Report of the Animal Procedures Committee for 2011

Presented to Parliament pursuant to Section 20(5) of the Animals (Scientific Procedures) Act 1986.

Ordered by the House of Commons to be printed on 20 June 2013

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ANIMAL PROCEDURES COMMITTEE

Membership as at 31 December 2011

Sara NATHAN OBE (Chairman) – Freelance journalist and former editor of Channel 4 News. Has a portfolio of public appointments including as a member of the Judicial Appointments Commission, a member of the Solicitors Regulation Authority and a consultant editorial adviser to the BBC Trust. She has previously served on the boards of Ofcom and the Human Fertilisation and Embryology Authority and as a member of the Commission on Youth Crime and Anti-Social Behaviour.

Hannah BUCHANAN-SMITH BSc PhD – Professor of Psychology, the University of Stirling.

Michael DENNIS BSc – Head of Primate Programme, Health Protection Agency.

John DOE MIBiol PhD – Partner, Parker Doe Partnership LLP.

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.

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

Hilary NEWISS BA – Solicitor (non-practising), Trustee and Non-Executive Director with a portfolio of interests and appointments.

Ian PEERS BSc (Hons) PGCE M.ed. Psych PhD FRSS – Global Head Statistics, Discovery Sciences, AstraZeneca.

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

Mark PRESCOTT BSc (Hons) PhD – Head of Research Management and Communications, 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 at the Edinburgh liver transplantation programme.

David SMITH MPhil CBiol MSB PhD Reg. Tox (IOB) EUROTOX FBTS – A senior director of toxicology for AstraZeneca.

Sarah WOLFENSOHN BSc MA VetMB Cert LAS FSB Dip ECLAM MRCVS RCVS – Independent veterinary consultant.

CHAIR'S LETTER TO THE SECRETARY OF STATE FOR THE HOME DEPARTMENT AND TO THE NORTHERN IRELAND MINISTER OF HEALTH, SOCIAL SERVICES AND PUBLIC SAFETY

I enclose with pleasure the Animal Procedures Committee's report for 2011.

The report summarises the significant work contributed by the Animal Procedures Committee in 2011 and represents the advice that we have presented to the Department.

During 2011 considerable time was devoted to responding to the Home Office consultation on the EU Directive 2010/63. The Committee recognises that the Directive represents an improvement in standards within many Member States and that there is a recurring theme of openness and transparency. However, the Committee was concerned that some of the provisions would fall short of the current requirements of the UK Animals (Scientific Procedures) Act 1986 if copied out into UK legislation. It is important to note that the Committee therefore favours option 3: to implement the requirements of the Directive where these are more stringent than the Animals (Scientific Procedures) Act and to retain some of the higher UK standards and requirements that were in force on 9 November 2010.

The Committee also continued its work on cumulative severity and held a successful joint workshop with the Home Office to which key stakeholders were invited to participate and share perspectives and ideas on this subject.

I am very grateful to all those who have contributed to the APC's work and particularly thank our retiring members whom we wish well for the future.

SARA NATHAN

INTRODUCTION

This report describes the work carried out during 2011 by the Animal Procedures Committee.

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

- 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.

- In its consideration of any matter the Committee shall have regard for 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 to whom it reports and its membership. On joining the Committee, members agree to be bound by its Code of Conduct (see Annex B). Annex C details the membership of the Committee's Sub-Committees and working groups. A register of members' interests is on the APC website[1].

The full Committee met five times during 2011. In addition, there were a number of Sub-Committee/Working Group meetings and an annual conference, held jointly with the Home Office Inspectorate, which provided a forum for learning, discussion and debate.

[1] The APC website http://webarchive.nationalarchives.gov.uk/20130222193642/http://www.homeoffice.gov.uk/agencies-public-bodies/apc/

THE COMMITTEE'S WORK DURING 2011

1. The Animal Procedures Committee (APC) has four Sub-Committees. These are the Applications Sub-Committee, the Education and Training Sub-Committee, the Housing and Husbandry Sub-Committee and the Primate Sub-Committee. This year there were are also two working groups: the Cumulative Severity Working Group and the Implementation of Directive 2010/63/EU Working Group. The Directive Working Group took over more of the work of the Committee as the implementation of the new Directive drew closer.

Committee representation and visits

2. The Committee made a number of visits to establishments licensed under the Act. As is usual, the purpose of the visits was to develop and discuss relevant issues with those involved in animal research and testing, increase the outreach of the Committee and share understanding and best practice among the Committee membership. The Committee makes no public comment about these visits. The Committee is grateful to the establishments for the open approach they have shown in facilitating these visits.

3. Members of the Committee attended the annual Certificate Holders Forum which brings together those responsible for designated establishments where research under the Animals (Scientific Procedures) Act is permitted to take place.

4. The Committee held a successful annual conference jointly with the Animals (Scientific Procedures) Inspectorate in November. The purpose of the conference was to respond to a request to provide advice to Ministers on the functions, role and remit of the new national committee and the outcome was a paper drafted for further consideration by the Committee in 2012.

5. The Chair attended the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) annual science review meeting, in order to build connections with important stakeholder groups.

6. Professor Bobrow from the Academy of Medical Sciences was invited to the Committee's October meeting to provide members with an overview of the recommendations of the Academy of Medical Sciences' report on the regulation of the use of animals containing human material in research (ACHM). A key recommendation was that the Animal Procedures Committee should be the national expert body to advise the Government on ACHM research.[2] This followed his visit in 2010 at the start of the consultation process.

7. Following the Committee's discussions on allegations made by the British Union for the Abolition of Vivisection (BUAV), concerned with animal care at Wickham Laboratories, the Committee sent a letter to the Minister which detailed their concerns (available at Annex G).

Applications Sub-Committee (ASC)

8. The Home Office refers a small number of project licence applications to the Applications Sub-Committee (ASC) for advice. Since 2004 the categories of licence being referred have included:

- any involving the proposed use of wild-caught non-human primates;
- any involving the proposed use of cats, dogs, equidae[3] or non-human primates in protocols of substantial severity;

[2] http://www.acmedsci.ac.uk/p99puid222.html

[3] **Equidae** – the *Equidae* family of mammals which includes horses, asses and zebras.

- any projects with a substantial severity banding, or major animal welfare or ethical implications, involving (a) xenotransplantation[4] of whole organs, or (b) chronic pain models, or (c) study of the central nervous system; and

- applications of any kind raising novel or contentious issues or giving rise to serious societal concerns.

9. Any such applications that are referred to the APC are initially discussed by the ASC through open dialogue and written questions with each applicant.

10. It is the aim of the Committee to explore the total suffering experienced by the animals on the project, during their whole lifetimes, and to rationalise this against the expected benefits. The Committee will also seek the applicant's approach to the 3Rs[5], individual study and programme design, standards of housing and husbandry and the extent to which pain, suffering, distress and lasting harm can be avoided, recognised, alleviated and managed. All of this information is used in the harm/benefit assessment when deciding whether a project is justified.

11. There were seven licence applications referred to the Committee for advice in 2011.

12. The first referral concerned a programme of work that involved non-human primates in neuroscience studies. The Committee met the applicants and considered the individual procedures and the cumulative impact of these procedures on the animals involved over the duration of their lifetime. The Committee was satisfied with the level of care, cage facilities, frequency of attendance of care staff and frequency of veterinary assessment. Although the Committee considered that no individual procedures exceeded the moderate severity limit, it was recommended that, based on the cumulative suffering the animals were likely to experience, a substantial banding should be applied to this licence.

13. The second referral was a new application involving the use of mice in neuroscience studies.

14. In considering this application, the Applications Sub-Committee considered the lifetime experience of the animals involved, the lay summary of the project, the cost to the animals (in terms of well-being), the justification and proposed benefits of the project and whether the proposed project was novel. The ASC also considered the housing and husbandry during and after the surgical operations and were satisfied that there was appropriate care.

15. The third referral was a new application as the proposed work involved neuroscience studies using non-human primates. The Committee was keen to fully explore the overall severity of suffering experienced by the animals and questioned the realisable benefits in the near future. After due consideration there was a consensus to recommend that the application should be approved.

16. In August the APC received three applications involving the use of non-human primates in procedures of substantial severity to develop animal infection models. The APC raised a number of questions about the applications and were subsequently given informative presentations by the applicants which set out the methodology and potential benefits of the projects. Following the meeting with the applicants, the Committee's considerations included the lifetime experience of the animals, the lay summaries of the projects, the cost to the animals (in terms of potential suffering), the justification and the proposed benefits of the projects. The ASC considered that the applicants had provided full and reasoned responses on the issues raised.

17. In November the Home Office referred an amendment to an existing project licence that involved the use of non-human primates in neuroscience studies. The ASC met the applicant and requested clarification and explanations of the methodology. The ASC questioned the lifetime experience of the animals, the harms to the animals (in terms of pain, suffering and distress), the justification and proposed benefits of the project. The APC was content that the applicant had fully considered refining the procedures and ameliorating suffering, and that there was a balance of benefits in support of the research.

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

[5] 3Rs: the Replacement, Reduction and Refinement of animal experiments

Primates Sub-Committee (PSC)

18. The role of the Primates Sub-Committee (PSC) is to advise the wider Committee on issues relating to the acquisition, housing, care and use of non-human primates in scientific procedures. Under the Animals (Scientific Procedures) Act, unless an exception is agreed, animals listed in Schedule 2 to the Act, including non-human primates, may not be used unless they have been bred at a designated breeding establishment or obtained from a designated supplying establishment.

19. As UK demand for non-human primates exceeds domestic supply, the Home Office has, for some years, agreed that UK designated establishments can import such animals from specified overseas breeding and supplying centres, where assessed as acceptable. As part of the acceptance process, Home Office Inspectors appraise the suitability of overseas centres using details provided about the breeding or supplying centres, and information gained during Inspectorate visits, to determine whether the centres meet acceptable standards of animal care and accommodation. Acceptance is based on these appraisals, consideration by the APC and further information supplied by UK users.

20. In June 2011, the Primates Sub-Committee was asked to consider, as requested by the Animals (Scientific Procedures) Division, the acceptability of a new quarantine and holding facility (for macaques) in Europe.

21. In weighing up the potential experiences of the animals within this request, the APC advised that the request should not be approved. However, it was noted that substantially improved new facilities were under construction at the establishment. With the APC given sight of those plans, and if the macaques were to arrive and be housed in the new facility (and the standards met the proposed plans), it would not oppose approval.

Directive 2010/63/EU Working Group

22. A considerable amount of the APC's time in 2011 was dedicated to commenting on the European Commission (EC) Directive 2010/63/EU (hereafter termed 'the Directive') which, on 1st January 2013, is to replace and update the 1986 Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes.

23. In June 2011 the Home Office published a consultation document seeking comments for the options for transposition of the Directive. Following that consultation, the Committee submitted options (August 2011) to the Animals in Science Regulation Unit for its consideration. A copy of the full response is available on the APC website.[6]

24. The Committee recognises that the Directive represents an improvement in standards within many Member States in a number of areas, including: the authorisation of animal use; training for those using and caring for animals; implementation of the 3Rs (including the use of humane alternatives); and animal housing and care. The Committee welcomes the recurring theme of openness and transparency across the Directive. However, the Committee equally recognises that a number of its provisions would fall short of the current requirements of the UK Animals (Scientific Procedures) Act (ASPA) if the Directive were to be directly 'copied out' into UK legislation.

25. The Committee therefore considered that the UK should retain some of the higher UK standards that were in force in the UK on 9 November 2010, as permitted by Article 2 of the Directive.

26. The Committee additionally noted that the effective implementation of the legislation, including the retention of those elements of the ASPA that have a positive impact on welfare and science, are critically dependent on the standards set out in the new guidance notes.

[6] http://webarchive.nationalarchives.gov.uk/20130222193641/http://homeoffice.gov.uk/publications/agencies-public-bodies/apc/Animal-procedures?view=Standard&pubID=944451

27. The Committee considers that the production of the new guidance notes should be a transparent process involving the full range of interest groups including researchers from academia and industry, animal technologists and care staff, animal behaviour and welfare scientists, veterinarians and members of animal welfare and 3Rs organisations. This is essential in order to ensure that the interests of animals and science are fairly balanced.

National Committee on the Use of Animals in Scientific Procedures

28. As part of the transposition of the Directive there is a requirement to replace the APC with a new National Committee on the Use of Animals in Scientific Procedures. The APC, at its November conference, considered the format, functions, remit and potential expertise required of the new committee. Following the conference, a forward look paper on the new committee was drafted by the Committee with an aim to submit it to Ministers in early 2012 for consideration and to provide advice.[7]

Cumulative Severity Working Group

29. The transposition of the European Directive on 1 January 2013 means that the actual severity experienced by animals in research and testing will be reported for the first time. The assessment of actual severity will include consideration of the lifetime experience of the animals, also expressed as 'cumulative severity'. This includes examining housing and husbandry, transport and length of time under procedure as well as the severity of the experiments themselves.

30. The Cumulative Severity Working Group met on five occasions in 2011. The working group had been established to consider how to proceed with the review of the assessment of cumulative severity in non-human primates used in neuroscience research. The Working Group gathered evidence from funders of research, scientists and welfare groups. The background and terms of reference of the review have been published on the APC website together with an appendix on the UK system of severity and classification. [8]

31. The APC Chair attended a meeting of academic users of non-human primates and representatives of the research funding organisations at the Wellcome Institute in March. At that meeting the background to the establishment of the Cumulative Severity Working Group was explained, and the Chair was able to hear and share the views of users. In order to ensure the working group had sufficient current expertise it was also agreed to invite, on a temporary basis, two neuroscientists and a currently working veterinary surgeon to join the group. Professor Roger Lemon from University College, London, Professor Wolfram Schultz from the University of Cambridge and Professor Paul Flecknell from Newcastle University joined the group.

32. The APC is grateful to Professors Lemon, Shultz and Flecknell for agreeing to join the group and for working so hard on preparing its ongoing outputs.

33. In June 2011 the Committee held a successful joint workshop (with the Animals (Scientific Procedures) Inspectorate to which members of the scientific community were invited. The primary aim of the workshop was to develop an evidence-based approach to defining and assessing cumulative severity in, but not limited to, non-human primates in neuroscience research. A key output of the workshop was to help define the questions needed to be asked in a proposed call for evidence, to elicit the right sort of information and identify areas where further research is required.

34. The main elements of the workshop consisted of active participation by delegates in four break-out groups:

- effects of food and fluid control and interpretation of body weight data;
- behavioural effects and interpretation of performance on tasks;

[7] http://webarchive.nationalarchives.gov.uk/20130222193641/http://homeoffice.gov.uk/publications/agencies-public-bodies/apc/advice-national-committee/?view=Standard&pubID=1014280

[8] http://webarchive.nationalarchives.gov.uk/20130222193641/http://homeoffice.gov.uk/publications/agencies-public-bodies/apc/review-cumulativeseveritytor?view=Standard&pubID=864678

- physiological effects and markers; and
- novel ways of measuring animal welfare.

35. As a result of the feedback from the workshop the Committee proposed to follow this up by drafting a questionnaire that could be circulated as a 'call for evidence' to stakeholders.

CIOMS Consultation

36. In June the International Council for Laboratory Animal Science (ICLAS) and the Council for International Organisations of Medical Sciences (CIOMS), invited the APC to review and comment on the revised 2011 international guiding principles for biomedical research involving animals. The original international guiding principles were drafted in 1985 and these are now being revised. The Committee was pleased to forward its views.[9]

Infringements

37. The Home Office reports on infringements under the Act to the Committee. These are separately reported by the Home Office[10], Annex E details the process.

New Committee Members

38. APC recruitment procedures are governed by guidance from the Office of the Commissioner for Public Appointments in order to comply with the Nolan principles, and an independent assessor monitors the recruitment process to ensure compliance. Appointments to the APC are made by Home Office and Northern Ireland Ministers.

39. Members of the APC are appointed as individuals, not as representatives of particular organisations.

40. There is a statutory requirement for there to be a solicitor, barrister or advocate on the APC, so, in spite of the end of the APC being in sight, it was necessary to appoint a new lawyer at the end of Professor Dawn Oliver's term. During the year Professor Dawn Oliver, who had completed her second (and final) term of appointment, retired from the Committee. The Chair and the Committee thanked Professor Oliver for the valuable contribution she has made to its work. Ms Hilary Newiss was subsequently appointed into the statutory position as lawyer.

41. During the year Mr Robert Kemp and Professor Keith Kendrick stood down from the Committee. The Chair and Committee wish to thank them for the valuable contribution they have made to its work.

CoPSAC Consultation

42. Following a consultation exercise during 2010 and early 2011, the APC responded to an invitation to comment in April on a revised version of the *Code of Practice for Scientific Advisory Committees* (see Annex F). Following this consultation the Government Office for Science published a revised *Code of Practice for Scientific Advisory Committees*.[11]

The Committee's Work Programme for 2012

43. The main priorities for the Committee's programme for 2012 will include its advisory work associated with the transposition of Directive 2010/63/EU into UK legislation, and progressing the Committee's work on cumulative severity. The Committee's work programme for 2012 is detailed in Annex H.

[9] http://webarchive.nationalarchives.gov.uk/20130222193641/http://homeoffice.gov.uk/publications/agencies-public-bodies/apc/committee-reviewresponse?view=Standard&pubID=1127560

[10] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/116914/008_asru_annual_report_2011.pdf

[11] http://www.bis.gov.uk/assets/goscience/docs/c/11-1382-code-of-practice-scientific-advisory-committees.pdf

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. 2011

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 four 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 2011-12, the Home Office allocated a budget of up to £27,500 respectively from which to make such payments.

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

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

Ministers

9. The Home Secretary in practice delegates her responsibilities under the Act to another Minister in the Home Office, who administers the Act in England, Scotland and Wales. From May 2010, Lynne Featherstone MP took responsibility for research using animals. In Northern Ireland the administration of the 1986 Act is the responsibility of the Department of Health, Social Services and Public Safety (DHSSPSNI) for whom since May 2011 Edwin Poots MLA has been the responsible Minister replacing Michael McGimpsey MLA.

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; and

(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 31 DECEMBER 2011

Membership of current Sub-Committees and Working Groups are listed below.

Current Sub-Committees and Working Groups and their memberships are listed below.

Applications Sub-Committee

Ms Sara Nathan **(Chair)**
Professor Hannah Buchanan-Smith
Dr John Doe
Dr Peter Hunt
Ms Hilary Newiss or Dr Simon Glendinning
Dr Ian Peers
Professor John Pickard
Dr Mark Prescott or Dr Penny Hawkins
Mrs Sarah Wolfensohn

Primates Sub-Committee

Professor John Pickard **(Chair)**
Professor Hannah Buchanan-Smith
Mr Michael Dennis
Dr Mark Prescott
Mrs Sarah Wolfensohn

Directive 2010/63/EU Working Group

Dr Penny Hawkins **(Chair)**
Dr Peter Hunt
Ms Hilary Newiss
Dr Ian Peers
Dr Ken Simpson
Dr David Smith

Cumulative Severity Working Group

Professor John Pickard **(Chair)**
Professor Hannah Buchanan-Smith
Mr Michael Dennis
Ms Sara Nathan
Dr Mark Prescott
Mrs Sarah Wolfensohn

Co-opted Members Cumulative Severity Working Group

Professor Paul Flecknell (Newcastle University)
Professor Roger Lemon (Institute of Neurology)
Professor Wolfram Schultz (Cambridge University)

ANNEX D

APPLICATIONS SUB-COMMITTEE

1. The Applications Sub-Committee met on five occasions during 2011. 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.

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 the Secretariat for secure distribution to the Applications Sub-Committee. The Sub-Committee will meet, interview the applicant if necessary, and formulate draft recommendations.

4. When possible, 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

5. It is proposed that the APC Chairman should be an *ex officio* member of the Sub-Committee, and attend all meetings.

6. 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

INFRINGEMENTS PROCESS

1. The Home Office provides the Committee with an annual summary of infringements. These are breaches of the 1986 Act, or of licence or designated establishment conditions. Once Home Office action on the infringement has been completed a report is forwarded to the Committee for information. Under the current Home Office framework infringements are reported in four categories, A–D[12].

Category A Infringement

The characteristics of a category A infringement may include the following:

- no evidence of intent to subvert the ASPA 1986 controls;
- no significant refinement or reduction consequences;
- resolved or remedy in place within days of discovery;
- no disputed facts and no likelihood of representations being made;
- no prospect of prosecution.

Typically the outcome of a category A infringement is to note details of the infringement with no further action necessary.

Category B Infringement

The characteristics of a category B infringement may include the following:

- significant refinement or reduction concerns;
- future compliance concerns;
- not resolvable within days of discovery and further action needed;
- facts not disputed and no likelihood of dispute over the course of action proposed;
- not sufficiently serious for referral for prosecution, revocation of licences or withdrawal of a certificate to be considered;
- may be recurrent or persistent category A infringements.

Typically the outcome of a category B infringement will be to send a letter of admonition (i.e. a warning) to those involved, although in some cases the Home Office may require further action (such as additional training or altered management practices) and might apply an additional condition to the licence or certificate.

Category C Infringement

The characteristics of a category C infringement may include the following:

- serious refinement or reduction concerns;
- future compliance concerns;

[12] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/116914/008_asru_annual_report_2011.pdf

- disputed facts and evidence of untruthfulness or attempt to evade responsibility;
- variation, suspension or revocation of licence or certificate is merited but referral for prosecution is not merited;
- may be recurrent or persistent problems of a lower category.

Typically the outcome of a category C infringement is to amend, revoke or suspend the licence or certificate and to send a letter of admonition to the licensee or certificate holder.

Category D Infringement

The characteristics of a category D infringement may include the following:

- serous contraventions which merit referral for possible prosecution;
- the Inspectorate undertakes a preliminary investigation only, sufficient to establish whether prosecution is or is not an option;
- if prosecution is contemplated, further investigation is then undertaken by the police and the Inspectorate.

The outcome of a category D infringement is for the Home Office to refer the case to the Crown Prosecution Service (in England and Wales) or the Procurator Fiscal (in Scotland) for them to consider prosecution.

2. The Committee recognises that publishing material in relation to infringements may be in breach of the Data Protection requirements. For further explanation of the Inspectors' Infringements process, please see the Compliance and Infringements section of the Animals Scientific Procedures Inspectorate & Division Annual Report 2011.

ANNEX F

6 May 2011

SIGsciencestrategy@bis.gsi.gov.uk

Dear Sir/Madam

ANIMAL PROCEDURES COMMITTEE (APC) COMMENTS ON THE DRAFT CODE OF PRACTICE FOR SCIENTIFIC ADVISORY COMMITTEES (COPSAC 2011)

As Chair of the APC I am responding on its behalf to the Draft CoPSAC 2011, and welcome the opportunity to do so.

Chapter 2 SAC Purpose and Expertise

(Ref para. 15) The APC does not see the need for this last sentence, as it would be self-evident that any lacunae in expertise should be acknowledged and addressed – not just, or particularly these.

(Ref para. 24) The APC does not consider the last part of the last sentence to be practical, i.e. "but the principles of open and fair Public Appointments should still be followed.". We would end the sentence after the word "the roles", the process sounds disproportionate to us.

(Ref para. 25n2) The last sentence of the paragraph which refers to "Mid-career professionals….." is an odd sentence to have in this sort of code. Is it really necessary?

Responsibilities of Chairs

(Ref para. 25n3 & 27) Should there be some detail about the distinction between a scientific and lay chair and the different support they may require? There should be considerations that induction processes should read as to explicitly include the chair – at the moment it looks as if chairs do not undergo induction. The draft Code also contains plenty of material on the responsibility of a chair, but, conversely, little on the secretariat support to be provided for the chair.

Chapter 4 – SAC Support and Departmental Relationships

(Ref para. 45) Last sentence – Who is it that should decide what is considered sufficient secretariat support and whether (agreed) sufficient secretariat support has been met.

(Ref para. 45n) The Home Office does not include SAC Chairs in the choice of Secretariat.

Chapter 6 Communication and Transparency

Publication of applications or cases

(Ref para. 98) Is "if appropriate" enough here? Some "cases" are wholly and necessarily confidential and are not published on the web site.

Communication with the media

(Ref para. 106n3) The APC considers that independent press advice would be too costly – so has this protection that "protocols should be established to enable departmental communications staff to fulfil the role without prejudice?" effectively disappeared.

Additional comment

There is nothing in the draft regarding protocols if the chair, committee members or the secretariat do not abide by this guide.

Should the Code of Practice contain guidelines to stop a department doing exactly as it likes, depending on resources etc. in such a way that the SAC can barely function or not allowing independent press advice during a disagreement for "budgetary reasons"?

Grammatical amendments

The words in bold are to be added to the paragraphs.

Preface to 2011 Revision

Consultation carried out during 2010 and early 2011 has shown that the 2007 Code of Practice for Scientific Advisory Committees (CoPSAC or "the Code") is still widely considered to be a useful guide **to** the processes and practice of providing independent scientific advice to government departments.

Chapter 1 – Introduction

3. The basic principles which government departments should follow in assembling and using scientific advice, as set out in the Guidelines, are that departments should:

- think ahead and identify early the issues on which they need scientific advice and early public engagement, and where the current evidence base is weak and should be strengthened;
- **seek** a wide range of advice from the best sources, particularly when there is uncertainty; and
- publish the evidence and analysis and all relevant **and available** papers **where possible**.

The context in which Scientific Advisory Committees work

6. The function of a Scientific Advisory Committee is to help government collect scientific information and make judgements about it **and how and whether it should be applied**.

8. A scientific adviser, whether a committee or a person, is generally responsible for providing scientific **and related** input to assist policymaking or analysis.

Balance of expertise

The paragraph is unnumbered – should it be paragraph 17? Also the paragraph numbering is out of order, e.g. paragraph N after paragraph 23 is unnumbered.

Yours sincerely

Sara Nathan

ANNEX G

Lynne Featherstone MP
Parliamentary Under-Secretary of State
Home Office
2 Marsham Street
London SW1P 4DF

16 February 2011

Dear Minister,

ASPI Report into compliance at Wickham Laboratories

At the December meeting of the Animal Procedures Committee (APC), the committee discussed the Animal Scientific Procedures Inspectorate's (ASPI) report into compliance at Wickham Laboratories following allegations by BUAV.

One APC member was an independent reviewer of this investigation, along with another observer (a former APC member) from outside the Home Office. I welcome this initiative to involve the APC in observing such an investigation and I trust their input was helpful to ASPI.

The APC was very concerned about the issues that were raised in the Inspectorate's report and I would like to offer the support of the APC in advising on how progress can be made in such matters.

The APC was particularly concerned at the actual or perceived conflicts of interest the report highlighted involving the Named Veterinary Surgeon. This individual was responsible for the veterinary care of the animals, was the managing director, part co-owner, and responsible for employing the Certificate Holder. The APC believes that the Home Office should consider the conflicts issue arising when one individual holds multiple roles and its potential impact on upholding the regulation and good animal welfare.

The APC was also concerned at the lack of guidance on ensuring that the Named Veterinary Surgeon remains competent and able to fulfil their duties, particularly given that existing Named Veterinary Surgeons are not required to undertake the now mandatory training for newly appointed Named Veterinary Surgeons or any other continuing professional development. The APC recommends that the ASPI should review the role of the Named Veterinary Surgeon, encompassing both training and CPD and give guidance as to the professional standards expected. The Committee appreciates this, will, in due course, require dialogue with the Royal College of Veterinary Surgeons and Laboratory Animals Veterinary Association.

The APC was also concerned at the lack of training of staff in identifying humane endpoints that resulted in unnecessary suffering that the report revealed.

The APC accepts that adoption of alternative assays can be difficult due to the involvement of the appropriate regulatory authority and the sponsoring company, as well as the establishment and the ASPI. However, the Committee would like to see this issue given high priority in the current discussions on the Coalition agreement to work towards reducing the use of animals.

The APC understands that the Inspectorate carries out risk-based inspections. The APC would like to know more about how these risks are assessed and inspections undertaken particularly as a previous exposé (1992-3) had indicated a lack of compliance at this establishment. Similarly, the committee is concerned at any possible reduction in the Inspection regime if the minimum inspection in the new Directive is adopted.

The Committee would be willing to offer its continuing support to the ASPI in advising on improvements in practice – particularly in the area of risk-based approaches to inspections, alternatives to assays which have death as an endpoint for over half the animals tested and conflicts of interest.

Yours sincerely

Sara Nathan

ANNEX H

APC WORK PROGRAMME FOR 2012 onwards

OBJECTIVE	TARGET DATE
Applications Sub-Committee	
Consider and advise on applications for project licences referred to the Committee by the Home Office.	As required
Primates Sub-Committee	
Develop a mechanism for horizon scanning of current situations/trends in the use of primates in medical research and the understanding of diseases, excluding regulatory toxicology.	2012
Consideration of overseas centres supplying non-human primates to UK laboratories.	As required
Cumulative Severity Working Group	
Publish Call for Evidence questionnaire and consider responses.	On going
Directive 2010/63/EU Working Group	
Advise on and evaluate revisions to the European Directive and their transcription into UK legislation, guidance and Codes of Practice.	On going
Infringements	
Trend analysis of recent infringements data.	2012

ANNEX I

GLOSSARY

Embryo aggregation chimaera – an embryo containing genetically distinct types of cells.

Embryonated egg – an egg which contains an embryo.

Equidae – the family of mammals that 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", i.e. experiments conducted using cells, tissues or organs in an artificial environment, outside a living organism.

In vivo – refers to experimentation done in a whole, 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.

3R's – 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

ASC – Applications Sub-Committee

ASPA – Animals (Scientific Procedures) Act 1986

CRO – Contract Research Organisation

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

NDPB – Non Departmental Public Body

NVS – Named Veterinary Surgeons

PSC – Primate Sub-Committee

SAC – Scientific Advisory Committee