Report of the Animal Procedures Committee for 2006

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

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ANIMAL PROCEDURES COMMITTEE

Membership as at 31 December 2006

Sara NATHAN (Chairman) – Freelance Journalist and former Editor Channel 4 News. Has a portfolio of public appointments including Ofcom Board Member and Judicial Appointments Commissioner.

John DOE MIBiol PhD – Head of Product Safety, Syngenta.

Michael FESTING MSc PhD DSc FIBiol CStat – Consultant Statistician.

Simon GLENDINNING BA BPhil DPhil – Reader in European Philosophy in the European Institute at the London School of Economics and Political Science.

Penny HAWKINS BSc PhD – Deputy Head of Research Animals Department, Royal Society for the Prevention of Cruelty to Animals.

Robert HUBRECHT BSc PhD CBiol FIBiol – Deputy Scientific Director, Universities Federation for Animal Welfare.

Peter HUNT MPhil PhD MIBiol FIAT RAnTech – Biological Standards Officer, Cardiff University.

Robert KEMP FIAT RAnTech – Astra Zeneca (retired).

Keith KENDRICK BA PhD CBiol FIBiol – Gresham Professor and Head of Cognitive and Behavioural Neuroscience, Babraham Institute.

Graham MOORE BVM&S MRCVS – Veterinary Surgeon and Consultant in Science Policy and Scientific Affairs.

Timothy MORRIS BVetMed PhD CertLAS DipACLAm DipECLAM CBiol FIBiol MRCVS – Head Animal Research Ethics, GlaxoSmithKline.

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

John PICKARD BA MA MB BChir FRCS MChir F Med Sci – Professor of Neurosurgery, University of Cambridge.

Mark PRESCOTT BSc PhD – Programme Manager, National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs).

Ken SIMPSON BMSc (Hons) MBChB (Hons) MSc MD PhD FRCP (Edin) – Medical Practitioner the Edinburgh liver transplantation programme.

APC Secretariat
Phil Banks (from Nov 2006)
Philip Brenner
Richard West (to August 2006)

CHAIR'S LETTER TO THE RT HON JACQUI SMITH MP, SECRETARY OF STATE FOR THE HOME DEPARTMENT AND TO MICHAEL McGIMPSEY MP, THE NORTHERN IRELAND MINISTER FOR HEALTH, SOCIAL SERVICES AND PUBLIC SAFETY

I have pleasure in submitting to you the Animal Procedures Committee's Annual Report for 2006.

I took over the chair of the committee at the beginning of 2006 from my predecessor, the Reverend Professor Michael Banner who had had a long and successful chairmanship. The Committee membership has changed substantially in the last year with eleven Members retiring at the end of their terms and five new ones coming on board. I am very grateful to members both old and new for their commitment, knowledge and support in the last year.

As a career journalist, it isn't surprising that I have been pursuing a theme of "informed openness" on the Committee's activities. I hope to make our conduct of business more transparent and to encourage open, informed and constructive debate on the subject of animal testing.

The role of overseeing the regulation of animal use for experimentation remains a challenging one. The Committee has no regulatory powers but believes that the advice it offers the Home Secretary through Ministers and Officials in relation to the use of Animal (Scientific Procedures) Act 1986 is critical given the pace of developments in this area. A significant factor in the Committee's composition and effectiveness is that members give their time and expertise as individuals and not as representatives of particular organisations.

The Committee has had another productive year. We hope that our contribution has been recognised and that the Home Department continue to appreciate the efforts of our members and secretariat to assist Ministers in sensitive and difficult decision making.

SARA NATHAN

INTRODUCTION

This report describes the work carried out during the year 2006 by the Animal Procedures Committee.

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

- It shall be the duty of the Animal Procedures Committee to advise the Secretary of State on such matters concerned with the Act and her functions under it as the Committee may determine or as may be referred to the Committee by the Secretary of State; and

- 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.

Annex A to this report sets out some information about the Committee, including its legislative background, the Ministers it reports to and its membership. On joining the Committee, members agree to be bound by its Code of Conduct (see Annex B). Among other things this requires members to 'declare any personal or business interest which may, or may be perceived (by a reasonable member of the public) to influence their judgement'. A register of members' interests is on the APC website[1].

The full Committee met five times during 2006, and in addition there were thirteen sub-committee and six working group meetings. As in previous years we also held an annual conference that provided an additional useful forum for learning, discussion and debate. Annex C details the membership of the Committee's sub-committees and working groups.

In accordance with guidelines from the Office of the Commissioner for Public Appointments, the Committee operates a performance appraisal system. Each year the Chair assesses each member's performance against the following criteria:-

- Adherence to the Committee's Code of Conduct;

- Attendance at meetings of the full Committee; at sub-committees and working groups; and at the Committee's annual conference;

- The member's contribution to the general work of the Committee in terms of his or her particular skills and experience.

Members are able to comment on the appraisal, and if desired make representations to a senior Home Office official. Ministers take these appraisals into account when deciding whether a member should be re-appointed. The Chair's performance is also assessed, using similar criteria, by a senior Home Office official, though this did not take place in 2006 due the retirement of the previous Chair and the appointment of a new Chair in this year.

[1] The APC website www.apc.gov.uk.

THE MAIN POINTS FROM THE COMMITTEE'S WORK IN 2006 WERE AS FOLLOWS:

- Acceptance of overseas centres supplying non-human primates to UK laboratories: a report by the Primates sub-committee of the Animals Procedures Committee. **(Annex E of this report)**
- Review of Schedule 1 of the Animals (Scientific Procedures) Act 1986: Appropriate methods of humane killing. **(Annex G of this report)**
- An update for the housing and care of animals used in scientific procedures; an aide-mémoire for users and staff comparing proposed changes to European legislation to existing UK codes of practice **(Annex J of this report)**
- Education and Training Sub-Committee report on modular training. **(Annex K of this report)**
- This report concludes with the Committee's work plan for 2007. **(Annex M of this report)**
- Ongoing work carried out by our sub-committees.
- The appointment and induction of the Chairman and 5 new Committee members.
- The consideration of one project licence application.

THE COMMITTEE'S WORK DURING 2006

Applications Sub-Committee (ASC)

1. The Home Office refers a small number of project licence applications to the Committee for advice. Since 2004 the categories of licence to be referred include:

- any involving the proposed use of wild-caught non-human primates;
- any involving the proposed use of cats, dogs, equidae[2] or non-human primates in protocols of substantial severity;
- any projects with a substantial severity banding, or major animal welfare or ethical implications, involving (a) xenotransplantation[3] of whole organs, or (b) chronic pain models, or (c) study of the central nervous system;
- applications of any kind raising novel or contentious issues, or giving rise to serious societal concerns. (For example, any application involving the genetic modification of non-human primates or embryo aggregation chimaeras[4] involving dissimilar species.)

2. There was just one specific project licence application referred to the Committee for advice in 2006; the application involved the use of non-human primates in procedures of substantial severity to develop animal infection models of microorganisms. This application was discussed first by our Applications sub-committee (ASC), then again with representatives of the organisation making the application before putting the sub-committee's consideration to the full Committee.

The Home Office accepted the Committee's advice and in granting the licence, the Minister asked that this project be closely monitored to ensure that refinement and reduction opportunities will be maximised.

Primates sub-committee (PSC)

3. The role of the PSC is to advise the Committee on issues relating to the acquisition, housing, care and use of non-human primates in scientific procedures. In 2006 the PSC considered the acceptability of two establishments as sources of primate imports to the United Kingdom from Asia. In considering its advice, the sub-committee was informed of the last Inspectorate visits to each site and of the improvements made. In both cases approval was granted for up to 2 years.

4. In 2005 the PSC started work on advice relating to formalising existing criteria for its consideration of overseas establishments. It held several meetings, and received much assistance from the Inspectorate which carries out visits to overseas breeding centres. The sub-committee finalised its report early 2006[5]; Acceptance of Overseas Centres supplying non-human primates to UK Laboratories.

[2] **Equidae** – the Equidae family of mammals which have a single functional digit although the second and third digits persist as splint bones. Equids include horses, asses and zebras. N.B. Certain technical and scientific terms are defined at their first occurrence in footnotes. They are summarised in a glossary at the end of the report, which also contains a list of acronyms used.

[3] **Xenotransplantation** – the transplantation of cells, tissues or organs from an animal of one species to an animal of a different species.

[4] **Embryo aggregation chimaeras** – A collection of embryos containing genetically distinct types of cells.

[5] The report of the Primates sub-committee on overseas primate sources was sent to the Home Office in February 2006. www.apc.gov.uk/reference/primate-sources-report.pdf

5. The sub-committee also considered the Weatherall Report[6] that was published late 2006, a formal response from the full Committee will follow in 2007.

The Research and Alternatives sub-committee (RASC)

6. In May 2004, the Government set up The National Centre for the Replacement, Reduction and Refinement of Animals in Research (NC3Rs), this facility superseded the Research and Alternatives sub-committee's research and development role.

7. In total, for the period 1987 to 2005, fifty nine research grants directed towards Replacement, Refinement and Reduction were funded by the Home Office, following advice from the Research and Alternatives Sub-committee.

The final project funded by the Home Office up to the beginning of 2006 was:

- Central Science Laboratory: Evaluation and validation of electrochemiluminescent method for the detection of *Clostridium botulinum* toxins A, B, E and F in foodstuffs.

This project was aimed at replacing the current standard mouse bioassay with an electrochemiluminescent based assay format. However, results showed that cross-reactivity between C. botulinum strains and other non-clostridial species occurred. Additionally the possible use of this technology as a screening tool to reduce the number of tests requiring the mouse bioassay was also evaluated. Unfortunately, false positive results severely limited the application of this technology as a replacement of the current standard or as a screening tool to reduce the number of tests which require the mouse bioassay. The researchers concluded that a considerable amount of development work would be required for this technology to be considered as a viable replacement for the mouse bioassay.

8. The Research and Alternatives sub-committee is therefore to wind down and will end its work in 2007.

Education and Training sub-committee (ETSC)

9. Last year's Annual Report[7] reported on the sub-committee's review of the training modules for personal and project licence applicants under the Animals (Scientific Procedures) Act 1986 (ASPA) and good progress was made this year. In this work the sub-committee sought to:

- provide an overview of current training requirements for both personal and project licensees;
- define core competencies and learning outcomes appropriate for personal licence applicants;
- propose revisions to the structure of modules 1 to 4; and
- identify issues requiring further consideration, including review of module 5 training for project licensees.

10. The sub-committee also received considerable assistance from a member of the Home Office Inspectorate, who attended meetings as an observer/advisor. A report was prepared and submitted to the Minister in February 2006[8]. The Minister responded to the review in November 2006 and outlined a requirement for further advice in relation to accreditation of training.

[6] The use of non-human primates in research, December 2006. A working group report chaired by Sir David Weatherall FRS FMedSci. www.royalsoc.ac.uk/downloaddoc.asp?id=3696

[7] Report of the Animal Procedures Committee for 2005, Oct 2006.

[8] The report of the Education and Training Sub-Committee on Modular training was sent to the Home Office in February 2006.

Housing and Husbandry[9] sub-committee (HHSC)

11. The APC attaches great importance to the housing and husbandry of animals used in research, due to its importance for the lifetime welfare of the animals involved. This year the sub-committee's main tasks were:

i. To examine the format of the existing users' and breeders' Codes of Practice, with the aim of providing recommendations relating to any future changes in European legislation. The Council of Europe has revised its recommendations on the care and housing of animals used in research with these recommendations coming into force on June 15th 2007. In August 2006 the sub-committee published an aide-mémoire (Annex K) that outlined significant differences between the UK codes and the revised recommendations with the aim of assisting users to take steps to ensure that their housing reflects present knowledge and good practice.

ii. To identify areas of animal use, where there is little data on housing and care. Also to explore, what mechanisms exist for promoting good practice and implement their use. For the remainder of the year the sub-committee met to consider policy concerning standards of animal housing and husbandry for animals from overseas non-designated sources, a report on which is due in 2007.

Suffering and Severity Working Group

12. As reported last year, in 2005 the Laboratory Animals Science Association (LASA) proposed a pilot study of a retrospective system to measure substantial severity. This took forward work initiated and reported on by the RSPCA and the Boyd group[10]. To avoid duplication, the APC Working Group decided to collaborate with this study. The Home Office provided funding for a consultant to analyse the study and prepare a report[11].

13. This LASA Working Group is comprised of representatives from nine establishments drawn from industry/pharmaceutical organisations (3), large universities (3) and major government research institutes (3). The Group includes project licence holders, a personal licensee, a Named Veterinary Surgeon and a Home Office liaison officer. Members of the APC Working Group on Suffering and Severity and a Named Animal Care and Welfare Officer (NACWO) have also participated. A Home Office Inspector attended all meetings as an observer/advisor.

14. Working within the terms of reference provided by the APC, the LASA Working Group has devised a method of providing information about suffering and severity experienced by individual animals measured retrospectively.

15. Last year's annual report detailed the development of a two grid intensity-duration model, to indicate (i) maximum severity and (ii) severity over the remainder of the procedure. This had the potential to provide a representative picture of intensity and duration of severity over a wide range of different procedures. This year the Group applied the two-grid model to a series of procedures to gain user feedback. Users have commented that the system was understandable, intuitive to apply and workable in terms of its capacity to portray the severity of adverse effects in more complex procedures.

16. All LASA Working Group members consider the introduction of a retrospective severity assessment process to be beneficial, but are mindful of the additional bureaucratic burden that this would bring. The working group has collected estimates of resources required for introduction of retrospective reporting of severity, and early indications are that for some establishments the burdens would be considerable. The Home Office confirms that the two-grid system of severity assessment offers a practical tool and has asked that development work continue.

[9] **Husbandry** (animal) - the practice of breeding, raising and caring for animals.

[10] www.boyd-group.demon.co.uk/, a UK based forum for open exchange of views on issues of concern related to the use of animals in science.

[11] A report of the initial APC/LASA pilot study can be seen on the APC website www.apc.gov.uk/reference/lasa-report.pdf

17 By the end of this reporting year the Group had carried out the following additional analyses;

Modification of the two-grid system to simplify the process as a means of reducing the burden of its use:

- The Group has devised a rationalised scheme and tested it against the original examples used in the pilot study.
- The Group concludes that compared with the simplified scheme the original two-grid system is more straightforward and easier to use in practice, and better captures severity (particularly duration).

Reporting severity within the annual returns:

- To avoid the need for numerous additional columns in the returns (reported laboratory data), which would greatly complicate the process, the LASA Working Group recommends that severity data be returned using additional rows, one for each banding, at the end of the returns form.
- The Group is clear that retrospective severity data require retrospective statistics, and recommends a change to retrospective reporting across the board.

Reducing the resource impacts required to report severity data:

The Group has conducted a critical look at the data required in the current annual Returns, and made specific proposals for changes that could streamline and facilitate the process. These suggestions are in line with the recommendations of the Davidson Review[12] which urges changes by the end of 2007.

Other means of reporting severity data:

The Group has considered alternative means of conveying the harm-benefit assessment involved in animal testing procedures. These will be reported in the LASA Working Group's second report which will be prepared late 2007. These alternatives aim to list ways of linking severity data with outcomes of specific research.

Severity assessment examples of difficult procedures:

The Working Group considered issues arising in examples of mild and more substantial wild animal work and the use of fish.

Review of Schedule 1 of the Act

18. The humane killing of a protected animal is not a regulated procedure requiring authorisation by a project or personal licence, if it is undertaken at a designated place for a scientific purpose, and if it is performed by a method listed in Schedule 1 of the Animals (Scientific Procedures) Act as appropriate to the type of animal. In 2001 the Animal Procedures Committee was requested by the Minister 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.

19. The Working Group has met nine times and prepared a report[13] for the Minister. Published in December 2006, the report takes in a broad spectrum of information and makes 13 recommendations with the aim of ensuring practice reflects current scientific evidence and making the Code of Practice for humane killing more

[12] Davidson Review: Implementation of EU legislation; Gold-plating – Animal Scientific Procedures a case study.

[13] Review of Schedule 1 of the Animals (Scientific Procedures) Act 1986 – Appropriate methods of humane killing. December 2006.

user-friendly. The report recommends that the regulatory process be sufficiently flexible to allow for rapid implementation of refinements and good practice. The Minister's response to the recommendations is given in Annex H of this report.

20. As a follow-up to the Schedule 1 report, the working group agreed to continue to monitor new research into the use of CO_2 with a view to deciding whether with new evidence, the technique should remain an acceptable method of humane killing of rodents. Preliminary results indicate that pain receptors of rats are activated when they suddenly encounter high (>50%) CO_2 concentrations[14]. Such new findings suggest that higher filling rates in chambers for euthanasia would cause significant welfare problems, whilst a slower rate, often much slower than current practice, induce unconsciousness before such high concentrations are reached. The Working Group will update the Committee in autumn 2007.

Revision of Directive 86/609 Working Group

21. Directive 86/609/EEC is the key legislative act of the European Community that directly protects laboratory animals in the member states of the European Union. The Directive includes measures related to the use of animals in scientific procedures such as their housing and care, requirements for the authorisation of persons and establishments and the minimisation of pain, suffering and distress of these animals. It was adopted in 1986 but has not been changed since despite significant advances in technology and understanding. In 2002 the Commission acknowledged the need to review and update the Directive.

22. The initial stage of this review involved the establishment by the European Commission of a Technical Expert Working Group, which was tasked with providing information on a list of topics detailed by the Commission. Additional advice was sought from the European Food Safety Authority and Consultants were appointed by the Commission to carry out a preliminary impact assessment of possible options for a revised Directive.

23. The APC has closely followed developments with the review of 86/609/EEC and in 2006 set up a Working Group so as to be in a position to provide input to the process. In view of the potential impact on the UK regulatory system of any changes to the Directive, the APC decided it should respond to the Commission's consultation for experts and expert groups and, between April and July 2006, the Working Group prepared this response. The information obtained from this consultation will enable the European Commission to complete an impact assessment and to identify the most appropriate policy options to include in a new Directive.

Infringements

24. The Home Office provides the Committee with an annual summary of infringements. These are breaches of the 1986 Act, or of licence or certificate conditions. Once Home Office action on the infringement has been completed a report is forwarded to the Committee for information.

25. In December, the Home Office supplied the APC with a report of infringements that had been completed in 2005. The Committee are grateful to the Home Office for sharing this information as it provides the Committee with an opportunity to analyse breaches and discuss strategies for dealing with any problems.

26. As was indicated in last year's Annual Report, the Committee recognise the concern that publishing material in relation to infringements may be in breach of data protection requirements. Mindful of both the concerns about personal privacy and the Committee's endorsement of openness, the Committee would like to confirm that it does react appropriately to infringements. The publication of such information is a matter for the Home Office itself rather than through the Animal Procedures Committee.

[14] www.nc3rs.org.uk/CO2ConsensusReport.

Work programme for 2007

27. We discussed the Committee's work programme for 2007 at our Annual Conference in November 2006. Late in 2006 the Parliamentary Under Secretary of State (Joan Ryan MP) asked the Committee to consider three issues relating to the operation of the 1986 Animals (Scientific Procedures) Act in accordance with the Home Office Simplification Plan and Better Regulation. In 2007, the Committee will advise on personal licence and mandatory training requirements; the criteria for the discharge of genetically altered animals from the controls of the Animals (Scientific Procedures) Act. The Committee's work programme for 2007 is detailed in Annex M.

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

3. The Act applies throughout the United Kingdom. For work taking place in England, Scotland and Wales the Home Office issues licences under the Act on behalf of the Home Secretary. In Northern Ireland, licences are issued by the Department of Health, Social Services and Public Safety. In each department there is an Inspectorate consisting of professional staff with medical or veterinary qualifications which examines and advises on all applications for authorities under the Act. The inspectors also inspect establishments and the licensed work being carried out there.

The Committee

4. The function of the Animal Procedures Committee is to provide the Home Secretary and the Northern Ireland Minister of Health, Social Services and Public Safety with independent advice about the Act and their functions under it. The 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 2006. During 2006 Ministers appointed a new Chairman and five new members: Ms Sara Nathan (Chair) took up office in January 2006, Dr Mark Prescott, Dr Peter Hunt, Dr Simon Glendinning, Dr Penny Hawkins and Dr Ken Simpson were each appointed for a period of 4 years. This year also saw the retirement of 11 Committee members, the Committee would like to thank Professor Chris Atterwill, Professor Don Broom, Professor Graham Bulfield, Dr David Clark, Professor Stephen Clark, Professor Alan Holland, Dr Maggy Jennings, Dr Gill Langley, Professor John Martin, Professor Alan McNeilly, and Professor Genevra Richardson for their commitment to this committee and wish them well.

5. The Animals (Scientific Procedures) Act 1986 requires

- that there must be at least 12 people on the Committee (in addition to the Chair) 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).

- By convention there is normally a philosopher on the Committee, although this is not a statutory requirement.

6. Members are appointed for terms of up to 4 years and can be re-appointed once. The 1986 Act specifies that payments may be made to the Chairman by way of remuneration, and that other members can receive reimbursement for any reasonable out of pocket expenses incurred by them in the performance of their duties. During the financial year 2006/2007, the Home Office had budgets of £10,000 and £16,000 respectively from which to make such payments.

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

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

Ministers

9. The Home Secretary in practice delegates his responsibilities

under the Act to another Minister in the Home Office, which administers the Act in England, Scotland and Wales. At the beginning of 2006 that Minister was Andy Burnham MP, and was replaced by Joan Ryan MP in May 2006. 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 (DHSSPSNI). At the beginning of 2006 the responsible Minister in DHSSPSNI was Shaun Woodward MP; he was replaced by Paul Goggins MP in May 2006.

ANNEX B

THE ANIMAL PROCEDURES COMMITTEE'S CODE OF CONDUCT

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

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

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

3. The 1986 Act adds that:

(i) in its consideration of any matter the Committee shall have regard both to the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures;

(ii) the Committee may perform any of its functions by means of sub-committees and may co-opt as members of any sub-committee any persons considered by the Committee to be able to assist that sub-committee in its work;

(iii) the Committee may promote research relevant to its functions and may obtain advice or assistance from other persons with knowledge or experience appearing to the Committee to be relevant to those functions;

(iv) the Committee shall in each year make a report on its activities to the Secretary of State who shall lay copies of the report before Parliament; and

(v) members of the Committee shall be appointed for such periods as the Secretary of State may determine but no such period shall exceed four years and no person shall be re-appointed more than once.

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

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

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

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

(i) familiarise themselves with the terms of reference of the Committee;

(ii) undergo any required induction training;

(iii) declare any personal or business interest which may, or may be perceived (by a reasonable member of the public), to influence their judgement. This should include, as a minimum, personal direct and indirect pecuniary interests, and should normally also include such interests of close family members and of people living in the same household. A register of interests will be kept up-to-date and will be open to the public;

(iv) not participate in the discussion or determination of matters in which they have a personal or business interest, and should normally withdraw from the meeting (even if held in public) if their interest is direct and pecuniary;

(v) make a declaration of interest at any Committee meeting if it relates specifically to a particular issue under consideration, for recording in the minutes (whether or not a Committee member withdraws from the meeting);

(vi) not misuse information gained in the course of their public service for personal gain or for political purpose, nor seek to use the opportunity of public service to promote their private interests or those of connected persons, firms, businesses or other organisations;

(vii) not hold any paid, or high profile unpaid, posts in a political party, and not engage in specific party political activities on matters directly affecting the work of the Committee. When engaging in other political activities, members should be conscious of their public role and exercise proper discretion; and

(viii) understand and accept that they are appointed as individuals and not as representatives of organisations by which they are employed or with which they have significant contacts.

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

(i) ensuring that the Committee meets at appropriate intervals, and that the minutes of meetings and any reports to the Secretary of State accurately record the decisions taken, and where appropriate, the views of individual members;

(ii) representing the views of the Committee to Ministers;

(iii) representing, where appropriate, the views of the Committee to the general public;

(iv) ensuring that new members are briefed on appointment;

(v) sitting on the panel which advises Ministers on new appointments and re-appointments.

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

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

(i) an offence under section 24 of the Animals (Scientific Procedures) Act 1986;

(ii) a breach of confidence under common law; or

(iii) a criminal offence under insider dealing legislation

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

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

ANNEX C

MEMBERSHIP OF APC SUB-COMMITTEES AND WORKING GROUPS AS AT 1 DECEMBER 2006

Proposals for the membership of current sub-committees and working groups and their memberships are listed below.

Research and Alternatives Sub-Committee

Dr Michael Festing (Chair)
Mr Graham Moore
NB RASC will close down when last remaining project is completed (March 2007)

Education and Training Sub-Committee

Mr Graham Moore (Chair)
Dr Michael Festing
Mr Robert Kemp

Co-opted Members:

Dr Maggy Jennings **(retired from the chair 31 March 2006 but remains a co-opted to sit on Module 5 working group)**
Bryan Howard (ex Sheffield University)
Manuel Berdoy (Oxford University)
Jane Smith (Boyd Group)
Janet Watson (Astra Zeneca)

Primates Sub-Committee

Professor John Pickard (Chair)
Dr Robert Hubrecht
Dr Mark Prescott
Dr Peter Hunt

Housing and Husbandry Sub-Committee

Dr Robert Hubrecht (Chair)
Mr Robert Kemp
Dr Tim Morris
Dr Mark Prescott
Professor Keith Kendrick
Dr Penny Hawkins

"Applications" Sub-Committee

Ms Sara Nathan (Chair), with one of each of the following pairs

Dr Robert Hubrecht	Or	Professor John Pickard
Mr Graham Moore	Or	Dr John Doe
Professor Dawn Oliver	Or	Dr Simon Glendinning
Dr Mark Prescott	Or	Dr Peter Hunt

Schedule 1 Working Group

Dr Tim Morris (Chair)
Mr Robert Kemp
Co-opted member:
Mr Terry Priest (Manchester University)

Suffering and Severity Working Group

Professor Dawn Oliver (Chair)
Professor John Pickard
Dr Robert Hubrecht
Mr Graham Moore
Mr Robert Kemp

Revision of Directive 86/609 Working Group

Mr Graham Moore (Chair)
Dr Peter Hunt
Professor Dawn Oliver
Dr Penny Hawkins
Dr Ken Simpson

ANNEX D

APPLICATIONS SUB-COMMITTEE: MODUS OPERANDI

1. The Applications sub-committee will be ready to meet on the first Wednesday of March, May, August and November. Where necessary it will also be ready to meet on the same date as the full APC Committee meetings in February, April, June, September, October and December. It may also be specially convened at other times if necessary. The aim of the sub-committee will be to complete consideration of any issues that affect an application within 30 calendar days. This will partly depend on the Home Office at an early stage identifying cases to be referred to the sub-committee. The sub-committee expects to review around 8 cases per year.

2. The sub-committee will comment on the broader issues raised by applications and on specific details where appropriate. Where necessary it may seek to interview the licence applicant(s).

Involving the full APC in the decision making process of the sub-committee

3. When an application is received from the Home Office, it will be copied to all members of the APC, so that they will have an opportunity to pass on to the sub-committee any concerns or questions. The sub-committee will meet, interview the applicant if necessary, and formulate draft recommendations.

4. On occasions where the sub-committee is meeting on the same day as the full APC those draft recommendations can be discussed by the main Committee.

5. On other occasions, the sub-committee's recommendations will be circulated to all APC members for comment. The sub-committee will consider whether to amend its recommendations in the light of those comments, and then forward its definitive advice to the Home Office. At the next meeting of the APC, the sub-committee's advice will be reported retrospectively, and it will be open to any APC member to raise any issue of concern.

Rolling membership

6. It is proposed that the APC Chairman should be an ex officio member of the sub-committee, and attend all meetings.

7. Other members of the APC may be brought into the sub-committee depending on their expertise and the subject of the licence application.

ANNEX E

ACCEPTANCE OF OVERSEAS CENTRES SUPPLYING NON-HUMAN PRIMATES TO UK LABORATORIES: A REPORT BY THE PRIMATES SUB-COMMITTEE OF THE ANIMALS PROCEDURES COMMITTEE

Executive summary

This report presents the APC Primates Sub-Committee's (PSC) recent work on the acquisition and supply of non-human primates[1] for use in research and testing under the Animals (Scientific Procedures) Act 1986. The objective of this part of the Sub-Committee's work programme has been to review and where necessary make recommendations that will improve the process for acceptance of overseas centres which supply primates to UK laboratories.

The Home Office Inspectorate and the PSC both have a responsibility to provide advice to the Home Office on the acceptability of centres as a source of primates, and the proposals in the report are intended to help both bodies give better informed advice in this respect. The report provides the basis for the development of a more structured system of assessment and acceptance of breeding and supplying centres, so that there is a clear audit trail of the decisions made in each case.

A second and equally important objective is to update current UK processes with regard to the breeding and supply of primates. Although the PSC and Home Office cannot actually set standards for the centres, we hope that the important processes will help reduce the negative impact on primate welfare of the whole process of acquisition.

Lastly, the report contributes to greater transparency by setting out more detail about the way that overseas centres supplying primates to the UK are assessed by the Home Office and how advice from the Home Office Inspectorate and the PSC is formulated.

The PSC has been pleased to note progress made over the years. For example, there have been improvements made in husbandry and care after visits to centres, both by the Home Office Inspectorate and clients. The visits have provided a visible presence and helped press for, and encourage, improvements in animal welfare, with advice and support being offered. It is important to ensure that this type of progress continues.

The main focus is on macaque species but the principles within the document are applicable to marmosets and other species of non-human primate supplied to the UK.

Summary of recommendations

The PSC has already amended its own procedures and expectations as described within the report. In addition the report contains a series of recommendations to the Home Office which are summarised below.

[1] Non-human primates are hereinafter referred to as primates.

The PSC recommends that:

1. The criteria for assessing centres together with information on the process used by the Home Office and the PSC to assess centres should be made widely available so that everyone is aware of the standards that the facilities are working to. In the interests of transparency, the criteria should be published as an annex to the Annual Report of the APC, and on the Home Office and APC web-sites.

2. It should be a formal requirement that all applications should be passed to the PSC for discussion and formulation of advice. Discussion with the Inspector/s responsible for visiting the centres is extremely helpful and should remain an essential part of this process.

3. The criteria set out in section 6 of this report should be used by the Home Office as a basis for assessment of the acceptability of suppliers of primates. The PSC will use these in the formulation of its independent advice to the Home Office.

4. All overseas centres should have a clear strategy designed to help them to achieve the required minimum standards set out in this report within a reasonable timeframe. The Sub-Committee and the Home Office Inspectorate should regularly monitor progress towards this goal.

5. All new centres should be visited by a Home Office Inspector prior to consideration of the centre's details by the Sub-Committee. Staff from research establishments applying to source primates from a new centre should also be encouraged to visit the facilities, but this should be as well as, not instead of, the Inspectorate. If an urgent and legitimate need arises for animals to be obtained from an overseas breeding centre, and the animals in question cannot be obtained from one that is already accepted by the Home Office, then a decision to accept a new centre may be based on the revised application form and accompanying information alone. However, this would be on a 'one-off' basis, with a visit necessitated if further animals were requested.

6. Once a centre has been accepted, it should be revisited by the Home Office Inspectorate at two-yearly intervals prior to re-acceptance, in order to continue to promote and monitor improvements in standards. Additional visits may be necessary where there are specific issues that need to be addressed.

7. The Home Office Inspectorate should maintain a user-friendly database or spreadsheet for those importing primates that will allow easy identification and comparison of standards at all overseas centres supplying primates to the UK. Resources should be made available to facilitate this if necessary.

8. The Home Office, in conjunction with the PSC, should review the criteria for acceptance of centres (and the process if appropriate) at three-yearly intervals, or earlier if this becomes necessary.

ANNEX F

MINISTER'S RESPONSE TO ACCEPTANCE OF OVERSEAS CENTRES SUPPLYING NON-HUMAN PRIMATES TO UK LABORATORIES: A REPORT BY THE PRIMATES SUB-COMMITTEE OF THE ANIMALS PROCEDURES COMMITTEE.

Sara Nathan
Chair of the Animal Procedures Committee
c/o APC Secretariat
1st Floor Seacole Building
2 Marsham Street
London
SW1P 4DF

Report By The Animal Procedures Committee (Primates Sub-Committee): Acceptance Of Overseas Centres Supplying Non-Human Primates To Uk Laboratories

In February 2006 the Animal Procedures Committee (Primates Sub-Committee) published its report on the acceptance of overseas centres supplying non-human primates to UK laboratories. I am grateful to the Committee for the consideration it has given to this important issue.

In responding to the report, I wish to record my thanks to you and to the Committee for the time and thought that has been put into it. I am very grateful for the advice it contains.

My detailed response to the Committee's current report and recommendations are set out in the annex to this letter.

JOAN RYAN
Parliamentary Under Secretary of State
Home Office

REPORT BY THE ANIMAL PROCEDURES COMMITTEE ON THE ACCEPTANCE OF OVERSEAS CENTRES SUPPLYING NON-HUMAN PRIMATES TO UK LABORATORIES: A REPORT BY THE PRIMATES SUB-COMMITTEE OF THE ANIMALS PROCEDURES COMMITTEE

Government Response by Joan Ryan, MP
Parliamentary Under-Secretary of State for the Home Department

Introduction

The Government recognises that the responsible, limited use of non-human primates for experimental and other scientific purposes still plays an essential part in producing new knowledge and insights that underpin advances in healthcare and bring other benefits not currently achievable by other means. The majority of procedures that involve the use of primates are conducted as part of the regulatory testing designed to ensure the efficacy and safety of potential pharmaceuticals. We are also aware that the use of non-human primates is an issue of public concern.

Under the terms of the Animals (Scientific Procedures) Act 1986 (ASPA) non-human primates, together with some other sensitive species, are given special protection and can only be used where animals of no other species area suitable. In addition, under the 1986 Act, unless the Secretary of State has authorised an exemption, non-human primates used in regulated procedures must be obtained from a designated breeding or supplying establishment. As the UK demand for purpose-bred animals exceeds the numbers produced by the UK designated breeders we receive regular requests to use animals from overseas sources.

The current policy and processes for authorising the use of non-human primates from overseas sources is based on a number of measures brought in to support the ban on the use of wild-caught primates introduced in 1995. In effect we will only allow the use of animals from overseas centres we believe produce purpose-bred animals to acceptable welfare standards.

Typically we require detailed information on the standards and performance of each overseas centre seeking to supply non-human primates for use in the UK. It is then our usual practice for the Inspectorate to visit these potential sources and to advise on their acceptability. The Animal Procedures Committee is then asked to offer independent advice on the suitability of the overseas source based upon information supplied by the overseas centre and the Inspectorate.

Suitable overseas sources are usually accepted for periods of up to two years. In some cases acceptance is conditional on specified improvements being made within a given time frame. The ASPD licensing team maintains a list of breeding and supplying centres that have been accepted and details are made available to potential users as required. Once a centre has been accepted by the Home Office it is not necessary to re-appraise it before approving each subsequent request to use animals from the same source.

The Committee's Report and recommendations

For ease of reference, I have set out my response to the Committee's report against the eight principal recommendations presented in its summary of recommendations.

Recommendation 1

We recommend that the criteria for assessing centres together with information on the process used by the Home Office and the PSC to assess centres should be made widely available so that everyone is aware of the standards that the facilities are working to. In the interests of transparency, the criteria should be published as an annex to the Annual Report of the APC, and on the Home Office and APC web-sites.

Response

I accept this recommendation.

I fully agree that greater public awareness of the process of acquisition and supply and the principles that underpin it is to be actively encouraged. To this end, the Animals Scientific Procedures Inspectorate's (ASPI) Annual Report for 2005 outlined the process used by the Home Office to assess and monitor centres that supply non-human primates to UK laboratories. The relevant extract is attached as an appendix to this note.

In addition, as regards the criteria upon which assessment of overseas breeding centres is based, we will update these periodically so that we are able as far as possible to ensure the centres meet the main provisions of the Home Office code of practice for the housing and care of animals in designated breeding and supplying establishments. The criteria will also be updated to clearly identify qualifying standards of housing, husbandry and care, pre-export conditioning, transport, breeding management (including minimum weaning age) and record keeping, and, where relevant reducing dependency on wild-caught breeding stock.

Recommendation 2

We recommend that it should be a formal requirement that all applications should be passed to the PSC for discussion and formulation of advice. Discussions with the Inspector/s responsible for visiting the centres is extremely helpful and should remain an essential part of this process

Response

I accept the principle behind this recommendation. In practice, the Committee's advice has been sought in almost every case. The only exceptions have been where legitimate requests to acquire non-human primates from overseas sources have arisen at short notice.

Currently when seeking the advice of the APC on the acceptance of a centre, we provide the ASPI commentary on the centre and make provision for the Inspectorate to give further technical input if appropriate. In future this will be done on a case by case basis. In my view, having established objective criteria for acceptance, this represents the preferred arrangement. This will allow the Committee's attention to be drawn to and focus on cases where the Inspectorate has identified deficiencies in the agreed normal qualifying standards or where potential acceptance of a breeding centre raises other issues of particular concern. For those exceptional cases where the advice of the Committee is not sought, the Committee will be notified of the decision and supplied with the supporting documentation.

The efficiency and flexibility of this risk-based approach to the assessment of overseas breeding and supply centres, and the avoidance of unnecessary duplication and delays, also fits well with the objectives of the Better Regulation programme.

Recommendation 3

We recommend that the criteria set out in section 6 of the report should be used by the Home Office as a basis for assessment of the acceptability of suppliers of primates. The PSC will use these in the formulation of its independent advice to the Home Office

Response

I accept the need to extend and make more specific the current broad acceptance criteria established in 1996 and I appreciate the consideration that has gone into advising on what these criteria should be. The report is clear in its description of the goals we should move towards and we continue to work towards raising standards at those centres overseas that wish to supply animals for use in UK laboratories.

However, the degree of influence we are able to exercise in achieving this is in my view more likely to come about through continuing to work with these centres to make steady progress towards those goals.

In keeping with this approach, the Inspectorate has recently codified the provisions we currently expect approved places to meet and will publish them shortly.

Recommendation 4

We recommend all overseas centres should have a clear strategy designed to help them to achieve the required minimum standards set out in this report within a reasonable timeframe. The Sub-Committee and the Home Office Inspectorate should regularly monitor progress towards this goal.

Response

This will be a consideration when requests for acceptance are received.

We must strive to work with others to move towards the use of animals that are not the offspring of wild-caught animals. However it is clear that although our influence has already led to progress in this direction, it will take more than pressure from the UK alone to make further substantial changes to the current situation.

In particular other countries such as the United States and our EU partners also need to apply pressure to bring about change. Without such action, the UK's comparatively small need for these animals will not be enough to unilaterally bring about the investment and change.

Whilst seeking to engage the support of others to bring about change, we must continue to maintain the momentum for further improvements that our previous policies have made possible.

Recommendation 5

We recommend all new centres should be visited by a Home Office Inspector prior to consideration of the centre's details by the Sub-Committee. Staff from research establishments applying to source primates from a new centre should also be encouraged to visit the facilities, but this should be as well as, not instead of, the Inspectorate. If an urgent and legitimate need arises for animals to be obtained from an overseas breeding centre, and the animals in question cannot be obtained from one that is already accepted by the Home Office, then a decision to accept a new centre may be based on the revised application form and accompanying information alone. However, this would be on a 'one-off' basis, with a visit necessitated if further animals were requested.

Response

I place a particularly high value on the insights and information obtained by Inspectorate visits and the catalyst for change that such visits have to date proved to be. However, I consider it essential that we adopt a risk-based approach to the Inspectorate's overseas visiting programme. Within this framework the Inspectorate will normally visit before giving advice on a new centre but, as currently, I believe this should remain an operational decision for the Inspectorate. However, I will expect exceptions to be justified. I also reserve the right to commission Inspectorate visits to actual or potential overseas sources as the need arises.

Recommendation 6

We recommend that once a centre has been accepted, it should be revisited by the Home Office Inspectorate at two-yearly intervals prior to re-acceptance, in order to continue to promote and monitor improvements in standards. Additional visits may be necessary where there are specific issues that need to be addressed.

Response

Again this will be taken into account within the risk-based framework for overseas visits within which the Inspectorate will normally consider a visit necessary before giving advice on the continuing acceptability of a centre, and may regard a visit as appropriate if concerns about an accepted centre are raised. However, as with

visiting new centres, I believe this must remain an operational decision for the Inspectorate, but I will expect exceptions to be justified.

Recommendation 7

We recommend that the Home Office Inspectorate should maintain a user-friendly database or spreadsheet for those importing primates that will allow easy identification and comparison of standards at all overseas centres supplying primates to the UK. Resources should be made available to facilitate this if necessary.

Response

I believe that the spirit of this recommendation is already being observed under the arrangements currently in place. Although it is not held in a single database, the Inspectorate already has the information it requires to fulfil its functions in this area and to advise individual users on what is required and what is available. The Inspectorate also allows those who may reasonably wish to acquire non-human primates from overseas sources to have the objective information it holds on accepted sites. I am not convinced that there would be real benefits in restructuring the information already held. In addition, current legal and other considerations prevent the wider disclosure of this information to third-parties. I should also mention that within the processes being established for the revision of Directive 86/609/EEC we are exploring the merits of an EU resource as a central repository for this information.

Recommendation 8

We recommend that the Home Office, in conjunction with the PSC, should review the criteria for acceptance of centres (and the process if appropriate) at three-yearly intervals, or earlier if this becomes necessary.

Response

I welcome and accept this recommendation, which is in line with current practice, subject, as ever, to my retaining the discretion to commission such advice at any time.

JOAN RYAN
Home Office

Appendix – From the Animals (Scientific Procedures) Inspectorate Annual Report 2005

ACQUISITION OF NON-HUMAN PRIMATES FROM OVERSEAS (NON-DESIGNATED) SOURCES

1. Introduction

Measures concerning the acquisition of non-human primates (referred to as "primates" in the rest of this chapter) from overseas sources were introduced in 1996. The principle underlying those measures was that the Home Office should be aware of all importation of primates by designated establishments. Approval for the acquisition of primates from non-designated sources would be given only if the conditions at the breeding or supplying centre were acceptable to the Home Office, each consignment of animals would require separate prior authorisation and following each acquisition the Home Office would be supplied with various items of information relating to the health and welfare of the animals. As the circumstances under which primates are acquired have evolved since the measures were introduced, the inspectorate undertook a review of the process during 2005. This chapter gives an account of that review and its conclusions.

2. Background

2.1 Requirements to Obtain Animals from Designated Sources

As one of the types of animal listed in Schedule 2 of the Animals (Scientific Procedures) Act 1986, non-human primates (referred to as ‘primates’ in the rest of this Annex) to be used in regulated procedures must have been obtained from a designated breeding or supplying establishment unless the Secretary of State has authorised an exemption from the Standard Condition of the project licence required by Section 10(3)(b) of the Act. This requirement is reinforced through a similarly worded Standard Condition of the Certificate of Designation (Scientific Procedure Establishments).

2.2 Overseas Sources of Primates

Since the introduction of the 1986 Act the numbers of primates, and particularly Old World species, bred in designated establishments have been insufficient to meet needs of users in the UK and the majority of animals have been acquired from overseas sources. New World species, being easier to breed and maintain in captivity in the UK, have been imported much less frequently.

Until the early to mid 1990s most Old World primates (macaques and baboons) imported for use in regulated procedures were taken from the wild. However, with the establishment of primate breeding centres overseas, animals bred in captivity became increasingly available and by 1995 the majority of macaques used in the UK were of captive-bred origin. That same period also saw a decrease in the use of baboons, partly because of the difficulty in acquiring captive-bred animals.

Since 1996 most of the Old World primates used in the UK have been cynomolgus macaques, the majority of which were acquired from a single breeding centre. Smaller numbers of cynomolgus macaques have been imported from Israel, China and, in recent years, Vietnam. Requests to acquire rhesus macaques from overseas breeding centres have been more sporadic; all such animals have been acquired hitherto from Chinese breeding centres. Most of the imported macaques have been used for regulatory-driven work, principally pharmaceutical safety evaluation and vaccine potency/toxicity testing.

2.3 Introduction of Current Control Measures

In a written answer to a parliamentary question on 1 March 1995 the Home Secretary announced that the use of wild-caught primates in scientific procedures would be banned except where a project licence applicant could establish exceptional and specific justification. The Secretary of State set out a raft of administrative measures to ensure the effectiveness of that ban and to implement various recommendations from the Animal Procedures Committee concerning the acquisition and use of primates.

The section of that answer relevant to the acquisition of primates from non-designated sources is reproduced below. Although the text of the APC's advice and the Secretary of State's written answer emphasised controls at the project licence level, the measures were extended to the acquisition of primates by designated breeding and supplying establishments where ultimate use of the animals or their progeny in regulated procedures was intended.

Extract from the Secretary of State's Written Answer to a Parliamentary Question on 1 March 1995.

In the light of the [Animal Procedures] *committee's advice, I have taken a number of administrative steps to ensure the effectiveness of such a ban* [the use of wild-caught primates]. *I have decided that:*

(i) a condition will be placed on a project licence authorising the use of non-human primates, requiring records relating to the breeding and conditions of housing and husbandry at the breeding centre(s) from which the animals are obtained – and in the case of wild-caught animals the conditions in any holding centre – to be available for inspection by the Home Office;

(ii) waivers under section [sic] 10(3) of the 1986 Act to allow the use of purpose-bred primates from non-designated sources will be conditional upon lifetime records being supplied;

(iii) if the source of the animals is not know [sic] when the project licence application is prepared, or if the proposed source is likely to change, a condition will be placed on the licence that the source must be agreed by the Home Office before the animals are obtained and any procedure commences;

(iv) the inspectorate will take into account the potential adverse effects, for example during transport, which may occur to the animals concerned before arrival in the United Kingdom; and

(v) the Home Office will keep under review the availability of the information about primate use, and will ensure that as much is published as is permissible within the restraints of the legislation and the need for commercial confidentiality.

[Hansard 1 March 1995, 577 – 578]

The principle underlying the new measures was that the Home Office should be aware of all importation of primates by designated establishments. Approval for the acquisition of primates from overseas sources (or from other non-designated sources) would be given only if the conditions at the breeding or supplying centre were acceptable to the Home Office. Each consignment of animals would require separate prior authorisation, with approval of the transport arrangements in each case. Following each acquisition the Home Office would be supplied with various items of information including individual records and details of health status both on arrival and during the subsequent four weeks.

These requirements were embodied in a series of additional conditions applied to every project licence authorising the use of primates and certificate of designation for relevant breeding or supplying establishments. The measures related only to animals intended for use in regulated procedures or for breeding and supply for this purpose; the Home Office has no formal remit to approve non-designated centres nor to authorise the transport of animals to a designated establishment, the latter being the responsibility of DEFRA.

3. Acceptance Process

3.1 Appraisal by the Home Office of Overseas Breeding Centres

Before primates can be acquired from an overseas breeding centre it is necessary for the Home Office to have appraised and accepted the use of that centre.

The aim of the appraisal process is to ensure compliance with the content of section 9.2 of the Home Office Code of Practice for the Housing and Care of Animals in Designated Breeding and Supplying Establishments (1995 HC 125) insofar as it relates to the import of primates. This section recommends the use of reputable established breeding colonies which have high standards of health care and management similar to those outlined in the Codes of Practice issued by the International Primatological Society (IPS) International Guidelines for the Acquisition, Care and Breeding of Non-Human Primates. It is expected that those responsible for importing primates should be familiar with IPS guidelines and encourage their implementation in the centres from which animals are being acquired. Additionally the Code of Practice indicates that the transport of primates must comply with the International Air Transport Association's Live Animals Regulations including the design and construction of containers.

Those expectations underpin the principles, which are applied in appraising overseas breeding centres and which are reproduced below.

Principles applied in appraising overseas breeding centres (1996)

- Primates should be group-housed in cages or enclosures providing sufficient space for them to express a wide behavioural repertoire. No animal should be housed singly except on grounds of health or welfare or for conditioning prior to despatch.
- Primates should not be subjected unnecessarily to adverse environmental conditions.
- Primates should not be weaned at an earlier age than is necessary. Specific justification will be required if weaning is at less than 6 months of age.
- If primates are conditioned prior to shipment the period of confinement should be kept to a minimum. Animals should not be confined in cages, which are unduly restrictive.
- No Primate shall be supplied to the UK as captive-bred if it has been bred or maintained in a semi-natural environment such as an island or equivalent bounded, free-range park or reserve.
- The breeding centre should have a policy of producing increasing numbers of F2 (or beyond) primates for scientific purposes. The number of wild-caught animals introduced into the colony for breeding should be in accordance with restrictions imposed by the national authority. *(In this context the term F0 denotes a wild-caught animal, F1 an animal bred in captivity from a wild-caught parent and F2 an animal bred from parents, which have themselves been bred in captivity.)*
- The breeding centre should have in place recording systems adequate to provide lifetime records.

The process for accepting an overseas (non-designated) breeding centre as a source of purpose-bred primates for use in regulated procedures involves the submission to the Home Office of written details of the breeding centre in a standardised format. This information is scrutinised by at least two members of the Inspectorate before advice is given to senior licensing officials (acting on behalf of the Secretary of State) on whether, and on what terms, to accept the centre. If officials consider that further consultation is advisable, the opinion of the APC Primate Sub-Committee is sought.

Although submitted details of an overseas breeding centre may provide much of the information required to appraise its acceptability some key elements of the housing, care and management of the facility can be assessed only by visiting the establishment. Since 1996 almost all of the accepted breeding centres have been visited by the Inspectorate. During the past two years appraisal of each of the major overseas breeding centres by the Inspectorate has included a visit. Recent visits have enabled appraisal of the following:

Staffing, including staffing levels, training and experience, culture and attitude;

Animals, including general condition of breeding animals, pre- and post weaned stock and hospitalised animals;

Health monitoring procedures;

Record keeping, including breeding, husbandry and veterinary records;

Housing, including fine detail of cage design, provision of environmental enrichment and general state of repair in all holding areas including those used for animals exported to countries other than the UK;

Diet, including source, storage, preparation, variation and presentation of foodstuffs;

Transport crate construction and for some centres, the type of transport used and local routes followed;

Where relevant, methods used for trapping wild monkeys, training & management of trappers and associated transport, quarantine and stock holding.

Other activities pursued by the centre or its staff, including those that might be viewed as incompatible with the supply of animals to the UK.

Typically, overseas centres have been accepted for periods of two years. In some cases acceptance has been conditional on specified changes being made or practices adopted within a given time frame. On other occasions centres have been accepted with the stated expectation that there will be further developments of good husbandry and housing practices during the period of acceptance. Once a centre has been accepted by the Home Office, it is not necessary to re-appraise it before approving each subsequent request for acquisition by the same or another user. However, in some recent cases involving exceptional acquisitions of single consignments of marmosets from non-commercial establishments, the breeding centres in question have been accepted only for the one acquisition.

3.2 Application for Permission to Acquire Primates from Non-Designated Sources

Current policy requires that each separate acquisition of non-human primates from an overseas breeding centre is authorised in advance. Requests for approval of each acquisition are made using a standard pro-forma for which a minimum of two weeks notice is generally required. Applicants seeking permission to acquire primates from non-designated sources are required to demonstrate that no animal suitable either for the purpose specified in the project licence or for supply for use in regulated procedures can be obtained from a designated breeding or supplying establishment. Acquisition requests are checked to ensure that the centre in question is already accepted and that the proposed journey is appropriate.

3.3 Submission of Information Following Each Acquisition of Primates from a Non-Designated Source

Holders of project licences or certificate of designation who have acquired primates from non-designated sources are required to provide the Home Office with specified pieces of information relating to the health and welfare of the animals as soon as is practicable after their arrival. Additional Conditions (project licence and certificate of designation) specify the information to be provided as follows:

Confirmation that the animals arrived safely and in accordance with the agreed transport arrangements;

Copies of lifetime records for all animals;

A copy of the report of the veterinary inspection on arrival; and

Within six weeks of receipt, details of morbidity and mortality arising during the first four weeks following arrival in the UK.

4. Conclusions

4.1 Appraisal by the Home Office of Overseas Breeding Centres

4.1.1 Submission of Details by the Overseas Breeding Centre

The principles applied in appraising overseas breeding centre were drafted in 1995/6 shortly after publication of the Home Office Code of Practice for the Housing and Care of Animals in Designated Breeding and Supplying Establishments. It is appropriate now to revise those principles to take account of refinements in housing and husbandry practices both at the overseas breeding and supplying centres and at establishments in the UK.

As a guiding principle the centre should meet the relevant standards set out in the Home Office code of Practice for the Housing and Care of Animals in Designated Breeding and Supplying Establishments at least in respect of animals destined for the UK. Minor deviations from those standards may be acceptable provided that they do not have adverse consequences for the welfare of the animals at the centre.

The importance of providing primates with a complex and enriched environment has come to be recognised more fully by the breeding centres and a range of suitable measures to improve the housing has been, and continues to be, introduced. As a principle, appraisal of the housing at overseas centres should include consideration of cage complexity and environmental enrichment, and opportunities for social interaction in addition to simple cage or pen dimensions.

Current expert advice embodied in the European Convention ETS 123 Revised Appendix A is that young macaques should not normally be separated from their mothers earlier than 8 months of age, preferably 12 months, apart from infants which are unable to be reared by their mother. Most of the overseas centres breeding old world primates, currently accepted by the Home Office, wean animals at between eight and twelve months of age. The Home Office Code of Practice for the Housing and Care of Animals in Breeding and Supplying Establishments sets a minimum weaning age of six months. While future European legislation & guidance is likely to lead to a revision of the Code of Practice, it may be untenable to mandate a more exacting standard in overseas breeding establishments than is currently applicable in the UK. However, a significant change in minimum weaning age will take a breeding centre several years to effect and it is reasonable when appraising centres that wean animals at less than eight months to take account of the reasons for, and likely changes to, that practice. In any event, weaning at less than six months of age remains unacceptable.

4.1.2 Visits to Overseas Breeding Centres by the Inspectorate

The role of the Inspectorate in visiting overseas breeding centres has not been formally defined and has evolved since 1996 from informal ‘interest’ visits into more structured monitoring visits from which recommendations on the acceptability of overseas centres can be made with greater confidence. Visits by members of the Inspectorate should continue to be risk-based, depending on the perceived need to monitor standards of husbandry and care or progress of improvements and when appropriate should be timed to coincide with application for acceptance or re-acceptance of an overseas centre. Centres not previously accepted should normally be visited before completing the appraisal of the centre and advising officials on their acceptability. For exceptional and urgent single acquisitions of animals from European breeding centres there may be less justification for visiting the centres as they should already be working within European Convention Guidelines under their national regulatory authorities.

4.1.3 Records of Breeding and Information about Conditions of Housing and Husbandry at the Breeding Centres – Role of Project Licence Holders and Certificate Holders

One of the administrative measures announced in March 1995 was to require, through a condition on the project licence that records relating to the breeding and conditions of housing at the breeding centre(s) should be available for inspection by the Home Office. Additional conditions to effect that measure were placed not only on project licences involving the use of non-human primates but also on certificates of designation for relevant

user, breeding and supplying establishments. The project licence additional condition places a further responsibility on project licence holders to keep the records in a prescribed form.

The purpose of this measure was to place responsibility for maintaining current information about the overseas centres with the project licence or certificate holders seeking to acquire the animals. In practice, although details of an overseas centre may have been obtained initially by one licence or certificate holder, once a centre has been accepted, the details are held by the Home Office. It would be sensible to review the additional conditions regarding primate acquisition to take account of this.

4.1.4 Journey Details

The information provided in acquisition requests in respect of the proposed transportation of animals varies in the level of detail. Many, but not all, applicants include a copy of the DEFRA journey plan, which provides appropriate details of each stage of the journey and enables a more meaningful appraisal of the potential impact of transport on the animals. It would be useful for this information to be provided in all cases.

4.2 Submission of Information Following Each Acquisition of Primates from a Non-Designated Source

4.2.1 Consistency of Information

Although the Additional Conditions of the project licence and certificate of designation prescribe the information to be submitted after arrival of the animals, the lack of a standardised report format has led to significant variation between establishments in the way in which the information is presented. Reviewing the information against the original request and confirming that all of the required details have been provided can be both difficult and time-consuming. A simple reporting arrangement could be used to improve the quality of the information received and facilitate its timely review.

4.2.2 Lifetime Records

Since 1996 there has been a requirement for lifetime records of animals to be provided. Paragraph 8.10 of the current Home Office Guidance on the Operation of the ...Act clarifies that approval for the acquisition of primates is conditional upon life-time records being supplied with the animals and made available to the Home Office upon request. Key information that may be abstracted from the lifetime records includes date of birth, age and bodyweight at weaning, bodyweight prior to despatch and medical history. The captive-bred filial status (F1, F2, F2+ etc) of imported animals is not always readily discernible from the lifetime records; this is information that could be obtained and retained by the Home Office for future reference if desired. The minimum weaning ages of animals in a consignment is also useful information to have readily to hand in the Home Office. However, to save duplicating paperwork other information in the lifetime records could reasonably be kept at the establishment and made available to the inspector on a visit.

ANNEX G

REPORT ON SCHEDULE 1 – APPROPRIATE METHODS OF HUMANE KILLING

Executive summary of recommendations

Format of Schedule 1

1. Reduce section 6 of the Schedule 1 Code of Practice and replace with a more easily updateable and user friendly format that provides a framework for humane euthanasia but also allow flexible and rapid dissemination of the details of current good practice.

2. Ensure regulations allow humane killing be seen as a process whereby refinements such as sedation prior to anaesthesia or anaesthesia prior to physical methods are included in the scope of Schedule 1.

Changes to Schedule 1

3. Extend Schedule 1 to include decapitation of non-precocial rodents up to seven days old.

4. Remove CO_2 as an acceptable Schedule 1 method for birds.

5. Provide advice on filling rates for CO_2 chamber filling rates for rat and for mouse humane killing. The rapid introduction of availability of other gases (such as argon) as an alternative to CO_2 for humane killing of mice and rats is desirable but a final recommendation on this matter will be reconsidered in one year from now when more published scientific information is expected to be available.

6. Include as Schedule 1 methods for birds:

    a) argon, nitrogen or other inert gases, or any mixture of these gases in atmospheric air with a maximum of 2% oxygen by volume; or

    b) any mixture of argon, nitrogen, or other inert gases with atmospheric air and CO_2 provided that the CO_2 concentration does not exceed 30% by volume and the oxygen concentration does not exceed 2% by volume.

7. Provide advice on humane killing of neonatal rodents.

8. Remove CO_2 as an acceptable Schedule 1 method for rabbits.

9. Alter the weight threshold for rats and guinea pigs at which the dislocation of the neck would be permissible to 500 grams for guinea pigs and 300 grams for other rodent

Further work on Schedule 1

10. The use of CO_2 for rodents is an area of current scientific uncertainty

    a) The Home Office should strongly encourage research into practical implementation for methods such as the use of inert gases as a potential welfare improvement on the use of CO_2 for rodents.

    b) The Home Office and Animal Procedures Committee should closely monitor ongoing research into the use of CO_2 for rodents, with a view to deciding whether CO_2 should remain as an acceptable

method of humane killing rodents under Schedule 1, or if methods of administration of CO_2 need better definition.

11. Humane killing techniques for embryonated eggs require further work. This is being undertaken by the European authorities and should take into account advice available to other Government departments and current scientific consensus.

12. Humane killing techniques for fish require further work. This should be included as part of consideration of any future APC work plan on fish.

Note

13. The recommendations in this report have been made with full consideration of our Terms of Reference and responsibilities, including regard to both the legitimate requirements of science and industry and to the protection of animals against avoidable suffering. The recommendations have also been made in the context of the better regulation agenda aimed at reducing administrative burdens on business and the public sector.

Annex H

MINISTER'S RESPONSE TO REPORT ON SCHEDULE 1 – APPROPRIATE METHODS OF HUMANE KILLING.

Animal Procedures Committee Report – Schedule 1 – Appropriate Methods Of Humane Killing

In January 2007 the Animal Procedures Committee published its report on Schedule 1 of the Animals (Scientific Procedures) Act 1986. I am grateful to the Committee for the consideration it has given to this important issue.

In responding to the report, I wish to record my thanks to you and to the Committee for the time and thought that has been put into it. I am very grateful for the advice it contains which will help determine how we proceed with regard to a number of important matters.

The report recognises the need for inclusive, evidence-based policies and the need to minimise the regulatory burden without compromising animal welfare. It also acknowledges that humane killing is an issue where ongoing research is likely to improve our understanding of key issues in the foreseeable future. In addition, it rightly highlights the importance of effective communication with stakeholders and timely implementation of good practice to ensure welfare gains are achieved.

A number of recommendations recognise the need for consultation with stakeholders before final decisions are made and I have asked that this is started as soon as is practicable and that you are kept informed of progress.

My detailed response to the Committee's report and recommendations are set out in the annex to this letter.

MEG HILLIER

REPORT BY THE ANIMAL PROCEDURES COMMITTEE ON SCHEDULE 1 OF THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986

Government Response By Meg Hillier, MP, Parliamentary Under Secretary Of State For The Home Department

Format of Schedule 1

Recommendation 1: Reduce section 6 of the Schedule 1 Code of Practice and replace with a more easily updateable and user friendly format that provides a framework for humane euthanasia but also allow flexible and rapid dissemination of the details of current good practice.

We agree that proper provision needs to be made for the rapid dissemination of good practice, and that the format and content of Schedule 1 and the associated Code of Practice need to be as user friendly as possible. However, as the Committee's report acknowledges (in paragraph 26), the issue of formatting changes is not clear cut. We are, therefore, pleased to take up the Committee's offer of further separate discussions to take this issue forward as a discrete item.

Recommendation 2: Ensure regulations allow humane killing be seen as a process whereby refinements such as sedation prior to anaesthesia or anaesthesia prior to physical methods are included in the scope of Schedule 1.

We agree that best practice requires that refinements are implemented in a timely way. Up to now we have done this by amending the conditions of issue of Certificates of Designation on a case by case basis. To supplement this, we will also communicate the benefits of such measures to Certificate Holders in our regular mailings.

Changes to Schedule 1

Recommendation 3: Extend Schedule 1 to include decapitation of non-precocial rodents up to seven days old.

As there is no animal welfare gain and some evidence that there might be a welfare cost associated with this killing method, I have asked that further consultation is carried out on the likely impact of this proposal before deciding whether this method should be added to Schedule 1. The proposal, which was previously supported by the Royal Society, would entail a significant change to Schedule 1. I understand this is not a killing method that is or will be used to kill surplus stock, rather it is a method used occasionally for experimental and other scientific purposes.

Recommendation 4: Remove CO_2 as an acceptable Schedule 1 method for birds.

As with recommendation 3, I have asked for further consultation to be carried out on the welfare implications, likely impact and practicalities of this recommendation. I understand that the evidence advanced by the Committee for animal welfare gains to be achieved by removing this method from Schedule 1 is not strong and that that this killing method is allowable under certain circumstances for the killing of poultry under commercial conditions and is a standard hatchery method for the killing of day-old chicks.

My attention has also been drawn to a draft report that is being prepared for publication in the Veterinary Record. I am informed its findings may be relevant to your recommendation.

Recommendation 5: Provide advice on filling rates for CO_2 chamber filling rates for rat and for mouse humane killing. The rapid introduction of availability of other gases (such as argon) as an alternative to CO_2 for humane killing of mice and rats is desirable but a final recommendation on this matter will be reconsidered in one year from now when more published scientific information is expected to be available.

We already require that a rising concentration should be used, and you have identified reference material providing advice on preferred filling rates. Pending further advice from the Committee, this has been publicised through a stakeholder mailing, and will be taken into account when Schedule 1 and the associated code of practice are revised.

Recommendation 6: Include as Schedule 1 methods for birds:

a) argon, nitrogen or other inert gases, or any mixture of these gases in atmospheric air with a maximum of 2% oxygen by volume; or

b) any mixture of argon, nitrogen, or other inert gases with atmospheric air and CO_2 provided that the CO_2 concentration does not exceed 30% by volume and the oxygen concentration does not exceed 2% by volume.

We propose to include consideration of the gas mixtures the Committee recommends in our further consultation on humane killing methods. In the meantime we will consider any request from designated establishments wishing to use those gas mixtures for the humane killing of surplus stock on a case-by-case basis.

The background work on this method of killing birds has been performed in the food-production sector for the humane killing of large numbers of poultry species primarily at slaughter weight. There is little experience of the use of these methods for other types of birds and in other contexts, and the equipment required for its small scale use in the laboratory setting is currently not readily available. We need to be certain that the use of these methods can be generalised to other species and stages of development, and adapted to the laboratory setting. There are considerable risks to deregulating killing methods of which designated places have little or no experience other than as research tools. Further studies on the use of inert gas mixtures for killing poultry (believed to be critical of associated welfare costs) will also be published shortly which will be relevant to this recommendation.

Recommendation 7: Provide advice on humane killing of neonatal rodents

I accept this recommendation. The Committee has identified a useful reference advising on good practice. We will circulate the key reference to stakeholders to reinforce good practice.

Recommendation 8: Remove CO_2 as an acceptable Schedule 1 method for rabbits.

I accept the main thrust of this recommendation. We will negotiate an end to use of this method, which is not widely employed, allowing a reasonable time for working practices to be changed. This can be achieved without formally amending Schedule 1

Recommendation 9: Alter the weight threshold for rats and guinea pigs at which the dislocation of the neck would be permissible to 500 grams for guinea pigs and 300 grams for other rodents.

I note that the Committee envisages that we should consult on the implications of this recommendation before any final decision is proposed and we will do so. The Committee questions the availability of staff competent to kill larger animals by this method. However we believe there is no welfare issue as certificate holders are required to ensure that it is only performed by competent staff. We have never had to take disciplinary action in a case of this method not being competently applied.

Further work on Schedule 1

Recommendation 10: The use of CO_2 for rodents is an area of current scientific uncertainty

a) The Home Office should strongly encourage research into practical implementation for methods such as the use of inert gases as a potential welfare improvement on the use of CO_2 for rodents.

b) The Home Office and Animal Procedures Committee should closely monitor ongoing research into the use of CO_2 for rodents, with a view to deciding whether CO_2 should remain as an acceptable method of humane killing rodents under Schedule 1, or if methods of administration of CO_2 need better definition.

We agree that further research is needed. The use of carbon dioxide is an area where the evidence base is incomplete and where the existing evidence is disputed. We are aware of relevant new research that will be published shortly, and additional work which may indicate that the alternative methods are not more welfare-friendly.

As the Home Office no longer directly funds research in the 3Rs (replacement, reduction and refinement), I have referred this recommendation to the National Centre for the 3Rs for further consideration.

Recommendation 11: Humane killing techniques for embryonated eggs require further work. This is being undertaken by the European authorities and should take into account advice available to other Government departments and current scientific consensus.

I agree that this and other published work should inform policy and practice.

Recommendation 12: Humane killing techniques for fish require further work. This should be included as part of consideration of any future APC work plan on fish.

I note the Committee's intention to do further work in this area, and look forward to seeing full details in due course.

MEG HILLIER
Parliamentary Under Secretary of State
Home Office

Annex I

CONSIDERATION OF POLICY CONCERNING STANDARDS OF ANIMAL HOUSING AND HUSBANDRY FOR ANIMALS FROM OVERSEAS NON-DESIGNATED SOURCES

Summary

The Animals (Scientific Procedures) Act 1986 requires that animals of the types listed in Schedule 2 should be acquired from a designated establishment. Standards of husbandry and care at these establishments, which are inspected by the Animals (Scientific Procedures) Inspectorate, are informed by Home Office Codes of Practice. However, it is sometimes necessary for researchers to obtain animals from overseas where the Home Office has no jurisdiction and in these circumstances the Secretary of State can approve the use of animals from non-designated premises. For ethical, scientific and welfare reasons, it is important that all establishments supplying animals for research in the UK, whether they operate within this country or abroad, should provide husbandry and care that meets animals' needs. It is also important that the mechanisms for ensuring that animals are only acquired from establishments with good animal welfare conditions should be transparent. The Housing & Husbandry Sub-Committee of the APC has, therefore, enquired into the mechanisms by which the Inspectorate currently assesses the standards of overseas suppliers of Schedule 2 species.

The Sub-Committee have found that the Inspectorate applies a hierarchical approach based on:

- type of animal,
- their protection under the Act,
- the number of animals being supplied,
- the ability of the Inspectorate to exert an influence in different source countries, and resource issues.

The Sub-Committee have also established that some users not only obtain information from their suppliers on health status but also seek information regarding housing and husbandry and other welfare issues. This we consider to be good practice. We have provided a number of recommendations to encourage this good practice which if implemented would provide greater reassurance regarding the welfare of animals imported for scientific research. The additional information would enable users to minimise stress caused by changes of husbandry and could help to improve the quality of science obtained from these animals.

Background

Currently, most animals used in research in the UK are bred in the UK, although in other countries there is more cross-border movement, especially within continental Europe. Looking to the future, there are a number of pressures that could lead to an increase in the proportion of animals imported into the UK. It has been argued that animal rights extremism may have increased the need to import animals but more general factors include the increased regionalisation and globalisation of research and trade.

In its Annual Report of 2003, the APC considered the issue of perceived over-breeding of laboratory animals leading to wastage. It concluded that for a number of reasons, including ethics, cost, regulation and reputation, laboratory animal breeders try to avoid over-breeding animals and that there is a tendency for underproduction rather than overproduction. It follows, that overseas supply of a number of the most commonly used species, will often be needed to accommodate a shortfall in availability within the UK. On the one hand, this can be seen as beneficial as it contributes towards avoiding overproduction but the welfare costs of transport, etc., also have

to be taken into account. Animals are also imported when a particular species, strain or line is only available from an overseas supplier. This is often the case for genetically altered (GA) animals and certain species of non-human primates. The vast majority of imported animals are rodents (Table 1)[10]. In contrast, the numbers of procedures carried out on imported non-human primates, dogs and cats (species for which there is particular public concern) are comparatively small. This reflects the different scales of use for these animals (over 80% of procedures are carried out on rodents). Nonetheless, imports of non-human primates, dogs and cats amount to a significant fraction of the total numbers of these species used in the UK, and therefore importation is an important consideration in their use.

The Animal (Scientific Procedures) Act (ASPA) requires that types of animal listed in its Schedule 2 (Table 1, column 1) are obtained from a breeder or supplier designated under the Act. Designation requires compliance with a Code of Practice for housing and husbandry. However, if an animal listed in Schedule 2 is not bred in, or is not currently available from such designated premises, then the Home Office can approve the use of such animals from non-designated premises. The majority of such animals will be supplied from outside the UK, although there may be times when a UK non-designated source is used, for example, wild rats for rodenticide studies and breeds of dogs other than beagles. In all cases, approval of the Secretary of State is required. This is often facilitated by use of the Home Office Application Form For Authority To Transfer Protected Animals[11]. This form enables assessment of the justification for the need to transfer the animals and provides information on transport arrangements so that a view can be taken as to whether the transport is likely to result in health or welfare problems for the animals involved. The Inspectorate has no jurisdiction outside the UK, and therefore, where animals are supplied from outside the UK, any site visits by the Inspectorate depends on negotiation and cooperation, and information is often provided in confidence to the Inspectorate.

Table 1. Scientific procedures by Schedule 2 species acquired from outside the UK (Source: Home Office Statistics of Scientific Procedures on Living Animals Great Britain 2005).

Species	Total Number of Procedures	Number of procedures on animals acquired from outside the UK	% of total procedures on that type of animal	% of total procedures on animals obtained from outside the EU or Council of Europe
Mice	1,961,049	13,479	0.7	0.4
Rats	424,527	2,333	0.5	0.3
Guinea pig	29,019	0	0.0	0.0
Hamster	4,232	1,527	36.1	0.0
Gerbil	5,057	1,133	22.4	1.3
Rabbits	22,818	454	2.0	0.2
Cats	500	110	22.0	0.0
Dogs	7,670	1,053	13.7	10.8
Ferrets	970	6	0.6	0.6
Pig (genetically modified)	–	–	–	–
Sheep (genetically modified)	3	0	0.0	0.0
Non-human primates	4,652	3,398	73.0	69.8
Quail (*Coturnix coturnix*)	140	0	0.0	0.0

[10] n.b. The number of animals used in experiments is not identical to the number of procedures carried out, as a small proportion of animals are reused.

[11] http://scienceandresearch.homeoffice.gov.uk/animal-research/application-forms/auth-trans/

It could be argued that, because of harmonisation of standards, there should be less concern regarding the import of animals from the European Union (EU) and Council of Europe countries. Currently, the UK has, in some aspects, more stringent standards of accommodation and care than some other EU and Council of Europe countries, but the reviews of Appendix A to the Council of Europe Convention ETS 123 and the European Directive 86/609 are expected to promote greater convergence towards common standards. Whilst the majority of non-human primates are obtained from outside the EU or Council of Europe countries, most mice and rats are obtained from within the UK, the EU or Council of Europe countries. Even so, in 2005, 9,931 procedures were carried out on animals obtained from outside the UK, EU or Council of Europe countries signatory to ETS123[12].

It is most important for ethical, welfare and scientific reasons that the standards of housing and husbandry of animals supplied from non-designated sources should be satisfactory. To this end, the APC Primates Sub-Committee (PSC) has recently considered the process by which the PSC and the Inspectorate inform themselves, and advise, on the acceptability of overseas suppliers of primates[13]. Expanding on this work, the Housing and Husbandry Sub-Committee has considered the welfare of all types of animal listed on Schedule 2 imported for use in scientific procedures in the UK. In our enquiries, we have, for practical reasons, restricted our consideration to Schedule 2 animals[14], as the sources of these are subject to regulatory approval by the Home Office. Our purpose in this document is to clarify and review the processes by which the Inspectorate and users obtain information and make decisions with respect to housing standards for Schedule 2 animals imported for scientific purposes.

Current system for ensuring standards for overseas suppliers

The Housing and Husbandry Sub-Committee has inquired into the current system adopted by the Inspectorate for ensuring standards for overseas suppliers. Most users of laboratory animals are likely to be highly motivated to ensure that the quality of the animals that they import is high, not least for ethical reasons, but also because it impacts on the quality of the science that they carry out, the management of the animals with respect to health status, and their reputation. In some cases, they visit their suppliers to inspect the animals and the conditions under which they are kept, and the Inspectorate collates feedback it obtains from UK users about welfare and suitability of animals from various sources. In the broadest terms, the Inspectorate uses a hierarchy of risk assessment to target their resources to best effect as outlined below, based on species, number of animals being supplied, their protection under the Act[15], the ability of the Inspectorate to exert an influence in different source countries, and resource issues.

1. Non-Human Primates

The importation and use of primates in scientific procedures is of particular public concern and this is reflected in the provisions made in the Act. The process by which overseas suppliers of primates are authorized has recently been reviewed by the Primates Sub-Committee in a report which notes that:

> "Project licences, which require the use of primates, are subject to a series of conditions on the licence which require authorisation of each consignment of animals from a centre considered acceptable to the Home Office. Each consignment of primates to be acquired from an overseas source requires separate authorisation prior to their acquisition, and this is given only if the conditions at the breeding or supplying centre are acceptable to the Home Office. If a centre is not considered acceptable, then the Home Office can refuse to allow it to be used as a source of animals.

[12] Home Office Statistics of Scientific Procedures on Living Animals Great Britain 2005 Table 2).

[13] http://www.apc.gov.uk/reference/primate-sources-report.pdf Acceptance of overseas centres supplying non-human primates to UK laboratories: a report by the Primates Sub-Committee of the Animals Procedures Committee.

[14] Schedule 2 to ASPA lists types of animal, which may be obtained only from a designated breeding establishment, unless an official exemption is granted.

[15] Special provisions are made for non-human primates, cats dogs and equidae under theAnimals (Scientific Procedures) Act 1986

Centres are currently assessed on the basis of a Home Office form[16]. Additional information is gathered from visits to centres by the Inspectorate and user-establishment staff. The information is scrutinised by at least two members of the Home Office Inspectorate and a recommendation made to the Animals Scientific Procedures Division (ASPD) of the Home Office. If ASPD consider that further consultation is advisable, the opinion of the PSC "may be sought", although in practice the PSC is asked for a view on all applications. ASPD can choose not to accept the advice of the PSC and has done so on one occasion.

All centres are informed of the Home Office decision on whether and on what terms they have been accepted. If judged to meet the expected standards, a centre will be accepted typically for periods of 2 years. If not, it is advised of the action necessary to achieve acceptance with re-consideration being conditional on appropriate action being taken. Current and prospective customers are informed of the decision promptly in any event."

The Primates Sub-Committee report made a number of suggestions to refine the process and identified criteria it considered important in the assessment of overseas sites. Nonetheless, it did not propose that these criteria should always be treated as absolute standards below which sites would automatically be rejected. This pragmatic approach allows an overall assessment of the institution rather than focussing on what might be a minor deviation from UK standards.

2. Dogs and cats

Requests to import dogs and cats are also given particular attention by the Inspectorate. While visits to the major overseas breeders of dogs and cats have not been as regular as for primate sources, informal visits have been made. These are often made jointly with the national responsible authority, such as the USDA in the USA. The Inspectorate has produced a form,[17] to be filled in by someone in a position of authority at the overseas breeding centre that provides a snapshot of dog or cat colony management and structure and of any likely welfare issues. The Inspectorate assesses requests for importation of these animals by considering the overseas institution's national standards, the information gathered during informal visits by the Inspectorate, and information gained through its links with other national authorities. In addition users/purchasers visit suppliers and provide feedback to the Inspectorate. All of this information can then be used to provide an informed decision on suitability.

3. Other species e.g. rodents, rabbits.

As for non-human primates, dogs and cats, the Inspectorate advises the Secretary of State on requests to use rodents and rabbits from overseas suppliers. However, in contrast to the situation with primates, cats and dogs, the number of potential suppliers is much greater. Conventional animals almost always come from well-known commercial overseas breeders with whom the Inspectorate will have had previous contact, will usually be aware of the standards in operation and, will have discussed variations between the supplier's national standards and those of the UK. However, the rapid development of genetic technology has resulted in the production of many new genetically altered mouse strains, many of which come from a few large scale producers but which may also come from a variety of academic sources (Universities, NGOs etc.), where the import is likely to be a "one-off". It would be a great strain on current resources, and so currently impracticable for the Inspectorate to visit all these sites before importation. Decisions are, therefore, made taking into account: past experience, if any, with the importer; the institution's national standards, independent accreditation schemes, such as AAALAC International (Association for Assessment and Accreditation of Laboratory Animal Care) or ISO (International Standards Association), and evidence regarding the health status and quality of the animals supplied by those wishing to purchase them. Health status is here used as just one indicator of welfare. If the Inspectorate have any concerns over the information provided in the Transfer of Animals request they will ask for supplementary information before coming to a decision.

[16] Home Office pro forma are available from the Home Office Animals in Scientific Procedures website: http://scienceandresearch.homeoffice.gov.uk/animal-research

[17] Home Office pro forma are available from the Home Office Animals in Scientific Procedures website: http://scienceandresearch.homeoffice.gov.uk/animal-research

Conclusion

The current system implements a performance standard that utilises the professional judgement of the Inspectorate. In our view, this is a flexible system, within which there can be continual improvement. While, in general, prescriptive standards are not set we consider that the Inspectorate are applying standards that are based on their perception of best current practice and a holistic view of the information gained regarding: the importer, the national standards in the source country, additional standards adopted by the supplier, health status, visits made by the Inspectorate, past experience, etc.

The system could be criticised on the grounds that there are differences in the type and extent of the checks carried out for different types of animals. The sub-committee is aware that there are considerable differences in standards between different overseas suppliers, which suggest that the welfare of at least some imported animals could be improved. We do not wish to make recommendations that might have negligible animal welfare benefits but which would have substantial resource implications for the Inspectorate or users. Nonetheless, we consider that the current approaches for collecting data on the welfare of species other than non-human primates, cats and dogs could usefully be enhanced in ways which that have minimal impact on cost and bureaucracy. We believe that a more structured approach which ensured that establishments and scientists involved in the use of animals are well informed of health, husbandry, care and transport issues prior to import would enable them to minimise change and stressors on the incoming animals. This would have benefits for animal welfare, the quality of science obtained from these animals and would draw the attention of overseas establishments to UK standards.

This report should be viewed as an advice paper that advocates best practice in terms of animal health and welfare reporting for those intending to purchase overseas supplies of animals for scientific procedures.

Recommendations

Importing animals for use in studies in the UK inevitably involves some risk regarding the health and welfare status of the animals. To help reduce this risk it appears that some users, in addition to the regulatory requirements already described in this document, obtain information from overseas breeders on the welfare and husbandry conditions for species other than primates, cats and dogs. To reduce unnecessary bureaucracy this process may be carried out in conjunction with a risk analysis that takes into account additional factors including the country of importation, the supplier and whether animals have been previously from this source. Hence, wider ranging, and more detailed questions might be asked from a small previously unused supplier, whilst a major breeder might be visited once every few years in conjunction with ongoing liaison between the two institution's veterinary teams. Similarly, institutions with little or no systems of over-view (regulatory or voluntary) would require a more detailed assessment.

We believe that this risk-analysis based approach to seeking information is good practice, as it enables importers to satisfy themselves with respect to the quality of the animals (which impacts on the quality of the science) and helps them to ensure that they are importing from an ethically acceptable source. A secondary benefit of asking such questions is that it can help to disseminate information regarding the standards expected in the UK. In the long term this may contribute towards raising global standards of welfare.

We therefore recommend that, in addition to collecting data on the health of imported animals, establishments should seek information from their supplier regarding the welfare and standards of housing and husbandry for all Schedule 2 imported species. This should form part of the responsibilities of the Ethical Review Process, which is responsible for "considering the care and accommodation standards applied to all animals in the establishment, including breeding stock.[18]". This approach avoids prescribing how any institution might organise itself, but encourages good oversight of the welfare of imported animals.

[18] http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/publications/guidance/ethical-review-process/chiefinspector.pdf?view=Standard&pubID=428459

We do not wish to be prescriptive as to how this information would be obtained or on the detail to be provided. Health and welfare issues vary by species, strain and genetic status, and should be assessed in the light of current knowledge and research. For genetically modified mice an expert working group set up as a response to the 2001 Animal Procedures Committee (APC) report on biotechnology has drafted a passport scheme,[19] which could form part of this process. As a minimum, the purchaser should obtain from the supplier information regarding health issues/status, whether animals are housed in appropriate social groups, what enrichment is provided, and whether the supplying institution meets or exceeds any national or professional standards relating to housing. Welfare information should be judged in the light of current UK standards for Breeders,[20] and the recent revision of Appendix A to Europe Convention ETS 123.[21]

In some cases, purchaser/user visits may be appropriate, and these are likely to be the best way to obtain accurate health and welfare information. Where this is not possible, plans, photographs or videos of the housing conditions can be valuable.

Summary

In order to encourage and enhance good practice with respect to importing animals of the types listed in Schedule 2, other than non-human primates, cats and dogs, we make the following recommendations:

1. It is good practice for the local Ethical Review Process (ERP) to establish a process that allows the institution to monitor and record health and previous housing or husbandry issues that could affect the welfare of imported animals and the quality of science derived from them. Animal suppliers should meet their own national standards, and health and welfare information should be assessed in the light of, current UK standards and the recent revision of Appendix A to Europe Convention ETS 123. Single or periodic communication between purchaser and supplier may be required to obtain this information depending on whether the import is a one-off or repeated. Some of this information might be obtained from a supplier's web site.

2. As such information may periodically be required by the Inspectorate, it is reasonable and prudent for ERPs to ensure that records are kept of the above process.

3. The procedure for obtaining authority to use Schedule 2 animals (currently the application form for authority to transfer schedule 2 animals) should include confirmation by the institution that: its ERP has oversight of enquiries that have been made into the health and welfare (including housing conditions) of the animals to be imported; and that the supplier's housing and husbandry conditions meet their national standards;

4. The aggregated information collected by ERPs should be reviewed at a National Level within two years. If deficiencies are identified, they could be used to inform a revision of the process by which requests are made to use protected animals.

Advantages:

- This system would require only minor changes to current forms and procedures by the Home Office.
- Any increase in the quality of animals imported would be likely to enhance science as well as animal welfare.

[19] http://www.nc3rs.org.uk/page.asp?id=231

[20] http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/publications/code-of-practice/housing-of-animals-breeding/?version=1

[21] http://www.coe.int/T/E/Legal_affairs/Legal_co-operation/Biological_safety,_use_of_animals/Laboratory_animals/

- Inspectorate load would not be substantially increased.
- Questions from users would bring standards to the attention of supplying establishments.

Disadvantages:

- There would be an increase in bureaucracy for some purchasers/users as they might need to increase the amount of information requested and subsequently maintained from suppliers. However, we understand that this is already current practice for some users.
- Reluctance to seek to use animals from non-compliant suppliers might impede research.
- The lack of defined minima would allow animals to continue to be used from breeders whose standards may in some instances fall below the minima for breeders within the UK.

Acknowledgements

The Housing and Husbandry Sub-Committee gratefully acknowledges the assistance of the Home Office Inspectorate, in particular the Inspectorate representative on the Sub-Committee, in producing this document.

Annex J

AN AIDE-MÉMOIRE FOR USERS AND STAFF COMPARING PROPOSED CHANGES TO EUROPEAN LEGISLATION TO EXISTING UK CODES OF PRACTICE.

Introduction

In the UK there are two Home Office documents providing recommendations for the housing and care of animals bred for and used in scientific procedures. The *Home Office Code of Practice for the Housing and Care of Animals used in Scientific Procedures* was published in 1989. This Code of Practice is now quite old, and the text reflects the 'engineering standards' approach common in such documents at the time. The *Home Office Code of Practice for the Housing and Care of Animals in Designated Breeding and Supplying Establishments* was published in 1995. This text reflects a move towards trying to set out performance standards, and is more sensitive to the behavioural needs of animals.

Understanding of the needs of animals has developed considerably since both Codes of Practice were produced. Animal welfare science has made a significant contribution in this respect, as has the expertise and commitment of many of those caring for laboratory animals.

In 1997, the signatory parties to the Council of Europe Convention ETS 123 agreed to revise the European guidelines on laboratory animal housing and care set out in the Appendix to the Convention. At a Multilateral Consultation, held in Strasbourg on 15 June 2006, the draft Appendix A was unanimously adopted by the Parties to the Convention, and will enter into force twelve months after its adoption, i.e. 15 June 2007. In addition, The Council of the European Union has announced its intentions to incorporate the revised Appendix into *EU Directive 86/609.*

The updated Appendix A to Europe Convention ETS 123 provides guidelines for the accommodation and care of animals, which are based on present knowledge and good practice and were arrived at through compromise between industry representatives, regulators and animal welfare scientists. In essence, the Appendix explains and supplements the basic principles of accommodation, welfare and care adopted in Article 5 of the Convention, and its object is to help authorities, institutions and individuals in their pursuit of the aims of the Council of Europe in this matter

Purpose

The purpose of this aide-mémoire is to highlight areas where there are differences between the existing UK codes of practice and the revised Appendix, so that users can take steps to ensure that their housing reflects present knowledge and good practice. This will have immediate advantages in terms of animal welfare, may improve the quality of the science, and should help to ensure that decisions made now are likely to comply with future changes in UK legislation.

This aide-mémoire is, however, only a summary, and users are strongly advised to read both the original text of the revision and its associated part B, which contains supporting information, both of which are available at:

http://www.coe.int/T/E/Legal_affairs/Legal_co-operation/Biological_safety,_use_of_animals/Laboratory_animals/

Outline of areas where the provisions of the revised Appendix provide significant changes compared to the existing codes of practice.

General provisions

- The emphasis of the revised Appendix has moved towards meeting the behavioural and ethological needs of the animals. The new minimum space recommendations are based on the space considered necessary to provide enrichment and to meet these needs. The revised Appendix emphasises, throughout, the importance of providing complex, stimulating and enriched environments for animals used in research. In particular, enrichment programmes should be based on the biology of the species and regularly updated. (General provisions 4.5.3).

- The importance of social housing is also stressed throughout; the Appendix states that "Single housing on experimental grounds should be determined in consultation with the animal technician and with the competent person charged with advisory duties in relation to the well-being of the animals" (General provisions 4.5.2).

- The importance of odour to some animals is acknowledged and cleaning regimes should take this and scent-marking behaviour into account (General provisions 4.9)

Species provisions

Rodents

- For enrichment, the importance of bedding, refuges and nesting material are emphasised (Rodents 4.2)

- Guinea-pigs should be provided with manipulatable materials such as hay (Rodents 4.2)

- Gerbils need a thick layer of litter or a burrow substitute that needs to be at least 20cm long (Rodents 4.2)

- The principles regarding quality and quantity of space are the same for animals in IVCs (Rodents 4.2).

- Minimum enclosure dimensions have been increased. The tables below indicate some important areas where current UK Codes of Practice (CoPs) do not meet the new recommendations (Rodents 4.3.1)

Minimum enclosure sizes for rodents (cm^2)

	UK CoPs (on procedure and in stock)	UK Breeder CoP (breeding animals)	Current Appendix A	Revised Appendix A
Mice	200	300	180	330
Rat – 250g	700	900	350	800
over 600g	800	900	350	1500
Guinea Pig – 250g	900	1500	600	1800
> 600g	1000	1500	600	2500
Gerbil – 60g	500	900	NS	1200

In this and subsequent tables, dimensions highlighted are those where current UK minima are less than the revised Appendix A.

Minimum floor areas for group housed rodents (floor area per animal cm^2)

	UK User CoP	UK Breeder CoP	Current Appendix A	Revised Appendix A
Mice – <30g	60	60	80	80
Rat – 250g	250	150	200	250
over 600g	400	400	350	600
Guinea Pig – 250g	400	400	200	600
> 600g	700	700	600	600
Gerbil – 60g	150	150	NS	250

Rabbits

- Enrichment should include roughage, hay blocks or chew-sticks as well as an area for withdrawal. In floor pens for group housing, visual barriers and structures to provide refuges and look-out behaviour should be provided. For breeding does, nesting material and a nest box should be provided (Rabbits 4.2)

- A raised area should be provided within cages. This raised area should allow the animal to lie and sit and easily move underneath, but should not cover more than 40% of the floor space. If there are good scientific or veterinary reasons for not using a shelf then cage size should be 33% larger for a single rabbit and 60% larger for 2 rabbits (Rabbits 4.3)

- Wherever possible, rabbits should be kept in pens. (Rabbits 4.3)

- Minimum enclosure areas, and area per rabbit and cage height have been increased as shown below

Enclosure Dimensions for rabbits

	UK User CoP	UK Breeder CoP	Current Appendix A	Revised Appendix A
Minimum Floor Area (cm^2) for single housed rabbits				
<2kg	2000	2000	2000	3500
<4kg	4000	4000	3000	4200
<6kg	5400	5400	4000	5400
Minimum Floor Area (cm^2) per animal for group housed rabbits				
<2kg	1300	1500	2000	3500
<4kg	2600	4000	3000	4200
<6kg	3300	5400	4000	5400
Minimum Cage Height (cm)				
<2kg	40	40	30	45
<4kg	45	45	40	45
<6kg	45	45	40	60

Note: Allowances for rabbits over 10 weeks of age are to be based on final body weight in the revised Appendix A.

Cats

- Enrichment should include: raised part-enclosed structures vertical wooden surfaces and toys. (cats 4.2)
- At least one litter tray of minimum dimension, 300 x 400mm should be provided for every two cats (cats 4.6)
- Sufficient beds for all cats
- The expert group on cats have recommended a very significant increase from existing UK and European guidelines for space allowances and enclosure sizes, based on scientific evidence which indicates that cats develop behavioural abnormalities indicative of chronic stress if inadequate space is provided.

Minimum floor area for group housed cats (m^2) and height allowances (m)

	UK User CoP	UK Breeder CoP	Current Appendix A	Revised Appendix A	
Floor areas				Single	Pair
<3kg	0.33	0.50	0.3	1.5	2.25
>3kg	0.5	0.75	0.4 (0.6 >4kg)	1.5	2.25
Height allowances					
<3kg	0.5	2.0	0.5	2.0	2.0
<3kg	0.8	2.0	0.5	2.0	2.0

Note: Revised Appendix A requires additional area of 0.75m2 for each additional cat AND a shelf area of 0.5m2 for single animal with additional 0.25 m2 for each extra cat.

Dogs

- Dog pen sizes are slightly less than those required in the UK, but were adopted to encourage social housing for dogs in Europe by combining two current European standard individual pens.
- Single-housing for more than four hours on experimental grounds should be determined in consultation with the animal technician and with the competent person charged with advisory duties in relation to the well-being of the animals (Dogs 4.1).
- Separate areas for different activities should be provided. This can be achieved by, for example, inclusion of raised platforms and pen sub-divisions (Dogs 4.2)
- Enrichment should include items to chew (Dogs 4.2)
- Dogs should be removed to a separate area and allowed to exercise, with other dogs where possible, and with staff supervision and interaction, ideally on a daily basis (Dogs 4.2).

Ferrets

- Ferrets should not be single-housed for more than twenty-four hours without justification on veterinary or welfare grounds (Ferrets 4.1).

- Social enrichment for ferrets can be provided through group housing and by regular handling (Ferrets 4.1).
- Enclosure dimensions have been increased as shown below to provide sufficient space for social interactions and for enrichment.

Minimum enclosure sizes for ferrets (cm^2)

	UK User CoP	UK Breeder CoP	Current Appendix A	Revised Appendix A
Under 600g	2250	2000	NS	4500
600g – 800g	2250	2250	NS	4500
>800g	4500	4500	NS	4500
Adult males	4500	5400	NS	6000
Jill and litter	NS	5400	NS	5400

Minimum floor areas for group housed ferrets (floor area per animal cm2)

	UK User CoP	UK Breeder CoP	Current Appendix A	Revised Appendix A
Under 600g	1500	1000	NS	1500
600g – 800g	1500	1500	NS	3000
>800g	3000	3000	NS	3000
Adult males	3000	3000	NS	6000
Jill and litter	NS	5400	NS	5400

Non-Human Primates

The Council of Europe provisions cover marmosets, tamarins, squirrel monkeys, vervets, macaques and baboons. To reflect current and recent UK usage, this aide-memoire will only cover marmosets, tamarins, squirrel monkeys and macaques. The provisions for primates emphasise the importance of volume rather than surface area for arboreal and semi-arboreal species.

General principles

- A person competent in the behaviour of non-human primates should be available for advice on social behaviour, environmental enrichment strategies and management (Non-human primates 4.1).
- Enclosures should be of adequate height to allow the animal to flee vertically and sit on a perch or a shelf, without its tail contacting the floor (Non-human primates 4.3.1).
- Enclosures should not be arranged in two or more tiers vertically (Non-human primates 4.3.1).
- Where possible, non-human primates should have access to outdoor enclosures (Non-human primates 4.3.2).

Marmosets tamarins and squirrel monkeys

- For marmosets and tamarins the volume of available space and the vertical height of the enclosure are more important than floor area, due to the arboreal nature and the vertical flight reaction of these species (Marmosets 4.3).

- Marmosets and tamarins frequently scent-mark their environment and the total removal of familiar scents may cause behavioural problems. Alternate cleaning and sanitation of the enclosure and the enrichment devices retains some of the territorial scent-marking (Marmosets 4.7).

- Regular handling and human contact are beneficial for improving the animals' habituation to monitoring and experimental conditions and facilitate training to co-operate with some procedures (Marmosets 4.8).

- Enclosure dimensions have been increased as shown below to provide sufficient space for social interactions and for enrichment.

Minimum enclosure area for single or group housed marmosets, tamarins and squirrel monkeys (m2)

Body weight (kg)	UK User CoP	UK Breeder CoP	Current Appendix A	Revised Appendix A**
Marmoset				
<0.7	0.25	0.55		0.5
0.7-1.4	0.50	0.55		0.5
Tamarins				
<0.7	0.25	1.5		1.5
0.7-1.4	0.50	1.5		1.5
Squirrel Monkeys				
<0.7	0.25	2.0		2.0
0.7-1.4	0.50	2.0		2.0

* For breeding pairs for marmosets/ tamarins; for a breeding group of 2 males and 3 females for squirrel monkeys

** For adult animals (> 5 months for tamarins/marmosets & > 6 months for squirrel monkeys)

Minimum dimensions for breeding groups of marmosets, tamarins and squirrel monkeys.

	UK Breeder CoP		Revised Appendix A		
	Min encl. area for breeding group (m^2)	**Min Height (m)**	**Min encl. area for breeding group (m^2)**	**Min Height (m)**	**Min vol per additional animal (m^3)**
Marmosets	0.55	1.5	0.5	1.5	0.2
Tamarins	1.50	1.5	1.5	1.5	0.2
Squirrel Monkeys	2.00	1.8	2.0	1.8	0.5

Macaques

- The design and interior dimensions of the enclosure should at least allow them to climb above human eye level (Macaques 4.3).
- Housing the animals in groups and in enclosures larger than the minimum group sizes and enclosure dimensions given in the table below should be encouraged (Macaques 4.3).
- Recommendations for enrichment are provided (Macaques 4.2).
- Enclosure dimensions have been increased as shown below to provide sufficient space for social interactions and for enrichment.

Minimum enclosure volumes for macaques and vervets (m3)

Weight (kg)	UK User CoP*	UK Breeder CoP*	Current Appendix A*	Revised Appendix A**
1.5	0.5	3.6	0.175	3.6
3.5	0.6	3.6	0.4	3.6
5.5	0.88	3.6	0.595	3.6
7.5	2.1	3.6	0.81	3.6

* Calculated as multiple of minimum enclosure floor area and minimum height

** For animals held for breeding purposes minimum volume 4.0m3

Note – for revised Appendix A:

1. An enclosure of minimum dimensions may hold up to two or three animals dependent on age

2. In breeding colonies no additional space/volume allowance is required for young animals up to 2 years of age housed with their mother.

Minimum enclosure sizes for macaques and vervets (m^2)

Weight (kg)	UK User CoP	UK Breeder CoP	Current Appendix A	Revised Appendix A
1.5	0.5	2.0	0.35	2.0
3.5	0.6	2.0	0.5	2.0
5.5	0.8	2.0	0.7	2.0
7.5	1.4	2.0	0.9	2.0

Minimum enclosure heights for macaques and vervets (m)

Weight (kg)	UK User CoP	UK Breeder CoP	Current Appendix A	Revised Appendix A*
1.5	1.0	1.8	0.75	1.8
3.5	1.0	1.8	0.8	1.8
5.5	1.1	1.8	0.85	1.8
7.5	1.5	1.8	0.9	1.8

*Minimum height for breeding animals of any weight to be 2.0m

Animals should be housed in indoor enclosures, providing appropriate environmental conditions, and of sufficient size to ensure all animals are provided with at least the minimum space allowances set out in table above.

- In certain climates, it may be possible to hold breeding and stock animals in entirely outdoor enclosures if adequate shelter from climatic extremes is provided.
- Macaques can easily be trained to co-operate in simple routine procedures such as injections or blood sampling and to come to an accessible part of the enclosure (Macaques 4.8).

Birds

- Birds should be housed in enclosures that facilitate and encourage a range of desirable natural behaviours, including social behaviour, exercise and foraging (Birds 4).
- For chickens, ducks, quail and pigeons (which have space allowances detailed in the existing UK Code of Practice) significant increases have been agreed for space allowances, in particular minimum enclosure dimensions. These have been accepted as the minimum to permit the birds to express a (reasonable) range of normal behaviours.

  E.g. 1kg chicken and duck – minimum enclosure size increases from 0.125m2 to 2m2.

  In addition, ducks require a pond of a minimum area of 0.5m2 and depth of 30cm.

  Minimum pigeon enclosure increased from 0.1225m2 to 2m2 and height increased from 35cm to 200cm.
- Guidance is provided on humane killing, marking and species specific guidance on accommodation provisions.

Amphibia & Reptiles

- In contrast to the UK Codes of Practice, the revised Appendix A provides tables giving recommendations, where appropriate, for minimum water surface area and minimum water depth.
- In addition the revised Appendix includes recommendations for enrichment, enclosure design, water quality, identification and husbandry.

Fish

- The revised Appendix provides an extensive discussion on husbandry and care, but there are no recommendations for species-specific requirements.

Acknowledgements

The Housing and Husbandry Sub Committee gratefully acknowledges the assistance of the Home Office Inspectorate, in particular the Inspectorate representative on the Sub Committee, in producing this document.

Annex K

ANIMAL PROCEDURES COMMITTEE EDUCATION & TRAINING SUB-COMMITTEE: REVIEW OF MODULAR TRAINING.

Part 1: Overview of modular training and review of modules 1 to 4 for personal licence applicants

Executive Summary

This report presents the first stage of the review by the APC Education and Training Sub-Committee (ETSC) of modular training for applicants for personal and project licences under the Animals (Scientific Procedures) Act 1986 (ASPA). The report:

- provides an overview of current training requirements for both personal and project licensees;
- defines core competencies and learning outcomes appropriate for personal license applicants;
- proposes revision to the structure of modules 1 to 4; and
- identifies issues requiring further consideration, including a review of module 5 training for project licensees.

In conducting this review, the Sub-Committee consulted widely with those directly involved in the development, delivery and accreditation of modular training courses. In addition, four persons with expertise in training licensees were co-opted to provide specialist advice. A list of members and co-opted members is given in Appendix 1. The ETSC is extremely grateful for the co-operation and enthusiasm of all who participated.

The conclusion of the review is that modular training provides a flexible approach which is highly appropriate to the UK system of regulation. However, existing modules can, with advantage, be restructured to better define expectations of training, for example in anaesthesia and surgery, and to provide a structure which is also suitable for the training needs of persons other than personal licensees.

A key concept re-enforced throughout the review is that the formal training provided in the modules is *only an introduction*, a point which needs to be emphasised in all training courses. The subsequent period of supervision remains central to the development of competence, and the ETSC proposes to develop guidance on this important topic.

At present, the content of the modules is specified as a syllabus, listing topics which should be covered. The review has developed guidance on training objectives, which have been broken-down into the core competencies and learning outcomes we consider to be essential for personal licensees. This report thus provides a contribution to the development of course content and delivery; it also clarifies the requirements for assessment and subsequent supervisory requirements, by providing an extensive knowledge and skill profile against which candidates can be assessed. This approach has the additional advantage that the learning outcomes provide a useful aide-mémoire which will help licence applicants to understand what is expected of them.

Training is fundamental to legislative compliance, animal welfare and good science and should not simply be viewed as a means of acquiring a licence. However, it is resource intensive, and there is clearly a need for better resources (time, money and expertise) to support trainers and accrediting bodies in their work. The ETSC believes that the importance of training, whether modular or as Continuous Professional Development (CPD), is not universally recognised, and that limitations to time or opportunity for training are counter-productive. Certificate holders, ethical review processes, employers and funders of research need to be aware of their responsibilities in this respect.

Lastly, the review has identified a need to reassess and clarify the roles and responsibilities of the various bodies responsible for overseeing and delivering licensee training. The ETSC intends to examine these issues at a later stage of the training review.

The report presented here is intended to support and help develop training for personnel working in the UK under the provisions of ASPA. However, competencies and learning outcomes are also relevant to the training of those in other countries who intend to carry out procedures on living animals, and it should therefore be of wider international interest.

Recommendations

(i) Modular training should be based on a learning outcomes approach and trainers, course organisers and the accrediting bodies should review current course content and delivery, and the assessment of trainees accordingly.

(ii) The general principle of a learning outcome approach should be endorsed by the Home Office. The specific learning outcomes, and the seven core competencies for personal licensees with which they are associated (set out in Section 3 of this report), should be endorsed by the Home Office and adopted as the basis for mandatory training for personal licensees.

(iii) The existing modules 1 to 4 should be replaced with modules A to E as described in Section 3.2 of this report. This arranges the learning outcomes in logical groupings and provides a clearer division between local and general anaesthesia and surgery. It should also provide a module (i.e. module A) that includes local issues, and is thus more appropriate for staff other than personal licensees, such as certificate holders who find such training useful, experienced workers from overseas who need to know about UK legislation and local rules, and those carrying out Schedule 1 euthanasia.

(iv) The development of the learning outcomes published in this report provides a template against which candidates can be assessed and the three accrediting bodies are encouraged to get together to review their methods of assessment in the light of these.

(v) The joint IOB/UAG MCQ database will need to be reviewed with respect to a learning outcome approach, and amended to take account of the different modular structure if accepted. We recommend that the Home Office identify a source of funding for this.

(vi) The importance of supervision and CPD training in achieving and maintaining competence and in contributing to good science and welfare needs to be more widely recognised within the research community, both locally within research establishments and by those funding research. Both modular and non-modular training needs to be adequately funded and resourced.

(vii) The impact of any changes introduced as a result of this report, and of how these work in practice, should be reviewed by the APC ETSC in consultation with the trainers, accrediting bodies and the Home Office, after five years.

Annex L

MINISTER'S RESPONSE: Animal Procedures Committee Education & Training Sub-Committee: Review of Modular Training.

Sara Nathan
Chair of the Animal Procedures Committee
c/o APC Secretariat
1st Floor Seacole Building
2 Marsham Street
London
SW1P 4DF

ANIMAL PROCEDURES COMMITTEE: EDUCATION AND TRAINING SUB-COMMITTEE REVIEW OF MODULAR TRAINING

In February 2006, the Education and Training Sub-Committee of the Animal Procedures Committee published its report on the first part of its review of modular training. I am grateful to the Committee for the consideration it has given to this important issue.

In responding to the report, I wish to record my thanks to you and to the Committee for the time and thought that has been put into it. I am very grateful for the practical proposals it contains, which will help determine the future content and format of licensee training.

There have been significant developments in science, technology and animal welfare since the modular training programmes were first established, and ideas on training needs, methods and resources have also developed in that time. In the light of this, the first element of the Animal Procedures Committee's review of current training is timely and to be welcomed. I look forward also to receiving the outcome of the further work the Committee is undertaking on the review of module 5 training for project licensees.

The proposals for alteration of the modules, and the introduction of specific learning outcomes and competencies provides a sound basis for taking the ideas forward and should improve the quality of training and applicants. However, this improvement will only be achieved if licensed establishments commit more resource in training, thereby increasing the compliance costs. Because of this we will need to consult further on the proposals and traditional arrangements before we commit to implementation. We expect training requirements will also have to be reviewed again, in due course, to take account of any revised European training requirements decided as part of the current review of Directive 86/609/EEC.

I also note that you have undertaken to reassess and clarify the roles and responsibilities of the accrediting bodies. In looking into this issue, it would be helpful if you could provide advice on how the effectiveness of the accrediting bodies can be evaluated; how they can be audited and by whom; whether there is any inconsistency between the courses offered by the accrediting bodies which needs to be remedied and how this might be addressed; and whether their assessment methods are sufficiently robust. I am sure that you will strike a proper balance in any recommendations you make on these points to ensure that any compliance costs are justified by the expected benefits of any proposed changes.

It would also be helpful if the Committee could advise by June 2007 on whether the introduction of the learning outcomes approach for personal licensees offers the opportunity to better mach personal licence authorities to evidence of satisfactory training having been undertaken.

My detailed response to the Committee's current report and recommendations are set out in the annex to this letter.

Annex

The Animal Procedures Committee Education & Training Sub-Committee:

Review of Modular Training

Government Response by Joan Ryan, MP, Parliamentary Under Secretary of State for the Home Department

Recommendation (i) Modular training should be based on a learning outcomes approach and trainers, course organisers and the accrediting bodies should review current course content and delivery, and the assessment of trainees accordingly.

Recommendation (ii) The general principle of a learning outcome approach should be endorsed by the Home Office. The specific learning outcomes, and the seven core competencies for personal licensees with which they are associated (set out in Section 3 of this report), should be endorsed by the Home Office and adopted as the basis for mandatory training for personal licensees.

Recommendation (iii) The existing modules 1 to 4 should be replaced with modules A to E as described in Section 3.2 of this report. This arranges the learning outcomes in logical groupings and provides a clearer division between local and general anaesthesia and surgery. It should also provide a module (i.e. module A) that includes local issues, and is thus more appropriate for staff other than personal licensees, such as certificate holders who find such training useful, experienced workers from overseas who need to know about UK legislation and local rules, and those carrying out Schedule I euthanasia

I welcome the APC's recommendations on modular training are welcome. A learning outcome approach will bring the modular training system into line with practices in the broader educational field. There is merit in the proposals for alteration of the modules, and the specific learning outcomes and competencies provide a good basis for taking the ideas forward and should improve the quality and benefits of training. However, this improvement will only be achieved by requiring licensed establishments to commit more resource to training, thereby increasing the regulatory burden. Because of this we will need to consult further on the proposals before we commit to implementation. Training requirements will also have to be reviewed again, in due course, to take account of any revised European training requirements decided as part of the current review of Directive 86/609/EEC.

Recommendation (iv) The development of the learning outcomes published in this report provides a template against which candidates can be assessed and the three accrediting bodies are encouraged to get together to review their methods of assessment in the light of these.

We agree that accrediting bodies should review and adapt their assessment methods to take account of the learning outcomes approach. However, we believe it would be best to defer the review until the wider stakeholder consultation has been carried out.

Recommendation (v) The joint IOB/UAG MCQ database will need to be reviewed with respect to a learning outcome approach, and amended to take account of the different modular structure if accepted. We recommend that the Home Office identify a source of funding for this.

The recommended review of the multi-choice question (MCQ) database assumes that such a database will continue to be the primary method used for assessment of trainees. However, this is not self-evident and it is of concern that no critical appraisal of the suitability of MCQs for the assessment of licensees has been done by the accrediting bodies to date. Reviewing the assessment processes is a function for the accrediting bodies to perform or organise and for which they charge fees. In view of this, we do not agree that the Home Office

should fund the review. We believe the funds required should primarily come from the revenue the accrediting bodies and course providers generate. In addition accrediting bodies could reasonably seek external funding for the further development of the question database, for example, from the National Centre for the 3Rs.

Recommendation (vi) The importance of supervision and Continued Professional Development (CPD) training in achieving and maintaining competence and in contributing to good science and welfare, needs to be more widely recognised within the research community, both locally within research establishments and by those funding research. Both modular and non-modular training needs to be adequately funded and resourced

Agreed. The importance of ongoing supervision, on the job training and Continued Professional Development has always been a central concept in the UK system of regulation. Initiatives to promote good practice in the supervision of licensees are to be welcomed and encouraged.

Recommendation (vii) The impact of any changes introduced as a result of this report, and of how these work in practice, should be reviewed by the APC ETSC in consultation with the trainers, accrediting bodies and the Home Office, after five years.

Agreed, subject to the caveat that changes to the legislative and administrative frameworks consequence on a change in EU legislation may necessitate a different review date. It is good practice to implement a system of review and development in which critical reflection on past events influences future practice. Periodic reviews of the licensee training system are necessary in order to ensure that there is continuing improvement. Learning outcomes in particular should be reviewed in the light of the changing needs of personal licensees.

Joan Ryan
Parliamentary Under Secretary of State
Home Office

Annex M

APC WORK PROGRAMME FOR 2007

The work of the Committee's Sub-Committees and Working Groups

Objective	Target Date
Primates Sub-Committee	
Advise Home Office as required on suitability of overseas sources of primates.	Ongoing
Assess the justification for the use of primate models in certain areas of research, especially brain research.	Provide advice to full Committee following the publication of response of the Weatherall Report sponsors.
Develop an overview of current situations/trends in the use of primates in medical research and the understanding of diseases, excluding regulatory toxicology.	Consider the resources required to maintain such an overview post Weatherall Report
Housing & Husbandry Sub-Committee	
Continue to explore, with the Home Office, what mechanisms exist for promoting good practice and how these are used.	Ongoing
Welfare of fish used in experimentation	December 2007
Education & Training Sub-Committee	
Finalise report on the revision of training modules 1-4, and present report to APC.	February 2006
Conduct workshop on training module 5.	May 2007
Prepare a report on module 5 to present to main APC.	September 2007
Consider and report on issues relating to accreditation of training courses, including clarification of expectations and roles, assessment of trainees and auditing of courses.	October 2007
Applications Sub-Committee	
Consider applications for project licences referred to the Committee by the Home Office for advice, and provide advice to Home Office.	As required
Suffering and Severity Working Group	
In light of successful preliminary pilot study on the retrospective assessment of suffering and severity, commission and monitor more widely scoped pilot study in conjunction with LASA.	January 2006

Schedule 1 Working Group	
Review outstanding questions from the APC report on the use of CO2 and insert gases on rodents.	Sept 2007
Revision of Directive 86/609 Working Group	
The APC 86/609 Working Group, on behalf of the full APC, will continue to monitor further developments and to input as appropriate into this review process.	When required

Glossary

Embryo aggregation chimaeras – a collection of embryos containing genetically distinct types of cells.

Embryonated egg – an egg which contains an embryo.

Equidae – the Equidae family of mammals which have a single functional digit although the second and third digits persist as splint bones. Equids include horses, asses and zebras.

Ethology – the scientific study of animal behaviour.

Husbandry (animal) – the practice of breeding, raising and caring for animals.

In vitro – literally "in glass", ie in an artificial environment, outside a living organism.

Retrospective reporting – the reporting of data already collected; a study of past events, in contrast to a prospective study, which attempts to predict what will happen in the future.

Three R's – stands for the replacement, refinement and reduction of animals in research.

Xenotransplantation – the transplantation of cells, tissues or organs from an animal of one species to an animal of a different species.

List of Acronyms

APC – Animal Procedures Committee

ASPA – Animals (Scientific Procedures) Act 1986

LASA – Laboratory Animal Science Association

LAVA – Laboratory Animal Veterinary Association

NACWO – Named Animal Care and Welfare Officer

NC3Rs – the National Centre for the Replacement, Refinement and Reduction of Animals in Research

NVS – Named Veterinary Surgeons

PSC – Primate Sub-Committee

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