Report of the Animal Procedures Committee for 2008

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 2008

Sara NATHAN OBE (Chairman) – Freelance Journalist and former Editor Channel 4 News. Has a portfolio of public appointments including (until December 2007) 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 (Hon), RAnTech – Astra Zeneca (retired).

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

Timothy MORRIS BVetMed PhD CertLAS DipACLAm DipECLAM CBiol FIBiol MRCVS – Director of Equine Science and Welfare, British Horse Racing Authority.

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
Philip Brenner

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

I am pleased to submit the Animal Procedures Committee Annual Report for 2008.

This year's key event was the publication of the European Commission proposal to amend Directive 86/609 and a large proportion of the APC's time has been devoted to work on this. One of the emerging issues from this proposal revolves around the reporting of severity for procedures. It is our view that there is a need for a common framework to ensure a consistent classification formula based on what the animals actually experience (in terms of the nature, level and intensity of adverse effects). Ideally this should be developed before the new directive amendments are finalised and adopted. The Committee, in collaboration with Laboratory Animal Science Association, reported on this issue in October 2008.

The Committee is contributing to the decision processes and supports the proposal's inclusion of the 3Rs, which would help to ensure that good welfare standards – currently stipulated in the UK licensing legislation – would be rolled out across the EU.

The APC devoted somewhat more time than usual this year to stakeholder engagement, attending a series of meetings held with private and public sector organisations in animal research and with animal welfare and protection groups. For the first time we held discussions with a range of contract research organisations which were extremely informative.

On behalf of the Committee I would like to thank those involved for contributing their time and expertise to our deliberations.

SARA NATHAN

INTRODUCTION

This report describes the work carried out during 2008 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 his 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 for the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures.

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 full Committee met four times during 2008, and there were also nineteen Sub Committee or 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.

Annex A to this report sets out some information about the Committee, including its legislative background, the Ministers to which it reports and its membership. On joining the Committee, members agree to be bound by its Code of Conduct (see Annex B), which 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]

N.B. Certain technical and scientific terms are defined at their first occurrence within this report in footnotes. They are summarised in a glossary at the end of the report, which also contains a list of acronyms used.

[1] www.apc.gov.uk.

THE MAIN OUTCOMES OF THE COMMITTEE'S WORK IN 2008 WERE AS FOLLOWS:

- The Applications Sub Committee produced guidance to applicants for the process of referral to the Applications Sub Committee.
- The LASA/APC Suffering and Severity Working Group published its report.
- The 86/609 Working Group submitted advice to the Home Office in relation to the revision of Directive EC 86/609.
- The Housing and Husbandry Sub Committee developed its project on fish welfare and euthanasia.
- The Education and Training Sub Committee continued its work on module 5 training and guidance for accrediting bodies.
- The Primates Sub Committee met with Contract Research Organisations.

THE COMMITTEE'S WORK DURING 2008

Applications Sub Committee (ASC)

1. 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 that are 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.

2. There were three specific project licence applications referred to the Committee for advice in 2008. One involved modeling cognitive processes that are pertinent to psychiatric disorders such as depression, autism or obsessive compulsive disorders.

The second proposed to investigate the effect of damaging the corticospinal tract with the aim of exploring potential ways to promote functional recovery after brain damage.

The third involved an application for the advancement of knowledge and possibly the development of novel treatment regimens in human disease associated with limb paralysis.

These applications were discussed first by the ASC by means of open dialogue and written questions with each applicant. The Sub Committee's deliberations were then put to the full Committee for final consideration and the Minister was advised accordingly.

In September, Mark Prescott and Robert Hubrecht represented the ASC following an invitation to observe refinements to the neurovirulence test allied to the batch release process of an oral poliomyelitis vaccine.

Towards the end of the year the ASC devoted its time to producing guidance for applicants to help them prepare for ASC review of their applications. The guidance provides some background to the purpose of the referral process and gives examples of some questions commonly asked by the ASC. The Guidance can be found on the APC website (www.apc.gov.uk) and in Annex E of this report.

Work of the Primates Sub Committee (PSC)

3. The role of the Primates Sub Committee (PSC) is to advise the full Committee on issues relating to the acquisition, housing, care and use of non-human primates in scientific procedures. In 2008 the PSC met three times to consider the continued acceptability of four establishments in Asia as sources of non-human primates imported into the United Kingdom.

[2] **Equidae** – the *Equidae* 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.

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

4. Schedule 2 to the Animals (Scientific Procedures) Act 1986 lists species that may not be used unless they have been bred at a designated breeding establishment, or obtained from a designated supplying establishment, unless an exemption is agreed. As UK demand for non-human primates exceeds the current domestic supply, the Home Office has for some years agreed that UK designated establishments can import primates from a small number of overseas breeding and supply centres. As part of the acceptance process, Home Office Inspectors visit overseas centres seeking to supply to the UK.

5. The PSC believes that frequent inspections are vital for the effective monitoring, maintenance and improvement of standards at overseas centres, and sought assurances that Home Office Inspectors would continue to visit overseas centres as part of the revised acceptance arrangements introduced in April 2008.

6. In the summer the Primates Sub Committee responded to the Scientific Committee on Health Environmental Risks (SCHER) public consultation for a 'scientific opinion on the need for non-human primates in biomedical research, production and testing of products and devices'. In summary the Sub Committee reported that there are still continuing needs to ensure that the use of primates is limited to situations where no alternatives exist and to develop new alternative approaches. Where the use of primates is necessary, this use should be justified in the context of the 3Rs of replacement, reduction, refinement and should be fully implemented. A full report of the Health & Consumer Protection DG findings was published in January 2009[4].

7. The Primates Sub Committee also held a series of meetings in 2008 with representatives of the key UK Contract Research Organisations to gain a better understanding of the current issues associated with sourcing non-human primates for UK scientific research and testing. The CRO representatives told the PSC that in their view:

- There are increasing demands to carry out research involving NHPs.
- There are concerns regarding the sustainability of sources of NHPs.
- Representatives of some pharmaceutical companies have conducted quality assessments of overseas NHP suppliers. It was however unclear to the PSC what the frequency of these assessments were and what prompted them.

8. This opportunity to hold dialogue with the CRO representatives was greatly appreciated. The Sub Committee believe these to be valuable formats for obtaining a balanced view of the needs of industry and welfare.

Education and Training Sub Committee (ETSC)

9. The Education and Training Sub Committee met four times in 2008. It focussed principally on developing its report on the role of module 5 training for project licensees, which defines core competencies and advice regarding the learning outcomes appropriate for personal licence applicants.

10. In addition, the ETSC contracted an independent education specialist to review existing licensee training courses and draft a guidance document for the accrediting bodies to assist their delivery of consistent and appropriate training for all involved in the use of animals in research and testing. During 2008 the Sub Committee drafted this guidance report which was reviewed twice by the accrediting bodies, and met with the Accrediting Bodies and training providers at their annual meeting. The ETSC is currently refining the guidance report.

[4] http://ec.europa.eu/environment/chemicals/lab_animals/pdf/scher_o_110.pdf

Housing and Husbandry[5] Sub Committee (H&HSC)

11. The Housing and Husbandry Sub Committee (H&HSC) devoted the majority of its four meetings this year to fish welfare. This was given priority because the numbers of procedures involving fish in the UK has increased steadily over the last three years[6]. In addition, when the Animal Procedures Committee published its review of Schedule 1 of the Animals (Scientific Procedures) Act 1986: Appropriate methods of humane killing[7] last year, it noted that there was a need for further consideration of appropriate techniques for fish euthanasia.

12. The H&HSC carried out a survey of those who use fish to find out which Schedule 1 techniques they currently believe to be acceptable for humane killing of fish used in research and testing. The Sub Committee also co-opted a group of scientists involved in fish biology and welfare research to: assess the literature on fish killing techniques currently in use and identify where evidence is lacking and where further research is needed. The H&HSC will produce a report setting out best practice for fish euthanasia, including catching and handling techniques. The report is scheduled for publication in summer 2009.

13. A member of the H&HSC participated in a workshop convened by the European Centre for the Validation of Alternative Methods (ECVAM)[8] to address *Three Rs Approaches in the Production and Quality Control of Fish Vaccines*. Increasing numbers of fish are used in the development, production and testing of vaccines for use in aquaculture, and some of the tests can cause severe suffering. The ECVAM working group is currently drafting a report setting out ways of replacing living fish in vaccine production and quality control, improving welfare and reducing numbers and suffering.

Suffering and Severity Working Group

14. The LASA/APC Suffering and Severity Working Group published its report on the retrospective reporting of severity in autumn 2008[9]. Following on from this publication the APC asked the Working Group to look into the following requests:

1. The House of Lords Select Committee on Animals in Scientific Procedures (2002) report paragraph 9.34[10] stated:

   "From the licences we have seen, we consider that the current system of assessing pain and suffering is already highly misleading. Licences are allocated into one of three severity bands, based on the experience of suffering of the "average" animal. We consider that if a procedure involves 20% of animals in mild severity, 70% in moderate severity and 10% in substantial severity, then this should be recorded".

2. In July 2004, the then Minister Caroline Flint MP, requested that the Animal Procedures Committee provide practical recommendations with a view to a new system for severity limits and bands. The Suffering and Severity Working Group was established to evaluate the following:

   "The strengths and weaknesses of the current system of severity limits and bands as a way of prospectively assessing suffering and severity. If significant weaknesses are perceived, what alternative system could be proposed."

15. In December the Working Group presented the Committee with a draft report on the reporting of suffering and severity. It discussed the current system under ASPA, where the assessment of suffering made in licence applications and reporting of severity bands in the Home Office Statistics, is predictive. As noted by the House of Lords Committee, this information may in fact mislead, since many will assume that the predictive 'assessment' provides an accurate picture of the actual suffering of animals when this is not in fact the case.

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

[6] Statistics of Scientific Procedures on living animals 2007 Home Office publication, http://www.homeoffice.gov.uk/rds/pdfs08/spanimals07.pdf

[7] http://www.apc.gov.uk/reference/schedule-1-report.pdf

[8] ECVAM is an independent organisation that was created to fulfil requirements of Directive 86/609 relating to the development, validation and use of alternatives. It also advises on general animal welfare issues and the Three Rs (http://ecvam.jrc.it/).

[9] Final report of a LASA/APC Working Group to examine the feasibility of reporting data on the severity of scientific procedures on animals. http://www.apc.gov.uk/reference/lasa_apc_final_report.pdf

[10] http://www.publications.parliament.uk/pa/ld200102/ldselect/ldanimal/150/150.pdf

16. The Working Group proposed that a better approach would be to establish a system for the retrospective reporting of the actual level of suffering experienced by each animal. This is in line with the proposal for the revisions of Directive EC 86/609 at the time of writing (see below), which also recommends retrospective reporting of severity.

A final version of the Suffering and Severity Working Group's conclusions will be published by July 2009.

Revision of Directive EC 86/609 Working Group

17. Directive EC 86/609 is the legislative act of the European Community that regulates the care and use of laboratory animals in the Member States of the European Union. The current Directive includes measures relating to the use of animals for scientific procedures such as their housing and care, requirements for the authorisation of establishments and the minimisation of pain, suffering and distress of animals used in research and testing. It was adopted in 1986 and has not been revised since then, despite significant advances in technology, knowledge of animal behaviour and welfare, and increased awareness of the need to address public concerns about animal use. In 2002 the European Commission acknowledged the need to update the Directive and began the formal process of review.

18. As a stakeholder involved in the UK process of regulating the use of laboratory animals, the Committee has formed a Directive EC 86/609 Working Group that has provided input to relevant bodies throughout the revision process. The Committee's aim is to support improvements to the regulation and harmonisation of animal use that could improve animal welfare, the quality of science and the implementation of the Three Rs. The Committee also recognises that it is important to ensure that UK legislation is not weakened, damaging public confidence in the regulation of animal use.

19. On the 5th November 2008, the Commission published its proposal for the revised Directive[11]. This includes a number of elements that would be new to EU legislation. For example, there are requirements for an ethical evaluation as part of the authorisation process, local Permanent Ethical Review Bodies (PERBs) that function in a similar way to the UK Ethical Review Process, authorisation for projects using animals at Member State level and explicit reference to the Three Rs. There is also a requirement for a National Animal Welfare and Ethics Committee (NAWEC) that would have a similar remit to the APC, with some additional functions.

20. The Committee's initial assessment of the proposal is that many of its requirements would benefit animal welfare, facilitate harmonisation and ensure a more "level playing field" for the EU scientific community. However, some sections of the text are open to different interpretations as they are currently drafted. The proposal also includes a number of restrictions on animal use that are of concern to some members, such as limiting the purposes of projects using primates, and it permits some techniques that are of concern to others, e.g. allowing death as an endpoint under certain circumstances. There is also no definition of severity levels, such as the "mild", "moderate" and "substantial" categories in the UK ASPA. This makes it difficult or impossible to make a judgement on some of the Articles within the proposal, since they are linked to certain severity limits.

21. At the last Committee meeting of 2008 the Minister Meg Hillier presented her opinions on the revised Directive and asked the Committee for its advice in four key areas: training requirements, ethical review, the proposal for a NAWEC and the classification and reporting of the severity of procedures. The Committee responded to the Minister in February 2009 (Annex F) and will continue to respond to relevant consultations as the revision process progresses throughout the year.

[11] Commission of the European Communities (2008) Proposal for a Directive of the European Parliament And Of The Council on the Protection of Animals Used for Scientific Purposes http://ec.europa.eu/environment/chemicals/lab_animals/proposal_en.htm

Infringements

22. 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.

23. In December 2008, the Home Office supplied the APC with a report of infringements that had occurred in 2007. The Committee is grateful to the Home Office for sharing this information as it provides the Committee with an opportunity to analyse breaches of the Act and discuss the strategies for preventing infringements and dealing with any problems.

24. The Committee recognise the concern 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 Appendix A of the Statistics on the use of animals in scientific procedures in Great Britain[12] for 2008.

25. The Committee was also notified directly of a potential infringement by an informant who wished to remain anonymous. The Committee take such information seriously but wish to point out that it does not have the resources or jurisdiction to carry out a specific investigation. In this instance, notification was relayed to the appropriate authorities.

The Committee's work programme for 2009

26. The Committee's work programme for 2009 was discussed at the APC Annual Conference in November 2008. It was acknowledging that work associated with Revisions to Directive EC 86/609 would be given priority. The Committee's work programme for 2009 is detailed in Annex I.

[12] http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/statistics/

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 2008.

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 2008/2009, the Home Office allocated 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, who administers the Act in England, Scotland and Wales. From July 2007, Meg Hillier 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 Michael McGimpsey MLA has been the responsible Minister.

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 31 DECEMBER 2008.

Membership of current Sub Committees and working groups are listed below.

Education and Training Sub Committee

Dr Michael Festing
Mr Robert Kemp
Dr Peter Hunt

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

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
Dr John Doe	Or	Co-optee
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 Robert Kemp

Revision of Directive 86/609 Working Group

Dr Penny Hawkins **(Chair)**
Dr Peter Hunt
Professor Dawn Oliver
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. Alternatively, 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 time. 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 up to 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 the Secretariat for secure distribution to the Application sub committee. 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

Guidance to Project Licence Applicants referred to the APC Applications sub-committee. February 2009.[13]

This guidance has been prepared by the APC Applications sub-committee (ASC) to help those with project licence applications referred to the APC to understand and prepare for ASC review of the application. It gives some background to the review and sets out some questions commonly asked of project licence applicants.

Background

It is the duty of the APC to advise the Secretary of State (SoS) on such matters concerned with the Animals (Scientific Procedures) Act 1986 and her functions under it, as the Committee may determine or as may be referred to the Committee by the SoS.

The APC has requested, and the SoS agreed to the referral of specific categories of project licence applications for consideration and advice.

Since 2004, the categories of application to be referred include:

1. Any involving the proposed use of wild-caught non-human primates;

2. Any involving the proposed use of cats, dogs, equidae or non-human primates in protocols of substantial severity;

3. Any with a substantial severity banding, or major animal welfare or ethical implications, involving a) xenotransplantation of whole organs, b) chronic pain models, or c) study of the central nervous system;

4. 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 involving dissimilar species).

Typically, the applicant is invited to meet with members of the ASC to discuss the application in person. ASC members are scientists and non-scientists (www.apc.gov.uk/aboutapc/workgroups.htm). The ASC does not wish to create additional work for project licence applicants, but has found it very helpful if applicants prepare the following in advance of the meeting:

1. A lay summary of the proposed project written so as to be readily comprehensible by a member of the general public (see Abstract section of the Project licence application form http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/publications/licences/project-licences/).

2. A schematic (e.g. graph, flow chart, GANTT chart) showing the number and scheduling (and if possible, relative severity) of all procedures involved in the project that impact on the welfare of the animals.

Preparation of these documents is, of course, voluntary, but assists the ASC to understand and explore the scientific justification for the project procedures and their costs to the animals.

Invariably, the ASC wishes to estimate the total suffering experienced by the animals on the project, during their whole life-times, and to rationalise this against the expected benefits.

[13] http://www.apc.gov.uk/reference/guidance_to_project_licence_applicants_update.pdf

Common questions asked of applicants

Background, objectives and benefits

- What are the key objectives of the project, and the likely benefits (e.g. in terms of scientific knowledge, human or animal health, the 3Rs)?
- How does the project relate to progress made under previous or current project licences?
- To what extent has previous research (*in vivo/in vitro*) and existing data, literature and knowledge influenced the licence application? How has unnecessary duplication of previous work been avoided?
- What is the likelihood of achieving the project objectives, and what factors are critical for success?
- What are the key ethical issues?

Experimental design and the 3Rs

- How was the experimental design decided, and how have each of the 3Rs been integrated into the entire plan of work?
- Why is it necessary to use animals to achieve the project objectives? Why are non-animal alternatives unsuitable?
- What is the justification for use of the particular animal species/model?
- Was the advice of a statistician taken on minimising the number of animals to be used per experiment, and the appropriate methods for data analysis?
- How else has animal use been optimised?

Scientific procedures and animal welfare

- What is the justification for the particular scientific procedures to be used, and what are their effects on the animals involved?
- How many animals will undergo each procedure?
- How will pain, suffering, distress or lasting harm be avoided, recognised, alleviated and managed?
- Will anaesthesia and analgesia be used? Has advice been taken on the most appropriate agents and regimens?
- How frequently and by whom are the animals monitored before, during and after each procedure?
- What are the relevant clinical signs and the humane endpoints that will be applied?
- How are the animals acclimatised to, or trained to co-operate with, procedures?
- What are the standards of animal accommodation, environmental enrichment and care?
- Will single housing of animals be necessary?
- From where will the animals be sourced?
- What will happen to the animals when the work is completed?

What is the rationale for nomination of the project severity band?

ANNEX F

REPORT ON THE EUROPEAN COMMISSION PROPOSAL FOR THE REVISION OF DIRECTIVE 86/609/EEC BY THE ANIMAL PROCEDURES COMMITTEE DIRECTIVE 86/609 WORKING GROUP.

Introduction

This report was produced by the Directive 86/609 Working Group in response to four questions relating to the Directive proposal and its implementation that were put to the APC by Home Office Minister Meg Hillier. The requests address (i) education and training, (ii) classification and reporting of severity, (iii) ethical review bodies and (iv) the National Animal Welfare and Ethics Committee. For each question, the Minister's request and the relevant Articles of the proposal are reproduced first and the Committee's discussion and conclusions follow.

1 Education and training requirements

The Minister's request:

The declared purposes of amending the directive include raising and harmonising standards, and promoting the free movement of trained labour within the Union: surprisingly the current proposal is that each Member State devises its own framework.

The proposal sets out general headings, but provides no syllabus or framework for delivery.

I believe that the work the Committee has done to date on education and training has the potential, with some further work, to form the basis of a potential UK model that we might develop and promote for wider use.

Article 20: Authorisation of persons

1. Member States shall ensure that persons are authorised by the competent authority before they carry out any of the following functions:

a) the carrying out of procedures on animals, including their killing by a humane method;

b) the supervision or design of procedures and projects;

c) the supervision of those taking care of animals.

2. Member States shall ensure that, for the purposes of the authorisation, the persons referred to in paragraph 1 have the appropriate education and training and have demonstrated the requisite competence.

Persons carrying out the functions referred to in point (b) of paragraph 1 shall have received instruction in a scientific discipline relevant to the work being undertaken and shall be capable of handling and taking care of the species concerned.

3. All authorisations of persons shall be granted for a limited period of time, not exceeding five years. Member States shall ensure that the renewal of an authorisation of persons is only granted on the basis of demonstration of the requisite competence.

4. Member States shall publish, on the basis of the elements set out in Annex VI, minimum requirements with regard to education, training and requirements for obtaining, maintaining and demonstrating requisite competence.

1.1 Background

Directive 86/609 currently does not specify a required level of competence for the various groups working within it, or how competence can be kept up to date or demonstrated. Each Member State can thus devise its own syllabus and standards for education and training, which leads to a lack of consistency in content and quality of training. For example, only approximately 35 % of Member States require that the competence of personnel is demonstrated or maintained.[14]

An impact assessment into proposals for the amendment of Directive 86/609, performed by the Commission of the European Committees (EC) in 2008, identified a potential for obstacles to the free movement of researchers between Member States due to different requirements for their education and training. The impact assessment recognised that variations in levels of training and qualification requirements across Member States could lead to inequalities in the costs of developing and performing scientific projects and could also restrict the freedom of movement of individuals between them.

1.2 Requirements for the new Directive

The Working Group believes that it is essential from a scientific and an animal welfare aspect to ensure that training is consistently of an appropriate standard across all Member States. If harmony within the Member States is to be attained, there needs to be guidance associated with the revised Directive on the form and depth of education and training required and the minimum competencies expected. The proposal refers to “minimum training standards” and the work of the APC Education and Training Sub-committee (ETSC) to establish the key competencies for personal licensees, could provide a basis for this minimal training. This is with the proviso that the training is followed by a period of close supervision until full competence is achieved. (The ETSC work on key competencies for project licence holders is still ongoing.)

Individual training records would need to be developed to log training and the attainment of competency. The records should also include a log of prior learning, some of which might provide exemption from topics in the modular courses. It could also be used for recording other relevant Continuing Professional Development (CPD). Such a system could be set up for use across all Member States.

1.3 The current UK system

The UK already has a well developed system for training Named Animal Care and Welfare Officers (NACWOs) and those who wish to hold a personal and/or project licence and the recent work by the APC should strengthen this. We believe that the UK modular training system sets the bar sufficiently high as regards the training of individuals, provided that there is a properly implemented system for CPD, training, supervision and demonstration of competency in place. The wording in the new Directive should thus not compromise the UK system in any way.

1.4 The FELASA system

Another model that could provide a basis for implementing the Directive throughout all Member States is the basic set of training requirements for four categories of staff developed by the Federation of European Laboratory Animal Science Associations (FELASA). Some Member States already have FELASA accredited courses in place,

[14] Prognos AG (2007) Study on the impacts of different options for the Revision of Directive 86/609/EEC on the protection of laboratory animals. http://ec.europa.eu/environment/chemicals/lab_animals/pdf/prognos_summary.pdf

such as Germany, Sweden, Spain, Portugal, Finland, France and Switzerland. There has recently been a steady stream of applications for FELASA accreditation of courses, for example currently from the Netherlands.

1.5 Comparison of the UK and FELASA training systems

There are no FELASA accredited courses in the UK at present, but the content and accreditation process of the UK modular system and FELASA are similar. For example, the Institute for Animal Technology visits NACWO courses to accredit the contents and course deliverers every 5 years. FELASA also accredits courses, deliverers and colleges every 4 years. The APC ETSC took the FELASA recommendations into account when reviewing modules 1 to 5 and when drawing up competencies and learning outcomes for them.

There are some key differences between the FELASA and UK modular systems, however. In general, the UK system focuses on learning outcomes and core competencies whereas FELASA is more syllabus-based. Nevertheless, the APC considers that the modular system is compatible with FELASA. For example, the FELASA requirement for 80 hours of training in Category C is often seen as very different from the equivalent course provision in the UK, which is generally one and a half days for module 5. However, this can be interpreted flexibly,[15] so in the Committee's view any additional supervision, in-house training, attendance at relevant meetings and other CPD that project and personal licensees receive after modular training can be regarded as making up a longer period of training. This would need to be formalised, for example through harmonised CPD programmes.

If the Commission decides that the FELASA system will be the model for training throughout the EU, communication between all the UK trainers and accreditation bodies[16] and FELASA will be necessary to ensure that the Directive can be implemented without weakening the UK system of education and training including Modules 1 to 5. This is especially important given the huge amount of work that has gone into developing the modular system by bodies such as the APC ETSC and others.

1.6 Comments on specific issues and roles

The Committee would like to comment on some specific aspects of Article 20 that it believes are especially important.

Training required for authorisation to perform humane killing (para 1a)
In the Module 1 to 4 report, the ETSC recommended that anyone required to perform humane killing should first attend a Module 1 course, which is sufficient in the opinion of the ETSC. This would then be followed by close supervision whilst performing the task, until full competence had been attained. The equivalent of this would be FELASA Category A.

Training required for "the supervision of those taking care of animals" (para 1c)
This was not part of the original ETSC remit, but it is covered under the FELASA recommendations. There is also training and qualification for animal technologists and NACWOs via the IAT, which is now being developed and made available to countries outside the UK.

The requirement for "maintaining and demonstrating requisite competence" (para 4)
This is recognised as an important requirement within the UK. Perhaps the development of training records and recording of relevant CPD events would assist in this requirement, coupled with re-training if a particular technique has not been used for some time. For example, some UK establishments have in-house training and competence schemes that automatically highlight when techniques have not been used and re-training is required.

[15] FELASA Category C requires "attendance at a basic course in laboratory animal science totalling not less than 80 h or the equivalent, whether taken as a block or as modules or the education and training accumulated by other acceptable means."

[16] The Institute of Biology, Universities Accreditation Group and Scottish Accreditation Group.

There is also a FELASA CPD scheme being developed that each Member State will be able to adapt. It is based on a system of credits gained through attendance at scientific meetings and so on, and should be completed in April 2009. The APC is aware that vocational education and training is an essential component of EU Policy,[17] although it is currently unclear to what extent such initiatives may extend to the use of animals in scientific procedures. The revised Directive, with its harmonisation objectives, should consider these EU training initiatives.

1.7 Conclusion

To conclude, the UK already has a well developed, modular education and training system that would comply with the requirements in the Directive proposal. Maintaining the modular system would also fulfil the Home Office Better Regulation initiative as it would have no additional impact on regulatory requirements. It is very important that the UK modular system is not compromised by the new Directive or its implementation.

2 Classification and reporting of severity of procedures

The Minister's request:

Europe will mandate a common system after the revision of the Directive is complete, and again ongoing work within the Committee, in collaboration with the Laboratory Animal Science Association, could go a long way towards providing a model consistent with the provisions set out in the current Commission proposal.

I would be grateful for the Committee's advice on how, building on this, a Europe-wide system might be designed.

Article 15: Classification of severity of procedures

Member States shall ensure that all procedures are classified as 'up to mild', 'moderate', 'severe' or 'non-recovery' on the basis of the duration and intensity of potential pain, suffering, distress and lasting harm, the frequency of intervention, the deprivation of ethological needs and the use of anaesthesia or analgesia or both.

Member States shall ensure that the procedures classified as "severe" are not performed if the pain, suffering or distress is likely to be prolonged.

Procedures performed under general anaesthesia, at the end of which and without a possibility to recover consciousness the animal is killed using humane method, shall be classified as "non-recovery".

The Commission shall establish the criteria for classification of procedures.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall by [*within 18 months of the entry into force of this Directive*] be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 51(3).

2.1 Background

The Directive certainly needs to include a severity classification system that is based on the nature, level and intensity of adverse effects. However, there are flaws in the text of this Article and far more thought is needed into both the wording and how the aims will be achieved. As a result, we are unable to suggest how the UK should implement the proposal as currently laid out.

[17] See http://www.europa.eu.int/eures/main.jsp?catId=8566&acro=living&lang=en&parentId=7777&countryId=FR&living

2.2 Points on drafting

The categories as proposed appear not to include a "mild" category. This needs to be added or the existing lowest category could be amended to "up to and including mild" (which was presumably the intention). The term "severe" also sounds confusing as the highest category of suffering is "severe severity". We suggest that this be replaced with the term "substantial".

It needs to be made clear whether this Article refers to prospective or retrospective classification or both. The wording should also clarify that the full lifetime experience of each animal is to be considered, that is, all possible sources of pain, suffering, distress or lasting harm from the sourcing of the animal to euthanasia including housing and care, identification method and so on.

2.3 Terms and guidance

The Committee discussed whether it was appropriate for the proposal to prescribe the terms to be used, i.e. "up to mild", "moderate", etc. as opposed to allowing each Member State to define its own terms. The consensus was that the terms used in the proposal are widely accepted in Europe; however there is no evidence as to the consistency of their use. This lack of clarity and definition is a serious problem.

Guidance on precisely what is meant by each of these terms is absolutely essential in order to set up an effective system for classifying, recognising and reporting suffering; all those involved have to be confident as to what the terms mean. Some countries have produced guidance on severity classification such as Switzerland, the UK and New Zealand, but these are not particularly comprehensive (NB Switzerland and New Zealand use numbers for their categories, whereas the LASA/APC Working Group recommended descriptive terms).

2.4 Conclusion on severity classification

Serious thought needs to be given to the classification of severity, and especially the guidance that is provided, during the 18 months when the classification criteria are to be drawn up. Practical examples of the different categories are essential and these need to be drawn from a range of disciplines; for example, a "substantial" or "severe" surgical procedure will produce very different adverse effects from a substantial toxicology or psychology procedure, but all will fall within the same category. Clear generic advice that will enable people to consistently classify procedures is also important and it will be no easy task to produce guidance that is readily understandable and usable by all.

We understand that the Commission is about to form an expert Working Group on severity classification, and it is essential that all of the above issues are properly addressed.[18] Many other articles depend on the severity classifications being in place, including paragraph 2 of the severity article itself, so sound guidance on approaches to categorising severity is crucial for the effective implementation of the Directive. A solution could be an amendment to the Directive proposal referring to an Annex with more comprehensive guidance on severity classification.

Article 49: Reporting

2. Member States shall collect and make publicly available, on an annual basis, statistical information on the use of animals in procedures, including information on the actual severity of the procedures and on the origin and species of non-human primates used in procedures.

2.5 Conclusion on reporting

The Working Group strongly supports the requirement for reporting of actual severity of procedures, or "retrospective" reporting. This is in agreement with the findings of the Suffering and Severity Working Group, which concluded that reporting actual severity would increase transparency and the accountability of the Competent Authority. The APC/LASA Working Group on Severity has already submitted its report on retrospective assessment and reporting

[18] The APC/LASA Working Group on Severity could also offer input into the Commission's Working Group

of suffering and severity to the Home Office, and we support its conclusions. It could also provide the basis for an Annex to the Directive to provide further guidance in this area.

3 Ethical review bodies

The Minister's request:

This is also an established Committee interest, and advice is now required as to how the ethical review components of the proposal might best be unpacked to ensure that each tier of review focuses on the most relevant issues, without any unnecessary duplication; and how the accumulated analysis and advice with respect to each proposal can be used to best effect.

Article 25: Permanent ethical review body

1. Member States shall ensure that each breeding, supplying and user establishment sets up a permanent ethical review body.

2. The permanent ethical review body shall include the designated veterinarian, the person(s) responsible for the welfare and care of the animals in the establishment and, in the case of a user establishment, a scientific member.

3.1 Background

There are only three mandatory classes of members listed in Article 25; the designated veterinarian, the person responsible for animal care and welfare and, in the case of a scientific establishment, a scientific member. This would be too small a panel to fulfil all of the suggested tasks in the vast majority of establishments. For breeding establishments presumably the article means there could be just two people on the panel.

At least one "lay" or independent member should also be included. We note the inherent difficulty in defining what is meant by "lay" as well as the problems in translating this term for other Member States. In the UK, "lay" may be understood, in this context, to mean non-scientific, but is sometimes used to mean unconnected with the research (but possibly working for the same organisation or a scientist who is unaffiliated with the organisation). It is more useful to consider the benefits that such members would bring; for example, a broader view of the issues without a direct interest in the research projects going ahead. We have suggested "unaffiliated" as an example of a suitable term and have also retained the word "independent" because the proposal already includes that term and it helps to clarify what is intended by the term "unaffiliated".

Moreover, the "designated veterinarian, the person(s) responsible for the welfare and care of the animals in the establishment and, in the case of a user establishment, a scientific member" should be disinterested, that is, they should not take part in the research in question. If they are involved in the scientific use of animals, then alternative qualified persons should be found to fill their role.

3.2 Conclusion on composition of ethical review body

In light of the above, we suggest that paragraph 2 be amended to read as follows (amendments in bold):

2. The permanent ethical review body shall **represent a range of different perspectives on the use of animals** and include as a minimum the designated veterinarian, the person(s) responsible for the welfare and care of the animals in the establishment, **an unaffiliated, independent member** and, in the case of a user establishment, a scientific member.

Although the UK Home Office guidance includes a more comprehensive list of members, we have refrained from recommending specific further members, such as a statistician, within the Directive. Surveys by the APC and others

in the UK have found that flexibility with respect to ethical review body composition and function is essential, with scope for local interpretation according to local needs. It would thus be preferable for the guidance to the new Directive to explain which types of member can be considered and what each should bring to the process.

Article 26: Tasks of permanent ethical review body

1. The permanent ethical review body shall fulfil the following tasks:

   a) provide ethical advice to the staff dealing with animals on matters related to the welfare of animals in relation to their acquisition, accommodation, care and use;

   b) advise the staff of the establishment on the application of the requirement of replacement, reduction and refinement and keep it informed on the latest technical and scientific developments on the application of those requirements;

   c) establish and review internal operational processes as regards monitoring, reporting and follow up in relation to the welfare of animals housed or used in the establishment;

   d) review annually all projects which are of more than 12 months duration, focusing in particular on:

      – the numbers, species and life stages of animals used in the preceding year;
      – the justification for the numbers, species and life stages of animals needed for the subsequent year;
      – the use of humane methods of killing and how new developments in relation to the use of animals in procedures have been taken into account;

   e) based on the review referred to in point (d) or, in the case of deviations from the project authorisation, examine whether the project authorisation needs to be submitted for amendment or renewal;

   f) advise on re-homing schemes, in particular in relation to the appropriate socialisation of the animals to be re-homed.

2. Member States shall ensure that the records of any advice given to the establishment by the permanent ethical review body and decisions taken regarding that advice are kept.

The records shall be submitted to the competent authority upon request

3.3 Background

Note that the current UK local ethical review process may or may not include a formal "body", although it generally does, whereas the Directive proposal requires an ethical review body rather than expanding the concept into a "process". However, the functions of the "permanent ethical review body", as described in Recital 29 and Article 26, *should* already be adequately fulfilled by UK ERPs and the wording of the proposal does not preclude the UK system as it is. In practice, many ERPs concentrate on project licence review and we welcome the additional emphasis on other functions in the proposal. We believe that the current Home Office guidance on ERP form and function is adequate and appropriate as it stands.

3.4 Tasks of the ethical review body that should be included

The tasks of the permanent ethical review body listed above do not appear to cover project applications. The APC has previously stated that "Local ERP provides an opportunity for establishments to ensure that planned research does not fall outside the establishments own comfort area. Review of applications should add value to the establishment's ethical assessment and not manage, refine, or duplicate what the Home Office (regulatory body) does except in specific cases when the establishment justifies this to applicants." Local review of project applications should therefore be included, not least because it will be difficult for the ethical review bodies to conduct retrospective reviews if they were not involved in the original review at the application stage.

The roles of the ethical review body should include oversight of training and competence. This is an essential component of facilitating an appropriate culture of care and preventing infringements.

The UK ERP acts by providing advice to the Certificate Holder and one would expect the ethical review bodies to work in the same way, but the Directive proposal does not identify any person to fulfil the role of a Certificate Holder.

3.5 Retrospective review

Article 26 (1d) requires the annual review of all projects over 12 months in duration.[19] We would advise opposing this clause as this encompasses the vast majority of projects and will put undue administrative burden on establishments. For example, at one UK university this would mean adding the annual review of 130 to 140 licences to the other duties of the ERP. Appropriate retrospective review is undoubtedly necessary but the ethical review bodies should have the freedom to decide on the frequency on a case-by-case basis. A better wording would encompass the concept of conducting interim/retrospective review(s) of an appropriate number and frequency for each project. The proposal also does not specifically mention retrospective review by the ethical review body at the end of each project.

3.6 Conclusion on tasks of ethical review body

The Working Group believes that the proposals provide a coherent way for local ethical review to operate usefully and adequately and in co-ordination with the Home Office's ethical assessment and the work of the national ethical body, without duplication or placing undue burden on establishments. However, the remit of the ethical review bodies should include project licence applications, oversight of training and competence, and retrospective review, as above. As with education and training, the Directive should not compromise or add undue burden to the UK system of local ethical review, which has been extensively developed and reviewed.

4 National Animal Welfare and Ethics Committee

The Minister's request:

It is likely that if the NAWEC becomes the new European requirement then in due course such a committee would supersede the Animal Procedures Committee as the statutory independent national advisory body.

With that in mind, I would welcome preliminary advice from the Committee on what changes would be required if the APC was to be transformed to become this new body, and what alternative models might be considered.

In each case I would ask the Committee to think not just about how the current UK systems could be adjusted to comply – but to consider what the best models would be if we did not already have related systems in place.

Article 47: National animal welfare and ethics committee

1. Each Member State shall establish a national animal welfare and ethics committee that shall advise the competent authorities and permanent ethical review bodies in matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practices.

2. The national animal welfare and ethics committee shall exchange information on the operation of permanent ethical review bodies and ethical evaluation and share best practice within the Community.

[19] Note this is at odds with Recital (39), which says that retrospective assessment is needed only "in certain cases".

4.1 Background

Paragraph (1) sets out the role of the National Animal Welfare and Ethics Committee (NAWEC) within its home Member State. The wording "matters dealing with" means that the remit of the NAWEC can be interpreted as all Three Rs, including alternatives, and questioning the necessity of and justification for animal use.

Paragraph (2) expands the role of the NAWEC to include gathering information on the operation of local ethical review bodies and ethical evaluation within its Member State and sharing best practice with other Member States.

The NAWEC would have to liaise with the national reference laboratory for alternative methods, which will be responsible for the validation of alternative methods replacing, reducing and refining the use of animals (Article 46). It would also liaise with the bodies responsible for implementing Article 45 on alternative approaches.

Clearly, setting up a NAWEC will represent a major change for some Member States, but will presumably not be such a significant undertaking for the UK, which has the APC as a model. The question is whether to adapt the APC or set up a new body to fulfil this requirement.

The core roles of the APC (listed in Appendix I) and the NAWEC are essentially the same, that is, to advise on ethics and the Three Rs (although the APC advises the Secretary of State and the NAWECs would advise the Competent Authority and ethical review bodies). The remit of the NAWEC is expressed differently to that of the APC, with emphasis on outreach by the Committee both within and outside the Member State (areas (1) to (3) below are the APC's summary):

1. Ensure sharing of best practices relating to the acquisition, breeding, accommodation, care and use of animals in procedures.

2. Advise the ethical review bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures.

3. Gather information on the operation of ethical review bodies and ethical evaluation, sharing best practice within the Community.

4.2 "Best practice" with respect to refinement

Area (1) refers to "best practices", which by definition means improving upon the standards required by the Directive. We believe that "best" is open to interpretation and requires definition, so "current good practice" may be a better term. Individual HO Inspectors may already encourage good practice, but the NAWEC would help to ensure better consistency and support for Inspectors who are trying to facilitate welfare improvements. The NAWEC would help to formalise sharing of best practice, e.g. by actively following up its recommendations, raising awareness of the scientific and welfare benefits of better practice, and liaising with the Inspectorate to clarify how Inspectors work to achieve this and what further support they require.

The term "ensure" (Article 47 para 1) implies that the NAWEC will have powers over and above the APC, which is an advisory body.[20] *This would require a change in legislation. In this scenario, the APC may also need a broader range of expertise either on the Committee or at its disposal, depending on the level of priority given to this role. It could be argued that the APC already facilitates good practice as it is, or there may be a case for increasing the membership so that the NAWEC can expand its input into ensuring good practice. Between these two extremes, the NAWEC could receive input from and liaise with other expert bodies as appropriate.*

[20] We question whether it would be feasible for the NAWEC to "ensure" good practice; the role of facilitating good practice would be more realistic.

With respect to sharing good practice in refinement, we believe that there are already adequate mechanisms such as LASA forums, the NC3Rs and forums set up by scientific welfare bodies such as the RSPCA and UFAW to explore specific issues in the Three Rs. The NAWEC oversight could be to extend the work of the APC in identifying these organisations and systems and ensuring that they are accessible to all, rather than actually managing the outreach and good practice sharing itself..

4.3 Ethical review

Areas (2) and (3) would necessitate direct communication between the NAWEC and the ethical review bodies. There is currently no easy way of contacting ERPs and some means of information exchange would need to be set up to do this. This could include an electronic forum or "virtual committee", meetings of which several examples already exist (e.g. the RSPCA Lay Members' Forum), the Certificate Holders' Forum, NAWEC members attending ethical review meetings, the production of reports to communicate best practice etc. It should be noted that that the proposals do not include an equivalent to the Certificate Holder, hence there would not necessarily be a Certificate Holders' Forum, which is a valuable national link between establishments. Thought would also need to be given as to the kind of advice that NAWEC would give to ethical review bodies and how this would differ from that given by the Home Office Inspectorate, for example.

As for (1), the role of the NAWEC in (2) and (3) could be to ensure that the work already done in this area is accessible to all, rather than setting up further initiatives. For example, LASA and the RSPCA have both worked extensively on ethical review. Further collaboration on the ethical review bodies would fall within the remit of both LASA and the RSPCA, which are currently engaged in a joint project to set out good practice guidelines for the seven core functions of the ERP. The RSPCA has also produced a range of resources for ERPS and lay members.

Presumably "operation of ethical review bodies" in (3) refers to information on the practical workings of the ethical review bodies, e.g. composition, protocols for project evaluation and review, discussions of harm-benefit analysis, reviews of housing and care etc. It is less clear what is meant by "ethical evaluation"; possibly examples of the factors that were considered when evaluating particular (anonymised) projects. It is important to recognise that sharing current good practice between ethical review bodies at an international level is a very important concept but the scale of the task should not be underestimated

What the ethical review bodies would be sharing, and why, needs to be very carefully considered. Two key objectives should be (i) to ensure that they are achieving consistent (and consistently good) outcomes and (ii) to share information and experiences about effective systems, thereby preventing other establishments from wasting time by setting up unnecessarily unwieldy processes. Much serious thought will have to be given to the criteria for success.

For effective information gathering, some kind of formal protocol for surveying ethical review bodies would have to be set up. This could be a standardised (possibly annual) report in some format or it could take a more flexible approach. Ethical review bodies will also need to be encouraged to contact NAWEC ad hoc about their initiatives. Clearly, there would also need to be some kind of forum for the NAWECs to communicate with one another. A programme for temporarily exchanging members, within and between Member States, could form part of this.

4.4 What if the NAWEC had to be set up without the APC as a basis?

It is hard to think of an alternative approach that does not involve setting up an overarching Committee, with a prescribed membership to ensure that all stakeholders are involved, with sub-committees and working groups to tackle specific issues and co-opted expertise where required – i.e. the APC model. There would certainly have to be a sub-committee with the time and expertise to facilitate the best practice information gathering and exchange roles as set out in the proposal. It would be necessary to employ someone to manage this, if the NAWEC would be allowed to do so, or for the HO to provide someone as it currently does for the APC Secretariat. If legislation were changed so that the NAWEC could "ensure" best or current good practice, then there could also be a statutory requirement for a certain level and composition of membership (and more funding to allow this).

4.5 Conclusion

In conclusion, the APC performs most of the tasks set out for the NAWEC. Its remit – and membership – could be expanded to encompass the requirements of the proposal. The Committee would have to be reconstituted under the new Directive in any case, which would allow for necessary changes to the Committee and its operation. Members of a new or reconstituted APC/NAWEC should be paid, as there is likely to be a considerable increase in workload that would be involved and this would reflect the importance of the role of the NAWEC. The UK NAWEC should also retain the other duties of the APC that are listed in the current ASPA guidance notes, such as advising on licence applications and infringements.

ANNEX G

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4 March 2009

THE ANIMAL PROCEDURES COMMITTEE'S PRELIMINARY ADVICE ON ISSUES ARISING FROM THE EUROPEAN COMMISSION PROPOSAL TO AMEND DIRECTIVE 86/6O9 EEC.

Thank you for your letter of 19 February providing the Animal Procedures Committee's preliminary advice on issues arising from the European Commission Proposal to amend Directive 86/609 EEC.

With respect to education and training I agree that we can build on, and must not weaken, the current UK framework, and that harmonisation and the expected free movement of skilled labour are dependent on there being a common EU framework, rather than multiple national frameworks.

I also accept the principles set out in your analysis of the reporting of the severity of procedures. Indeed, as this article is central to the impact and operation of many elements of the proposal, I believe that not only should there be clarification on some of the technical issues, but a common framework allowing the consistent classification of severity, based on what individual animals actually experience, must be developed and agreed before the new directive is finalised.

On the subject of Ethical Review Bodies I agree that there is room for improvement with respect both to their composition and functions — whilst at the same time ensuring there is no unnecessary duplication of functions which might be better done by other elements of the resulting regulatory regimen.

I am particularly grateful for your analysis and advice of how a National Animal and Ethics Committee might be developed. Although the issue requires further thought, your preliminary advice has provided what appears to be a practical way forward.

I would also like to thank the Committee for the timeliness of this advice. In commissioning the advice I was conscious that I was asking for advice at relatively short notice — but that to set a later deadline would have run the risk that the advice would have been received too late to inform the partial impact assessment and formal consultation that officials are currently working on.

Your timely and clearly presented of advice will assist with these: and hopefully the consultation will validate and demonstrate the degree of stakeholder support for a number of the points made in your report.

Thank you for your swift work. As you know I will shortly be going on maternity leave but expect to back in October. In my absence Shahid Malik MP will be covering my role.

If you need to contact him please come through my office as usual.

Meg Hillier

ANNEX H

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28 October 2008

ANIMALS (SCIENTIFIC PROCEDURES): UPDATED RESPONSE TO THE ANIMAL PROCEDURES COMMITTEE'S REPORT ON THE ANNUAL STATISTICAL REPORT

I am writing to update you on the current position regarding our response to the Animal Procedures Committee's report on the Statistics of Scientific Procedures on Living Animals that was published in 2005.

You will be aware that my predecessor Andy Burnham wrote on 31 January 2006 to the Animal Procedures Committee with a response to each of the recommendations. He commented that he was

" very grateful for the wide-ranging advice it [the report] contains, which will help shape the further consideration we give to the future content and format of the published statistics. I accept the broad thrust of its recommendations and have asked my officials to implement them quickly where possible" and that ".

In taking them forward we will also take account of Office of National Statistics (ONS) guidelines for the publication of statistical information and the expanded role for the ONS announced recently, current and future European reporting requirements under directive 86/609/EEC, the regulatory impact of any new provisions, and the transitional arrangements and lead-times required to capture and publish new data".

I am able to report that the current situation is that consideration of and/or action on 10 recommendations has been completed; thirteen are waiting for developments with the revision of EU Directive 86/609; one will be considered in light of the APC report on severity (this report is also being considered along with other points in two other recommendations); three for developments in the wider Home Office (in particular regarding a searchable database); and 7 are still under consideration or will be implemented in the 2008 report.

I attach the Minister's response of January 2006 to each of the recommendations, along with an updated position on each.

Meg Hillier

Recommendation 1

Whilst it has been the practice for the statistics for Northern Ireland to be produced separately, the Act does not expressly require this. Even though a much larger number of procedures are carried out in Scotland, they are not recorded separately. One UK publication would assist clarity as well as saving some administrative costs. **We therefore recommend that the Home Office and the Department of Health and Social Services and Public Safety for Northern Ireland should consider amalgamating their statistics publications.**

Response

The Committee is correct in pointing out that the Animals (Scientific Procedures) Act 1986 does not specifically require the separate publication of statistics for Great Britain and Northern Ireland. Although it has been the practice to publish them separately, it is possible for the statistics to be combined in one document provided the document is laid before Parliament and the Northern Ireland Assembly (when the Assembly is in devolution mode) by their respective Ministers. In addition, the data must continue to be presented separately to allow Parliament to focus on information relating to Great Britain and the Assembly to focus on information relating to Northern Ireland. My officials will liaise with the Department of Health, Social Services and Public Safety for Northern Ireland with the aim of implementing this new approach in 2006.

Update

Andy Burnham wrote to Shaun Woodward at the Department of Health, Social Services and Public Safety for Northern Ireland on 22 December 2005 and he confirmed that he supported the proposal. We will endeavour to do it in time for the 2008 Report, bearing in mind the Office of National Statistics (ONS) guidelines for the publication of statistical information and the expanded role for the ONS. It is important to note though that the GB and NI statistical reports will still need to be presented separately to Parliament and the NI Assembly respectively; and that supplementary questions arising from the statistical report indicate that there is a greater interest in maintaining and developing distinct regional figures.

Recommendation 2

We are conscious that it may be difficult to change the RDSD database software. However, within this constraint, **we recommend that the Home Office actively seeks to anonymise and publish the database of Returns in a fully searchable and relational form, and, if possible, to permit comparison of different years' Statistics.** This would allow individuals to interrogate the information contained in the database for themselves.

Response

There is no doubt that the database represents a valuable resource and we recognise the arguments for making it more widely available and searchable. The present recommendation raises issues of timing, cost, feasibility, confidentiality and likely levels of demand, all of which will need to be considered further and satisfactorily resolved before a final decision to implement can be taken. I am mindful that costs might be minimised and functionality maximised if this proposal can be taken forward within existing corporate programmes encompassing other classes of Home Office statistical information. I have asked my officials to explore the scope for such a solution.

Update

The Home Office is currently looking at ways of making a range of Research, Development and Statistics information available on the Internet — and this will include allowing users to construct their own search patterns. This project is still in the developmental stage and the APC recommendation will be implemented once the work has been completed and trialled.

It is important to note that anonymity will remain an important issue. We committed to ensuring that no individual person or Designated Establishment should be identifiable from the Statistical Report, and this will be an essential requirement of any system which is developed.

Recommendation 3

Our view is that *licence abstracts should be made searchable according to key words that bear relationship to the headings in the* ***Statistics***. The practicality of this suggestion should be considered by the Home Office as more abstracts become available.

Response

I agree that the abstracts should be searchable. It is our intention to take this forward as the Departmental web-site is further developed.

Update

As above, the Home Office is looking at ways to improve the search facility across the Departmental website and this will provide the tools to search the abstracts database. This would also require additional advice to stakeholders and/or the HO staff, and additional quality assurance measures, to ensure appropriate key-words are used. Any additional user costs would not well accord with Better Regulation, unless it is demonstrated to be outweighed by the proposed benefit.

Recommendation 4

The Statistics should aim:

i. **overall, to promote informed debate and enhance transparency about the use of animals in scientific procedures by the appropriate collection, analysis and presentation of data to Parliament, the public, Government Ministers and Departments and other interested parties; and, as part of this,**

ii. **to assist readers' understanding of why and how animals are used under the Animals (Scientific Procedures) Act 1986 and to help to inform public debate on harm-benefit assessment under the Act — this will include providing data that can assist in answering Parliamentary Questions;**

iii. **to discern historical trends in the use of animals under the Act;**

iv. **to allow monitoring of the effects of changes of policy on animal use under the Act;**

v. **to help in monitoring areas in which work on the Three Rs is being most effective; and**

vi. **to provide information on the licensing process itself.**

Response

The collection and publication of timely, accurate and relevant information is required to serve these and a wider range of public interests, including facilitating open Government and evidence-based policy development. The annual statistical report plays an important part in this. In giving further consideration to the APC's recommendations we will need to consider Office of National Statistics guidelines for the publication of statistical information, and also be mindful of compliance costs and lead times, and what information might be more efficiently and effectively produced and published by other means, such as thematic Inspectorate reviews, consultations or third-party initiatives.

Update

We have considered this further and we have certain concerns as the recommendation goes beyond what the statistics can reasonably be expected to do. At present, it is a National Statistics Publication, which requires it to be factual and accurate and fulfils the Animal (Procedures Act) 1986 requirements: Importantly the National Statistics Guidelines limit the nature of any commentary or analysis embedded in the report. Some of the issues of interpretation and presentation to promote understanding of animal use run counter to the ONS requirement that such publication provide only the facts without any additional 'spin". Particular care must be taken when explaining or justifying policy changes progress with the 3Rs, and non-statistical insights into the licensing process. These issues are better addressed through other HO publications such as the ASPI Annual Report, the APC Annual report (and perhaps an ASPD Annual Report), the Home Office web-site — or the NC3Rs Annual Report.

Recommendation 5

Additionally, the process of collating such statistical data, through completion of the Returns, can enable project licence holders and establishments critically to review their use of animals. **Individual establishments should collate data on animal use returned from individual project licensees and provide the resulting summary information to their ERPs, so that the Returns can be used as an opportunity to consider trends in animal use within establishments, and so target local efforts to implement the Three Rs.**

Response

This represents existing good practice. Prompted by this recommendation, we have written to all designated establishments to promote this practice, and to illustrate how this information can support the aims and objectives of the local ethical review processes.

Recommendation 6

The objectives of the *Statistics* should be stated in the publication itself; and the definition of the term 'procedure' in this context should be clarified.

Response

We will take this into account when we review the structure and content of future annual statistical reports.

Update

Having considered this further we believe that the objective of the Report is to meet the requirement of the Act to provide a statistical return relating to scientific procedures performed on living animals, and that this is plain from the current format. The term "procedure" is clearly defined in Annex A of the report, which is available on the Home Office website.

Recommendation 7

With regard to the objective of "discerning historical trends in animal use", the Minister should bear in mind that **any changes to the *Statistics* should, as far as possible, ensure compatibility with historical tables in the publication.**

Response

This is existing policy and practice.

Recommendation 8

With regard to the objective of "monitoring of the effects of changes of policy on animal use under the Act", **it is valuable to report on uses of animals that have been disallowed under administrative provisions** subsequent to the inception of the Act, in order to help inform readers of current limits imposed on animal use. **However, rather than presenting information on such restricted uses as blank rows in the relevant Tables (as is current practice), there should be footnotes stating that no animals were used, because the particular use is no longer permitted.** This would indicate the current situation more clearly than a blank row, which could be open to misinterpretation.

Response

We will take this into account when reviewing the structure and content of future annual statistical reports bearing iii mind the principle identified in recommendation 7.

Update

Thematic papers in the ASPI Annual Report are the means by which this will be done, although we would expect deletion of these blank cells from the annual report itself will result in supplementary questions from those seeking reassurances that policy is being properly applied.

Recommendation 9

Information presented in the *Statistics* on the species and types of animals used under A(SP)A 1986 should be enhanced in the following ways

i. **Non-human primates — The *Statistics* should identify all non-human primates to species level.**

ii. **Endangered species — The *Statistics* should record numbers of animals for each CITES-listed endangered species used.**

iii. **Wild animals — The use of wild animals should be identified and counted in the Statistics, in order to monitor trends in use. There should also be a distinction, by genus, between wild animals used in their natural environment and animals that are wild-caught (whether in Britain or abroad) but used in the laboratory.** This would require a new question in the Returns form. **We note that importation of wild-caught primates for use in research and testing requires specific and exceptional authorisation by the Home Office, and that data on numbers of such animals used are already available. These figures should be published.** Data on the use of wild and wild-caught animals should be presented in the published Statistics in the form of a table showing species used against broad categories of purpose, with any more detailed information, relating for example to purpose, legislative reason for use or severity, made available in the full web-based version (see paragraph 12.11 below for further discussion).

iv. **The main groups should also be identified for large numbers of other animals which presently have little or no information. This includes birds, fish, reptiles and amphibians. Data on 'species used' should be collected for all four groups.** We suggest that these data be presented according to the following categories, which should be reviewed on a regular basis and, if necessary, amended in light of changing patterns of use (bearing in mind the need to maintain historical trend analysis):

- **Birds — The numbers of the main species and genera included in "other birds" should be enumerated separately, probably as pigeons, ducks, zebra finches, starlings, tits and corvids, retaining a (smaller) "other birds" category. Table 2, which deals with Schedule 2 animals, should continue to list only C. *coturnix*, but in all other Tables quail species should be merged to yield one figure.**

- **Fish — Information should be provided on the use of zebra fish, salmon and trout (being the main farmed fish used), and the main species used in ecotoxicity testing, with the remaining fish in an "other fish" category.**

- **Reptiles — This category could usefully be sub-divided into lizards and snakes (being the main groups used), and "others".**

- **Amphibians — Figures should be broken down into "*Xenopus* species"; "other frogs"; "toads"; "axolotls and "other amphibians".**

- **"Other mammals" categories — The species/genus information that is already collected for the categories "other rodents", "other carnivores", "other ungulates", and "other mammals" should be made publicly available.**

- **Camelids — This category could be discontinued, since very few/nil are used.**

- **Dogs — These could be represented as "beagles" and "other including cross-bred dogs", since there seems to be no further value in separating greyhounds as a breed.**

- **Great Apes — Despite the current administrative prohibition on the use of these species, the Returns codes for gibbons and Great Apes should be retained and explanatory footnotes added to the relevant species Tables (see Recommendation 8 above).**

- **Cephalopods — If the Minister accepts the APC's recommendation to extend the protection of the Act to cephalopods other than *Octopus vulgaris*, the numbers in each broad cephalopod grouping (e.g. octopi, cuttlefish etc.) should be published.**

The proposed changes detailed above are based on responses to our consultation and are suggested with the aims of:

- enhancing transparency, especially with regard to welfare implications of using different species and types of animals;

- assisting in monitoring changes in animal use;

- identifying needs for guidance on best practice in animal care and use;

- helping to prioritise strategies for funding work on the Three Rs.

The proposals apply to all relevant current Tables. To avoid over-complicating and/or over- lengthening the printed summary of the *Statistics*, some of the further species/genus information suggested here would be reported only in the full version of the *Statistics* available on the web (and printed for Parliament — see recommendation 32, below).

Response

We will give further detailed consideration to the benefits, feasibility and resource impact of these proposals and consult with stakeholders before reaching a final decision on whether and how far they should be implemented. In particular we will consider whether the main benefits of making available some additional information under these headings can be realised without changing the format and content of the annual statistical report.

Update

We still await future EU reporting requirements decided as part of the current review of Directive 86/609 which the Animals (Scientific Procedures) Act 1986 transposes into UK law. We will give further consideration to recommendation 9 of the Animal Procedures Committee's 2005 report on the Statistics of Scientific Procedures on Living Animals when the review of EU Directive 86/609 is published and we see what it contains. Collecting such information would pass a significant compliance cost onto users — the main benefits of having a snapshot of animal use in this amount of detail would be more efficiently achieved by an Inspectorate thematic review.

Recommendation 10

Tables dealing with the source of animals should refer to "animals", not "scientific procedures."

Response

We will give further detailed consideration to this recommendation when we consider any related requirements for statistical data arising from a revised EU Directive 86/609 when a draft is made available.

Recommendation 11

The Home Office should require reporting of the true "origin" of animals (defined as their place of birth) when this differs from their proximate "source". This would help in providing more meaningful information on some of the welfare costs involved in the supply of animals, which at present are difficult to discern, because 'source" refers to the immediate place from which an animal has been obtained and can therefore mask Journeys from the animal's place of birth to a supplying establishment. The change would mean that suppliers would have to specify the place of birth of any animals not bred by them. **Since a similar problem of definition applies to the EU statistics, the Home Office should also inform the EC of this change and the reasons for it.**

Response

As with recommendation 10, EU requirements will be a key issue in our further detailed consideration of this recommendation. However, there may be ways of providing some of this information without altering the statistical collection and report. I have asked my officials to explore the scope for such a solution. Update

The report continues to refer to "source" rather than "origin'. To change it would mean that it would be out of synch with the definition used in the EU statistics. Consequently this change cannot be accommodated save at an additional cost to users unless and until the EU requirements change.

Recommendation 12

"Origin" (where this differs from source) should be divided into the same categories as those for sources of Schedule 2 animals. In addition, the proximate sources and origins (where these differ from source) of non-Schedule 2 animals should be returned and reported similarly.

Response

The same considerations apply as for recommendations 10 and 11.

Recommendation 13

For the summary version of the *Statistics* (see recommendation 32, below) it is absolutely essential that the data in the Tables on the genetic status of animals are abstracted into clear summaries and presented in a form easily understood by the lay reader. The more detailed version of the *Statistics* should contain the full Tables, integrated into clear explanatory text, with all further necessary background in footnotes or in 'boxes' adjacent to the Tables, so that they are totally self sufficient in their understanding.

Response

See recommendation 32, below.

Recommendation 14

A section in the *Statistics* is required explaining clearly the procedures used to produce, identify, and maintain mutant animals (including ENU mutagenesis) and the procedures and types of animals involved (including embryo donors, surrogate mothers, use of stem cells for knock-outs, founder animals, and chimaeras) to produce and maintain GM animals. This will help to clarify the data in Tables 3.1, 3.2 and 3.3.

Response

Additional information is already available from other sources. To avoid overloading the statistics document, we believe that a better approach would be to provide a list of relevant references, rather than reproducing the information in full.

Update

This technical rather than statistical information has not been included in the report itself. There are websites where this information can be obtained. We are looking at whether the ASPD website should have a page that explains these terms that can be associated with the Statistics page for reference purposes.

Recommendation 15

For clarity

(i) procedures involving artificially-induced mutant animals should be separated from those involving genetically modified animals; and

(ii) the headings in the last three columns (before totals) in Tables 3.2 and 3.3 should be changed to:

- **use in fundamental or applied studies other than toxicology (the column is actually headed "use in further regulated procedures");**
- **use in production of biological materials or other similar procedures;**
- **use in toxicology or other safety evaluation.**

Response

As with a number of other recommendations, we will give further detailed consideration to this recommendation when we consider any related requirements for statistical data arising from a revised EU Directive 86/609.

Recommendation 16

At the very least, there is a need for clarification of the animal welfare implications of data reported in the *Statistics* for artificially-induced mutant and genetically modified animals that show no apparent adverse effects and are bred but not otherwise used in regulated procedures. In this regard, **we recommend that the Home Office review its method of counting and presenting data on GM and mutagenised lines, and, in particular, give further consideration to the following possible strategies:**

(1) To continue to count, report in the *Statistics* and include in the annual totals, all GM and artificially-induced mutant animals bred but not otherwise used, but to distinguish between those which suffer adverse effects and those which suffer no obvious adverse effects,

Note that this strategy, and (2) below, would require an agreed means of assessing the adverse effects experienced by the different genetically altered lines of animals — see paragraph 5.2.8 in our report.

(2) To count and report these animals in the *Statistics* as above, but exclude from the annual totals those which appear to suffer no adverse effects, so as to provide transparency whilst at the same time meeting concerns about inflating the annual figures;

(3) To treat artificially-induced mutant and GM animals in the same way as spontaneous mutants, and therefore to exclude from the *Statistics* entirely those bred but not otherwise used and which appear to suffer no adverse effects. This would require that these animals (like spontaneous mutants showing no adverse effects) be released from the Act, unless or until they were used in a regulated procedure, and so would require a change in Home Office policy.

Response

We will consider this recommendation further in the light of the APC's recent report on severity; other work being undertaken on welfare assessments of genetically altered animals; and future EU reporting requirements.

Update

The APC report has now been published and we will be considering its findings. The Minister has agreed that the option of assessing suitability for discharge should be considered further for GA lines which have no evidence of adverse welfare. ASPI will take this forward in collaboration with the APC.

Recommendation 17

Although only a small number of animals are likely to be involved at present, **we recommend that the Home Office consider enumerating the production and use of cloned animals separately.**

Response

We will consider the costs and benefits of this recommendation in consultation with stakeholders, along with other suggested additions to the statistical tables. Update

We will address this in the margins of dealing with recommendation 16.

Recommendation 18

Table 9 of the *Statistics, Techniques of particular interest*, gives some, albeit limited, information about particular procedures. However, although potentially useful, the data collected and reported under this heading could be made more pertinent and relevant to severity. **The techniques listed in Table 9 should be reviewed and changed as necessary so that they better represent procedures in current use that may cause substantial suffering.** In future, there should be periodic reviews of the headings in this Table, and changes made to ensure that the techniques covered are the most appropriate (bearing in mind historical trend analysis).

Response

We will consider the costs and benefits of this recommendation in consultation with stakeholders, along with other suggested additions to the statistical tables and future EU reporting requirements.

Recommendation 19

It should be ensured that areas that seem ripe for replacement and areas in which there appears to be growth in the number of animal procedures are enumerated separately in the *Statistics*. Appropriate categories might be decided in dialogue with the NC3Rs.

Response

We will consult the NC3Rs on what might be helpful to their work, and the means by which such information might best be obtained and published.

Update

Discussion will be held with NC3Rs each year following publication of the statistical report.

Recommendation 20

An Appendix illustrating examples of applications of the Three Rs was included in the *Statistics* for 1998 (Appendix C, pages 97-99 in Home Office 1999) and subsequently made available on the Home Office website. This should be re-introduced.

Response

The original examples from 1998 are available on the Home Office website. We believe that current examples would be better included in the NC3Rs or Animals Scientific Procedures Inspectorate annual reports. I have asked my officials to explore the options with the NC3R

Update

To comply with ONS guidelines (minimizing the non-statistical content of the annual report) these will be given consideration in preparation of the ASPI annual report and our dialogue with NC3Rs,

Recommendation 21

In due course, consideration should also be given to the inclusion of a summary report on the work of the NC3Rs, in order to highlight any recent advances in the Three Rs and, wherever feasible, correlate these with published statistical data.

Response

The NC3Rs will report on its work annually to the Minister for Innovation and Science. I do not believe there is a need for a similar report in the Home Office Statistics of Scientific Procedures on Living Animals. We will assist the NC3Rs, as far as we can, with statistical data where this will enhance their report.

Update

Our web-site provides links to NC3Rs, and our stakeholder mailings draw attention to its publications and events.

Recommendation 22

With respect to use of anaesthesia and analgesia, the annual Returns and *Statistics* publication should classify regulated procedures as follows:

1. those performed entirely under general anaesthesia, from which the animal does not recover consciousness (i.e. those in which the animal is 'terminally anaesthetised');

2. those in which the animal may experience little or no pain or discomfort, which would be equal to or exceeded by the stress of administering an anaesthetic and/or analgesic (excluding those in which the animal is terminally anaesthetised);

3. those in which the animal may experience pain or discomfort exceeding that in (2) but which will be alleviated by use of anaesthesia and analgesics (excluding those in which the animal is terminally anaesthetised); and

4. those in which the animal may experience pain or discomfort which, for experimental reasons, cannot be alleviated by use of anaesthesia and/or analgesics.

Response

We will consider this recommendation further in the light of the APC's forthcoming report on severity and possible changes to the European reporting requirements.

Update

The APC report has now been published and we are considering its findings. We will also take this recommendation into account when we consider the relevant requirements of a revised EU Directive 86/609 when a draft is made available

Recommendation 23

The question of whether or not animals bred for regulated purposes and not used should be counted and reported in the *Statistics* should be kept under review. We further recommend that Ethical Review Processes (ERPs) in designated establishments maintain awareness of the issues, monitor production strategies and work to ensure that surpluses are minimised.

Response

We note the first part of this recommendation. Current policy is that animals not used in scientific procedures should not be recorded in the annual statistics as it would extend the coverage of the statistics well beyond the boundaries of our powers to regulate under the 1986 Act and have been ruled out when considered previously.

The second part of the recommendation reiterates the existing expectation and, in the light of this recommendation, we have written recently to all designated establishments to promote this practice.

Recommendation 24

Reporting requirements in respect of animals killed for tissue for in vitro use should be kept under review. We further recommend that, within each designated establishment, numbers of animals killed by Schedule I techniques to provide tissue for *in vitro* use (which are already recorded) are reported to the establishment's ERP, so that they can be reviewed annually — in order, for example, to implement and monitor the effectiveness of strategies to ensure that when animals are killed, as many as possible of the organs and tissues that become available are actually used.

Response

Again, we have noted the first part of this recommendation. Schedule 1 killing is not a procedure under the 1986 Act and is, therefore, not recorded in the statistics of scientific procedures as it would extend the coverage of the statistics well beyond the boundaries of our powers to regulate under the 1986 Act and have been ruled out when considered previously. The second part of the recommendation has been drawn to the attention of certificate holders.

Recommendation 25

The Home Office should review the categories included under primary purpose and target body system for current relevance and pertinence. We make the following suggestions, based on responses to our Consultation and discussions within the Working Group:

Response

We will take this recommendation into account when we consider the relevant requirements of a revised EU Directive 86/609 when a draft is made available.

Recommendation 26

The categories in Tables 10 and 10a should be reviewed, and this should include consideration of the following points:

- **under the General *safety/efficacy evaluation* column, Finished cosmetics and Cosmetic ingredients could now be deleted (retaining the information as footnotes – see Recommendation 8); and *Food additives and Other foodstuffs* should be merged into a single heading (possibly 'novel ingredients and food');**
- **under Other purposes, the *Tobacco Safety* column could also be deleted (again, retaining the information as footnotes – see Recommendation 8);**
- ***Pharmaceutical safety/efficacy evaluation* should be re-classified — for example, it could be divided into three categories: 'chemical materials', 'vaccines' and 'other biological substances'; and 'vaccines' could be further divided into 'developmental' or 'batch' testing. We note, however, that, as the Table is currently formatted, this would involve considerable additional complexity.**

Response

We will take this recommendation into account when we consider the relevant requirements of a revised EU Directive 86/609 when a draft is made available.

Recommendation 27

The categories recording tests to satisfy UK and other legislative requirements (Table 11) should be made more specific. (In this context, we note that the number of different categories will likely be reduced with continued EU harmonisation of legislation — e.g. the category for procedures performed to meet national legislation specific to *One EU country only (not UK)* should eventually be unnecessary.)

Response

We will take this recommendation into account when we consider the relevant requirements of a revised EU Directive 86/609 when a draft is made available and the likely reporting requirements are clearer.

Recommendation 28

Table 12 sub-divides toxicological procedures into 20 types of test. The classification is in accordance with OECD guidelines and the Table or accompanying commentary should clarify this point.

Response

We agree and will consider implementing this in the next statistics publication.

Update

We plan to address this in the 2008 report.

Recommendation 29

The disciplines listed in Table 5 reflect a classification that may not be currently relevant and, moreover, appears to combine field of research with end-use. **We recommend changing the headings in Table 5 to reflect current descriptions of disciplines e.g. to remove *Anatomy* and to include the headings *Developmental biology* and *Cell biology*.** Cancer research would perhaps fit more appropriately in a classification by reference to disease or condition (whether as purpose or end-use — see Recommendation 30 below). The heading *Tobacco* is no longer relevant and should be removed (retaining an explanatory footnote — see Recommendation 8).

Response

We agree, subject to any issues raised by the need to ensure compatibility with historical tables and European reporting requirements.

Update

We will take this recommendation into account when we consider the relevant requirements of a revised EU Directive 86/609 when a draft is made available and the likely reporting requirements are clearer.

Recommendation 30

It is clear that, where the purpose of a procedure is other than toxicological, to describe its purpose by reference to primary target body system (Table 4a) and field of research (Table 5), gives little if any information about the application and end-use of such research. For this reason, **we recommend a revision of Table 4a that would enable licensees to indicate whether the programme of work in the project licence is specifically directed against a disease or condition. Information would be captured by extending the list of systems currently in Table 4a (so none of the information currently obtained is lost); retaining the *Other, Multiple systems* and *System not relevant categories* and including a column asking: *Is the work directed against a disease/disorder?*** Examples of possible headings are listed below.

Examples of possible headings to extend Table 4a

Note that these headings do not represent how the table would look and consideration would need to be given to the appropriate format e.g. whether each system column should be sub-divided according to whether the work is directed against a disease/disorder or not.

Human systems	Cancer research, Cardiovascular Ear, nose and throat Endocrine and metabolic Genetics Gynaecology and Obstetrics Haematology Hepatic Immunological Infection Mental health Musculoskeletal/connective tissue Neurological Nutritional/gastro-intestinal Ophthalmological Pain research Renal and urological Respiratory Skin
Animal systems	Infection, Other
Other systems	
Multiple systems	
Is the work directed against a disease/ disorder?	

Response

We will consider the costs and benefits of this recommendation in consultation with stakeholders, taking account of any issues raised by the need to ensure compatibility with historical tables and European reporting requirements.

Update

We have reconsidered this and believe that it would be better to wait for the outcome of the revision of the EU Directive.

Recommendation 31

The present method of counting animals and procedures (in which each is counted once, at the start of the procedure) leads to a number of difficulties, including the following:

In any given year, it is impossible to discern the total numbers of animals being used and procedures actually underway, and there is no indication of how many uses last longer than 12 months. Thus it can be argued that the content of the *Statistics* does not match the full title of the publication.

Counting animals only once at the start of a complex or lengthy reported procedure may provide an incomplete picture of the full use ultimately made of the animals. This leads to internal inconsistencies in the *Statistics*, such as omissions in the *Statistics* of the use of anaesthesia and of techniques of particular interest.

The present method of counting, being 'prospective' (i.e. counting animals and procedures' it is possible that the range of system options for animals could be extended, to mirror those for humans when they begin) does not lend itself to a system of reporting the severity of adverse effects *actually experienced* by animals when they are used in scientific procedures. This would require a retrospective system of reporting (i.e. counting animals at the conclusion of the procedures).

In the case of re-use, the present system of counting animals and procedures can cause internal inconsistencies in the *Statistics* and consequent misunderstandings.

In order to address difficulties arising from the present system of counting animals and procedures, **we recommend that the Home Office give serious and detailed consideration to changing the method of counting employed in the current annual Returns and in the *Statistics* publication. This should include consideration of (a) the possibility that numbers of animals only, and not procedures, could be reported and published along with separate re-use data; and (b) the possibility of adopting a system involving either (i) modified prospective counting in which each animal is counted in every year it starts on a procedure and in every year in which that procedure continues; or (ii) retrospective counting plus duration codes in which each animal is counted when its use in a regulated procedure is completed and a new code is added, to record the duration of each procedure.** The advantages and disadvantages of these two systems are summarised overleaf.

Advantages and disadvantages of three different methods of counting

Characteristic	Current: prospective	Modified prospective	Retrospective + duration codes
Information on numbers of animals in use in any given year	Incomplete: counts animals (and procedures) only in year started.	Complete: counts animals first used in the given year; and also uses started in the previous year(s) continuing in the given year.	Incomplete in any given year: because animals are only counted at the conclusion of procedures which may have started in a previous year. However: complete data can be discerned retrospectively, from data on duration of procedures.
Information on duration of procedures	Provides no information on duration. Can mask techniques of concern which are carried out in subsequent year(s), after a procedure is first started. Does not capture data on long- term procedures lasting more than a year.	Provides information on animal use lasting longer than a year, and makes explicit 'returnable' techniques used in any subsequent year(s) after the procedure is first started. Does not capture data on long term procedures started and finished within a year; nor distinguish shorter-term procedures crossing the year-end.	Provides complete information on duration by means of specific duration codes.
Possible link with data on actual severity of animal procedures	Not possible, because counting is prospective not retrospective	Not possible, because counting is prospective not retrospective	Possible, because counting is retrospective. Also records duration of procedure – an important part of severity assessment.
Effects on historical compatibility of data	Present system: no change.	Historical trends would be maintained, because animals first used in any given year would be reported separately, as in the present system.	Historical trends would not be maintained initially – but there could be dual recording for the first year (prospective and retrospective) thereafter numbers should increasingly become comparable with previous years.

Response

The accounting rules are based upon the European reporting requirements, and are explained in the annual report. We will consider this recommendation further in the light of the APC's forthcoming report on severity and possible changes at the European level.

Update

The APC report has now been published and we will be considering its findings. We will also take this recommendation into account when we consider the relevant requirements of a revised EU Directive 86/609 when a draft is made available

Recommendation 32

The *Statistics* should be made available in two versions: a full report and a summary, entitled respectively

- **Full report:** Scientific Procedures on Living Animals. *Great Britain Statistics and Other Information.* This would be aimed at those seeking full information about animal procedures; and
- **Summary:** *Scientific Procedures on Living Animals. Great Britain [Main Points.* This version would be aimed at the general reader who seeks only basic information.

Response

The preparation and publication at the Home Office web-site of a more reader-friendly summary document is already under consideration for implementation with the next statistics publication.

Update

A concise version of the report is now published in hard copy and a full report with all the tables made available on the Home Office website. The hard copy has been reduced from 101 to less than 50 pages. The text and commentary to the report has also been made more user friendly with the adoption of bullet points and simplified text.

Recommendation 33

Both the Full report and the Summary should be placed on the Home Office website in formats that allow the documents to be searched, with links enabling readers to move between sections of the two reports with ease. The Summary should also be printed in glossy format, for wide circulation, while the Full report should be printed for Parliament, but otherwise made available only on the web.

Response

A number of these points are addressed above. We will consider carefully how the main benefits can be most efficiently realised.

Update

See recommendation 32. The search facility part of the recommendation is dependant on the Home Office's work on making databases more searchable. See Recommendation 2.

Recommendation 34

The presentation of both publications should be redesigned to make them more user- friendly. In particular:

- **the explanatory text and data should be integrated, so that they form a unified, continuous narrative;**
- **pictorial representations of data, such as charts, graphs and histograms, and colour should be used wherever possible;**
- **it should be ensured that each Table or Figure contains, or is adjacent to, all the information the reader needs to understand it — this could involve the use of footnotes, but should avoid the need to cross-reference other parts of the report; and**
- **in the web versions, there should be hyperlinks within the documents, to published project licence abstracts and related material.**

Finally, in relation to presentation, we have already recommended that the RDSD database of annual Returns should also be made available as anonymised raw data in fully searchable and relational form, in order to permit individuals to interrogate the information and hence construct their own Tables (Recommendation 2).

Response

The need for a more user-friendly statistical publication was a key motivating factor behind the request to the APC for advice on these issues. The basic premise of this recommendation is, therefore, already accepted. The APC's detailed suggestions will be taken into account as this work is taken forward.

Update

See recommendation 32.

ANNEX I

APC WORK PROGRAMME FOR 2009 onwards

OBJECTIVE	TARGET DATE
Primates Sub-Committee	
Advice relating to the acceptance of overseas primate breeding centres and meeting with CRO's and Pharma	On going
Develop an overview (horizon scanning) of current situations/trends in the use of primates in medical research and the understanding of diseases, excluding regulatory toxicology.	On going
National Primate Strategy collaboration.	On going
Housing & Husbandry Sub-Committee	
Publish report on the welfare of fish used in experimentation.	August 2009
Education & Training Sub-Committee	
Finalise report on module 5 to present to main APC.	On going
Publish report on accreditation of training courses, including clarification of expectations and roles, assessment of trainees.	On going
Training exemptions, what if any qualifications / experience / assessment merit such exemptions.	April 2010
Infringements	
Trend analysis of recent infringements data	April 2010
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
Conduct review of the sub-committee's procedures	Feb 2009
Suffering and Severity Working Group	
Assess Severity banding classifications	June 2009
Schedule 1 Working Group	
Review latest research about the use of CO2 and inert gases	On going

86/69 Working Group	
Advice/Evaluate of the revisions to the European Directive	On going
Better Regulation	
Release of GA animal from the Act pilot study	2010
The outcome of APC recommendations past and present	2010

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 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", ie in an artificial environment, outside a living organism.

In vivo – refers to experimentation done in live isolated cells rather than a whole organism, for example cell culture.

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

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

NVS – Named Veterinary Surgeons

PSC – Primate Sub-Committee

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