Report of the Animal Procedures Committee for 2007

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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ISBN 9780102958010

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ANIMAL PROCEDURES COMMITTEE

Membership as at 31 December 2007

Sara NATHAN (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.

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

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

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

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

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

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

APC Secretariat
Phil Banks
Philip Brenner

CHAIR'S LETTER TO THE RT HON JACQUI SMITH 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 have pleasure in submitting to you the Animal Procedures Committee's Annual Report for 2007.

This was my second year as Chair of the Committee and it was largely spent consolidating the committee's work and responding to three specific requests for advice from the minister concerning the Better Regulation agenda.

The role of overseeing the regulation of animal use for experimentation remains challenging, particularly in light of the Home Office commitment to Better Regulation and following the outcome of the Judicial Review (see paragraph 18).

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

The Committee has had another productive year especially with respect to the Better Regulation and Home Office Simplification initiatives. I am grateful to both members and secretariat and hope that our contribution has been recognised and that the Home Department continue to appreciate our efforts to assist Ministers in sensitive and difficult decision making.

SARA NATHAN

INTRODUCTION

This report describes the work carried out during 2007 by the Animal Procedures Committee.

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

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

- In its consideration of any matter the Committee shall have regard for the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures.

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

The full Committee met five times during 2007, in addition there were eighteen Sub Committee and eight working group meetings. As in previous years we also held an annual conference that provided an additional useful forum for learning, discussion and debate. Annex C details the membership of the Committee's Sub Committees and working groups.

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

- Adherence to the Committee's Code of Conduct;

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

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

Members are able to comment on the appraisal, and if desired make representations to a senior Home Office official. Ministers take these appraisals into account when deciding whether a member should be re-appointed. The chair's performance is also assessed using similar criteria.

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

THE MAIN POINTS FROM THE COMMITTEE'S WORK IN 2007 WERE AS FOLLOWS:

- Better Regulation Advice on Personal Licensing and Mandatory Training.
- Better Regulation Advice on the release criteria for GA animals.
- Committee advice on the acceptability of three new substantially severe licence applications.
- Better Regulation: Summary report of the APC Working Group on the Ethical Review Process.

THE COMMITTEE'S WORK DURING 2007

Applications Sub-Committee (ASC)

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

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

2. There were three specific project licence applications referred to the Committee for advice in 2007; one involved developing animal infection models for advancement of knowledge about and determination of treatment regimes for Parkinson's disease. The second proposed gaining greater insight into the mechanisms by which neurons die in neurodegenerative conditions such as motor neuron disease, and to test the efficacy of novel therapeutic approaches for these disorders. The third involved an application for developing a treatment for diabetes based on the transplantation of embryonic pancreatic tissue.

These applications were discussed first by our Applications Sub Committee, then again (in open dialogue and written questions) with representatives of the organisation making each application before putting the Sub Committee's final deliberations to the full Committee for final consideration and reporting as advice to the Minister.

Work of the Primates Sub Committee (PSC)

3. The role of the 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 2007 the PSC met three times to consider the continued acceptability of four establishments in Asia as sources of non-human primates imported into United Kingdom.

4. Under ASPA, unless an exception is agreed, animals listed in schedule 2 to the Act, including non-human primates, may not be used unless they have been bred at a designated breeding establishment or obtained from a designated supplying establishment. As UK demand for non-human primates exceeds domestic supply, the Home Office has for some years agreed that UK designated establishments can import such animals from a small number of overseas breeding and supply centres. As part of the acceptance process, Home Office Inspectors visit overseas centres to ensure that they meet acceptable standards of animal care and accommodation. Acceptance is based on these assessments, APC consideration and further information supplied by UK users.

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

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

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

In October 2007, Meg Hillier, Home Office Parliamentary Under Secretary of State, asked the Committee to consider proposed revised arrangements for the acceptance of overseas non-human primate breeding and supply centres. Hitherto, overseas centres meeting acceptable standards of animal care and accommodation have been approved for a fixed period and have had to apply, periodically, for re-acceptance. This has caused planning and logistical problems for user establishments in the commercial sector. The proposal submitted to the Committee sought to replace fixed-term acceptances with a system under which acceptances would be subject to review (typically every two years) rather than renewal.

The proposed rolling systematic 'acceptance' process without specific end dates was designed to avoid the heightened negotiations that take place when UK users require animal imports from suppliers whose (currently) fixed term of acceptance has almost expired and to encourage the development of the relationship between suppliers and users.

The Sub Committee still believe that frequent inspections are vital; to monitoring, maintaining and improving standards at overseas centres.

5. The Sub Committee also considered the Weatherall Report[5] that was published late 2006 and a full Committee discussion of the report with Sir David Weatherall was held in November 2007.

Education and Training Sub Committee (ETSC)

6. The Sub Committee met 5 times in 2007. It focussed principally on developing its report on the role of module 5 training for project licensees, which defines core competencies and learning outcomes appropriate for personal licence applicants. In May the Sub Committee also held a stakeholder workshop as the first stage providing attendees opportunity for further comment on the following three themes:,

(i) defining the attributes and competencies of project licence holders;

(ii) developing learning outcomes for each competency;

(iii) defining which of these learning outcomes can be delivered within Module 5.

This prompted further discussion and has contributed to the development of a guidance document that is currently in preparation.

In addition, the 2006 APC annual report made reference to a request for further advice in relation to the accreditation of licensee training. The request followed commentary from the Accreditation Board representatives on the provision of guidance to those bodies that accredit training in the Animals (Scientific Procedures) Act 1986 to ensure the delivery of consistent and appropriate training for all involved in the use of animals in research and testing. In 2007 the Education and Training Sub Committee contracted an independent education specialist to review existing courses and draft a report for use as guidance.

Housing and Husbandry Sub[6] Committee (H&HSC)

7. The Housing and Husbandry Sub Committee completed its work on *A* Consideration of Policy Concerning Standards of Animal Housing and Husbandry for Animals from Overseas Non-Designated Sources (April 2007) (available at *http://www.apc.gov.uk*). This document notes that, for ethical, scientific and welfare reasons, it is important that all establishments supplying animals for research in the UK, whether they operate within this country or abroad, should provide husbandry and care that meets animals' needs. The document enquires into the measures taken by ASPI and users to reassure themselves regarding the standards of these suppliers and provides

[5] The use of non-human primates in research, December 2006. A working group report chaired by Sir David Weatherall FRS FMedSci. http://royalsociety.org/downloaddoc.asp?id=3696

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

recommendations regarding best practice. The document concludes that the aggregated information collected by ERPs regarding these imports should be reviewed at a national level within two years (by April 2009). If deficiencies are identified, this could be used to inform a revision of the process by which requests are made to use protected animals.

The Sub Committee devoted the majority of its five meetings to fish welfare. The numbers of procedures involving fish has increased steadily in the last three years. Fish are mainly used in fundamental research, vaccine research and development as bio-indicators of man-made and natural pollutants and, increasingly, in GM technology.

In 2005 the APC produced a paper (APC (05)17)[7] on the use of fish in scientific procedures which suggested a commitment to commission a scoping study on the welfare of fish used in experimentation, giving the Committee an overview of potential fish welfare problems. Since then, considerable research effort has been directed towards reducing stress by providing good water quality (see review of Appendix A ETS 123)[8] . However stress can also be reduced via other aspects of husbandry, including the provision of suitable enclosures and enrichment, the ability to perform species-specific behaviours such as schooling and anti-predator behaviour and sympathetic handling It is also important to minimise any pain, suffering or distress caused by the procedures themselves. The H&H Sub Committee used the APC paper as a source of material to set up a working group on fish welfare. The original remit was to consider a review of experimental design, bearing in mind applicability and compliance with current EU Regulatory Guidelines in relation to vaccine batch testing, and to propose more effective implementation of humane end points in fish experimentation.

The European Centre for the Validation of Alternative Methods (ECVAM) set up a workshop on *Three Rs Approaches in the production and Quality Control of Fish Vaccines* towards the end of 2007. The Sub Committee sent a representative to the workshop, which was held in January 2008, and will be ensuring that its activities complement those of ECVAM in this area.

Suffering and Severity Working Group

8. As reported in the 2006 APC Annual Report, in 2005 the Laboratory Animal Science Association (LASA) proposed a pilot study of a retrospective system to measure substantial severity. This took forward work originally initiated and reported on by the RSPCA and the Boyd Group[9]. Rather than duplicate similar studies the Suffering and Severity Group funded part of the preparation of a report examining the feasibility of reporting data on the severity of scientific procedures on animals in collaboration with LASA.

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

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

11. The 2006 APC Annual Report detailed the development of two "intensity-duration grids" for reporting, which indicated (i) maximum severity and (ii) severity over the remainder of the procedure. The Group have applied this tool to a series of procedures to gain user feedback on its suitability and application. Users commented

[7] Taking forward the Committees work on fish. http://www.apc.gov.uk/reference/APC-05-17-fish.pdf

[8] The European Convention for the Protection of Vertebrate Animals used or experimental and other scientific purposes (ETS No. 123) Guidelines for Accommodation and Care of Animals http://www.rspca.org.uk/servlet/BlobServer?blobtable=RSPCABlob&blobcol=urlblob&blobkey=id&blobwhere=1199787212016&blobheader=application/pdf

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

that the system was understandable and capable of providing a more representative picture of severity than is in current operation. However its complexity meant it was more burdensome than the current process, additionally based on the worked examples it became apparent that small differences in the judgement of duration led to wide variation in the codes that classified severity.

The APC/LASA working group published their conclusions on the pros and cons of the retrospective reporting of severity on the 1st October 2008.

Schedule 1 Working Group

12. The humane killing of a protected animal is not a procedure requiring authorisation under a project or personal licence, if it is undertaken at a designated place for a scientific purpose, and if it is performed by a method listed in Schedule 1 of the Animals (Scientific Procedures) Act 1986 as appropriate to the type of animal. The Committee's report "Schedule 1 – Appropriate Methods of Humane Killing" (December 2006) acknowledged that humane killing is a process where ongoing research is likely to improve our understanding of key issues. The Schedule 1 Report also stated that the working group would continue to monitor continuing research into the use of CO_2 with a view to deciding whether it should remain an acceptable method of humane killing of rodents under Schedule 1.The working group reported to the Committee in autumn 2007 that there had been no substantive new information in relation to the use CO_2 in this area.

Revision of Directive 86/609 Working Group

13. Directive 86/609/EEC is the key 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 related to the use of animals for scientific procedures such as their housing and care, requirements for the authorisation of persons and establishments and the minimisation of pain, suffering and distress of these animals. It was adopted in 1986 and has not been revised since then, despite significant advances in technology, with a number of its provisions being open to interpretation. The Directive also does not include mandatory ethical review or compulsory authorisation of experiments. Furthermore, it does not explicitly mention the concept of the 3Rs – Reduction, Refinement and Replacement which is a generally recognised approach to facilitate more humane science and reduce animal use. In 2002 the European Commission acknowledged the need to update the Directive and began the formal process of review.

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

Throughout 2007 the Committee received no indication that the Commission was in a position to submit a formal proposal for a revised Directive for inter-service consultation. Following a limited consultation with National Competent Authorities and NGOs in January/February 2007, DG Environment circulated a draft proposal for inter-service consultation within the Commission in November 2007. Inter-service consultation was completed on 16 January 2008.

Better Regulation

14. Late in 2006 the then Parliamentary Under Secretary of State Joan Ryan MP asked the Committee to consider three issues relating to the operation of the Animals (Scientific Procedures) Act 1986 arising from the Home Office Simplification Plan and Better Regulation programme.

In 2007, the Committee advised on

- Personal licence and mandatory training requirements (Annex E);
- The criteria for the discharge of genetically altered animals from the controls of the Animals (Scientific Procedures) Act 1986 (See Annex G); and
- Guidelines for best practice in relation to ethical review processes (Annex I).

15. *Personal Licensing*

In December 2006 the then Minister asked for the APC for advice on personal licensing and mandatory training in relation to Better Regulation and the Home Office Simplification Plan. In particular, the Committee was asked whether the current personal licence (both the application form, and the resulting licence authorities) might be simplified to grant broad general authorities in line with the training that an applicant has already successfully completed.

In considering options for simplifying the process of applying for a personal licence, members of the Sub Committee were concerned that the development of broad general authorities where a licensee was authorised to carry out any of a standard list of procedures, i.e. a "blanket" authority, carried a potential risk of some reduction of standards of competence in the future. The argument for this was that giving licensees authority to carry out procedures that they do not use immediately, or that they will need to develop competence in over time, will result in an assumption of competence without confirmation through specific training or supervision. Such authorities may also result in personal licensees extending the use of techniques authorised under their licence without ever receiving any further review, internal or external, before beginning their work.

Therefore the Sub Committee advised that any introduction of broad general authorities should be supplemented with an ongoing monitoring system that ensures sufficient robust supervision and training. It was also acknowledged that this suggestion could actually result in a possible increase in the regulatory burden, however the requirement to provide monitoring already exists under the responsibilities of project licence holding.

A copy of the Committee's response "Advice from the Animal Procedures Committee on personal licensing and mandatory training"[10] is available from the APC website.

16. *The criteria for the discharge of genetically altered animals from the controls of the Animals (Scientific Procedures) Act*

The Animals (Scientific Procedures) Act 1986 regulates the use of animals in experimental or other scientific procedures that may cause pain, suffering distress or lasting harm. Furthermore, the view is taken that Genetically Altered (GA) animals should be assumed to be potentially more prone to pain, suffering, distress or lasting harm, as a result of the genetic alteration, than the background strain from which they are derived. As a result the Home Office regulates their production, breeding and use[11].

However the Home Office accepts that there will be some lines of GA animals that are not predisposed to these harms, and have made administrative provision for the discharge of such lines the Act, at least for breeding purposes. To date no such lines have been discharged from the controls of the Act; some stakeholders have commented that in their view the amount of proof required to release a strain from the controls of the Act seems to be set so high as to prevent anyone from trying.

[10] www.apc.gov.uk. See Annex E of this report.

[11] See "Guidance on Genetically Altered Animals and the Animals (Scientific Procedures) Act 1986" See Annex G of this report, and www.apc.gov.uk.

To address this matter the Minister asked for the Committee's advice on whether the current discharge criteria should be revised in the light of the current state of knowledge on welfare assessments and phenotyping methods, in order to remove any unnecessary obstacles currently preventing strains being discharged from the controls of the Act without weakening the provisions for the welfare of GA animals.

To maintain welfare standards (as distinct from health standards) in its advice (October 2007) the Committee suggested that before a GA animal could be discharged from the Animal (Scientific Procedures) Act 1986 there would need to be a structured welfare assessment (or other form of post release monitoring) carried out to provide sufficient objective evidence that, despite genetic alteration, such animals did not have adverse phenotypes that could cause physical or psychological suffering.

17. *Ethical Review Processes*

The Committee circulated a survey asking for views on the ethical review processes (ERPs). There was a gratifyingly high number of responses which were that essentially practitioners saw no pressing need for fundamental change to the role and functions of the ERP but favoured measures to refocus their activities and improve their effectiveness and efficiency. They supported the provision of additional written guidance and workshops to disseminate good practice – a final report of the Committee's considerations was submitted to the Minister in February 2008.

Judicial Review

18. The British Union for the Abolition of Vivisection (BUAV) was granted permission to seek judicial review of a number of issues arising from Ministerial decisions related to its 'Cutting Edge' campaign about primate research at Cambridge University and The Home Office's current interpretation of the Animals (Scientific Procedures) Act 1986. The Judicial Review, initiated by the British Union for the Abolition of Vivisection (BUAV) in December 2003, was the subject of a full hearing in the High Court in July 2007. The hearing considered four issues relating to the implementation of the Animals (Scientific Procedures) Act 1986:

1. **Severity limits for protocols** (the BUAV argued that in certain projects in which marmosets were used to study neurological disease the severity limits should have been set at substantial rather than moderate);

2. **Post-operative care** (the BUAV argued that after operation animals should receive constant observation and that some adverse effects and deaths that occurred during the work in the post-operative period show that care provided was inadequate);

3. **Death as an adverse effect** (the BUAV argued that the death of an animal – i.e. simply that it is no longer living, as distinct from any suffering preceding death – should be considered in the cost benefit assessment of a project licence application as an adverse effect); and

4. **The status of the "Home Office Guidance Note: Water and Food Restriction for Scientific Purposes"** (the BUAV argued that this note is a variation of a code of practice as specified in the 1986 Act and the procedure given in the Act for approving and publishing such material was not followed).

In his written judgement, Mr Justice Mitting ruled against the Home Office on issue 1 and against the BUAV on issues 2, 3 and 4. The Home Office was granted leave to appeal the ruling on issue 1. The BUAV was refused permission to appeal the rulings on issues 2, 3 and 4, but was subsequently granted permission to appeal the decision with respect to issue 2. Both appeals were heard on 12 and 13 March 2008. In its judgement issued on 23 April 2008, the Court of Appeal upheld the Secretary of State's appeal on issue 1 and dismissed the BUAV's cross-appeal on issue 2. The Home Office was awarded costs.

Infringements

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

In December 2007, the Home Office supplied the APC with a report of infringements that had been committed in 2006. The Committee are 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 strategies for dealing with any problems.

The Committee recognise the concern that publishing material in relation to infringements may be in breach of the data protection requirements. Mindful of both the concerns about personal privacy and the Committee's endorsement of openness, the Committee would like to confirm that it does give all information received in relation to infringements due consideration. The publication of such information is a matter for the Home Office itself rather than through the Animal Procedures Committee.

The Committee's work programme for 2008

20. We discussed the Committee's work programme for 2008 at our Annual Conference in November 2007. The Committee's work programme for 2008 is detailed in Annex K.

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 2007. During 2007 Ministers re-appointed Mrs Dawn Oliver for her second term of appointment.

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 2007/2008, the Home Office had budgets of £10,000 and £16,000 respectively from which to make such payments.

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

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

Ministers

9. The Home Secretary in practice delegates her responsibilities under the Act to another Minister in the Home Office, which administers the Act in England, Scotland and Wales. From May 2006, Meg Hillier MP has taken 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 (her) 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 2007.

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

Education and Training Sub Committee

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

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

Primates Sub Committee

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

Housing and Husbandry Sub Committee

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

"Applications" Sub Committee

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

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

Schedule 1 Working Group

Dr Tim Morris **(Chair)**
Mr Robert Kemp

Co-opted Members:
Mr Terry Priest (Manchester University)

Suffering and Severity Working Group

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

Revision of Directive 86/609 Working Group

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

ANNEX D

APPLICATIONS SUB COMMITTEE: *MODUS OPERANDI*

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

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

Involving the full APC in the decision making process of the Sub Committee

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

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

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

Rolling membership

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

7. Other members of the APC may be brought into the Sub Committee depending on their expertise and the subject of the licence application.

ANNEX E

APC EDUCATION AND TRAINING SUB-COMMITTEE: ADVICE ON PERSONAL LICENSING AND MANDATORY TRAINING IN RELATION TO BETTER REGULATION AND THE HOME OFFICE SIMPLIFICATION PLAN.

1. Introduction

In her letter of December 15th 2006 (attached as Annex A), the Minister asked the APC for advice on aspects of the operation of A(SP)A that had been raised in the Home Office Simplification Plan. Her requests for advice included on personal licences and mandatory training, as follows:

"Several stakeholders have made representations that the current personal licence (both the form of application, and the resulting licence authorities) might be simplified to grant broad general authorities in line with the training that has been successfully completed.

I would welcome, by April 2007, your initial thoughts on such proposals and, if you believe they have merit, whether the system should be changed now, or when the training courses are adjusted in line with the Committee's previous advice that training should be based on learning outcomes."

Jon Richmond, in his letter of January 11th 2007 (attached as Annex B), provided further information, in particular that ASPD considered there may be some scope within the provisions set out at Section 4 of the 1986 Act and that legal advice is being taken on this, with a view to standardising some generic lists of licence authorities at different levels of competence taking into account current training provision, and detailing consequential changes to licence conditions. He also pointed out that the APC had previously considered this as part of its 10 year review of the 1986 Act (relevant extract attached as Annex C), and had advised that:

1. Personal licences should specify one of two levels of procedure (basic or advanced) which correspond to the required training modules (basic equating to Modules 1-3 and advanced to Modules 1-4);

2. In some limited cases, animals should be specified by group (e.g. rodents) rather than by individual species;

3. Sponsors should be required to make more focused declarations about applicants' training and, possibly, eligibility; and

4. Conditions should be added to both personal and project licences to strengthen the arrangements for the supervision of licences.

In considering its response to the Minister's request, the APC's Education and Training Sub-Committee (ETSC) has taken account of:

- any need to update its previous advice on the personal licence system; and
- the possible impact of changes to the licensing system when giving further thought to future training requirements.

2. Discussion of simplification of the Personal Licence application process by the grant of broad general authorities

The Sub-Committee first considered what constituted the "broad general authorities" referred to in the Minister's request and agreed that this should be taken as relating to the standard wordings for the procedures the licensee was authorised to perform.

The Home Office Inspectorate has already compiled a list of standard wordings that cover techniques under Modules 1-3 and 1-4, and that could be further developed to assist the applicant. The wordings describe what is being done to a given animal rather than detailing the purpose, a common misunderstanding on personal licence applications. The list covers only what are considered to be mainstream procedures; specialist techniques are, and should remain, outside this standardised listing.

It is understood that certain pharmaceutical companies already have bespoke lists of techniques, though these are likely to differ between companies.

One potential difficulty is that currently there is no legal opinion on what qualifies as "specified regulated procedures" (see Section 4 (1) of the Act). If a legal opinion were to be given that lists of procedures with standard wordings can be authorised, wording would need to be such that it did not limit their flexibility for interpretation.

In considering options for simplifying the process of applying for a personal licence, members of the Sub-Committee were concerned that the development of broad general authorities where a licensee was authorised to carry out any of a standard list of procedures, i.e. a "blanket" authority, carried a potential risk of some reduction of standards of competence in the future. The argument for this was that giving licensees authority to carry out procedures that they don't use immediately, or that they will need to develop competence in over time, will result in an assumption of competence without confirmation through specific training or supervision. Such authorities may also result in personal licensees extending the use of techniques authorised under their licence without ever receiving any further review, internal or external, before beginning their work.

Therefore the introduction of broad general authorities in such a way should be supplemented with an ongoing monitoring system that ensures sufficient robust supervision and training. It was argued that this could actually result in a perceived increase in the regulatory burden as there may, for instance, appear to be a greater responsibility on project licensees; however, it is simply stressing a responsibility of the project licence holder that already exists.

There is currently little guidance on the requirements for supervision and how these should be interpreted in practice. The ETSC has previously highlighted this as an issue to be addressed. It is also aware, however, that the Laboratory Animal Science Association (LASA) will be publishing a report on supervision in May 2007 (http://www.lasa.co.uk/downloads/Supervision_for_PILs_2007.pdf). The LASA report sets out the responsibilities of all concerned and aims to provide guidance on good practice with respect to the supervision process, based on the Module 1-4 core competencies described in the APC Review of Modular Training.

A further advantage of standardised wordings would be in relation to secondary availability where licensees work at an additional establishment. Currently, the description of standard techniques at the establishment may not correspond with that in the licensee's own licence, a potential source of technical infringements. It was therefore considered important that procedures in any list were worded flexibly enough to be acceptable to interpretation by all establishments.

The ETSC also proposed that for the assistance of applicants it would be useful for ASPD to publish a flow chart or guidance summary of the application process and issuing of licences.

Taking all the above factors into account, the Sub-Committee considered that, in principle, the use of simplified broad general authorities could be incorporated in the personal licence application process.

3. Comments on the APC's previous recommendations in 1997 report

3.1. Personal licences should specify one of two levels of procedure (basic or advanced) which correspond to the required training modules (basic equating to modules 1-3 and advanced to modules 1-4)

As discussed under (2) above, the ETSC understands that lists of standard wording for specified regulated procedures have already been produced by the Inspectorate for Modules 1-3 and Modules 1-4 but these have not yet been published and are not yet on the web site. Probably 85% of the procedures carried out by licensees would be covered by the lists. However, there may be a potential problem of competency and supervision when there is a standardised list of approved procedures and all such techniques are included by default in the personal licence. This emphasises the need for a robust framework to ensure ongoing supervision and training.

The use of standard lists of specified regulated procedures, corresponding to the skill levels associated with successful completion of Modules 1-3 and of Modules 1-4 training, i.e. basic and advanced, would be facilitated via the electronic application format by means of a pull-down "menu",

There would be three options for use of these standard lists when applying for a personal licence:

1. Have a 'click here to insert all techniques' button, where all standard techniques associated with the skill level would appear automatically at a single click; or

2. Have a drop down list of the standard techniques and the applicant picks only those which are applicable; or

3. As a variation of (2) above, have a drop down list of the standard techniques and the applicant deletes any that are not applicable.

3.2. In some limited cases, animals should be specified by group (eg rodents) rather than individual species.

Although in agreement with the principle of this recommendation, the Sub-Committee considered that the example given, namely "rodents", was inappropriate as such a grouping was too broad. This would also apply to most other common laboratory animals, where they were far too dissimilar to be specified by group.

However, it was felt that some limited species grouping would be permissible and helpful where animals have similar characteristics, such as sheep and goats, or some types of birds, which could be split into suitable groupings, such as poultry, waterfowl and small wild birds. It may also be appropriate for small laboratory rodents to be 'grouped' provided a reasonable diversity of training has been undertaken, e.g. exemption from training for gerbils where training in mice, rats and hamsters has been undertaken.

3.3. Sponsors should be required to make more focused declarations about applicants training and, possibly, eligibility.

Currently licence applications are signed by sponsors but who may then have no further contact with the applicant. Sponsorship is a legal requirement (see S4(3) of the Act) and while it was agreed that it would be possible to ask more focused questions on the application form, the Sub-Committee could not see any benefit in extending the current sponsorship declaration as the sponsor was likely to be too remote from the applicant to provide more detailed information on eligibility and training. It was more important to have in house records of training and supervision available for inspection.

3.4. Conditions should be added to both personal and project licences to strengthen the arrangements for the supervision of licensees.

Overall, the Sub-Committee did not consider that additional conditions on personal and/or project licences were necessary. It did, however, point out that, at an early stage in its review of modular training, a review of licensee supervision had been planned. The LASA report, in providing an explanation of legal requirements

and responsibilities of personal licensees, complemented the intentions of the Education and Training Sub-Committee.

It was agreed that some establishments already have good systems of supervision in place, however it was also accepted that establishments would benefit from guidance on putting into place a robust framework to ensure appropriate supervision. In the first instance, as a matter of improving and spreading knowledge of good practice, the LASA Report would seem ideally suited in terms of highlighting what would be required.

As is often the case, the requirements of supervision are likely to be interpreted differently by different establishments, so it would be important not only to have guidance but for the local Ethical Review Process (ERP), on behalf of the Certificate Holder, to have oversight. The Home Office could also have oversight via the ERP's records.

4. Timing of any changes to current procedures

The Education and Training Sub-Committee has considered the timing of any changes to the personal licensing system in relation to the Sub-Committee's work on training and, in particular, in relation to its already submitted recommendations on personal licensee training (Modules 1-4) with its focus on learning outcomes. It does, not consider, however, that there would be any need to delay implementation of the changes considered under Section (2) above, i.e. those concerned with provision of standardised wording and lists of techniques. At most, there should only be a need in the future to make minor modifications to wording, not to the amended process itself.

5. Summary of advice

5.1. In principle, the use of simplified broad general authorities could be incorporated in the personal licence application process.

5.2. The timing of such changes (5.1. above) to the personal licence application process is not dependent on implementation of the APC's previous advice that training is based on learning outcomes.

5.3. The introduction of broad general authorities should be supplemented by an ongoing monitoring system that ensures robust supervision and training. In this respect, the LASA Report on Supervision provides guidance and highlights good practice.

In relation to the APC's previous recommendations in its Annual Report for 1997, the Sub-Committee also considers that:

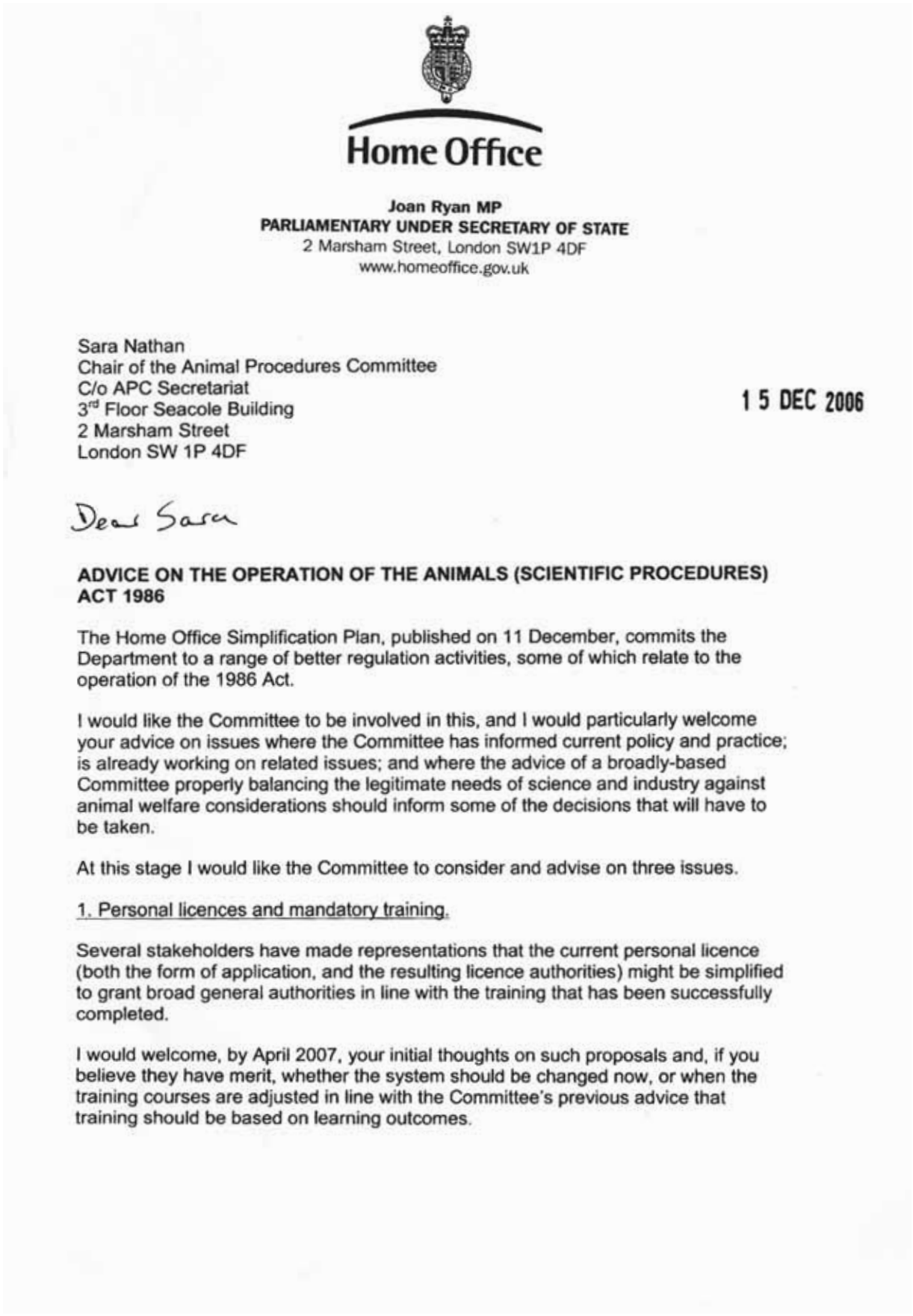
5.4. There is scope for some limited species grouping of licence authorities.

5.5. There would be no benefit in requiring sponsors of applicants for personal licences to make more focused declarations on eligibility and training.

5.6. Additional conditions on personal and project licences in relation to the supervision of licensees are not necessary.

5.7. Oversight of systems of supervision should be provided by an establishment's Ethical Review Process, on behalf of the Certificate Holder.

Appendix A – Extract from Minister Letter, 15th December 2006



Home Office

Joan Ryan MP
PARLIAMENTARY UNDER SECRETARY OF STATE
2 Marsham Street, London SW1P 4DF
www.homeoffice.gov.uk

Sara Nathan
Chair of the Animal Procedures Committee
C/o APC Secretariat
3rd Floor Seacole Building
2 Marsham Street
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15 DEC 2006

Dear Sara

ADVICE ON THE OPERATION OF THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986

The Home Office Simplification Plan, published on 11 December, commits the Department to a range of better regulation activities, some of which relate to the operation of the 1986 Act.

I would like the Committee to be involved in this, and I would particularly welcome your advice on issues where the Committee has informed current policy and practice; is already working on related issues; and where the advice of a broadly-based Committee properly balancing the legitimate needs of science and industry against animal welfare considerations should inform some of the decisions that will have to be taken.

At this stage I would like the Committee to consider and advise on three issues.

1. Personal licences and mandatory training.

Several stakeholders have made representations that the current personal licence (both the form of application, and the resulting licence authorities) might be simplified to grant broad general authorities in line with the training that has been successfully completed.

I would welcome, by April 2007, your initial thoughts on such proposals and, if you believe they have merit, whether the system should be changed now, or when the training courses are adjusted in line with the Committee's previous advice that training should be based on learning outcomes.

Appendix B – Extract from Jon Richmond's, Animal Scientific Procedures Division letter 11th January 2007

APC ADVICE – BETTER REGULATION

Joan Ryan wrote to you on 15 December commissioning advice from the Animal Procedures Committee on three issues to do with the operation of the Animals (Scientific Procedures) Act 1986 currently being considered within the Home Office's better regulation agenda[12, 13]. She indicated that officials would provide you with more detailed guidance on the advice required, timescales and the relevant background documents. The Minister stressed that it is essential that the delivery of the advice fits in with the timetable for the wider ASPD better regulation programme.

Background

Following recent reviews, including the Cabinet Office review of regulation in the pharmaceutical sector, the Davidson Review and the PWC administrative burdens project, the aim of the ASPD better regulation programme is to simplify current regulatory requirements and administrative processes under the 1986 Act and reduce compliance costs whilst maintaining animal welfare standards. As part of this we will also benchmark current best practice and evaluate specific proposals, including some put forward by stakeholders. We are not considering proposals that would require changes to the legislation, or other Parliamentary time, to deliver.

The project will be overseen and managed within the framework for implementation of the Home Office Simplification Plan, and will actively involve operational level practitioners from both industry and academia; licence holders and named persons; and (to further ensure that the protection of animals is not compromised) those with a special interest in animal welfare.

1. Personal Licences and mandatory training

As Joan Ryan explained in her letter, several stakeholders have made representations that the current personal licensing process (including the form of application, and the resulting licence authorities) might be simplified to grant broader general authorities in line with the modular training that applicants have successfully completed. We believe there may be some scope to do this within the provisions set out at section 4 of the 1986 Act.

The Committee previously considered this as part of its ten-year review of the 1986 Act[14], and advised that:

(i) Personal licences should specify one of two levels of procedure (basic or advanced) which correspond to the required training modules (basic equating to modules 1-3 and advanced to modules 1-4)[15];

(ii) In some limited cases, animals should be specified by group (e.g. rodents) rather than by individual species;

(iii) Sponsors should be required to make more focused declarations about applicants' training and, possibly, eligibility; and

(iv) Conditions should be added to both personal and project licences to strengthen the arrangements for the supervision of licensees.

More recently, we have accepted the Committee's advice that modular training should be revised to incorporate a learning outcomes approach and, although the Committee may wish to reflect further on whether changes to the

[12] The Davidson Review

[13] Home Office Simplification Plan

[14] Chapter 7, Appendix F, APC Annual Report 1997 (see also Annex C of this document

[15] To help in this work a draft list of techniques which would fall into the basic and advanced categories will be produced shortly by the Inspectorate.

licensing system impact on training needs, feel that the time is now right to consider adjusting the personal licence system to reflect the impact of mandatory training.

As a result we are taking legal advice on what is permissible under the terms of section 4 of the 1986 Act with a view to standardising some generic lists of licence authorities at different levels of competence taking into account current training provision, and detailing consequential changes to licence conditions. The detailed work in this area will be taken forward by the Inspectorate working with a variety of stakeholders.

This matter is being raised with the Committee now for two reasons.

- First, to allow to Committee to reflect on whether it wishes to update its previous advice on the personal licence system.
- Second, in order that the Committee can take account of the possible changes to the licensing system when giving further thought to future training requirements.

Appendix C – Extract from the 1997 APC Annual Report: *Report of the Animal Procedures Committee on its Review of the operation of the Animals (Scientific Procedures) Act 1986.*

CHAPTER 7
REVISION OF THE PERSONAL LICENCE SYSTEM

INTRODUCTION

1. Concern was expressed in the material submitted to the review about the level of bureaucracy that the Animals (Scientific Procedures) Act 1986 has introduced. One aspect of this was the personal licence system.

2. The Committee agreed that the present personal licensing system was unsatisfactory for a number of reasons including:

(i) it did not formally place sufficient responsibility on the project licence holder for the competence and conduct of those working under the authority of the project licence;

(ii) it did not take account of the mandatory training programme introduced in 1994;

(iii) it resulted in a number of technical infringements of the Act which had no animal welfare implications; and

(iv) it took up a disproportionate amount of Inspectorate and administrative effort in the Home Office when much of the control over animal procedures was exercised through the project licence.

3. We asked the Home Office to propose an alternative system. This chapter outlines, and gives a preliminary evaluation of, the proposed system. Further consideration and wider consultation will be necessary before we can offer our final advice on the proposals.

BACKGROUND

4. Under Section 3 of the Act, regulated procedures on living animals may not be performed on the authority of a project licence alone. Those carrying out regulated procedures must also hold a personal licence.

5. Section 4 of the Act requires that personal licence applications be endorsed by a suitably qualified personal licence holder who has knowledge of the applicant's qualifications, training, experience and character. The sponsor shall, if practicable, occupy a position of authority in the designated establishment where the individual proposes to work. A personal licence remains in force until revoked, but is reviewed by the Secretary of State at least every five years.

6. Applications are currently made on the attached form (Annex 1) which becomes a schedule to the licence itself.

7. Sections 6 to 9 of that form address the suitability of the applicant to carry out regulated procedures: specifically, the applicant's qualifications and experience. Section 21 provides for a character reference from the sponsor. It is impossible for the inspector assessing the application to confirm practical competence ahead of the licence being granted. Indeed, given the number of personal licence holders, it is unlikely that, after a licence has been granted, the Inspectorate will see sufficient work for any one individual to be able to assess that person's competence.

8. A requirement came into effect in April 1994 for personal licence applicants to have satisfactorily undertaken mandatory training courses. This bears directly on the competence of applicants but, at the same time, constrains the inspector's discretion; there can now be few grounds for querying the eligibility of a person who has successfully completed modules appropriate to their application, and whose qualifications, training, experience and character are endorsed by a suitable sponsor.

9. At the time of application, the inspector can only confirm that a person is qualified to undertake a procedure, has taken appropriate training, is sponsored by a suitable licence holder, and will be properly supervised. It is unreasonable to expect competence to exist without experience (which logically, can only follow the granting of licence authority to use a particular technique with a specified species).

10. The formal training requirements cannot guarantee prior competence. Nor can they overcome the disadvantages of experienced licensees ceasing to work with animals for periods of time or focusing their practice within a narrow band of particular techniques. Training remains the explicit responsibility of the designated establishment and supervision the responsibility of the project licence holder.

11. Currently, a record of techniques performed under supervision must be kept by personal licence holders (see paragraph 4.4 of Appendix V to the Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986) but there is no formal means of recording the achievement or maintenance of competence of a personal licensee to apply a technique to a particular species.

12. Section 15 of the personal licence application details and limits the techniques that the licensee will be allowed to perform and, in each case, the types of animal that can be used. Licensees are strongly encouraged to retain only those authorities that they are currently using. These, taken together, result in regular and repeated requests for minor amendments to the list of techniques or the types of animal.

13. It is important to stress that control over the severity of procedures applied to animals lies in the **project** licence and not in the **personal** licence. The personal licence holder has (and will continue to have) responsibilities for the welfare of animals undergoing regulated procedures, but their welfare is also addressed directly through the terms and conditions of the project licence and through the statutory roles of the persons named in the certificate of designation for the establishment.

PROPOSED CHANGES

14. The following modifications to the personal licence system have been proposed by the Home Office:

(i) Licences will specify one of two levels of procedure (basic or advanced) which correspond to the required training modules (basic equates to modules 1-3 and advanced to modules 1-4) – an illustrative list of techniques which would fall into the basic category will be produced;

(ii) In some limited cases, animals will be specified by group (e.g. rodents) rather than by individual species;

(iii) Sponsors will be required to make more focused declarations about applicants' training and, possibly, eligibility; and

(iv) Conditions will be added to both personal and project licences to strengthen the arrangements for the supervision of licensees.

15. Revised standard licence conditions will require assessments of competence to be noted in the personal licensee's records by the nominated supervisor. Inspectors will then be able to determine whether procedures have been authorised and whether licence conditions are being fully met.

EVALUATION OF THE PROPOSAL

16. Our first concern in evaluating these proposals was whether they might adversely affect animal welfare. We do not believe that they will. Implementing the proposals would allow Inspectorate resources to be re-deployed to deal more effectively with areas where their scientific expertise and professional judgement can best be used: the assessment of project licence applications and inspection. Their work will be directed, therefore, less at unnecessary bureaucracy and more towards the support of animal welfare and the implementation of the letter and spirit of the Act.

17. Modifying the personal licence system as proposed will achieve three ends. It will:

(i) Acknowledge that responsibility for ensuring supervision of technical competence lies with the project licence holder, and not with the named persons or the inspector who advises on a licence application;

(ii) Recognise the contribution and reinforce the importance of the accredited training programme; and

(iii) Remove the mismatches which currently occur between the excessive detail in the personal licence and the technical requirement of the project licence by linking the personal licence authority with the wider grouping of techniques and species in the training modules.

18. There should also be a decrease in the number of technical infringements of licence conditions – essentially minor infringements caused by the present level of detail within licences and which do not cause any additional suffering or adversely affect the study being carried out.

19. We believe that the proposed changes to the personal licence will continue to meet the requirements of Section 4 of the Act.

20. No changes to the project licence or certificate of designation are proposed in this chapter. The personal licence will remain an integral part of the wider and comprehensive licensing framework.

21. No additional burden on the licence applicant, sponsor or supervisor is foreseen. This may not appear consistent with paragraph 17(i) above. We contend, however, that project licence holders should already be performing this function; the new arrangements reinforce this.

22. We will be asking our Education and Training Sub-Committee to consider whether, under the new system, the need for some form of periodic retraining should be explored with the accrediting bodies.

23. The main disadvantage lies in the perception of greater latitude in the application of the Act enabling the licensee to perform a broad range of procedures on several species. However this will always be balanced by the specification of authorities in the project licence and the supervisory role of the project licence holder. We must also be satisfied that certificate holders, assisted by their named persons, are not disadvantaged in meeting their obligation to take all reasonable steps to prevent the performance of unauthorised procedures.

24. We are concerned that these proposals might disadvantage those who have set up computerised or other systems to monitor licence authorities and to ensure that unauthorised procedures are not carried out. We welcome, therefore, the Home Office proposal to consult more widely on these proposals before deciding whether to implement them. We look forward to being able to comment further in the light of any responses received.

CONCLUSIONS

25. Whilst the proposed system does offer some advantages over the present system, particularly in terms of reducing unnecessary bureaucracy, the Committee does still have concerns about how it might operate in practice. We believe, however, that it is worth exploring further through a wider consultation process which, we understand, the Home Office will carry out following the publication of this report. We look forward to seeing the results in the New Year and will offer further advice thereafter.

ANNEX F

Minister Response: Better Regulation – Advice on Personal Licensing and Mandatory Training in relation to Better Regulation and the Home Office Simplification Plan.

Sara Nathan
Chair of the Animal Procedures Committee
APC Secretariat
3rd Floor Seacole building
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SW1P 4DF 16 MAY 2007

ADVICE ON THE OPERATION OF THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986

Thank you for your letter of 25 April 2007 providing advice on the simplification of personal licences and mandatory training.

I am grateful for the thorough consideration the Committee has given to this issue and for its timely advice. The advice is extremely helpful and will now be fed into the review of the personal licence application process and information requirements that is being carried out as part of the ASPD Better Regulation Programme.

The review is due to be completed by the end of the year.

Yours sincerely

JOAN RYAN
Parliamentary Under Secretary of State
Home Office

ANNEX G

Full Report: Better Regulation – The criteria for the discharge of genetically altered animals from the controls of the Animals (Scientific Procedures) Act 1986.

Note: For the purposes of this document, the Working Group has used the term Genetically Altered (GA) as distinct from Genetically Modified (GM). The meaning of GA is defined as that used by the Home Office, Animal in Scientific Procedures Division.

A genetically altered animal is defined as:– an animal in which the heritable DNA has been intentionally altered, or which carries a genetic mutation recognised as harmful, or the progeny of such an animal.

This definition includes

- Animals produced by genetic modification [as defined in the Genetically Modified Organisms (Contained Use) Regulations 2000].
- Animals produced by induced mutagenesis
- Animals created by nuclear transfer procedures
- Animals created by the use of certain selective breeding strategies
- Harmful mutant lines arising from spontaneous mutations

It excludes animals with changes that are not heritable, such as gene therapy or DNA immunisation.

Please see point 1.11 for an explanation of the possible implications regarding the interpretation of this distinction.

1. Preliminary Discussions

1.1. It is currently possible to discharge GA animals from the Animal (Scientific Procedures) Act 1986 if there are full health records for two generations including records of the full life span over one generation, showing no adverse effects. The basis for this requirement is that some adverse effects may arise in the second generation but not in the first[16]. However, this level of evidence is perceived to be excessive by some since in the majority of cases animals from GA lines are not normally maintained beyond 6-12 months of age.

1.2. If GA animals were found to suffer after removal from the Animal (Scientific Procedures) Act 1986, some mechanism would have to be in place to ensure that the GA line in question came back under its control.

1.3. It is generally accepted as anomalous that GA animal lines lacking a specific gene through a spontaneous (normal) mutation may be outside of the Animal (Scientific Procedures) Act 1986 if no welfare problems are detected, whereas lines where the same gene had been deliberately manipulated would fall within it.

Proposal for change.

1.4. The Minister has asked for the Committee's advice on whether the current discharge criteria should be revised in the light of the current state of knowledge on welfare assessments and phenotyping methods, in order to ensure that animals are not placed within the controls of the Animal (Scientific Procedures) Act 1986 if they are not likely to suffer, but without weakening the provisions for the welfare of protected animals.

[16] Broom DM (1997) Assessing the welfare of transgenic animals. In Zutphen LFM & van der Meer M (eds) *Welfare Aspects of Transgenic Animals*, Springer, pp. 58-67

1.5. To maintain welfare standards (as distinct from health standards) it was agreed that before a GA animal could be discharged from the Animal (Scientific Procedures) Act 1986 there would need to be a structured, formal welfare assessment (or other form of post release monitoring) carried out to provide sufficient objective evidence that, despite genetic alteration, such animals did not have adverse phenotypes that could cause physical or psychological suffering.

Points to consider in relation to changing existing regulation.

1.6. Experimentally produced GA animals (primarily rodents and fish) are major contributors to the total number of animals reported annually as having procedures carried out on them under the Animal (Scientific Procedures) Act 1986. Other species currently listed in the annual statistics as genetically modified or with a harmful genetic defect are rabbits, sheep, domestic fowl and amphibians. However, it was felt that any changes to regulations should be limited to rodents, amphibians and fish in the first instance.

1.7. Breeding of any GA lines can only be carried out under a project license by trained personnel holding personal licences, or with appropriate delegated authority.

1.8. Spontaneously occurring mutants do not automatically come under the Act (except when kept for scientific purposes) even though they are subject to the same "suffering and severity" issues as those that are experimentally induced.

1.9. There is always some uncertainty about the level and nature of adverse effects that might occur following a deliberate genetic manipulation. There is therefore no obvious case for the creation of a GA line to fall outside of the Animal (Scientific Procedures) Act 1986 as it is difficult to be certain that no adverse effects will occur. However, it is generally accepted that a large number of GA lines, once established, show normal general behaviour and no apparent suffering that can be attributed to the genetic alteration.

1.10. GA animals are generally kept in controlled environments. If released from the Animal (Scientific Procedures) Act 1986 some GA lines might ultimately be housed in more conventional environments where their physiology could be affected in unpredictable ways. GA animals released from the Act would therefore still have to be monitored to determine whether being kept under different environmental conditions did result in them experiencing pain, suffering, distress or lasting harm. Alternatively, they may have to be released on condition that the same environmental conditions are maintained. Strategies to rapidly detect and alleviate suffering would be required, as is normal procedure required by the Animal (Scientific Procedures) Act 1986. There would also need to be a robust means of tracking the fate of "ex-Act" animals following release.

1.11. Notwithstanding the point above, there is one issue the Working Group were not in a position to consider: – would it be permitted to keep some GA animals released from the Animal (Scientific Procedures) Act 1986 outside of secure, regulated environments? This is because the GM Act (Genetically Modified Organisms (Contained Use) Regulations 2000: Defra) requires only GM animals to be contained within a secure environment unless given a consented release order. A small number of GA lines might not be covered by the GM Act so this will have to be clarified before any GA line is considered for release from the Animal (Scientific Procedures) Act 1986.

1.12. However, under the conditions issued with Certificates of Designation, any GA animal having been subjected to a completed series of regulated procedures shall continue to be kept at a designated establishment under the supervision of a veterinary surgeon. If an animal were to meet specific criteria that might enable discharge from the Animals (Scientific Procedures) Act 1986 it would thus still remain at a designated establishment unless a named veterinary surgeon issued certification that it would not suffer if it ceased to be kept at a designated establishment. It is the Working Group's opinion that veterinary certification for such release would not be issued, particularly if GA animals were involved.

1.13. The group did generally agree that certain lines of animals that have biomarker inserts (for example *luciferase* gene systems or Cre-recombinase lines) are unlikely to suffer as a consequence of being GM animals. Thus, such animals are potentially suitable candidates for possible discharge from the Animal (Scientific Procedures) Act 1986. However, the actual numbers of animals affected might be quite small.

1.14. It was considered that applications would only be made if the period of observations required to be carried out on a GA line to apply for its release from the Animal (Scientific Procedures) Act 1986 was reduced. In general it was thought that a more realistic period of longevity (currently two generations with one full life span) would be the maximum expected lifespan of animals from a GA line for scientific purposes (i.e. 6 to 12 months). An exception would obviously be where age-related phenotypes were expected or animals were to be kept for longer periods.

1.15. Finally, to allay public concerns in connection with GA animals, it would be a useful precaution to emphasise that (i) full health and welfare records would be kept to monitor animals and ensure that they were not suffering any adverse effects, in the same way as required under the Act; and (ii) release from the Animals (Scientific Procedures) Act 1986 does not mean release from captivity and would not enter any food chain.

2. Welfare Assessment of GA Animals

The Working Group agreed that any decision on the feasibility of releasing GA animals from the Animals (Scientific Procedures) Act 1986 will critically depend upon the ability to assess their welfare effectively, both before and after release.

One of the Group's members reviewed the scientific literature on current developments in welfare assessment of GA animals. Some suggestions from that the review are set out below and further information is given in the Appendix Section 7.

- The approach recommended by researchers addressing this issue is to use welfare "score sheets" to assess GA animal welfare and to detect whether adverse phenotypes are present.
- This should be carried out at various life stages, taking into account the fact that some adverse effects do not become apparent until adulthood or towards the end of an animal's life.
- One research group (Mertens and Rülicke) has produced a fully evaluated assessment protocol, but work is ongoing by others and there is no evidence of an agreed method that is in common use.
- It takes time to assess the welfare of GA animals properly; resource issues (e.g. with respect to staffing levels) have been identified when trialling assessment schemes.

3. Considerations of the Working Group

Summary of the Meeting:

3.1. Discussion of information gathered on GA 'Welfare' screening.

The Group agreed that currently there is no formally accepted welfare screening methodology that could be applied to any GA line under consideration for discharge from the Animals (Scientific Procedures) Act 1986.

Dr Hawkins contacted a variety of EU colleagues and contacts and found that a COST Paper is being drafted on a related matter, and that pre-weaning assessment methodologies are also in development.

Following the deliberations of the previous working group meetings it was clear that until a formal welfare assessment of GA animals could be determined, the Working Group did not feel that it would be able to endorse a proposal to discharge such animals from the Animals (Scientific Procedures) Act 1986.

3.2. Proposed advantages and disadvantages of changing the criteria for the release of GA Animals from the controls of the Animals (Scientific Procedures) Act 1986.

The Group felt that it would be useful to lay out the advantages and disadvantages by relating them to; (i) the Three Rs, (ii) science (note that this refers to the advantages and disadvantages *for scientists*, and does not refer to scientific validity) and (iii) reducing bureaucracy.

3.3. What advantages would result from releasing GA animals from the Animals (Scientific Procedures) Act 1986.

Three Rs:

3.3a. Releasing GA animals from the Act would require adequate welfare assessment, which would encourage and promote the use of comprehensive welfare screens. This would reduce the potential for suffering, as adverse effects would be detected and alleviated more effectively. Such a system could also help promote more widespread improvements in welfare assessment and the uptake of more objective monitoring schemes.

3.3b. Some lines could potentially be bred and supplied more efficiently through commercial breeders, since under the proposed changes, licences would not be required for breeding lines released from the Act.

Science:

3.3c. A comprehensive assessment screen would have to be used to establish that welfare is not compromised, which would potentially help counter the apparent public perception that all GM animals experience suffering.

3.3d. Releasing GA animals from the Animals (Scientific Procedures) Act 1986 would provide more logical consistency in a system where, at present, GA animal lines lacking a specific gene through a spontaneous (normal) mutation may be outside of the Act, whereas lines where the same gene had been deliberately manipulated would fall within it (irrespective of whether any harmful phenotype is reported or not).

Bureaucracy:

3.3e. It would reduce time taken in bureaucracy, in particular the paperwork involved in animal movement forms for specific GA animals.

3.3f. It would reduce the risk of technical infringements, for example where people may breed GA lines without realising that both project and personal licence cover is required.

3.4 What disadvantages would result from releasing GA animals from the Animals (Scientific Procedures) Act 1986

Three Rs:

3.4a. There may be concerns that the welfare monitoring of GA lines could be less stringent once they are outside the Animals (Scientific Procedures) Act 1986. There is also no indication as to what mechanisms would be in place to ensure that such lines would be brought back under the Act if adverse effects became apparent.

3.4b. There are currently no fully validated welfare assessment protocols, that have been endorsed by professional bodies, that could form the basis of an effective “welfare” screen for GA (or even non-GA) lines.

3.4c. Release from the Act could result in GA animals undergoing changes in diet or environmental conditions that might subsequently reveal a negative impact on health and welfare.

Science:

3.4d. Under the current Animals (Scientific Procedures) Act 1986 any form of bio-sampling for the specific purpose of genotyping (i.e. not solely carried out for individual identification) is a regulated procedure. The vast majority of GM animals need to be genotyped, so even if a line was released from the Animals (Scientific Procedures) Act 1986 there would not be a large reduction in the number of reported procedures. (NB this would clearly not be the case were the wording of the current Act to be altered to permit tissue taken for identification to be used for other purposes)

3.4e. Technically, releasing GA animals from the Animals (Scientific Procedures) Act 1986 would result in an under reporting of the number of animals used for scientific procedures. This could be interpreted negatively by the public and lead to perceptions that numbers are being artificially reduced for political purposes, or that there has been a reduction in openness and transparency relating to animal use. There may also be concerns that GA animals could end up being housed outside of designated establishments (for example entering the food chain or being released into the wild).

3.4f. No assessment protocol could be completely effective, so there would be occasions where GA lines would have to be brought back under the Animals (Scientific Procedures) Act 1986. Such cases might result in adverse publicity and reduced public confidence in the validity of the assessment and release protocol.

3.4g. Even if welfare assessment protocols were to be agreed upon, they might prove too onerous for many organisations to contemplate using them.

Bureaucracy:

3.4h. Once released from the Animals (Scientific Procedures) Act 1986, GA animal handling would be controlled under the Defra; Genetically Modified Organisms (Deliberate Release) Regulations 2002. Nevertheless, it was questioned whether there was sufficient overlap between the two legislative processes (See discussion point 1.11 – only GM animals would be covered, not all GA).

3.4i In contrast to point 3.3f, the Group could foresee a potential increase in the incidence of accidental infringements, without welfare implications, caused by miss-classification of animals. Though such technicalities could be classed as an administrative failure, this issue is important since the point of this Better Regulation exercise is to reduce such problems for establishments.

3.5 Additional considerations regarding GA lines carrying reporter genes or region-specific or inducible constructs as distinct from other GA lines.

The sub-Committee considered whether GA lines created for the purpose of visualising genes, or as part of the process for the control of spatial and temporal aspects of genetic modification, should be considered as distinct from other GA lines. These would include: (1) reporter constructs (e.g. luciferase, lac-z, green fluorescent protein etc.), (2) constructs that can only be used to delete or over-express genes when in combination (through breeding) with other constructs (e.g. Cre-Lox) or (3) lines with inducible constructs that allow a specific genetic modification to occur at any point in time following the administration of a chemical agent (e.g. tetracycline or tamoxifen. The reasoning behind this is that that such specific lines should, by definition, exhibit no harmful phenotype and could only do so following their exposure to a particular 'trigger' factor (e.g. when a particular chemical is administered to the animals or when they are bred together with another GA line).

It was recognised that the activation of any "trigger factors" for scientific purposes would obviously bring such animals under the Animals (Scientific Procedures) Act 1986 but it was felt that there would be very few instances where researchers might wish to remove GM lines with inducible constructs from the Animals (Scientific Procedures) Act 1986.

In general it was concluded that releasing the above types of animals from the Act, in conjunction with appropriate welfare assessment and monitoring protocols and other relevant safeguards, could provide a useful "test case" for helping to validate the process and perhaps lead to the consideration of applications for releasing other types of GA lines in the future.

3.6 Working Group Proposals.

The sub-committee concluded that there were four options that it could suggest in relation to the Minister's request for advice regarding revision of the current discharge criteria for GA animals under the Animals (Scientific Procedures) Act 1986. These are listed below in bold, with supplementary comments in italics.

(1) Keep the current rules and modify them to remove any ambiguity by stating that all GA animals must remain under the auspices of the Animals (Scientific Procedures) Act 1986.

This was viewed by the sub-committee as being the 'no release' option; removing the possibility of any flexibility within the interpretation of the Animals (Scientific Procedures) Act 1986. As a secondary impact, this option reduces any driver for developing an effective GA animal welfare assessment screen.

(2) Keep the current rules but recommend that a review of the situation be conducted after an acceptable welfare screening protocol has been validated.

This option allows for flexibility in the future, such that new developments in welfare assessment could be incorporated into the implementation of the Act. However, it would rely on industry or academia/industry collaboration taking the lead in developing an acceptable welfare assessment screen.

(3) Adopt (2) but make an immediate exception for reporter and inducible GM construct lines subject to a pilot study of GA welfare screening to confirm absence of harmful phenotypes.

This was considered to be the most favourable proposition, as lines carrying reporter gene sequences, or constructs that can only be used for GM following exposure to other "trigger" factors, are likely to present relatively low risk with regard to the likelihood of adverse phenotypes. This option also includes a driver to develop a welfare screen, as this is commensurate with the release of GA animals. It also has a potential 3Rs benefit in that it could lead to more efficient utilisation of such lines in future.

(4) Adopt (3) but allow all GA animals to be released from the Act, while a standardised welfare screen is developed in parallel.

The Sub-committee considered that this option would be difficult to control and would not be appropriate in the absence of properly evaluated and accepted welfare screens.

The majority view of the Working Group was that any welfare screen would need to set the type, scale and duration of quantitative welfare measurements at a practical level for scientific establishments. It was envisaged that the responsibility for post release monitoring of animals would lie with the holding establishment rather than the Animals (Scientific Procedures) Inspectorate.

The precise details of an acceptable screen were considered outside the remit of this initial exercise and the development of such an assessment system would require further consultation with experts and professional bodies.

It should also be noted that, with respect to bureaucracy, it would be necessary to test stakeholder opinion regarding the acceptability of developing a welfare assessment screen in addition to specialist phenotype screens. The Group were also mindful that most establishments already carry out animal health monitoring which is likely to

involve some welfare assessment. What is recommended here is that a further, validated post release process is developed.

However, the establishment of an effective pre – and post-release assessment scheme could ultimately lead to broader significant benefits for both animal welfare and science, not just GA animal monitoring.

4. Animal Procedures Committee discussion.

The Working Group presented their proposals and supporting information to the full Committee for their consideration. The Committee endorsed the Working Group's conclusions. However, in the subsequent discussion Committee members raised a series of issues, listed below, for which there has been insufficient time to provide further opinion.

- At the Animals (Scientific Procedures) Act 1986 conception it is believed that legislators took a precautionary approach to providing guidance on the possibility of releasing animals from the controls of the Act, largely because of a lack scientific evaluation of the harmful consequences and likelihoods from such an action. The Committee would have discussed if the precautionary approach assumption is still valid in light of GA technological advances and current welfare knowledge.

- Given the suggestion to develop definitive welfare assessment for GA animal release and the prediction that this may increase beaurocracy, the Committee would have also wished to explore how further welfare assessment might affect the current approaches involving veterinary (professinal) judgement and evaluate the differences and similarities between the two approaches.

To conclude the Committee would ask that this report be viewed as a preliminary paper; consideration for the discharge of GA animals from Animals (Scientific Procedures) Act 1986 is an extremely far reaching topic. The Committee is aware that proposals presented in this report, if implemented, represent significant changes to current policy.

5. Appendix: Supplementary information on Welfare Assessment

Introduction

Most of the welfare assessment schemes have been set out and/or evaluated by (i) Mertens and Rülicke, (ii) van der Meer et al., (iii) Jegstrup et al. and (iv) the GA Mouse Welfare Assessment Working Group. Professor Nicol is also examining behaviour as an indicator of welfare status in an ongoing project funded by the NC3Rs.

Mertens & Rülicke

Mertens & Rülicke (1999) selected parameters from the literature and designed score sheets for (i) birth and first 24 hours; (ii) days 2-10; (iii) day 11 – weaning; (iv) weeks 4 to 12; (v) weeks 7 – 12, including first gestation/litter; and (vi) 13th week onwards. They describe a pilot study that found the score sheets to be feasible and recommend 10 complete life histories per genotype (5 of each sex) for basic characterisation and welfare assessment. The score sheets were available online but are no longer easy to find (hard copies are available).

More detail is given in Mertens & Rülicke (2000) which says that founders and individuals from the F1, F2 and F3 generations should be assessed. The authors state that the number of individuals required depends on a number of factors and suggest, as a rule of thumb, a minimum of 10 animals per genotype: wild type, hemi – or heterozygous and homozygous (5 of each sex) born in either F1 or F2 generation, i.e. 30 mice.

The most recent paper by Mertens and Rülicke (2007) does not set out any new schemes but is a summary of their project to date. The authors state that "the first few generations of newly created mutant strains (founders, F1 and F2) need to be characterised with respect to their phenotype using health and welfare assessment guidelines" to ensure that wellbeing is unaffected[17]. Claudia Mertens believes that full lifespan data is required.

van der Meer et al.
van der Meer et al. (1999) sets out a series of behavioural and morphological tests for neonatal transgenic mice, scored according to four levels of response; 0 (behaviour or response absent), 1 (signs of primitive response), 2 (clear but not yet mature response) or 3 (mature and full response in all aspects of execution such as coordination or strength). This is combined with data on life span, survival rate and *post mortem* pathology etc.

van der Meer et al. (2001) develops the scoring system further with a limited number of sensitive, easy to determine and non-invasive parameters (selected from the previous studies). There are three score sheets, two for the pre-weaning period (day 0 – day 6 and day 10/day 14) and one for the weaning and post-weaning period. The paper describes a trial of the sheets, in which it was found that monitoring on days 0 to 6 took < 5 min per litter of 4 –6 pups; days 10 and 14 took 5 – 10 min per litter; after weaning 15 – 20 min was required per litter. The authors conclude that score sheets are feasible provided that time and funding are sufficient and technicians are well-instructed. Ways of reducing monitoring time are suggested, e.g. binding sheets into a log book.

Jegstrup et al.
Jegstrup et al. (2003) suggests four goals for a GA welfare assessment protocol:

- reveal any special needs or problems with a transgenic strain;
- cover the informational needs of the purchaser/user of the strain for handling, housing and breeding;
- refine the transgenic animal model by recommending relevant humane endpoints;
- prevent the duplication of animal models already developed.

The authors state that the existing welfare evaluations in the literature cover different aspects and none of them fulfil all four of the goals that they set out[18]. They suggest that a way forward would be to combine current protocols and test the result on strains with different welfare problems, selecting the most useful parameters and putting these together into a new welfare assessment procedure. They planned to continue their work in this area and, according to the authors, some papers are almost ready for publication.

GA Mouse Welfare Assessment Working Group

The report of the GA Mouse Welfare Assessment Working Group (2006) calls for a standardised approach to welfare assessment and outlines a framework that aims to achieve this. It also states that basic welfare checks carried out by technicians are likely to identify "only the more gross/obvious abnormalities" and recommends that more formal, structured welfare assessments should be carried out for (i) newly bred and maintained GA lines and (ii) GA lines newly introduced into the establishment. This should be done in neonates, at weaning and then for the period for which adults are normally maintained for each line.

Another notable point from the Working Group's report is that, in the members' experience, information relating to the animals' welfare and care is frequently omitted when GA mice are transferred between research establishments (hence the requirement for a mouse passport). This suggests that there is also a risk that relevant information could be omitted if GA lines are discharged from the Act – unless changes are made to the current transfer paperwork.

[17] Mertens M & Rülicke T (2007) Welfare assessment and phenotype characterisation of transgenic mice. ALTEX **24:** 46-48

[18] They cite Morton & Griffiths (1985), Lloyd & Wolfensohn (1999), Costa (1997), van der Meer et al. (2001a and b), Mertens & Rülicke (1999), Rogers et al. (1999) and Irwin (1968).

Publications addressing welfare assessment of GA animals

GA Mouse Welfare Assessment Working Group (2006) *Assessing the Welfare of Genetically Altered Mice*. www.nc3rs.org.uk

Jegstrup I, Thon R, Hansen AK & Ritskes Hoitinga M (2003) Characterization of transgenic mice – a comparison of protocols for welfare evaluation and phenotype characterization of mice with a suggestion on a future certificate of instruction. *Laboratory Animals* **37:** 1-9

Mertens C & Rülicke T (1999) Score sheets for the monitoring of transgenic mice. *Animal Welfare* **8:** 433-438

Mertens C & Rülicke T (2000) Phenotype characterization and welfare assessment of transgenic rodents (mice). *JAAWS* **3:** 127-139

van der Meer M, Costa P, Baumans V, Olivier B & van Zutphen B (1999) Welfare assessment of transgenic animals: Behavioural responses and morphological development of newborn mice. *ATLA* **27:** 857-868.

van der Meer M, Rolls A, Baumans V, Olivier B & van Zutphen LFM (2001) Use of score sheets for welfare assessment of transgenic mice. *Laboratory Animals* **35:** 379-389.

Background to Better Regulation

Following recent reviews, including the Cabinet Office review of regulation in the pharmaceutical sector, the Davidson Review and the PWC administrative burdens project, the aim of the ASPD better regulation programme is to simplify current regulatory requirements and administrative processes under the 1986 Act and reduce compliance costs whilst maintaining animal welfare standards. As part of this we will also benchmark current best practice and evaluate specific proposals, including some put forward by stakeholders. We are not considering proposals that would require changes to the legislation, or other Parliamentary time, to deliver.

The project will be overseen and managed within the framework for implementation of the Home Office Simplification Plan, and will actively involve operational level practitioners from both industry and academia; licence holders and named persons; and (to further ensure that the protection of animals is not compromised) those with a special interest in animal welfare.

2. The criteria for the discharge of genetically modified animals from the controls of the 1986 Act

The 1986 Act makes provision for the protection of animals used for experimental and other scientific purposes and subjected to regulated procedures which may cause pain, suffering distress or lasting harm. We take the view that genetically modified animals should be assumed to be potentially more prone to pain, suffering, distress or lasting harm ("harm"), as a result of the genetic alteration, than the background strain from which they are derived. As a result we regulate their production, breeding and use[19].

Nevertheless, we have always accepted that there will be some lines of genetically modified animals that are not predisposed to these harms, and have made administrative provision for the discharge of such lines of protected animals (at least for breeding purposes) from project licences. To date no such lines have been discharged from the controls of the Act and some stakeholders have commented recently that the burden of proof required to release a strain from the controls of the Act seems to be set so high as to prevent anyone from trying.

In the circumstances, the Minister would welcome the Committee's advice on whether the current discharge criteria should be revised in the light of the current state of knowledge on welfare assessments and phenotyping methods, in order to remove any unnecessary obstacles currently preventing strains being discharged from the controls of the Act without weakening the provisions for the welfare of protected animals.

[19] See "Guidance on Genetically Altered Animals and the Animals (Scientific Procedures) Act 1986"

ANNEX H

Minister's Response: The criteria for the discharge of genetically altered animals from the controls of the Animals (Scientific Procedures) Act 1986.

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29 April 2008

CRITERIA FOR THE RELEASE OF GENETICALLY ALTERED ANIMALS FROM THE CONTROLS OF THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986

Thank you for your letter of 8 November 2007 providing the Committee's advice on the criteria for the release of genetically altered animals from the controls of the Animals (Scientific Procedures) Act 1986.

I have noted the four options considered by the Committee and I understand that there would be significant potential benefits in pursuing options 2) and 3). Furthermore, I believe that it would be particularly helpful if the APC and the Inspectorate could work together in doing so. I understand that several designated establishments with expertise in this area may also be willing to help.

I hope the ARC will be in a position to assist with this work. I have asked ASPD policy officials and the Chief Inspector to discuss the practicalities with you direct.

Please convey my thanks to the Committee for the consideration it has given to this important issue.

Meg Hillier

ANNEX I

Full Report: Better Regulation: Summary report of the APC Working Group on the Ethical Review Process.

1. Background to the Commissioning of this paper

The working group was asked to suggest advice that the Animal Procedures Committee (APC) could give to the Minister regarding local ethical review practices and the burdens of providing a local Ethical Review Process (ERP) on designated establishments. Specifically, the group was asked to:

(i) Consider whether there is evidence that some local ERPs may be imposing local requirements that run counter to efficient and effective regulation;

(ii) Propose advice of good ERP practices.

The questions posed at 1 above ideally needs to be answered by empiric study, which was clearly outside the remit and resources of this group. However, the group was able to draw on the group's own knowledge of ERPs in commercial, other non-academic, and academic establishments; a number of studies including studies from abroad already in the public domain, the Animal (Scientific Procedures) Inspectorate Review of ERP (2001) and opinion polling of attendees at the October 2007 Certificate Holders Forum of which the Committee received 50 responses and thank all those for their contribution.

2. Requirements for ERPs

There are 213 (as of December 2006) establishments designated under the Animals (Scientific Procedures) Act 1986 (ASPA) comprising academic organisations such as universities and research institutes, non-academic organisations such as hospitals and government bodies, and commercial organisations such as pharmaceutical companies and contract houses; these groups representing very different operational structures and methods with respect to their use of animals.

The ASPA requirements for designated establishments to operate a local ethical review process is set out clearly in Appendix J of the Guidance to the Act and can be summarised to three key functions[20].

i. To consider applications for project licences, amendments to existing project licences, and additional availabilities, with reference to the justification for the use of animals, and the balance between the likely welfare cost to the animals and the expected scientific benefit: and to promote the development and uptake of the 3Rs.

ii To provide opportunities for discussion, and to provide a source of support, advice and awareness on these issues. This includes: ensuring that staff are kept up to date: best standards of care and accommodation are sought and implemented; managerial systems are appropriate; staff (including personal and project licence holders) are trained and competent; and general aspects of 3Rs are considered with respect to all aspects of animal production, care and use.

iii. Retrospective review of ongoing projects in order to promote the development and uptake of the 3Rs.

[20] Review of the 'Ethical Review Process' in Establishments Designated under the Animals (Scientific Procedures) Act 1986, Published November 2001.

3. Overall context for Ethical Review

The Working Group used their knowledge of these three functions and the information from the Certificate Holders' poll in relation to the Better Regulation challenge to identify the following five areas that establishments should consider when planning and implementing the Local Ethical Review Process.

3.1 ERP Ownership

The Ethical Review Process has been established as part of ASPA for almost 10 years. The principle of Ethical Review is generally accepted by those subject to it as a reasonable and potentially helpful aspect of policy, providing useful and structured institutional review of licence applications pending Home Office submission, and informed and considered advice to Certificate Holders on a range of issues relevant to the management of animal use in their establishments.

Whilst there is no Home Office requirement for local ERPs to include any sort of committee, it is understood that all current ERPs do include a committee in some form. The role of these committees varies; many are involved in protocol review, whilst some focus on oversight of the whole process. This diversity should be taken as reminders that Home Office regulation of local ERPs is concerned with output. How the output is reached and what standards are met lies primarily with the 'parent' establishment.

It is the establishment's own responsibility to decide how their ERP should be implemented. Moreover, while the Home Office is obliged to advise if a proposed local ERP does not appear to meet the regulatory controls there is no requirement on establishments to seek advice from the Home Office on local ERP implementation.

3.2 'Localisation'

It is important to reiterate that The Animals (Scientific Procedures) Act 1986 is not prescriptive on how such ERP functions are completed, instead it allows establishments sufficient scope to construct their ERPs so as to accommodate and reflect local needs such as the existing structure of the establishment.

Establishments can differ quite radically in structure and needs, even within the various business sectors. The Working Group therefore recommends that Institutions should clearly define the outputs that they require from their ERP rather than merely identifying ERP structures and methods of working.

It is inevitable that there is variation in quality of the local ERPs that have been established. Nonetheless, it is the Working Group's experience that well designed local ERPs can be conducted in such a manner that licensees and stakeholders view it not as an extra burden to be tolerated but as a valuable resource of considerable local expertise available at the establishment. This can provide a significant contribution to enhancing the scientific value of the study by ensuring that it is well constructed and that welfare costs are minimised.

3.3 How can local ERP be improved?

There is no requirement that local ERPs should use a committee structure. Over-large committees may become cumbersome, but one advantage of a committee is that they often have reporting lines, which can be used to mobilise resources and high level action in establishments. The use of pre-existing committees has been suggested as a route to avoid duplication and added workload.

New licence applications (Protocol Review) are just one output expected from an ERP and should not be an excessive part of its workload in relation to the other outputs (as highlighted in Appendix J of the Guidance to the Act). Local ERPs 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 Inspectorate will subsequently do

except in specific cases when the establishment justifies this to applicants. Assessments should be risk-based in their context, scope and speed, and take into account other existing review and assessments, such as independent peer or grant review.

Establishments should consider how to carry out the process both fully and expeditiously. Subgroups, parallel review, the use of locally available information technology, and delegated authority from the Certificate Holder, can be a significant help in avoiding unnecessary delay. Such possibilities are dealt with further in Section 4.3 of this document.

3.4 Transparency

It is important that applicants are aware of their local ERP's structure and operation. If they are not, then it is very unlikely that they will feel that the ERP is a positive process. Institutions should ensure that the ERP's overall assessment criteria, basis of risk assessment, submission processes, expected timelines and outputs are available to applicants within the establishment. In the interests of transparency establishments should consider publicising the rationale and outputs of its local ERP at least internally and, ideally, externally as part of the establishment's statement of its position on the use of animals.

Regular monitoring of the various ERP activities, outputs and resources should be conducted and, if necessary, local policy should be reviewed and refined in response to local circumstances and changing needs.

3.5 Home Office involvement during local ERP consideration of licence applications.

The informal input from the HOI at an early stage of licence applications is generally welcomed by all parties and may allow applications to progress more efficiently through the establishment's ERP as well as their licence approval process. On the other hand, establishments should be careful to avoid any misguided relaxation of ERP's attention on the assumption that the application already meets the HOI's standards for submission. Moreover, ERPs should be aware that waiting for an inspector's response might result in unnecessary delays.

From the applicant's point of view the time taken to turn around an application depends on the time taken by the local ERP and the Home Office. Many licence applications take up to two months to go through local ERP, and some take considerably longer. The Working Group considers that shorter review times would seem to be an obtainable objective. Amendments to existing licences must also go through local ERP and are usually in response to a change in circumstances, new knowledge, or availability of new research tools. They are therefore often much more urgent than licence applications, the need for which is often known well in advance. It is very important that local ERPs should be constructed so as to minimise delays for licence amendments since this can be very damaging to research projects.

Whilst local ERPs should not try to anticipate the HOI's assessment of applications, some duplication of consideration is inevitable. It is important that local ERPs recognise that their own local perspective on proposals adds value which is distinct from that of the HOI.

4. Specific suggestions from the Working Group

4.1. Systems for running Local ERPs

1. There is no requirement for local ERPs to use any specified method or template in their operation. Whilst discussion between establishments is encouraged and can help stimulate new ideas in ERP, any move towards a national or group standard ERP would be unhelpful and likely to detract from the valuable flexibility of local approach allowed in ERP.

2. Establishments should be encouraged to explore the possibilities of adapting existing systems, such as existing committees, as an alternative to creating an additional and specific ERP committee. However, lay members should normally be represented in review or oversight of review.

3. The ERP's overall assessment criteria, basis of risk assessment, submission processes, expected timelines and outputs should be available to applicants within the establishment, and consideration given to publishing externally the overall desired outputs.

4. Committees may review proposals, or may oversee other systems. Many establishments have utilised or adapted IT systems to expedite the review process rather than wait for scheduled meetings or rely on slower, less flexible postal systems outside committee.

5. The current Home Office guidance in Appendix J of the Guidance on the Operation of the Act advises that ERP should involve "as many people as possible". This is a potential encouragement to unwieldy systems and the guidance should rather encourage a variety of participants from a range of perspectives, possibly drawing upon existing local sources of expertise and knowledge, such as a human ethics committee.

6. The use of appropriate deputies can help to avoid delays, but it is important that deputies are appointed reserve members of ERP and are fully briefed on their role and responsibilities.

7. Scheduled committee meetings with a low licensing workload held throughout the year can help to encourage productive consideration of other important ERP matters, such as promotion of the 3Rs and retrospective reviewing.

4.2. Relationship to Home Office's licence assessment

1. ERPs assessment of Project Licence applications or proposed amendments should be independent of the Inspectorate's assessment.

2. Receiving the HOI's early comments on licence drafts prior to ERP can be very helpful, and applicants are normally encouraged to discuss proposals with the HOI at an early stage.

3. The informed scrutiny of applications by experienced reviewers in ERP will inevitably improve applications at an early stage, and should assist the HOI to reduce subsequent delays.

4.3. Benchmarks for time taken in ERP licence processing

1. It would be unrealistic to suggest hard-and-fast expectations of ERPs in dealing with licence assessments, since applications and establishment circumstances are so widely varied and we encourage diversity of processes, local ownership, transparency perhaps through the publication of written documentation, terms of reference and details of local expertise.

2. Significant reductions in review times can be achieved in licence applications to continue work and/or with mild, moderate or unclassified severity limits. By using review systems outside formal committees and employing electronic communication, ERP output turn-around could be dramatically enhanced.

3. Applications for amendments to licences can be vastly different in scope. A fast-track system of review for the majority of project licence applications, amendments and retrospective reviews can be carried out by a sub-group of ERP. This is important and should be implemented wherever possible to reduce processing times. Such fast-track panels should represent key ERP perspectives, such as the NVS, NACWO, an experienced project licence holder, lay person and statistician.

In situations where there are no likely animal welfare implications in an amendment application (for example

substituting a deputy licence holder), an "ultra-fast track" system could even be used, using perhaps only two or three key reviewers;

Fast-track systems should have clearly stated criteria for the eligibility of applications for fast-tracking, agreed by ERP and the Certificate Holder, who takes advice from this sub-group. Full ERP scrutiny may be reserved for potentially contentious applications, such as certain species, substantial severity, or novel procedures;

Fast-track systems should make best use of available technology to expedite reviews. Arranging meetings for such groups is often the cause of frustrating delays, but electronic reviewing can speed up the process significantly, especially if reviews are sent simultaneously to reviewers who can then see others' comments as they are made.

4. Where applications are deemed sufficiently serious to require the attention of a full ERP body, it should be understood by applicants that this is likely to take longer.

5. Establishments may find it productive to establish audit trails so that they may periodically examine their efficiency in carrying out licensing reviews.

6. One concern noted during this review was the delays caused by having to deal with more than one Ethical Review Process, for example where secondary availability is requested. Researchers are often unaware that applications will need to be considered by another establishment, and of any different requirements these may have. ERPs should therefore consider how to deal with requests for secondary availability, for example whether or not a full review is needed, or whether or not to concentrate on only the aspects of the programme of work to be conducted at their establishment, make this process transparent and available to all licensees intending to work at their establishment. Effective communication between the ERPs involved, for example sharing of outputs, should minimise any duplication of effort and minimise delays for applicants.

4.4. Need to promote good practice in ERP

1. Whilst mutual representation between ERPs in different establishments is encouraged, this is usually between limited sets or pairs of establishments, and many ERPs work essentially in isolation. General information on good practice is valuable to ERPs and in short supply. It is also understood that The RSPCA Research Animals Department and the LASA Education, Ethics and Training Sub-committee will be working together to produce guidance on fulfilling the seven core functions of the ERP during 2008.

2. It is important that means are identified for dissemination of information between or drawn from disparate ERPs. The objective should not be harmonisation for its own sake, but sharing of good practice amongst diverse local processes. Internal and external publication of the desired outputs of the ERP would provide a framework for this dissemination.

3. The HOI often routinely sits in on ERP discussions and may be well placed to give advice on good practice, possibly in discussions within ERP meetings. Alternatively the Certificate Holders' Forum may be appropriate, since ERP exists to advise Certificate Holders on ethical issues. However, it seems important to ensure that information is broadcasted to all levels in the ERP.

4. It is suggested that establishments both individually and collectively through groups such as the Certificate Holders Forum, can take far greater ownership of the outputs and process, by examining, developing, defining their local needs and conditions to produce a local process that more closely meets the stated outputs for point 7.2 (Ethical Review Process 1998) efficiently and adds greater local value to the process.

5. Referenced reports on improvements to ERP

APPENDIX J: THE ETHICAL REVIEW PROCESS. PP99-100; GUIDANCE ON THE OPERATION OF ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986.

REVIEW OF THE 'ETHICAL REVIEW PROCESS' IN ESTABLISHMENTS DESIGNATED UNDER THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986, PUBLISHED NOVEMBER 2001.

THE ETHICAL REVIEW PROCESS 1998; HOME OFFICE EXPLANATORY STATEMENT;http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/publications/guidance/ethical-review-process/ethicalprocess.pdf

HOUSE OF LORDS SELECT COMMITTEE ON ANIMAL EXPERIMENTS. 24TH JULY 2002.

APC REVIEW OF COST BENEFIT ASSESSMENT IN THE USE OF ANIMALS IN RESEARCH. JUNE 2003

PRINCIPLES AND PRACTICE IN ETHICAL REVIEW OF ANIMAL EXPERIMENTS ACROSS EUROPE. DECEMBER 2005.

Additional background Information

Smith, J.A. and Boyd, K.M. eds. (1991) Lives in the balance: the report of a working party of the Institute of Medical Ethics. Oxford University.

Smith , J.A. and Jennings, M (2002) A resource book for lay members of local ethical review process. Royal Society for the Prevention of Cruelty to Animals: Horsham UK.

Cooper, J and Jennings, M (2007) Perceptions of the ERP – summary of discussions at the 2007 RSPCA Lay Members Forum. Royal Society for the Prevention of Cruelty to Animals: Horsham UK.

ANNEX J

Minister Response: Better Regulation – Advice on Personal Licensing and Mandatory Training in relation to Better Regulation and the Home Office Simplification Plan.

Sara Nathan
Chair of the Animal Procedures Committee
APC Secretariat
3rd Floor Seacole building
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29 April 2008

ETHICAL REVIEW PROCESSES

Thank you for your letter of 27 February 2008 providing the Committee's advice on local ethical review processes operated by establishments designated under the Animals (Scientific Procedures) Act 1986.

I note that the Committee felt unable to say whether local ERPs are adding an unnecessary additional regulatory burden as this could only be established by empiric study, which was outside the Committees remit and resources. am, however, grateful for the specific suggestions to assist ERPs to operate efficiently and effectively set out in section 4 of the Committee's report, relating, in particular to:

- systems for running local ERPs;
- the relationship between the work of ERPs and the assessment of project licence applications undertaken by the lnspectorate;
- risk based and fast track systems for ERP review of project licence applications;
- increased transparency and accountability of ERPs to their own licence applicants; and
- sharing of good practice in ERPS, especially where licensees have shared availability between two or more establishments.

The Committee's suggestions are well-founded and constructive and we propose to bring all of them to the attention of Certificate Holders.

Please convey my thanks to the Committee for the consideration it has given to this issue.

Meg Hillier

ANNEX K

APC WORK PROGRAMME FOR 2008

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

OBJECTIVE	**TARGET DATE**
Primates Sub Committee	
Advise Home Office as required on suitability of overseas sources of primates.	Ongoing
Develop an overview of current situations/trends in the use of primates in medical research and the understanding of diseases, excluding regulatory toxicology.	Ongoing
Housing & Husbandry Sub Committee	
Continue to explore, with the Home Office, what mechanisms exist for promoting good practice and how these are used.	Ongoing
Welfare of fish used in experimentation	Ongoing
Education & Training Sub Committee	
Prepare a report on module 5 to present to main APC.	October 2008
Consider and report on issues relating to accreditation of training courses, including clarification of expectations and roles, assessment of trainees and auditing of courses.	October 2008

Applications Sub Committee	
Consider applications for project licences referred to the Committee by the Home Office for advice, and provide advice to Home Office.	As required

Suffering and Severity Working Group	
In light of successful preliminary pilot study on the retrospective assessment of suffering and severity, commission and monitor more widely scoped pilot study in conjunction with LASA.	Joint publication October 2008
Schedule 1 Working Group	
Review outstanding questions from the APC report on the use of CO2 and inert gases on rodents.	Feb 2008
Revision of Directive 86/609 Working Group	
The APC 86/609 Working Group, on behalf of the full APC, will continue to monitor further developments and to input as appropriate into this review process.	When required

ANNEX L

Dates of appointment for members of the Animal Procedures Committee

Member	Date of Appointment	End of term
Ms S Nathan	1st Feb 2006	31st Jan 2010
Dr J Doe	1st Feb 2005	31st Jan 2009
Dr M Festing*	5th Sept 2005	4th Sept 2009
Dr S Glendinning	1st Nov 2006	31st Oct 2010
Dr P Hawkins	1st Nov 2006	31st Oct 2010
Dr K Simpson	1st Nov 2006	31st Oct 2010
Dr R Hubrecht*	5th Sept 2005	4th Sept 2009
Dr P Hunt	1st April 2006	31st Mar 2010
Mr R Kemp	1st Feb 2005	31st Jan 2009
Prof. K Kendrick	1st Feb 2005	31st Jan 2009
Mr G Moore*	1st Dec 2006	Resigned Jan 2008
Dr T Morris*	5th Sept 2005	4th Sept 2009
Prof. D Oliver*	1st March 2007	28th Feb 2011
Prof J Pickard	1st Feb 2005	31st Jan 2009
Dr M Prescott	1st April 2006	31st March 2010

* indicates a maximum of two terms served.

A register of members' interests is available on the APC website (www.apc.gov.uk) and is updated when we are notified of any changes.

GLOSSARY

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

Embryonated egg – an egg which contains an embryo.

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

Ethology – the scientific study of animal behaviour.

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

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

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

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

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

List of Acronyms

APC – Animal Procedures Committee

ASPA – Animals (Scientific Procedures) Act 1986

LASA – Laboratory Animal Science Association

LAVA – Laboratory Animal Veterinary Association

NACWO – Named Animal Care and Welfare Officer

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

NVS – Named Veterinary Surgeons

PSC – Primate Sub Committee

RSPCA – Royal Society for the Prevention of Cruelty to Animals

Printed in the UK by The Stationery Office Limited
on behalf of the Controller of Her Majesty's Stationery Office
ID5568105 10/08 409960 19585

Published by TSO (The Stationery Office) and available from:

Online
www.tsoshop.co.uk

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