council & Trustees
		Humane Slaughter Association	Chairman of Trustees
		Society for Animal Welfare in Israel	Chairman of Trustees
		Study for Companion Animal Studies	President

Name	Occupation	Organisation	Nature of interest
Professor Chris Atterwill	Director of Biosciences, Huntingdon Life Sciences	Cudos Ltd Natural Pharmacy Ltd Restart Resources Ltd ECVAM FRAME ATLA	Director & shareholder Director & shareholder Director & shareholder Member of Neurotoxicology Task Force Member Editorial board member
Mr Michael Baker	Chief Executive, Brooke Hospital for Animals	The British Union for the Abolition of Vivisection	Supporter
Professor Donald Broom	Professor of Animal Welfare, Department of Clinical Veterinary Medicine, University of Cambridge	EU Scientific Committee on Animal Health & Animal Welfare:	Member and Vice Chairman of Animal Welfare sub-committee
Professor Grahame Bulfield	Director and Chief Executive (to 31 October 2002) Vice-Principal and Head of College of Science and Engineering, Professor of Animal Genetics University of Edinburgh (from 1 November 2002)	Roslin Institute (Edinburgh) Roslin Biocentre University of Edinburgh Edinburgh Research and Innovation Limited B & K Universal Spongiform Encephalopathy Advisory Committee (SEAC) Scottish Higher Education Funding Council Genetics Society World Poultry Science Association British Cattle Breeders Club Institute of Biology Royal Society of Edinburgh	Certificate Holder Chairman Chairman Non Executive Director Non Executive Director Member Member Member Member Member Member Fellow Fellow

Name	Occupation	Organisation	Nature of interest
Professor Grahame Bulfield (<i>continued</i>)		Royal Agricultural Society of England	Honorary Fellow
		Royal Society of Arts	Fellow
		Scottish Enterprise/Royal Society of Edinburgh: Enterprise Fellowship Committee	Member
		BBC Rural Affairs Advisory Committee	Member
		Partnerships UK Advisory Board	Member
		Biotechnology and Biological Sciences Research Council	Member of Strategy Board (to July 2002)
		British Biotech plc	Shareholder
Dr David Clark	Honorary Senior Research Fellow University of Kent	Unilever plc	Shareholder
		European Centre for the Validation of Alternative Methods	UK representative on Scientific Committee
		European Cosmetics Trade Association	Chairman of Steering Committee
Professor Stephen Clark	Professor of Philosophy, University of Liverpool	Independent Review Panel on Borderline Products	Member
		Liverpool University	Member, animal use ethical review Committee
		Farm Animal Welfare Council	Member
		Universities Federation for Animal Welfare	Member
		British Union for the Abolition of Vivisection	Supporter
		Vegetarian Society	Member
		Animal Aid	Member
RSPCA	Member		

Name	Occupation	Organisation	Nature of interest
Professor Stephen Clark (<i>continued</i>)		Arts and Humanities Research Board Postgraduate Awards Panel	Member
		Boyd Group	Member
Professor Robin Dunbar	Professor of Psychology, University of Liverpool	Cameroon Wildlife Aid Fund	Trustee
		Ethical review committee, University of Liverpool	Member
Dr Michael Festing	Retired/freelance consultant	MRC Toxicology Unit University of Leicester	Research Scientist
		FRAME	Trustee and Chairman of “Reduction “ Committee
		Cambridge University	Module 5 Lecturer
		Bioscientific Events	Module 5 Lecturer
		Royal Veterinary College	Module 5 Lecturer
		Harlan UK	Consultant geneticist
		University of Leicester	PIL Holder
		Animal Research Committee Royal Society	Council member
		Institute of Laboratory Animal Research (ILAR) USA	Member
		Genetical Society	Member
		American Association for Laboratory Animal Science	Member
		American College of Laboratory Animal Medicine	Honorary Member
		Laboratory Animal Science Association	Member
		International Council for Laboratory Animal Science	Member of the governing board
		Research for Health	Dr Simon Festing (son) is Director

Name	Occupation	Organisation	Nature of interest
Dr Michael Festing (continued)		PPL Therapeutics GlaxoSmithKline Oxford Glyoscience Acambis Powerject Pharmaceuticals Alizyne Cambridge Antibody Shire Pharmaceuticals Celltech	Member and/or spouse is shareholder Member and/or spouse is shareholder Member and/or spouse is shareholder Member and/or spouse is shareholder Member and/or spouse is shareholder Member and/or spouse is shareholder Member and/or spouse is shareholder Member and/or spouse is shareholder
Professor Paul Flecknell	Director, Comparative Biology Centre, University of Newcastle	Pharmaceutical companies, Universities British Laboratory Animal Veterinary Association Registration Board for Registered Animal Technicians Association of Veterinary Anaesthetists Grant awarding bodies (e.g. Wellcome Trust Leverhulme, Animal welfare charities) Laboratory Animals Ltd Institute of Animal Technicians	Home Office PPL and PIL holder, Named Veterinary Surgeon Lecturing and Consultancy Member Member Senior Vice-President Research grants to Department Director & trustee Senior Vice-President

Name	Occupation	Organisation	Nature of interest
Mr John Gregory	Facility Manager, Central Biomedical Services, Imperial College of Science, Technology and Medicine, Hammersmith Hospital	Imperial College Institute of Animal Technology Institute of Biology Boyd Group Laboratory Animal Science Association Research Defence Society	Home Office PPL and PIL holder Chairman of Council Member of Accreditation Board Member Member Member
Mr Alan Holland	Senior lecturer in Philosophy, University of Lancaster	None	
Dr Robert Hubrecht	Deputy Director Universities Federation for Animal Welfare	Cancer Research UK Pharmaceutical Housing and Husbandry Steering Committee Universities Federation for Animal Welfare Laboratory Animal Science Association International Society for Applied Ethology Council of Europe Working Party for revision of ETS 123 Primate Society of Great Britain Association for the Study of Animal Behaviour International Primate Society European Marmoset Group American Association of Laboratory Animal Scientists	Ethical Advisory Committee Member Chair Member and Deputy Director Member and Council Member Member Observer for ISAE Member Member and UFAW representative Member Member Member

Name	Occupation	Organisation	Nature of interest
Dr Robert Hubrecht <i>(continued)</i>		Centre for Macaques Open University	ERP member ERP member
Dr Maggy Jennings	Head of Research Animals Department, RSPCA	RSPCA UKXIRA Animal Health Trust Boyd Group GlaxoSmithKline Laboratory Animals Science Association European Commission Ethical Review Panels Eurogroup for Animal Welfare	Member Member Member of ethics committee Member Member of CARE Committee Member of Ethics and Training Working Group Member Scientific Advisor
Dr Gill Langley	Scientific Adviser and Consultant, Dr Hadwen Trust	British Union for the Abolition of Vivisection One Voice group, France PETA, USA Vegan Society Focus on Alternatives Volunteers in Research and Testing	Consultancy payments Consultancy payments Consultancy payments Consultancy payments Chairperson Member
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	VicePresident VicePresident Member Director Consultant Research grants received Research grants received
Mr Robert McCracken	Barrister	None	

Name	Occupation	Organisation	Nature of Interest
Professor Alan McNeilly	Deputy Director, MRC Edinburgh	JNCC Society for Reproduction and Fertility Parkes Trust MRC University of Edinburgh University of Edinburgh	Consultant Chairman Trustee PPL & PIL Holder, Certificate holder, Board of Management: MRC Centre for Best Practice for Animals in Research. Honorary Professor Member Biological Research Resources Management Committee
Mr Graham Moore	Veterinary Consultant, Science Policy & Scientific Affairs, Pfizer Global Research & Development	ABPI Animal Research & Welfare Advisory Group ABPI Research and Development Committee American Association for Laboratory Animal Science Associate Parliamentary Group on Animal Welfare Bioscience Federation Animal Science Group British Veterinary Association European Federation of Pharmaceutical Industries and Associations (EFPIA) Research & Animal Welfare <i>Ad hoc</i> Group Federation of European Laboratory Animal Science Association (FELASA) Board of Management	Chair Member Member Member Member Member Vice-Chair Member

Name	Occupation	Organisation	Nature of Interest
Mr Graham Moore <i>(continued)</i>		Fund for the Replacement of Animals in Medical Experiments (FRAME) Reduction Committee	Member
		Laboratory Animal Science Association (LASA)	Member and Past President
		Royal Society for the Protection of Birds	Member
		Universities Federation for Animal Welfare (UFAW)	Member
		Pfizer Inc	Stockholder (self and wife)
Dr Tim Morris	Head of Comparative Medicine and Investigator Support, Department Of Laboratory Animal Science, GlaxoSmithKline Pharmaceuticals	GlaxoSmithKline	Employee, shareholder and Home Office Certificate Holder
		Universities Federation for Animal Welfare	Corporate donor
		American Association for Laboratory Animal Science	Member
		Association for the Assessment and Accreditation of Laboratory Animal Care International.	Ad hoc Specialist,
		Association of the British Pharmaceutical Industry	Member of Animal Research and Welfare Advisory Group
		European Federation of Pharmaceutical Industries Associations	Member of Animal Research and Welfare Committee
		Laboratory Animals Breeders Accredited Health Monitoring Scheme	Laboratory Animal Medicine Trustee
		Research Defence Society	co-opted member of Council
		MOD Animal Welfare Advisory Committee	Member

Name	Occupation	Organisation	Nature of Interest
Dr Tim Morris <i>(continued)</i>		Association of Veterinary Anaesthetists	Member
		British Inflammation Research Association	Member
		British Small Animal Veterinary Association	Member
		Laboratory Animal Veterinary Association	Member
		Laboratory Animal Science Association	Member
		British Veterinary Association	Member
		Royal Society of Medicine	Fellow
		Royal Veterinary College	Committee Member
		Institute of Biology	Fellow
		Laboratory Animals Ltd	Chairman and Editor of Journal
		European College of Laboratory Animal Medicine	President
		American College of Laboratory Animal Medicine	Member and Committee Chairman
Guide Dogs for the Blind Association	Member, Canine Research Ethics Committee		
Dr Iain Purchase	Visiting Professor University and Manchester and Consultant	Astra Zeneca plc	Shareholder & consultant
		Celltech	Shareholder
		Bayer AG	Consultant
		UK Interdepartmental Group on Health from Chemicals	Chairman
		Expert Group on Efficient Regulation	Chairman

Name	Occupation	Organisation	Nature of Interest
Dr Iain Purchase <i>(continued)</i>		<p data-bbox="818 266 1102 553">International Council for Science: Preparation of a monograph on Genetically Modified Food for Health and Nutrition for the International Council of Science</p> <p data-bbox="818 587 1102 748">CONCAWE (The oil companies European Organisation for Environment, Health and Safety)</p> <p data-bbox="818 782 1102 897">HERA (Human and Environmental Risk Assessment of household cleaning chemicals)</p>	<p data-bbox="1118 266 1403 358">Project leader on behalf of the International Union of Toxicology</p> <p data-bbox="1118 587 1240 610">Consultant</p> <p data-bbox="1118 782 1240 805">Consultant</p>
Professor Geneva Richardson	Professor of Law, Queen Mary, University of London	Medical Research Council	Member

ANNEX D

Members' attendance at meetings during 2002

The full Committee met on five occasions during 2002: on 13 February, 10 April, 26 June, 9 October and 11 December. Attendance at those meetings is shown below.

Professor Banner	5
Professor Anderson	3 ¹
Professor Atterwill	3
Mr Baker	0 ²
Professor Broom	5
Professor Bulfield	3
Professor D Clark	4
Professor S Clark	3
Professor Dunbar	2
Dr Festing	4
Professor Flecknell	2 ¹
Mr Gregory	4
Professor Holland	3
Dr Hubrecht	3
Dr Jennings	4
Dr Langley	4
Professor Martin	3
Mr McCracken	5
Professor McNeilly	4
Dr Morris	5
Mr Moore	1 ³
Professor Purchase	3 ¹
Professor Richardson	4

Notes

- (1) Professor Anderson, Professor Flecknell and Professor Purchase retired from the Committee on 30 November 2002.
- (2) Mr Baker resigned from the Committee in March 2002.
- (3) Mr Moore joined the Committee on 1 December 2002

ANNEX E

Membership of sub-committees and working groups as at December 2002

The four sub-committees and six working groups that are currently in existence as at December 2002 and their memberships are listed below.

Research and Alternatives sub-committee

Professor D Clark (chair)

Dr Jennings

Dr Festing

Mr Moore

Education and Training sub-committee

Dr Jennings (chair)

Dr Festing

Mr Gregory

Primates sub-committee

Professor Dunbar (chair)

Professor Atterwill

Dr Hubrecht

Dr Jennings

Dr Langley

Professor McNeilly

Accommodation and Care sub-committee

Dr Hubrecht (chair)

Professor Broom

Mr Gregory

Dr Jennings

Dr Morris

Cost/Benefit working group

Professor Banner (chair)

Professor D Clark

Professor Holland

Dr Jennings

Professor Martin

Overbreeding working group

Professor McNeilly (chair)

Mr Gregory

Miscellaneous working group

Professor Broom (chair)

Mr Gregory

Schedule 1 working group

Mr Gregory (chair)

Professor Broom

Dr Morris

One other co-opted member

“Applications” working group

Professor Banner (chair)

Dr Hubrecht

Dr Langley

Mr Moore

Professor Richardson

“Cambridge Primates – allegations by BUAV” working group

Professor Holland (chair)

Professor Atterwill

Dr Jennings

ANNEX F

Letter from the Chairman to Angela Eagle MP about a non-human primates application

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

From the Chairman
Reverend Professor Michael Banner MA DPhil

Angela Eagle MP
Parliamentary Under-Secretary of State
Home Office
50 Queen Anne's Gate
London SW1H 9AT

21 May 2002

Dear Ms Eagle

PRIMATES APPLICATION 40/2382: ADVICE OF THE ANIMAL PROCEDURES COMMITTEE (APC)

The Home Office referred this application to the APC for advice, as it involves the use of non-human primates in procedures of substantial severity. As a first step the Committee formulated several questions about the application, and it was grateful to the applicant for replying comprehensively to them. We then discussed this application at our meeting on 10 April, and I am writing to present the Committee's advice. I apologise for the delay.

2. At the meeting on 10 April the Committee found the application difficult to assess. However, it recommended by a majority vote of 11 to 4 that the application should be allowed on the basis that reassurances are obtained on the particular concerns set out below.

The Committee's particular concerns

3. The Committee was reassured to hear about the high level of support, including substantial involvement by the Animal (Scientific Procedures) Inspectorate, which will be available during the treatment, but they would like to have more information about the welfare assessments which will be used. What quantitative assessments of welfare are used? As well as aspects of the animals' physical welfare, how are psychological aspects to be measured and monitored during the MPTP treatment stage? We would also have expected more information on the expected harms to the animals' welfare and on the specification and identification of endpoints. Could the evaluation and alleviation of psychological and physical stress be shown by means of tables, noting endpoints, harms and how they would be alleviated? Such tables were used in two recent applications referred to the Committee involving research into Chronic Obstructive Pulmonary Disorder. We suggest that the applicant should use such tables. A comparison of actual with predicted harms through the life of the project will not only help monitor the animals, but will also be useful for any similar future projects.

The Committee's general concerns

4. The Committee had other, more general concerns, and we will be discussing these further in our Cost/Benefit working group. The Committee considered that although the benefits of the project were explained well, the description of the costs to the animals, and how these would be alleviated was less clear. Although standard operating procedures were submitted, they covered technical matters rather than welfare matters, and did not cover all the proposed procedures. The Committee considered that it would have been difficult to carry out a fully informed cost/benefit assessment. We would also have found it helpful to have more information about the establishment's standards of husbandry, and staff knowledge of primate behaviour, although we recognised that the applicant and the Inspectorate might have this information. The Committee considered that, from the material supplied, an assessment of the costs and benefits would have been particularly difficult for the lay person. A clear, comprehensive but (as far as possible) non-technical explanation of costs and benefits would, we believe be essential to enable lay members of the Ethical Review Process to make informed and considered decisions both at the initial assessment stage and at periodic reviews.
5. I should also like to receive clarification on one other aspect of this application which caused some concern. We presume that, as is normal practice, where a substance is used on the animals which does not have full toxicological data, there will be careful dose escalation from very low dose levels in order to minimise unpleasant side effects.
6. The APC would be grateful for the Home Office's comments on the particular concerns set out in paragraph 3 and for your clarification about dose escalation.

Yours sincerely

MICHAEL BANNER

Letter from Bob Ainsworth MP, Parliamentary Under Secretary of State, Home Office

Reverend Professor Michael Banner MA DPhil
Chairman, Animal Procedures Committee
Room 978
50 Queen Anne's Gate
London SW1H 9AT

25 June 2002

PROJECT LICENCE APPLICATION PPL 40/2382: ADVICE OF THE ANIMAL PROCEDURES COMMITTEE

Thank you for your letter of 21 May in which you set out the Committee's advice on an application for a project licence involving the use of non-human primates in procedures of substantial severity (PPL 40/2382). I am grateful for the care that the Committee has taken in considering this application and have noted the Committee's majority recommendation that it should be approved.

As to the concerns of the Committee about specific aspects of the application, you will wish to know that the applicant has agreed to revise the text describing the physiological and behavioural adverse effects of the experimental procedures, their incidence and proposed methods of prevention or control, and to use a table format.

As to the concern that the experimental drugs in the project should be used in such a way as to minimise their unpleasant side effects. This is indeed the normal expectation in any programme of work and is the normal practice. However, there are circumstances where dose escalation studies are not necessary, because the minimum effective dose required to produce satisfactory results is already published in the scientific literature or is known from previous studies at the establishment.

In the light of the above, I have concluded that the application should be granted.

I have also noted the Committee's more general comment that it found it difficult from the material presented on the form of application to draw informed conclusions about the potential benefits and likely welfare costs of the work and that it intends to discuss this further in its cost/benefit working group. I am aware that the Committee has been conducting a review of the cost benefit assessment and look forward to receiving its report in due course.

Yours sincerely

BOB AINSWORTH

ANNEX G

Letter from the Chairman to the Home Office about the House of Lords Select Committee's report

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

From the Chairman
Reverend Professor Michael Banner MA DPhil

Trevor Coble
Animal Procedures & Coroners Unit
Home Office
50 Queen Anne's Gate
London SW1H 9AT

25 October 2002

Dear Trevor

COMMENTS BY THE ANIMAL PROCEDURES COMMITTEE ON SOME ASPECTS OF THE REPORT OF THE HOUSE OF LORDS SELECT COMMITTEE ON ANIMAL EXPERIMENTATION

I understand that you are currently contributing to the Government's response to the report of the House of Lords Select Committee on Animal Experimentation. Several of the recommendations in the report would directly affect the Animal Procedures Committee (APC), and there are several other recommendations on which the APC might wish to comment. At some later stage the Committee will be having extensive discussions about all the recommendations in the Select Committee's report. However I hope it will be helpful if I offer the comments of the APC on aspects of some of the recommendations in the report which are of particular interest or concern to the Committee. I hope that our comments will assist in the preparation of the Government's response, although I recognise that it is of course for Ministers to respond to these recommendations.

Recommendation: the Animal Procedures Committee should invite submissions from the Royal College of Veterinary Surgeons, the Farm Animal Welfare Council and others to establish the appropriate application of the 1986 Act or the modification of its regulations for experimental farm animals (paragraph 3.17)

2. The Committee welcomes the opportunity to consider the efficacy of the Act and regulations as applied to experimental farm animals.

Recommendation: the Inspectorate should be subject to periodic review, by a body other than the Inspectorate itself (paragraph 5.13)

3. The Committee already reviews and monitors the operation of the Act at the meetings of the main Committee and its sub-committees which take place throughout the year, and the work of the Inspectorate is included in that monitoring. For example, we are currently carrying out a detailed review of the Cost/Benefit assessment. The Committee believes that it has the potential to provide an informed, thorough and critical scrutiny of the Act and to play a key role in ensuring that this important area of public concern is subject to independent examination.
4. It is also the case that the Committee stands ready to take part in the “quality assurance” of any future investigation, as suggested by Mike O’Brien in connection with the allegations in 2000 about Harlan-Hillcrest. We have not discussed in depth the details of such an involvement by the Committee, but in principle a suitable scheme would strengthen our monitoring role.
5. The report suggests however that public confidence in the Inspectorate could be enhanced if there were an independent reviewing body, and that the APC might carry out such a role. However the report is silent on exactly what is envisaged. For example, such a body could
 - examine allegations of malpractice by the Inspectorate;
 - review the Inspectorate’s work in general;
 - review the efficacy of the regulations imposed; or
 - do all of these.

The report suggests that the reviewing body “would need to have access to all the Inspectorate’s records, including notes of what was seen and done during inspections of designated establishments.” That suggests that an on-going, detailed and far ranging review is envisaged.

6. As currently constituted we do not believe that it would be possible for the APC to carry out the detailed inspectorial role which appears to be envisaged. Our members do not have the time or the skills to carry out detailed audits of the Inspectorate’s work, and we do not believe that it would be the best use of the expertise that we do possess.
7. I should draw your attention to one other matter. Paragraph 5.49 of the report states “We have also heard that the APC cannot always obtain all the papers it needs to carry out its scrutiny role effectively.” A footnote indicates that this statement was based on Mr McCracken’s evidence. It is unfortunate that the report does not refer to my subsequent letter to the Chairman of the Committee, where I clarified a matter where Mr McCracken may not have been entirely clear. In his evidence he had referred to the APC’s examination of licence applications, and had suggested that the APC was hindered in its function of advising the Secretary of State because it did not see the analysis by the Inspectorate of the application. I was concerned that the Lords Committee might have gained the impression that the APC had been refused sight of these analyses. I explained that it was not the case that the Committee had asked for the Inspectorate’s reports and been refused them, and I stated that I had no recollection of the Committee ever asking the Home Office for documents or information of any kind and being refused. It is unfortunate that the Lords Committee does not appear to have taken account of my clarification.

Recommendation: consideration should also be given as to whether members of the APC should be paid (paragraph 5.51)

8. You will recall that I presented the Committee's arguments in favour of payment for all members of the APC in my letter to Angela Eagle of 25 September 2001. As I said in that letter, in recent years the APC has increased and widened its membership, and has, with Ministerial approval, taken a more active role. It has a professional, dedicated and authoritative position at the centre of the debate on animal experimentation. The Committee firmly believes that it should maintain this role. The time burden of meetings can be high. For example, in the year 2000 one member who was a member of two working groups had to attend more than twenty meetings. In addition, in order to carry out the Committee's enhanced role, individual members have to devote much more expense and effort to the APC than simply attending meetings. I hope you will take our reasoning into account when considering the Government's response to this recommendation of the Select Committee.

Recommendation: the APC Secretariat should be strengthened and separated from the regulators (paragraph 5.52)

9. Whether or not the Home Office asks the APC to take on additional work, I welcome the recommendation that the APC Secretariat should be strengthened. The current complement of one grade 7, one HEO and one AO has struggled to take forward all the work of the main Committee, its sub-committees and working groups, and this has been exacerbated by staff absences. This has meant that over the last two years we have made significantly slower progress than we hoped on several areas of work. As you know, we recently had the additional temporary help of a secondee from the Ministry of Agriculture and Forestry of New Zealand. The fact that that secondment was so very useful shows up a weakness in the current staffing complement despite the recent staff absences, and indicates that the Secretariat's staffing complement should be increased by one post. The scientific subject matter of most of our work indicates that the additional member of staff should be scientifically qualified.

10. I was grateful to hear from the APC Secretary that you had recently agreed in principle to another secondee from New Zealand, qualified in Applied Physiology and Animal Welfare Science, who we hope will start work in the new year. This further secondment will, I am sure, demonstrate the value of suitably qualified scientific support to the Committee. However, that should not be seen as a reason for delaying achieving adequate, permanent staffing of the Secretariat.

11. The report suggests that the Secretariat should be separated from the regulators. I do not understand precisely what is proposed, nor the reason for the proposal. I note however that in his evidence to the Select Committee, Mr Lyons of "Uncaged" asserted that "the independence of the APC was.... doubtful as its secretariat was based in the Home Office, and worked closely with the regulators."

12. As you know, until 1999 the function of APC Secretary and policy support to the Home Office on animal procedures was carried out by one post holder. It was recognised then that the two functions should be separated, and since then the APC Secretary and his staff have been a separate section of AP&CU. Staff in the Secretariat are answerable to the APC Chairman, although naturally and quite properly they liaise on a regular basis with AP&CU staff in other sections. I am satisfied that the Secretariat acts independently as the APC's support and executive arm, confidentially when necessary. The regular liaison between the Secretariat and the rest of AP&CU is handled sensitively by all those involved, and is of great practical assistance to the Committee.

Recommendation: the current APC research budget of £280,000 should be given to a Centre for the three Rs to disburse (paragraph 7.23)

13. As you know, this research budget is administered by the Home Office on the advice of our Research and Alternatives sub-committee (RASC). The Committee believes that many worthwhile research projects have been funded by this budget, as RASC members have the expertise to identify useful projects. We would therefore be loath to relinquish our advisory role in this area. However, if the Government fully accepts the parallel recommendation – that a Centre for the three Rs be set up (paragraph 7.18) – we would not oppose the transfer of our research budget to such a centre. However, the Centre would need to have the means, experience and independence to administer the budget successfully. In connection with the Select Committee’s recommendations on research, the Committee also welcomed recommendations 10 to 13, relating to initiatives by Government to increase research into alternatives to the use of animals.

14. I hope these comments are helpful. As I stated earlier, the Committee might wish to comment further when the Government’s response to the Select Committee’s report is published.

Yours sincerely

MICHAEL BANNER

ANNEX H

Letter from Bob Ainsworth MP, Parliamentary Under Secretary of State, Home Office

Reverend Professor Michael Banner MA DPhil
Chairman, Animal Procedures Committee
Room 978
50 Queen Anne's Gate
London SW1H 9AT

9 July 2002

Dear Reverend Banner

ANIMAL PROCEDURES COMMITTEE: RECOMMENDATIONS ON BIOTECHNOLOGY

My predecessor, Angela Eagle, wrote to you on 11 July 2001, thanking you for the Animal Procedures Committee's report on biotechnology and indicating that she would respond in detail when she had received advice on the report. I can now provide you with that substantive reply. I am sorry that it has taken so long to do so.

First, may I say that I am grateful to the Committee for the time and hard work it has put into this report, which covers important issues. I was also interested to read the report by the Royal Society on the use of genetically modified animals and I note that its conclusions and recommendations were very much along the same lines as the APC report. In particular, both reports make reference to possible changes to the Home Office annual statistical report with respect to the production and use of GM and non-GM animals and both call for more work on how to assess the welfare issues surrounding the production and use of GM animals. I am pleased to note that the majority of the APC recommendations endorse current policy. As to the remaining recommendations, my comments are as follows:

Recommendation 8

I would be grateful; for the Committee's view on how the Home Office 3Rs research funds could be used to take this forward.

Recommendation 11

This is the responsibility of DEFRA as it relates to the transport of animals. The Home Office does not regulate this but we are aware that it is well covered by existing rules, which prohibit the movement of animals unfit for transport.

Recommendation 14-18

I believe that these would best be put to the Laboratory Animal Science Association and others to consider and take forward. Although a number of welfare assessment systems are in use or being developed, there is currently no recognised system that we can at this stage endorse or mandate for general use.

Recommendation 9

This is already current practice, but we can confirm in one of our regular circulars to Certificate of Designation holders that all welfare costs are to be considered in relation to GM animals by including a condition in the project licence.

Recommendation 10

There are existing national and international data bases which can be/are used for this purpose. It is not immediately clear where a further national database would make a contribution and this would not be a project on which the Home Office should necessarily take a lead. However, applications for funding from the 3Rs budget administered by the APC could be considered.

Recommendation 20

There is currently a wider consultation on the presentation of the annual statistics and we will take this recommendation into account when considering the outcome.

Recommendation 21

The review of the Ethical Review Process was completed last year, and has resulted in identification and dissemination of best practice. The recommendations made by the Prime Minister's Pharmaceutical Industry Competitiveness Task Force for streamlining the licensing process have been or are being implemented. The report by the Expert Group on Efficient Regulation, covering similar ground, is being carefully considered to see if there are any new points on which we should take action. These different strands of work have all provided relevant and useful information on the impact of the regulatory system on researchers. The current work being undertaken by the House of Lords Select Committee will I am sure add to this, and I see no need at present for further research in this area.

Yours sincerely

BOB AINSWORTH

***ALLINGTON TOWERS
19 ALLINGTON STREET
LONDON SW1E 5EB
020 7035 5291 or 5519***

From the Chairman
Reverend Professor Michael Banner MA DPhil

Bob Ainsworth MP
Parliamentary Under Secretary of State
Home Office
50 Queen Anne's Gate
London SW1H 9AT

10 December 2002

Dear Minister

ANIMAL PROCEDURES COMMITTEE (APC): RECOMMENDATIONS ON BIOTECHNOLOGY

Thank you for your letter of 9 July giving the Home Office's response to the recommendations of the APC's report on biotechnology. The Committee discussed the Home Office's response at its meeting on 9 October, and I am now passing on our conclusions. I regret to say that the Committee was very disappointed with the brevity of the Home Office's response, not least in the light of the extensive expenditure of time and thought both by the respondents to our consultation exercise and by the members of our working group. I should like to comment on the response to our report as a whole and on certain specific recommendations.

2. The background to the Committee's examination of developments in biotechnology is that we recognised that the developments in biotechnology offered science a major advance in investigative technology. This was of course to be welcomed, but we also recognised that these developments posed particular challenges to the working of the Animals (Scientific Procedures) Act 1986. We considered that the responses to these challenges needed to be considered before, not after the event, as corrective action might otherwise be impossible.
3. We and many of the respondents to our consultation exercise recognised that the increasing opportunities to use genetically modified (GM) animals would lead to increased use of animals. We were concerned that this might also lead to increasing welfare costs. And we were clear that the opportunities presented by GM technology presented novel ethical issues.
4. As you said in your letter (and as we ourselves frequently noted) many of our recommendations reflect current practice. Your letter states that those recommendations endorse current policy. We infer from that statement that the Home Office approves recommendations 1 to 7, 12, 13 and 22. It would be helpful if you could specifically endorse each of those recommendations.
5. When the Committee discussed your letter we thought that the Home Office should have gone much further than noting what was current practice. I do not think it unreasonable to ask for a more strategic response. For example, it would be helpful if you could comment on what can be now be done to re-

emphasise and restate these points in the light of the increasing use of GM animals. Our working group on biotechnology included past and current licence holders, and it was certainly not apparent to them that certain of the recommendations reflected current practice. That indicates that there may be a gap between what the Home Office considers is current practice and perceptions in science and industry. You stated, in your response to recommendation 9, that you could confirm current practice about monitoring welfare consequences in one of the regular Home Office circulars. We suggest that many more of the recommendations which reflect current Home Office practice should also be brought to the attention of the user community and ERP committees by means of Home Office circulars. Our report provided detailed analysis and suggestions about cage-side assessments, databases etc, and we would look to the Home Office to take these forward proactively. It would be helpful if you could comment on these suggestions.

Recommendations about welfare assessments of GM animals

6. Many of our recommendations referred to efforts to improve and promulgate the welfare assessment of GM animals. In your response, you suggested that the APC or the Laboratory Animal Science Association (LASA) could take this forward. I am sure that you will be pleased to hear that earlier this year the APC convened a series of meetings with the major funding bodies to discuss these recommendations. The funding bodies have decided to establish an expert working group to develop welfare assessment schemes for GM mice. This working group will review potential welfare issues for GM animals and current practice and make recommendations on best practice for welfare assessments. The Home Office should consider incorporating any recommendations the working group may make into guidance notes for the user community. The Home Office should also keep in close and supportive contact with the working group. For example, we understand that the group has accepted that the establishment of a welfare database (our recommendations 10 and 19) would be valuable, but that there are real practical difficulties. It would be reassuring to know that the Home Office was actively engaging in taking this forward.

Comments on other individual recommendations

7. The Committee noted that DEFRA administers the regulations about transport of animals (recommendation 11). However, it would be helpful if you could describe how the particular welfare needs of animals being kept in germ-free or minimum disease-barriered conditions on long journeys are catered for. What advice with a view to minimising any untoward welfare effects of transport on such animals could the Home Office give the user community and/or to DEFRA on the treatment of genetically modified animals before, during and after transport?

8. We accept that there have been several recent examinations which have looked at licensing procedures (recommendation 21), not least the House of Lords Select Committee on Animal Experimentation. However, while there has been much anecdotal opinion recorded in those fora, there is a lack of independent research into the real impact of ASPA regulation. Indeed, the report of the Select Committee stated in this connection that “the reality is hard to discover”. It would therefore be helpful if you could comment on our recommendation.

9. Recommendations 23 and 24 were for the AEBC. It would be helpful if you could confirm that these have been forwarded to that committee.

10. The APC looks forward to receiving a detailed response to each of the recommendations made in our report, and to what we hope are the further practical suggestions we make in this letter. I, with some of the APC members who served on the working group on biotechnology, would be pleased to attend a meeting with your officials if that would be helpful. The two of us might also discuss these issues at the meeting that officials have arranged on 12 December.

Yours sincerely

MICHAEL BANNER

ANNEX I

ANIMAL PROCEDURES COMMITTEE

Syllabus for an Introductory Course for Named Animal Care & Welfare Officers

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). 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.
2. Provide a forum for discussion of the ethical issues involved in the use of animals for biomedical research and describe how these are addressed within the framework of both UK and European legislation and by the UK Ethical Review Process.
3. 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.
4. Develop an understanding of the regulation, administration and spirit of the Act.
5. 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.
6. Develop an awareness of the Ethical Review Process and the role the NACWO is expected to play.
7. 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.
8. 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.
9. Promote the exchange of ideas and experiences during the course but also later by networking with others in a similar position.
10. Develop an awareness of continuing developments within the field of laboratory animal science and the need to keep up to date with scientific advances.
11. 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 (Anaesthetics) Act 1954, 1964
- Veterinary Surgeons Act, 1948, 1966
- Rabies Act 1974
- Balai Directive 92/65

2. Demonstrate an understanding of the ethical issues involved in the use of animals by society and have an appreciation of the wide range of views on animal use, in particular those used in biomedical research. Describe how these ethical issues are addressed within the framework of UK and European legislation and by the UK Ethical Review Process.

3. 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

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

- design of the licence
- the NACWO's contribution
- the mechanism for performing a cost benefit analysis

5. 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

6. 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

7. Recognise and quantify pain, suffering and distress in animals:
- signs to look for
 - scoring systems
 - severity limits/bands, constraints upon adverse effects, humane endpoints
 - actions to be taken

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 and consist of multi-choice and short answer questions. Delegates who achieve a 50% or higher mark will be issued with a Certificate of Successful Achievement.

ANNEX J

APC WORK PROGRAMME FOR 2003

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

Objective	Target Date
<i>Research & Alternatives sub-committee</i>	
Report to main Committee on the Government's response to the House of Lords' Select Committee recommendations about research into alternatives	February 2003
Regular work on monitoring existing projects and identifying new ones	As necessary
Carry out review of strategy and report to main Committee	April 2003
<i>Primates sub-committee</i>	
Prepare report to main Committee on the supply and acquisition of primates	October 2003
Report to Home Secretary	December 2003
Examine issues re training of primates	December 2003
<i>Education & Training sub-committee</i>	
Consider House of Lord's recommendation that scientists and students visiting the UK should be allowed to work under the licences of established licence-holders	June 2003
Define and prioritise current education and training issues	June 2003
<i>Accommodation and Care sub-committee</i>	
To deal with husbandry and care issues which the main Committee refers or which are identified by the sub-committee	As necessary
<i>Cost/Benefit working group</i>	
Finalise report and circulate to APC	February 2003
Report to Home Secretary	February 2003
<i>Miscellaneous working group</i>	
Complete outstanding issues on cephalopods	February 2003
Complete remaining issues	February 2003
<i>Overbreeding working group</i>	
Report to APC	April 2003
Report to Home Secretary	May 2003
<i>Schedule 1 working group</i>	
Carry out consultation	March 2003
Make second interim report to APC	June 2003
<i>Cambridge Primates – BUAV allegations working group</i>	
Report to APC	June 2003
Report to Home Office	October 2003

B: Items for Consideration by the Main Committee

Objective	Target Date
Contribute to revision of EU Directive 86/609/EEC	As required
Consider how to raise the APC's profile with the user community and the general public	September 2003
Review Government's response to the House of Lords' Select Committee report	February 2003
Review of APC's future work	November 2003 (weekend conference)

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