Report of the Animal Procedures Committee for 2009

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

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ANIMAL PROCEDURES COMMITTEE

Membership as at 31 December 2009

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

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

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

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

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

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

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

Robert KEMP FIAT (Hon), RAnTech – AstraZeneca (retired).

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

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

Ian PEERS BSc (Hons) PGCE M.ed. Psych PhD FRSS – Director of Statistics, AstraZeneca.

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 at the Edinburgh liver transplantation programme.

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

Sarah WOLFENSOHN BSc MA VetMB Cert LAS FSB Dip ECLAM MRCVS RCVS – Supervisor of Veterinary Services and Named Veterinary Surgeon at the University of Oxford.

APC Secretariat
Phil Banks
Philip Brenner

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

I am pleased to submit the Animal Procedures Committee Annual Report for 2009.

As you are aware the Committee has a role in overseeing the regulation of animal use for experimentation. Though we have no regulatory powers we believe that the advice offered has been and continues to be critically important (as emphasised in Sir David Omand's review of the Committee, paragraph 48), particularly so given the recent developments in the proposed revision of the Directive 86/609[1] of which a large proportion of the APC's time has been devoted.

The Committee is contributing to the decision processes and supports the proposal's main principles. The new proposal appears to contain some innovative measures which if rigorously adopted would lead to improvements for laboratory animals.

However, there is some concern over possible caveats, poor text and implications. Our main impetus will be to promote minimum levels of permitted suffering where no other alternatives exist, a defined system of authorisation, inspection of animal use and ethical evaluation to determine likely harms versus benefits.

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

SARA NATHAN

[1] Directive 86/609/EEC: The aim of the revision of Directive 86/609/EEC is to strengthen the protection of animals used for scientific purposes, contribute to the reduction of animal use and ensure that animals used in experiments receive appropriate care and humane treatment in line with Article 13 of the Treaty on the Functioning of European Union (TFEU) which recognises animals as sentient beings. A further aim is to ensure that the "Three Rs" principle of replacement, reduction and refinement of animal use is fully integrated into national legislation. http://register.consilium.europa.eu/pdf/en/10/st06/st06106-re01.en10.pdf

INTRODUCTION

This report describes the work carried out during 2009 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.

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

- Adherence to the Committee's Code of Conduct;

- Attendance at meetings of the full Committee, at Sub Committees and Working Groups and at the Committee's annual conference;

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

Members are able to comment on the appraisal, and if desired make representations to a senior Home Office official. Ministers take these appraisals into account when deciding whether a member should be re-appointed.

The full Committee met four times during 2009, in addition there were twelve Sub Committee/Working Group meetings. As in previous years we also held an annual conference that provided an additional useful forum for learning, discussion and debate. Annex C details the membership of the Committee's Sub Committees and Working Groups.

Annex A to this report sets out some information about the Committee, including its legislative background, the Ministers to which it reports and its membership. On joining the Committee, members agree to be bound by its Code of Conduct (see Annex B). 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[2].

[2] The APC website www.apc.homeoffice.gov.uk.

THE MAIN EVENTS FROM THE COMMITTEE'S WORK IN 2009 WERE :

- Responses to House of Lords Inquiry into Revision of Directive EC 86/609 (May 2009).
- Home Office Consultation into Revision of Directive EC 86/609 (July 2009).
- Received a French Delegation Parliamentary working party visit of OPECST (Parliamentary Office for evaluation of scientific and technological options) concerning interpretation and negotiations relating to the revision of Directive 86/609/EEC (Sept 2009).
- Audit of the APC Appointments Process (November 2009).
- Cabinet Office Review of Non Departmental Public Bodies (December 2009).
- Visits to designated establishments.

THE COMMITTEE'S WORK DURING 2009

1. There are four Sub Committees which are set up on a permanent basis to advise the Committee about issues of continuing interest and concern. These are the Applications Sub Committee, the Education and Training Sub Committee, the Housing and Husbandry Sub Committee and the Primate Sub Committee. Additionally, Working Groups are established for a particular finite purpose and are disbanded when the objective has been achieved.

Committee representation and visits

2. The Committee makes regular visits to establishments licensed under the Act. The Committee finds these very useful to inform its work as an advisory body, build up contacts and discuss relevant issues with those involved in animal research and testing. It also raises the profile and increases the outreach of the Committee and assists in familiarising members with the practical issues. The visits are by invitation and are not inspections or visits to ensure compliance with the Animals (Scientific Procedures) Act, which is the responsibility of the Home Office Inspectorate. It is also agreed that the Committee makes no public comment about visits. The Committee is very grateful for these invitations.

3. At the beginning of the year, the Chair visited the new Biomedical Sciences Building at Oxford University.

4. In September, the Chair and selected members met with a French delegation from the OPECST (Office Parlementaire D'évaluation des choix Scientifiques et Technologiques[3]) concerning the work of the APC, the UK legislation regulating the care and use of animals in research and testing, ethical issues and French discussions on the revision of EU Directive 86/609.

5. In October, members of the Committee attended the annual Certificate Holders Forum which brings together those responsible for designated establishments where research under the Animals (Scientific Procedures) Act is permitted to take place. These fora provide an opportunity to network with other Certificate Holders and for new Certificate Holders to gain training and continuous professional development and form links with other experienced Certificate Holders and the Home Office Inspectorate [4].

6. The Committee would like to thank Newcastle University for the invitation to visit its animal housing facilities in early November. Members viewed a range of species and discussed scientific and animal welfare issues with researchers, animal technologists and care staff.

7. The Chair was invited to be a judge at the National Centre for the 3Rs (NC3Rs) Parliamentary event to highlight the latest 3Rs research. The posters were judged on the quality of the science, the impact on the 3Rs and the ability of the poster presenters to communicate their research to a non-specialist audience. The Chair also sat as a member of the 2009 NC3Rs new board members recruitment panel.

The Committee's work following BUAV allegations

8. In November 2009 the British Union for the Abolition of Vivisection (BUAV) issued a report making a series of allegations concerning animal care and use at Wickham Laboratories, Fareham, Hampshire. The allegations were also the subject of a newspaper article in the Sunday Times. The then Home Office Minister, Meg Hillier, MP wrote to the BUAV and explained that she would ask the Chief Inspector to look into the alleged issues and that she

[3] Assemblée Nationale. www.assemblee-nationale.fr

[4] Holders of Certificates of Designation have responsibility not only for ensuring that the fabric and staffing of designated places are maintained to appropriate standards but also for ensuring that reasonable steps are taken to prevent unauthorised procedures and adequate training is available for all animal users. Statement of Home Office policy 1 February 1993.

had asked Committee experts to independently oversee the Inspectorate's investigation. It is envisaged that a report of the investigation will be completed during 2010.

Applications Sub Committee (ASC)

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

- any involving the proposed use of wild-caught non-human primates;
- any involving the proposed use of cats, dogs, Equidae[5] 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[6] 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.

10. Any such applications that are referred to the APC are initially discussed by the ASC by means of open dialogue and written questions with each applicant. The Sub Committee's deliberations where possible, are then put to the full Committee for final consideration. Finally the advice is forwarded to the Minister.

11. Guidance has been prepared by the Applications Sub-Committee to help those with project licence applications referred to the APC to understand and prepare for ASC review of the application[7]. This Guidance gives background to the review process and sets out some of the questions commonly asked of project licence applicants. Invariably, the ASC wishes to estimate the total suffering experienced by the animals on the project, during their whole life-times, and to rationalise this against the expected benefits resulting from the research. The ASC will also ask questions on consideration of the 3Rs, individual study and programme design, standards of housing and husbandry and the extent to which pain, suffering, distress and lasting harm can be avoided, recognised, alleviated and managed. All of this information is used in our harm/benefit assessment when deciding whether a project is justified.

12. There were three licence applications referred to the Committee for advice in 2009.

Central nervous system studies

13. In March the Home Office referred a project licence application to the APC for advice, as the proposed work involved central nervous system (CNS) studies in rats and it was likely that the whole project would be classified in the substantial severity band.

14. The ASC met the licence holder for clarification and further explanations of the proposal. The Sub Committee considered whether the proposed application would be likely to result in the advancement of knowledge relating to epileptic seizures and the extent to which refinements to the animal model had been developed. There was considerable debate regarding the possibility that animals could suffer during seizures, although seizures are not reported to be distressing in humans and it appears to be reasonable to extrapolate this consideration to other animals. The Sub Committee was less certain about the possibility of seizures causing lasting harm, however, and indicated this concern in their advice through the Committee to the Minister.

15. In July the ASC received two further referrals for advice from the Home Office.

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

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

[7] http://apc.homeoffice.gov.uk/reference/guidance_to_project_licence_applicants_update.pdf

Development of an experimental model for viral respiratory infection

16. The first referral was a new application with the overall aim of the development of an experimental model for viral respiratory infection. This application was considered by the ASC, which formulated a number of questions about the application, and the ASC were grateful to the applicants for the clarifications and explanations offered, which it found very useful. The ASC asked questions about several issues, including the likely level of suffering of the animals; the number of animals that it was proposed to use; housing and husbandry issues; operative and post-operative care. The Sub Committee also asked questions about the application of the three Rs and the estimated total suffering experienced by the animals on the project, in order to rationalise this against the expected benefits. The ASC considered that the applicants provided full and reasoned responses on the issues raised.

Medical countermeasures for chemical agents

17. The second referral was an amendment to an existing project licence involving the use of non-human primates. The ASC considered that the applicants provided full and reasoned responses to the questions asked by the Applications Sub Committee.

Work of the Primates Sub Committee (PSC)

18. The role of the Primates Sub Committee (PSC) is to advise the full Committee on issues relating to the acquisition, housing, care and use of non-human primates in scientific procedures. 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 specified overseas breeding and supplying centres deemed acceptable. As part of the acceptance process, Home Office Inspectors appraise the suitability of overseas centres using details provided about the breeding or supplying centres and information gained during Inspectorate visits to determine whether the centres meet acceptable standards of animal care and accommodation. Acceptance is based on these appraisals, APC consideration and further information supplied by UK users. In 2009 the PSC met twice to consider the acceptability of two establishments as a source of primates imported for use in research in the United Kingdom, one in Europe and one in Asia. There follows a summary of our advice, which is anonymised for security reasons.

Centre 1 – Europe

19. The PSC were advised that this centre had been established as a European holding and supplying facility by a macaque breeding centre outside Europe, already deemed acceptable by the Home Office. It was also explained that a satisfactory visit to the parent site by representatives of prospective UK importers had recently taken place, and that the supply facility, like the parent site, is accredited to Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International[8] standards.

20. The sub-committee acknowledged that whilst accreditation schemes, such as that operated by AAALAC International, can contribute to quality assurance at primate breeding centres, they are known to be founded on guidance documents with different standards to those of the UK. The APC has established its own criteria for the assessment of such centres; see the Committee's Primates report on the acceptance of overseas centres supplying UK laboratories section 6[9]. In light of these criteria the PSC agreed to recommend approval of this establishment subject to a request that the Home Office Inspectorate visit the facility.

Centre 2 – Asia

21. The PSC could not reach consensus over the appropriateness of the centre. The Inspectorate had visited the breeding centre in March 2009 and reported generally good facilities and high standards of care. However it

[8] http://www.aaalac.org/about/index.cfm

[9] http://apc.homeoffice.gov.uk/reference/primate-sources-report.pdf

was noted that primates were singly housed before export, which can cause suffering and distress in highly social animals with complex behavioural needs. The Sub Committee also felt that there was a lack of environmental enrichment in the hospital caging and a lack of foraging opportunities in the holding pens. However it was accepted that not acknowledging this centre as a potential source of primates could be counterproductive and hamper future engagement for improvement. As a compromise the sub committee agreed to propose that provisional acceptance be granted to allow one consignment to be supplied to the UK.

22. As noted in our 2007 Annual Report Sir David Weatherall published his report[10] on the of non-human primates in research, an independent investigation into the scientific basis for the past, current and future role of non-human primates in research, and identified a need to develop a national primate strategy. It recommended the establishment of centres of excellence for primate research and the need to review the scientific impact of primate use. In work following up the 2006 Weatherall recommendations the Sub Committee began by considering a draft cross government department output regarding future UK non-human primate policy.

Education and Training Sub Committee (ETSC)

23. The Education and Training Sub Committee met five times in 2009 and held a workshop for providers of training for Home Office licensees. The meetings focussed principally on drafting a report on the role of module 5 training for project licensees, which defines core competencies, and on advice regarding the learning outcomes appropriate for personal licence applicants.

24. One of the outputs from the workshop was that attendees developed a list of teaching elements that need to be covered in taught courses that contribute to module 5 training.

25. The Sub Committee also attended the annual meeting of the Accrediting Bodies and recommended that the Accrediting Bodies[11] forward Annual Reports of their activities to the Committee. These reports would include amongst other information the numbers of people attending each course and the numbers of those who have successfully passed the assessment.

Housing and Husbandry[12] Sub Committee (H&HSC)

26. The APC attaches great importance to the housing and husbandry of animals used in research, due to its impact on the lifetime welfare of the animals involved. In 2009 the Sub Committee completed the drafting and publication of guidance on appropriate methods of humane killing for fish (Annex E). This complements the report by the Schedule 1 working group in December 2006, which reviewed the euthanasia guidelines in Schedule 1 of the Animals (Scientific Procedures) Act 1986[13].

Suffering and Severity Working Group

27. The Suffering and Severity Working Group prepared and published a report on the perceived strengths and weaknesses of the current system of severity limits and bands as a way of prospectively assessing suffering and severity (Annex G).

[10] http://www.acmedsci.ac.uk/images/project/nhpdownl.pdf

[11] The Accrediting Bodies are responsible for all training programmes under schemes recognised by the Home Office. They are independent bodies which are not associated either with the body providing the training or with the Home Office as the regulating body. Accreditation seeks to achieve common high standards for licensee training. The Scottish Accreditation Board, The Society of Biology Accreditation Board and the Universities Accreditation Group are currently recognised for this purpose. All training programmes for applicants on personal and project licenses should be accredited by one of the Accrediting Bodies under a scheme recognised by the Home Office.

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

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

28. From the Guidance on the Operation of the Animals (Scientific Procedures) Act 1986[14], severity limits and bands are explained:

"5.43 Licence holders are required by conditions in both project and personal licences to minimise any pain, suffering, distress or lasting harm. They should approach the limit of severity which has been authorised only when absolutely necessary to meet the specified objective [Sections 10(2) and 5(5)].

5.48 The assessment of the severity band for the project as a whole reflects the number of animals used on each protocol and the actual suffering likely to be caused as a result. It is based on the overall level of cumulative suffering to be experienced by each animal, not just the single worst possible case. It takes into account the proportion of animals expected to reach the severity limit of the protocol and the duration of the exposure to that severity limit, the nature and intensity of the adverse effects, and the actions to be taken to relieve the suffering."

29. The Working Group concluded that the present system of severity limits allows the Home Office to control permissible suffering imposed on animals during the course of experiments.

30. However the Working Group recommended to the full Committee that the Home Office should consider the abolition of the banding system. Currently banding is used by the Home Office Inspectorate to help in harm benefit analysis and to identify projects which should be submitted to the Committee for further consideration. Both of these functions of banding can be achieved by the provision by licensees of information predicting the degree of suffering and numbers involved. This would assist licensees, Ethical Review Processes and the Inspectorate in judging the likely harms to animals. It may also be more informative to the public.

31. Moreover, if retrospective reporting is adopted within the revised EC Directive and therefore UK legislation (see APC/LASA October 2008 report[15]), there could be a simple modification of the table in the current licence application form that includes a column for stating the severity limit. This could be replaced with a description of the predicted level of suffering for each protocol, including the numbers of animals expected to experience it. The working group hopes that predicted suffering could then be matched against the actual suffering experienced by animals (following retrospective analysis) at the end of the project. This would provide an indication of the accuracy of the predictions of suffering made at the beginning of the application process.

32. Since the 2001 House of Lords Select Committee report on Animals in Scientific Procedures was issued, licensees can, under the present legislation, only be requested on a voluntary basis to provide project licence abstracts which are short narratives and provide much "prospective" information about what the licensed research will involve. Many, but not all, licensees do now provide this information. The information provided in the proposed modified table outlined in the APC/LASA report could be included as part of the abstracts which licensees currently produce and which are published via the Animals (Scientific Procedures) Division web site.

33. Such a system would offer more transparency and the Committee believes the Inspectorate could account for the costs and benefits of procedures, while the existing limits would remain as a control system.

Revision of Directive 86/609 Working Group

34. Much of the work of the APC in 2009 was devoted to commenting on the revision of European Commission (EC) Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes, led by the 86/609 Working Group.

35. This Working Group was set up to generate submissions from the APC on the revision of Directive 86/609 to relevant bodies such as the UK Home Office and House of Lords. Most of the Working Group's output has been

[14] http://www.archive.official-documents.co.uk/document/hoc/321/321.htm

[15] http://apc.homeoffice.gov.uk/reference/lasa_apc_final_report.pdf

reactive, in response to calls for information, but it has also proactively communicated with the Minister on issues of special concern.

36. In May 2009 the Committee submitted its response to the Call for Evidence relating to the proposed revision of the EC Directive on the Protection of Animals used for Scientific Purposes by the Environment & Agriculture Sub-Committee of the House of Lords European Union Select Committee[16].

37. In June the Committee responded to the Home Office call for consultation on the proposed new Directive, which included a request for consideration of the estimated financial costs and benefits of the revised Directive. A copy of the full response has been posted on the APC website[17].

38. The APC believes that there are some significant, positive elements to the draft Directive. These include the increase in scope (e.g. the purposes of the procedures that are regulated); explicit reference to the Three Rs and requirements for their implementation; clearer requirements for staff competence; requirement for inspections by the Member State; and detailed requirements for authorisation of projects involving regulated procedures.

39. However, the Committee also has some concerns regarding the way in which the Directive proposal has developed. Some of the potential benefits for both animal welfare and science throughout the EU have been weakened, to the extent that the requirements of the Directive fall below UK legislation in some areas. The APC believes that Member States should be able to implement higher standards than those set out in the Directive if they wish to do so, for example with respect to animal housing and care. It has made this point in all of its submissions on the revision of Directive 86/609 and also in a letter to the then Minister, Meg Hillier, in November 2009 (See Appendix I).

Infringements

40. The Home Office provides the Committee with an annual summary of infringements. These are breaches of the 1986 Act, or of licence or designated establishment conditions. Once Home Office action on the infringement has been completed a report is forwarded to the Committee for information. Under the current Home Office framework infringements are reported in four categories, A – D[18].

Category A Infringement

The characteristics of category A infringement may include the following:

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

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

Category B Infringement

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

[16] http://apc.homeoffice.gov.uk/reference/apc_response_house_of_lords.pdf

[17] http://apc.homeoffice.gov.uk/reference/apc_response_home_office.pdf

[18] http://www.homeoffice.gov.uk/publications/science/769901/animals-annual-report-2009

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

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

Category C Infringement

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

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

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

Category D Infringement

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

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

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

41. The Committee recognises that publishing material in relation to infringements may be in breach of the Data Protection requirements. For further explanation of the Inspectors Infringements process, please see the Compliance and Infringements section of the Animals Scientific Procedures Inspectorate & Division Annual Report 2009.

New Committee Members

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

43. Members of the APC are appointed as individuals, not as representatives of particular organisations. However, there are certain skills and backgrounds that this technical and specialised Committee will always require in its membership, such as knowledge of animal welfare science, awareness of the range of views on animal use held by the public, and experience in the use of animals in scientific procedures. There is also a need to have expertise that will assist in consideration of particular topics that come to prominence. In 2009 the APC requested applications from candidates with skills and backgrounds in the following:

- statistics and experimental design;
- biotechnology;
- primate husbandry; and,
- veterinary practice.

44. The result of the recruitment process was that five new APC members were appointed in 2009. These were Professor Hannah Buchanan-Smith, Professor of Psychology, University of Stirling; Mr Michael Dennis, Head of Primate Programme, Health Protection Agency; Dr Ian Peers, Director of Statistics, Astra Zeneca; Dr David Smith, Senior Director Toxicology, Astra Zeneca and Mrs Sarah Wolfensohn, Director of Veterinary Services, University of Oxford. Their skills and experience will be of great benefit to the Committee. Appointments were announced by written ministerial statement in both the House of Lords and House of Parliament on 30 April 2009.

45. During the year Dr Michael Festing, Dr Robert Hubrecht and Dr Tim Morris completed their second (and final) term of their appointment and retired from the Committee. The Chair and Committee thanks them for the valuable contribution they have made to its work.

Audit of the APC appointments process

46. The Government is committed to maintaining a public appointments process that is efficient, effective and proportionate. To comply with this requirement, a routine audit was carried out on behalf of the Office of the Commissioner for Public Appointments by consultants from Ernst and Young into the recruitment of committee members appointed in 2009. We expect their report on the conclusions of the audit to be published in 2010.

APC and independent scientific advice

47. There are more than seventy five current Scientific Advisory Committees (SACs) across government, providing much valued independent advice to Government of which the APC is one. In the light of the events involving one of the Home Office's other statutory scientific advisory committee – the Advisory Council on the Misuse of Drugs (ACMD), considerable effort was devoted by the Scientific Advisory Committee (SAC) community towards maintaining the relationships between SACs and Government. A high-level statement of principles around scientific advice to government was published in December 2009. This has fed into a consultation process currently underway by the Government Chief Scientific Adviser on *Guidelines on Scientific Analysis in Policy Making* which will conclude in 2010[19].

[19] http://www.bis.gov.uk/go-science/principles-of-scientific-advice-to-government

Cabinet Office Review of NDPBs

48. In line with Cabinet Office guidelines for the quinquennial review of non-departmental public bodies (NDPBs), the Home Office commissioned a review of the Animal Procedures Committee. The review commenced in October 2009, and concluded in January 2010.

49. The overall aim of the review was to satisfy Ministers that the Animal Procedures Committee, for which they are accountable, is discharging the function that it was set up to deliver and that it represents value for money for the public.

50. The review was conducted by Sir David Omand GCB[20], assisted by Dr Iain Williams, Head of Science Secretariat, Home Office. The review considered:

a) the functioning and processes of the APC to assess how it carries out its work;

b) the composition of the Committee and the roles of members, secretariat and officials;

c) how the APC's agenda is set, and how decisions on what to investigate are made;

d) how the APC arrives at its decisions and general working practices;

e) how advice is provided by the APC, including issues relating to transparency and communication;

f) the likely future workload of the APC, and key future issues;

g) the resources available to APC and the costs in undertaking their duties.

51. The Home Office asked the reviewer not to assess or revisit specific advice made by the APC or to review the legislation under which the NDPB is established. This review has therefore been conducted against the existing Terms of Reference of the APC that are set out in the current legislation.

52. Sir David Omand sought the views of the APC Chair and members, relevant Home Office and Northern Ireland policy and scientific staff, and the Home Office Animals Scientific Procedures Inspectorate. The views of other key stakeholders and interested parties were obtained through a consultation request placed on the APC web-site.

53. A copy of the review is published on the APC website[21]. It concluded that the APC provided an important function for the Home Office, in particular the reviewing of specific licence applications. It also referred to the added value the Committee provided in its publication of wider, generic issue reports. The review made 22 recommendations, details of which are given in Annex J of this report. The APC will be considering these in detail and will work to address them.

The Committee's work programme for 2010

54. The Committee's work programme for 2010 was discussed at the APC Annual Conference in November 2009. It was clear that advisory work associated with revisions to the 86/609 Directive and its future transposition into UK legislation regulating animal care and use would remain a priority. The Committee's work programme for 2010 is detailed in Annex K.

[20] Sir David Omand was Permanent Secretary of the Home Office from 1997 to 2000. He is now retired and acts as a Trustee of the Natural History Museum.

[21] http://apc.homeoffice.gov.uk/reference/report_2009_10_ndpb_review.pdf

ANNEX A

BACKGROUND INFORMATION ABOUT THE COMMITTEE

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

The Legislation

1. The Committee was first appointed in 1987 and was set up by sections 19 and 20 of the Animals (Scientific Procedures) Act 1986 ("the Act"). The Act replaced the Cruelty to Animals Act 1876. The Act requires the licensing of any experiment or other scientific procedure carried out on living, protected animals which may cause them pain, suffering, distress or lasting harm. The Act regulates scientific procedures carried out on all vertebrate species except humankind – that is mammals, reptiles, birds, amphibians and fish – and one invertebrate species, *Octopus vulgaris*.

2. The Act also requires the licensing of places where certain species of animal are bred for use in regulated procedures. The species whose breeding is regulated in this way are genetically modified sheep and pigs, all primates, dogs, cats, all of the most common types of rodent used in scientific procedures, rabbits, ferrets, and quail.

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

The Committee

4. The function of the Animal Procedures Committee is to provide the Home Secretary and the Northern Ireland Minister of Health, Social Services and Public Safety with independent advice about the Act and their functions under it. The two Ministers are responsible for appointing members of the Committee. Members are experts from a wide variety of backgrounds, and the list at the beginning of this report sets out the membership as at the end of 2008.

5. The Animals (Scientific Procedures) Act 1986 requires

- that there must be at least 12 people on the Committee (in addition to the Chair) and
- that: at least two-thirds of the members must have full registration as medical practitioners or veterinary surgeons, or be qualified in a biological subject relevant to the work of the Committee;
- at least one member must be a barrister, solicitor or advocate;
- at least half of the members must not have held a licence under the Act during the last six years; and
- the interests of animal welfare should be adequately represented (this has tended to mean, in practice, the appointment of members associated with animal welfare organisations, but all members pay high regard to animal welfare).
- By convention there is normally a philosopher on the Committee, although this is not a statutory requirement.

6. Members are appointed for terms of up to 4 years and can be re-appointed once. The 1986 Act specifies that payments may be made to the Chairman by way of remuneration, and that other members can receive reimbursement for any reasonable out of pocket expenses incurred by them in the performance of their duties. During the financial year 2009-10, the Home Office allocated budgets of up to £10,000 and £26,000 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, who administers the Act in England, Scotland and Wales. From May 2010, Lynne Featherstone MP took responsibility for research using animals. In Northern Ireland the administration of the 1986 Act is the responsibility of the Department of Health, Social Services and Public Safety (DHSSPSNI) for whom Michael McGimpsey MLA has been the responsible Minister.

ANNEX B

THE ANIMAL PROCEDURES COMMITTEE'S CODE OF CONDUCT

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

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

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

3. The 1986 Act adds that:

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

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

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

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

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

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

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

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

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

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

(ii) undergo any required induction training;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(iii) a criminal offence under insider dealing legislation

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

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

ANNEX C

MEMBERSHIP OF APC SUB COMMITTEES AND WORKING GROUPS AS AT 31 DECEMBER 2009.

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

Current sub committees and working groups and their memberships are listed below.

Education and Training Sub Committee

Mr Robert Kemp **(Chair)**
Dr Peter Hunt
Dr David Smith
Mrs Sarah Wolfensohn

Co-opted Members Module 5 working group
Dr Manuel Berdoy (Oxford University)
Mr Bryan Howard (Sheffield University)
Dr Maggy Jennings (RSPCA)

Primates Sub Committee

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

Housing and Husbandry Sub Committee

Professor Keith Kendrick **(Chair)**
Professor Hannah Buchanan-Smith
Mr Michael Dennis
Dr Penny Hawkins
Dr Mark Prescott

Applications Sub Committee

Ms Sara Nathan **(Chair)**
Dr John Doe
Professor Dawn Oliver or Dr Simon Glendinning
Dr Ian Peers
Professor John Pickard
Dr Mark Prescott
Mrs Sarah Wolfensohn

Schedule 1 Working Group

Mr Robert Kemp **(Chair)**
Dr John Doe
Dr Ken Simpson

Suffering and Severity Working Group

Professor Dawn Oliver **(Chair)**
Mr Robert Kemp
Dr David Smith

Revision of Directive 86/609 Working Group

Dr Penny Hawkins **(Chair)**
Dr Peter Hunt
Professor Dawn Oliver
Dr Ian Peers
Dr Ken Simpson
Dr David Smith

ANNEX D

APPLICATIONS SUB COMMITTEE: *MODUS OPERANDI*

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

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

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

3. When an application is received from the Home Office, it will be copied to the Secretariat for secure distribution to the Application sub committee. The Sub Committee will meet, interview the applicant if necessary, and formulate draft recommendations.

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

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

Rolling membership

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

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

ANNEX E

Supplementary Review of Schedule 1 of the Animals (Scientific Procedures) Act 1986

Appropriate methods of humane killing for fish

1. Background

In December 2006 the Animal Procedures Committee published its review of Schedule 1 of the Animals (Scientific Procedures) Act 1986: Appropriate methods of humane killing[22]. This report noted that there was a need for further consideration of fish euthanasia. Specifically, the Working Group was aware that further research is required into the humane killing of fish and the humane killing of embryonated eggs; and that these are areas of continuing debate and active ongoing research. The Housing and Husbandry subcommittee was asked by the APC to provide a supplementary report on the humane killing of fish.

To inform the sub-committee about the use of current techniques we sent out a questionnaire to 20 establishments. Four responses were received (see appendix) for which we were very grateful, but the sample was too small to provide a useful overview. The subcommittee also recruited a group of scientists involved in fish biology and welfare research to: assess the evidence relating to the techniques currently in use, identify where evidence is lacking and where further research is needed, and advise on other techniques that should be considered. These experts provided opinions on best practice when using current techniques that we have included in this report in the interests of promoting refinement.

As noted in the previous Schedule 1 report, both the method of killing and the handling techniques associated with the killing process should be humane. The previous report also pointed out that killing is not humane unless either the animal loses sensibility instantaneously, or very rapidly (over one or a few seconds), or where loss of consciousness takes longer but the technique does not result in poor welfare (in this context we take poor welfare to mean – pain, suffering or other strong unpleasant feelings during induction of unconsciousness).

1.1 Practical factors that affect the choice of humane killing technique

As in the previous report, when considering our recommendations, we took account of the handling techniques involved in each procedure as well as the actual killing method. We also considered other important factors including equipment, labour and other costs, aesthetic concerns[23] and the safety risk to personnel of using the method.

Due to the range of species, sizes and developmental stages of fish used for research, it is unlikely that a single method will be suitable for humane killing in all circumstances. Specific issues that need to be considered include the resistance of the species to anaesthetics or hypoxia (e.g. eels), and any anatomical adaptations that may impact on the process. Practical issues include the numbers of animals to be euthanased, which may be thousands of individuals in the case of some studies involving the use of larval or immature fish forms. There may be practical difficulties in the use of some methods where procedures are carried out at places other than a designated scientific establishment (e.g. field sites), as well as the need to consider potential risks to the environment arising from inadvertent release of chemical compounds. The choice of euthanasia technique may also be influenced by specific housing conditions. For example, the use of recirculation as opposed to flow through tank systems could restrict

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

[23] We gave the welfare of the animal priority over the aesthetic concerns for the staff during our considerations. However, expecting people to use techniques that they are not comfortable with can have a negative impact on staff morale and the culture of care. This can affect people's ability to empathise with animals, which has consequences for animal welfare.

the application of some chemical killing methods. The requirement to confirm death may be problematic when killing large numbers of animals. Moreover, if large numbers of animals are stunned at the same time there is the possibility that some animals might recover before death has been confirmed. Experimental design is another factor, for instance in longitudinal studies subgroups of fish are taken from the same tank for euthanasia at different times so that killing *in situ* is not possible.

Finally, even for commonly used euthanasia techniques in fish, there is often only very limited evidence of their humaneness within the laboratory setting – hence the recommendation in the main APC report1 that there is a need for further research. In drawing up the current document it became apparent, from the experts' evidence, that much of the recent research activity relating to humane killing of fish has been carried out with respect to fish farming. We considered this to be valuable information that could be used to inform this document. However, there are obvious differences between the sectors, which need to be taken into account. For example, some species of fish used in research are smaller than commonly farmed fish, and some methods such as overdose of anaesthesia would not be appropriate for animals destined to enter the food chain but are an option under the ASPA.

2. Assessment of current Schedule 1 techniques

Schedule 1 lists the following methods as suitable for fish:

i. Concussion of the brain by striking the cranium with destruction of the brain before the return of consciousness.

ii. Overdose of an anaesthetic using a route and an anaesthetic agent appropriate for the size and species of animal.

Schedule 1 indicates that these methods are only appropriate subject to completion by methods that aim to ensure confirmation of death, specified in subparagraph 1 a. to f. of the Schedule.

2.1 Concussion

Concussion is a technique for killing fish that is commonly used in field studies but is not confined to this area of research. The major source of stress arising from this technique is likely to come from capture and handling (see section below on handling). As noted in paragraph 3.4 of the *Code of Practice for the Humane Killing of Animals under Schedule 1 to the Animals (Scientific Procedures) Act 1986*, physical methods of killing animals can be quick and humane if carried out competently and appropriate to the species and size of animal. It is worth noting here that some species may be difficult to kill by concussion (e.g. certain catfish which have bony plates protecting the brain, Those carrying out the technique should be trained, prepared to use a physical method and fully confident that they can perform the technique competently.

2.2 Anaesthetic overdose

Currently the most favoured method of euthanasia for fish is anaesthetic overdose using a suitable agent and route. Only MS222 is licensed as an anaesthetic agent for use with fish in the UK and European Union, however Schedule 1 does not limit the agents that can be used for killing. This flexible approach allows better and more effective agents to be adopted as scientific knowledge and drug development progress. The most common agents used for killing fish by anaesthetic overdose in the UK are benzocaine, benzocaine hydrochloride (ethyl aminobenzoate) and MS222 (tricaine methane sulphonate), although there are a number of other anaesthetic agents, such as quinaldine sulphate and 2-phenoxyethanol that may also be used.

Factors that need to be taken into account when choosing anaesthetic agents include speed of induction in the species of fish concerned, together with the likely aversiveness of the agent at the concentration used. The physical properties of the agent need to be fully considered (JWGR 2001), for example: the potential for irritancy, whether it

will dissolve correctly in the temperature of water in which the fish are held and the need to buffer acidic compounds such as MS222. Where the agent has to be dissolved in a solvent other than water, then any impact of the solvent on the fish also needs to be taken into account. Disposal of the agent after use is also an important factor.

For humane killing, anaesthetic agents must be used correctly. A concentration of anaesthetic solution which induces anaesthesia quickly will help to decrease the time exposed to the anaesthetic solution, and the overall handling time; both of which lower the overall levels of stress (Fox *et al*. 1997). However, a balance needs to be struck between the time taken to induce anaesthesia and the irritancy of the agent. With some agents it is not easy to reliably achieve correct concentrations. For example, 2-phenoxyethanol is not readily miscible in water so that, over time, the concentration of the anaesthetic in the water can change giving unpredictable results. Sudden changes in water quality and temperature can generate stress responses in fish (Wedemeyer 1997). Therefore care should be taken to minimise any temperature difference between the anaesthetic solution and the tank water. It was also suggested to us that dim lighting or even a darkened tank (with a dark plastic cover) may help to calm fish during anaesthesia or euthanasia, but we are not aware of data to support this.

Anaesthetics do not take effect instantly and some agents may be aversive during induction. The previous Schedule 1 review drew attention to the aversive nature of gases used for killing rodents, but it appeared to us that there might be a shortage of research on the humaneness of anaesthetic agents commonly used for killing fish, and on the most humane protocols for using these agents. For example, Close *et al*. (1996) in their discussion on the use of MS222 for euthanasia refer to only one paper by Brown (1988), which describes appropriate buffering of the agent. However, neither Close *et al*. (1996), nor Brown (1988) refer to the aversiveness, or otherwise of MS222. This is, perhaps not surprising as the issue has only become topical relatively recently for other taxa. We, therefore, asked whether there was evidence for anaesthetic agents commonly used for killing fish regarding aversiveness; and if they were aversive, how much, and for how long? Additionally, we asked whether there was any evidence regarding differing reactions to these agents by fish species commonly used in research. No literature on the subject was reported, but our advisory experts told us of anecdotal accounts that anaesthetics may, at times, cause aversive reactions in fish. These include: aversive reactions in trout when they are introduced to water containing the agent at the full recommended dose; aversive reactions in salmon when the agent is gradually introduced to their water; and catfish attempting to leave the water once the anaesthetic has been introduced. However, it is not known whether these responses were to the anaesthetics themselves or to variations in the effective buffering of anaesthetic solutions, especially when more concentrated solutions are used for euthanasia.

2.3 Stress prior to killing

In addition to stress caused by the killing methods themselves, it is important to consider stress caused by procedures leading up to the killing method. Many studies have demonstrated that fish are stressed by capture and handling (Billard *et al*. 1981; Barton & Iwama, 1991; Pickering 1992; Wendelaar Bonga 1997), and that this results in a biochemical and physiological stress response, which occurs almost immediately and can be evident for a prolonged time afterwards (Mazeaud *et al*. 1977). Handling stress, although short term, can impact on feed intake and immunology (e.g. Pickering *et al*. 1982), thereby causing further metabolic consequences. Alterations to the social environment can also induce increased cortisol production as an indicator of stress responses (Fox *et al*. 1997).

Emersion stress (stress resulting from removal from water) is a common paradigm in published studies on fish stress and is known to cause an acute stress response, including that of the hypothalamic-pituitary-interrenal (HPI) axis and elevated circulating cortisol (e.g. Sloman *et al*. 2001; Lankford *et al*. 2006). Fish typically display a period of intense activity during air exposure, which has been termed a maximal emergency response, and it has been suggested that capture and handling may cause psychological stress such as fear (Schreck, 1981; Yue *et al* .2004) – although the capacity for fish to be aware of such emotions is still debated (Braithwaite & Boulcott 2007). Fish also experience oxygen debt associated with the intense exertion and the restriction on normal ventilation (e.g. Ferguson & Tufts 1992; Davis & Schreck 1997) and an acute endocrinological stress response (commonly known

as handling stress) follows, presumably owing to the combination of psychological and respiratory stressors (see Portz *et al*. 2006 for a review).

There are, however, considerable differences between species in terms of their ability to cope with handling, with some showing more extreme reactions than others (Brydges *et al*. in press). Certain species are very sensitive to handling, for example, most species of salmonid are very stressed by handling and direct exposure to air, but other species appear to be less stressed (e.g. three spined sticklebacks, *Clarius* spp. of catfish).

2.3.1 Handling stress and experimental outcomes

Handling stress not only affects welfare but can also influence the outcome of experiments and trials. For example, Pottinger and Calder (1995) showed that the results of toxicological trials were affected by the degree of disturbance and handling experienced by the fish. Similarly, behavioural trials can also be compromised by stress; Pickering *et al*. (1982) found that brown trout *Salmo trutta* did not feed for 3 days after handling. Devising handling techniques that minimize distress would therefore help to improve the quality of data collected in experimental research.

However, as noted above, species vary in their responses to handling, and, as yet, there is no formal, standardised comparison of the effects of routine handling procedures across fish species. Age and size can also influence the ease with which fish are caught within a tank. For small fish, capture and handling is usually much easier than large fish over 500g which can have faster swimming speed and be difficult to handle due to their large size and strength. The longer it takes to catch the fish the more stressed they can become owing to prolonged chasing (Fox *et al*. 1997).

2.3.2 Stress from netting

Most laboratory and ornamental fish are still routinely caught using hand-nets. The fish are usually removed from the water and briefly held in the air. Netting affects both fish behaviour and physiology. Physical abrasion from the net can disrupt the mucous coating and scales, potentially increasing susceptibility to pathogens (FSBI 2002; Conte 2004). Additionally, impact with the net, conspecifics or other surfaces can cause physical damage to protruding structures such as the fins and eyes (Barthel *et al*. 2003). Prolonged chasing with a net causes stress, not only to the pursued fish but to conspecifics if they are present in the same tank (Barnett & Pankhurst 1998). In addition, there may be stress from exposure to air.

From the above, it is clear that netting, carried out for any husbandry process including euthanasia, should be done as gently and efficiently as possible. Stress from exposure to air should be minimised by reducing to a minimum the time taken to transfer the fish between the home tank and anaesthesia vessel. If conducted in a quick and efficient manner netting and handling can only take a few seconds, therefore, it is vital that researchers are properly trained to do so and we understand that this is covered in personal license training.

2.3.3 Stress from catching by hand

Fish are occasionally caught directly by hand. If fish are to be held directly this should only be done with wet hands, and preferably with soft, wet gloves (e.g. unpowdered latex gloves) to avoid damaging the mucous layer. However, many of the fish species used under the ASPA are too small to be effectively caught by hand or there may be other reasons why the technique is unsuitable (e.g. design of enclosure, swimming speed of the species involved, etc.).

2.3.4 Reducing stress by transferring fish in water containers

Methods of handling that allow fish to remain submerged in water are likely to reduce exertion, anoxia, stress and physical damage. An alternative to netting is to transfer fish in a vessel containing water. This can range in size from a small beaker to a large container on wheels dependent upon fish size. Transferring fish in water rather than in air is believed to be better practice but research is limited. Recent observations on a variety of fish species have shown that the time fish take to recover from handling and transfer between tanks can be reduced if the fish are transferred within a darkened, water-filled scoop rather than a dip-net (Brydges *et al*. in press).

For long transfers (>1 min), transfer in water is the preferable method. The water should be continuously aerated for all except the shortest of transfers as levels of oxygen may become depleted this can occur in as little as one minute, depending on factors such as fish size and water volume. It is advisable to cover the vessel with a lid so that the fish is not disturbed visually. The fish should have enough space to be able to turn around and be completely straight, so that this does not impose a confinement stress (Trenzado *et al*. 2003). On the other hand, too much space may allow fish to achieve speeds that could result in injuries. For heavier containers (~5+ kilograms), a trolley should be used for health and safety reasons. A trolley would also reduce any human induced motion changes that may cause stress. There are no comparable studies that enable us to definitively state a maximum acceptable transport time, but current knowledge relating to stressors in fish and common sense both dictate that transport times should be as short as possible.

2.3.5 Reducing stress by killing in home tank using an overdose of anaesthetic

Killing in the home tank negates the need for netting, capture, handling and transport and exposure to the air. If several fish are to be euthanased at once, it may be possible to add anaesthetic directly to a tank so that handling is minimised, but care should be taken to calculate the appropriate concentration of anaesthetic for: the volume of water in the tank, the number of fish in the water and to add it in a way that ensures rapid even dispersion. One way of achieving this is to take water from the tank, mix it with the agent and then slowly add it back to the tank. Assuming that the anaesthetic is not overly aversive, this would seem the quickest, most humane way of killing the fish and would presumably minimise stress although there is no scientific evidence for this.

However, killing in the home tank is not a common method as there are a number of disadvantages and practical issues. The technique can only be used with isolated tanks as opposed to tanks linked to a common filter system where the anaesthesia would contaminate the system and affect other fish. After applying the anaesthetic to an isolated tank, the whole tank and its contents would have to be rinsed to remove the anaesthetic. Under current legislation, the tank would also have to be visually isolated so that other fish did not witness the death. Moreover, when killing single fish, the fish would have to be held individually rather than in groups. The welfare impact of this on gregarious fish such as common carp, stickleback and zebrafish would need to be taken into account. In summary, this method could be difficult to implement without extra technical support or research time.

2.4 Conclusions

There appears to be an urgent need for research into humaneness of chemical methods of euthanasia. Research is needed both on the aversiveness or otherwise of the agents and on the methods of their use.

Netting prior to euthanasia can be humane provided that the capture time and time to euthanasia is short and that prolonged chasing and air emersion are avoided. There may, however, be more humane techniques that should always be considered first. For example, capture and transfer in water containers is likely to be more humane than netting and transport in air. The welfare benefits of different types of transport and capture should be taken into account when these techniques are used.

When killing fish, consideration should be given to any welfare benefits and the feasibility of euthanasia in the home tank.

3. Consideration of alternatives to current Schedule 1 techniques

There are a number of reviews available on the humane killing of fish. Notable amongst these are Close *et al*. (1996, 1997); CCAC (2005); AVMA (2007). These reviews list some alternative techniques that are not currently included in Schedule 1.

3.1 Maceration

Maceration is usually recommended as a method of killing for embryonic and larval forms or neonatal animals and involves the use of a mechanical device, with rotating blades or projections that cause immediate fragmentation and death. It has been suggested that maceration could be used for very small fish (<2cm) Close *et al*. 1996), although Close *et al*. (1997) recommended against whole body crushing. There appears to be little literature on the subject for fish, but maceration is used in agricultural practice to kill chicks aged up to 72 hours (HSA 2004, The Welfare of Animals (Slaughter or Killing) Regulations 1995 (as amended)). Maceration requires specialised equipment, which should be kept in excellent working order. Moreover, the rate at which animals are introduced should not be such that it causes the equipment to jam or animals to rebound from the blades. As death should be almost instantaneous in a properly designed macerator, the technique could be more humane than overdose of some anaesthetics, although the fish would still have to be caught and handled. The macerators would, however, have to be specifically designed for each fish size, and would need to be kept in good order. As a secondary consideration, the process is likely to be aesthetically unpleasant for operators. Moreover, the technique would only be viable where there was no further need for the individual body tissues of the fish.

3.2 Microwave radiation

Microwave radiation, using specially designed equipment to focus the radiation on the brain, is likely to result in rapid death of small animals (Close *et al*. 1997; AVMA 2007). However the technique would denature proteins limiting its value for some research projects, and we are not aware of the existence of specially designed microwave equipment suitable for euthanasing fish. Also, water is likely to reduce microwave penetration so the use of this method in aquatic animals would be likely to require their removal from water, with potential stress related to handling.

3.3 Chilling to stun or kill

If fish are slowly chilled they become less active. There is also the appearance of reduced reaction to stimulation, but true anaesthesia is unlikely to be achieved and there will still be some level of consciousness and sensation (Ross & Ross 2008).

It has been suggested that for farmed fish destined for slaughter, slurry ice might be used to desensitise the fish[24]. One of our experts noted that:

"I have observed this method of killing carried out with many different species. On each occasion the fish showed extreme aversive reaction and our studies have shown that they take a protracted amount of time to die (see for example, Robb & Kestin 2002; van de Vis *et al*. 2003). Immersion in ice slurry or ice should never be considered as a practical method by itself, however, our work has shown that this can be a suitable method of ensuring that fish do not recover from an electric stun as long as a stun of sufficient duration has been induced".

Moreover, Roth *et al*. (2009) report that exposing turbot to subzero temperatures results muscle contractions which can be associated with severe pain in addition to primary and secondary stress responses.

AVMA (2007) does not support the use of hypothermia or freezing because of concerns that crystal formation might cause pain. AVMA (2007) does, however, note that quick freezing may be acceptable as a method of killing previously deeply anaesthetised animals.

Some users have claimed that chilling tropical fish such as zebrafish by immersion in water at 4oC causes rapid cessation of gill movement and immobility (within seconds), They also report that even after short exposures

[24] http://www.fsbi.org.uk/phpbb/viewtopic.php?t=13

animals cannot recover if placed back into their standard water temperature. However, we are not aware of any research on this issue for tropical and other non-temperate species.

Cooling of foetuses followed by immersion in cold tissue fixative is allowed as a method of killing under Schedule 1 for mice, rats and rabbits. The use of similar methods for larval fish or immersion in liquid nitrogen has been suggested by some. Due to the Leidenfrost effect (where any liquid in contact with an object significantly hotter than its boiling-point boils immediately, enveloping the object in insulating nitrogen gas in the case of liquid nitrogen) it is important to consider carefully how tissue preservation is performed in order to ensure death is instantaneous. The use of pre-chilled surfaces, such as a copper plate, or pre-cooling can help to reduce potential problems by increasing the speed at which the core temperature of the animal will drop when using liquid nitrogen or similar methods. The size and surface area of the animal is also likely to be important in how rapidly cooling, and therefore death, occurs.

3.4 Electrical stunning

One technique that has received recent attention for farmed fish has been the use of electrical stunning. The use of electrical stunning as a method of sedation or anaesthesia is a logical extension of electro-fishing. Electro-fishing[25] as a technique has been effectively established in fish for many years and relevant literature extends over decades. Field sampling methods using this technique are very well known and an extensive literature exists on this well-researched technique (Cowx *et al*. 1990).

Electric stunners, in contrast to electro fishing, deliver a very much stronger pulse-field over a relatively short time period (usually only seconds). The field is sufficient to depolarise the brain and induce epileptiform activity during which it is presumed that the fish are not conscious. Electrical stunning has been reasonably well researched and a modest literature on its efficacy and effects is available, (see Ross & Ross 2008 for summary). Evidence for a stun can be gained either from EEG measurements, or from behavioural indicators (Kestin *et al*. 2002; Robb & Kestin 2002). Given a suitably strong electric field some fish have been shown to be stunned within half a second. Moreover, there is reason to expect that during this short time window, even if a self sustaining stun is not achieved, the brain is incapable of functioning in a way that would enable the fish to be considered sensible.

It is known that the duration that insensibility lasts is related to the fish species and the strength of the electrical field experienced by the fish (this is a function of the electric field in the water, the water conductivity and the fish orientation). It is also determined by the duration of exposure to the electric field and the frequency and type of waveform of the electric field. In addition, evidence from electric fishing suggests that larger fish are more susceptible than smaller fish to being affected by an electric field in the water.

3.4.1 Adverse effects from the use of electrical stunning

When sufficient current is supplied to achieve a stun, there is evidence that this can be associated with physical damage in fish (Lines & Kestin 2005). The type and extent of damage is believed to be species specific. For example, haemorrhage and broken bones are particularly common in salmonids (see for example (Robb & Roth 2003; Roth *et al*. 2003). It is reported that there is an apparent trade off between the duration of stun achieved, or the ability to kill, and the prevalence of carcass damage caused by the current.

In order to achieve a reliable stun there will always be the possibility of some form of damage to the animal as a result of the strong muscular contractions associated with a current great enough to induce a stun. Post stun damage will probably also exist that may not be readily visible upon dissection.

[25] Electro-fishing does not necessarily stun the fish. It usually uses pulsed DC and can be tuned to a particular waveform, amplitude and frequency. Once tuned, fish of a particular size (and species) are selectively affected at a particular setting, so a biased sample is captured. Small fish generally require a higher voltage and frequency than larger fish. The muscles of the fish are stimulated by the electric current and this causes some fish to swim towards the anode. The fish are captured either because of muscle exhaustion or because they are unable to coordinate an escape. It is possible that fish very close to the field are truly stunned, but usually, given the current involved, only for a very short time. However, if too high a current is used and fish are too close to each other, it is possible to kill fish.

There are further disadvantages to the use of electrical stunning as a means of euthanasia. Lines (pers. comm.) points out that if a voltage insufficient to cause a stun is applied for a sufficient amount of time, total muscle exhaustion takes place and that this can be confused with anaesthesia; by all behavioural measures the fish appear unconscious and it is only by means of EEG that its true conscious state can be determined.

3.4.2 Electrical stunning prior to euthanasia by immersion in an overdose of anaesthetic

This particular combination is most unlikely to be a reliable approach to euthanasing fish. When fish are stunned, opercular movement ceases. The heart may also stop though it may resume as the electric stun wears off if the animal is not killed by the stun. It is presumed that the slowing or cessation of opercular movement and the fall or cessation of circulation would prevent the anaesthetic agent from working effectively. Therefore in the intervening period between recovery from the stun and succumbing to the anaesthetic agent the welfare of the animal could be compromised, and additionally, the state of welfare would be difficult to determine.

Further, electric stunning should be carried out only in a purpose-designed environment where the geometry and the electrode size facilitate the generation of a uniform electric field so that, regardless of fish location and orientation, it is properly stunned. Therefore, home tanks would have to be designed to ensure reliable electric stunning without the risk that the fish might be exposed to an electric field that causes pain but not insensibility.

3.4.3 Electrical stunning prior to killing by destruction of the brain

This could be a suitable method of euthanasia provided that the destruction of the brain took place immediately after the stun. Electrical stunning is thought to produce an instantaneous stun and, with the correct set up it could be carried out without prior disturbance to the fish. The stun duration would have to be sufficient to prevent recovery during handling prior to killing by concussion or destruction of the brain.

There are clearly practical problems associated with this approach including, for group housed fish, finding a way to protect other fish from the effect of shocks. It is may be worth considering the use of a wet brail (net) or a water flow system to transport the fish into a purpose designed stunning tank or tube.

However, it should be possible to produce a current in a given environment that would be sufficient to reliably produce a simultaneous stun and kill, without recovery (see section below on electrical killing), thus obviating the need to carry out a concussion or other physical insult to the brain.

3.5 Electrical killing

Trials with electrical stunning have shown that fish can be made unconscious immediately by application of an electrical voltage or current at a range of frequencies. Maintenance of the applied voltage and current for some tens of seconds, depending upon species and size, results in death. Longer periods of exposure (several minutes) are capable of killing otherwise very resilient fish such as turbot, while a shorter exposure (for example 20 seconds) is capable of ensuring fish such as trout and salmon remain insensible and without the breathing reflex until death by asphyxiation. However, data are only available for a few farmed species of fish. The event itself may well be totally stress-free as stunning is immediate.

Recent work on electrical stunning of farmed fish has given good results (Lambooij *et al*. 2008 a,b). This work should provide a base from which to move forward and to thoroughly investigate the method for large and small scale euthanasia. Work would be needed to determine how best to administer the killing shock (see stunning above) and to address concerns about operator safety, ensuring that each fish was killed and not just immobilised.

3.5 Conclusions

Maceration using appropriate equipment can be a humane method of euthanasia, and it seems appropriate that consideration should be given to adding it to Schedule 1, subject to the use of appropriate equipment.

Whilst microwave radiation, using appropriate equipment, could be a humane method of euthanasia it should not be added to Schedule 1 methods at present because of the practical difficulties.

There is clear evidence that chilling is not appropriate as a method of stunning or killing for temperate fish species used for food. Research is, however, needed on the humaneness of chilling techniques for small tropical species such as zebrafish.

Although freezing following stunning would be humane, there is no particular benefit in including this as a Schedule 1 technique.

Because of the technical difficulties involved with using liquid nitrogen killing with liquid nitrogen should not be added to Schedule 1 as a technique to be used with conscious fish.

Electrical killing is an area where further research on species commonly used in research is justified.

4. Recommendations

1. Research is needed into the aversiveness or otherwise of anaesthetic agents such as MS222 when used for the euthanasia of fish, and on the most humane methods of using these agents. The APC asks that funding bodies should give consideration to developing this knowledge.

2. This report draws attention to the need to minimise the stressful effects of handling, for example by considering alternatives to netting, exposure to air and avoidable handling when euthanasing fish. Section 6 of the Code of Practice to Schedule 1 should emphasise, for fish, the requirement to refine the entire euthanasia process, including handling. Consideration should be given to providing specific guidance, (e.g. regarding transfer in water-filled containers, or killing in the home tank where these are appropriate).

3. Subject to the use of appropriate equipment, there may be a case for including maceration as a technique in Schedule 1.

4. Schedule 1 should not permit chilling before euthanasia or killing by freezing unless evidence of humaneness is forthcoming for particular fish species and life stages.

5. A series of well-designed trials of electrical euthanasia of a range of fish species would be timely and may result in a humane killing method that could be used in research facilities. The APC asks that funding bodies should give consideration to developing this knowledge.

These recommendations have been made with full consideration of the Terms of Reference and responsibilities of the Animal Procedures Committee, including regard to both the legitimate requirements of science and industry and to the protection of animals against avoidable suffering.

The recommendations have also been made in the context of the better regulation agenda with the aim of not increasing and where possible reducing administrative burdens on business and the public sector.

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Appendix APC fish euthanasia survey – summary of results

The summary results below are from two universities and two professional bodies.

University 1

If already cannulated, injection of an anaesthetic such as Safan.

If not cannulated:

- submersion in an excessive concentration of anaesthetic such as MS222.
- Sharp blow to the top of the head and, if necessary, subsequent transection of spinal cord followed by disruption of the brain or decapitation.

Species: rainbow and brown trout and chub.

University 2

Concussion followed by brain destruction. Larger fish such as salmon trout, carp, cod, whiting (>50g) can be hit on the head with an instrument such as a trout priest. Smaller fish such as stickleback and zebrafish can be concussed by the use of blunt tweezers which also causes pithing, or a sharp blow to the top of the skull.

In neuroanatomical studies, sometimes an overdose of anaesthetic followed by exsanguination – at least 10 times the normal dose should be used such that fish lose equilibrium in the first 15-30 seconds. Since fish can recover from anaesthesia they should be left in the anaesthetic bucket for at least 15 minutes. However, if following this

by exsanguination anaesthesia should still be maintained until gill tissues turn a light pink indicating loss of blood such that no recovery is possible.

Fish from <1g up to 1kilo in size.

Professional body 1

Overdose of anaesthetic (MS222 buffered to pH7). Fish are left for 20 minutes and when death is confirmed the animals are then decapitated to exsanguinate.

Species: zebra fish.

Professional body 2

Cited work at Bristol University that led to development of an electric stunning system which is now installed on many trout farms.

ANNEX F

Sara Nathan
Chair Of the Animal Procedures Committee
C/o SRG Secretariat
3rd floor Seacole Building
2 Marsham Street
London
SW1P 4DF

6 August 2009

Dear Sara

SUPPLEMENTARY REVIEW OF SCHEDULE 1 OF THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986: APPROPRIATE METHODS OF HUMANE KILLING FOR FISH

I am writing to thank the APC Housing and Husbandry subcommittee for producing the Supplementary Review of Schedule 1 relating to the humane killing of fish, and will comment on action that will now be taken in response to your recommendations.

Recommendations 1 and 5 refer to commissioning of research in this area. I will ask my officials to draw your advice to the attention of the National Centre for the 3Rs, other funding bodies, and animal welfare organisations.

Recommendation 2 relates to good practice with regard to handling fish. We will seek to raise awareness by sending the review to stakeholders with an interest in this area, including those responsible for training users, and to the Animals Scientific Procedures Inspectorate.

Recommendation 3 relates to including maceration as a technique in Schedule 1. This will be taken into account both when the current Schedule is revised, and in the technical discussions currently taking place in Europe.

Recommendation 4 refers to Schedule 1 prohibiting chilling or freezing before euthanasia unless there is evidence of humaneness. My officials will check that this technique is not currently authorised on any current licence in the belief that it is humane. We will wait to see future research in this area before considering taking further action.

The Committee's advice is timely, in view of the ongoing revision of Directive 86/609/EEC and, because of its relevance beyond the operation of the 1986 Act, we will send the report to the European Commission and Council of Ministers working party to inform work on the revised directive; and to DEFRA, which has responsibility for the welfare of fish in other contexts.

Yours sincerely

LORD BRETT

ANNEX G

REPORT OF THE SUFFERING AND SEVERITY WORKING GROUP ON THE STRENGTHS AND WEAKNESSES OF THE CURRENT SYSTEM OF SEVERITY LIMITS AS A WAY OF PROSPECTIVELY ASSESSING SUFFERING AND SEVERITY

Background

A number of expert bodies have made recommendations that the current system for assessing and reporting severity be reviewed

1. The House of Lords Select Committee on Animals in Scientific Procedures (2002) report paragraph 9.34[26] stated:

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

2. A Boyd/RSPCA report of discussions on categorising severity (2004)[27] and the APC review of Cost-Benefit assessment in the use of animals in research (2003)[28] also called for a similar review.

3. First, we note that at the time this and similar recommendations were made there was (and currently there still is) no system for the retrospective reporting of the actual levels of suffering of animals under procedures.

4. In July 2004 following, a request from the Minister to the Animal Procedures Committee for practical recommendations with a view to a new system for severity limits and bands, the Suffering and Severity working group was established to evaluate the following:

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

In October 2008 the APC/LASA Working Group[29] published their final report on retrospective reporting of severity which addressed the second topic.

This report addresses the first topic and evaluates the current system of using severity limits and bands.

[26] http://www.publications.parliament.uklpa/1d2001 02/Idselect/idanimal/1 5011 50.pdf

[27] http://www.boyd-group.demon.co. uk/severity_report.pdf

[28] http://www.apc.gov.uk/reference/costbenefit.pdf

[29] Final report of a L.ASAIAPC working Group to examine the feasibility of reporting data on the severity of scientific procedures on animals October 2008.
http://www.apc.gov.uklreference/lasa apc final report.pdf

Our approach

5. The Suffering and Severity working group consider that:

(i) the expected and actual levels of animal suffering in procedures should not be hidden and where possible greater detail should be provided;

and

(ii) the Home Office should be accountable for the level of suffering that it authorises when granting licences and for its oversight of animal procedures.

Severity classification

6. The current system of severity classification is as follows.

(i) Within project licenses, protocols are currently given mild, moderate, substantial or unclassified[30] *limits* based on the maximum suffering that is expected that any animal will be permitted to experience. Licencees are required to keep animal suffering below the severity limit. These limits are used as a licensing tool to control the maximum permissible suffering that might be experienced by any animal in a given protocol.

(ii) The licences themselves are allocated into mild, moderate, substantial or unclassified *bands*. Allocation into these bands is based on the overall suffering likely to be experienced by all animals undergoing regulated procedures within the authorised programme of work. It incorporates both the total numbers of animals that might experience mild, moderate, substantial suffering or unclassified suffering and the likely duration of the suffering in the allocated band at each level of suffering. The numbers of projects falling into each band are reported in the annual statistics[31] and currently are the only indicator available to the public of the degree of animal suffering that may be experienced by animals under the Act.

The banding system: subdivision of the "moderate" category

7. A number of stakeholders have criticised the classification system stating that the moderate limit appears to be a "catch-all" grouping and have called for a sub dividing of the moderate limit to differentiate further the extent of suffering predicted. The Suffering and Severity working group have considered this proposal and decided that it would be premature to reach a conclusion on this for the following reasons:

(i) According to the LASA/APC Working Group report of 2008 on retrospective reporting, which the working group commissioned and which the APC has forwarded to the Minister; "subdivision of the moderate category was viewed as an improvement of the descriptive power of the current classification system that could assist in tracking progress in refining procedures. The consensus of opinion was that refinement often takes place in small steps, and follow-on reductions in severity might not necessarily cross severity category boundaries (e.g. from moderate to mild), but might occur within categories (e.g. from the upper to the lower end of moderate).

(ii) To increase the number of severity categories would however increase the bureaucratic burdens of reporting, particularly if it is difficult to clearly delineate the boundary between upper and lower moderate.

[30] Paragraph 5.42 of the Guidance on the Operation of the Act defines severity classifications

Unclassified" is defined as performed entirely under general anaesthesia, from which the animal does not recover consciousness

[31] For published Statistics on the use of animals in scientific procedures in Great Britain 2007, http://scienceandresearch.homeoffice.gov.uk/animal research/publications-and-reference/statistics/

(iii) Any proposal to alter current severity classifications should be revisited once there is experience of retrospective reporting using the current three category classification.

It is desirable that the prospective and retrospective systems should be compatible with one another. Changes are already being considered because of the proposed revisions to EC Directive 86/609[32] and so additional changes to severity classification at this stage would be inappropriate.

The House of Lords Committee recommendation

8. With respect to the House of Lords Committee's proposal that licenses should provide a breakdown of suffering and severity, giving numbers of animals in each category, the Sub Committee conclude that this is not practical. At the times that a licence is being drafted by the applicant and then granted by the Home Office it will commonly not be possible to identify which animals, and how many animals, will undergo each predicted level of suffering under the procedures. Decisions as to this may only become possible after the procedures in question have commenced.

Conclusions on the Home Office ability to protect animals via severity limits

9. We consider that the present system of severity limits allows the Home Office to control permissible suffering imposed on animals during the course of experiments. We are satisfied that this system protects animals effectively.

Predictions of suffering

10. The assessment of suffering made in licences is purely predictive; it does not provide or purport to prove any information about the actual levels of suffering of particular animals or groups or numbers of animals on procedures. It provides information as to what licensees expect and what the Home Office licences. As the House of Lords committee stated, this information may in fact mislead, since many readers will assume that the predictive 'assessment' provides a picture of the actual suffering of animals when this is not in fact the case.

11. A better approach would be to establish a system for the retrospective reporting of actual suffering which would, if implemented, provide all the necessary information in a way that is not misleading. As noted above the APC has recently forwarded proposals for such a system to the Home Office.

Accountability of the Home Office

12. As to the accountability of the Home Office for the limits that it sets, this will be greatly enhanced once a system for retrospective reporting is introduced. Then it will be possible for the actual suffering experienced by animals to be compared with the limits set at the onset that were approved by the Home Office and to hold the Home Office accountable for those decisions.

Dissemination of information

13. We do, however believe that there would be merit in requiring the licensees to predict the degree of suffering that might be experienced by animals in their projects and the number of animals within each limit. Such information would avoid the potential for misleading readers that the current banding system involves.

[32] lex.europa.eu/LexUriserv/LexUriServe.do?uri=COM:2008:0543:FIN:EN:PDF

APC recommendation

The APC recommends that the Home Office should consider the abolition of the banding system

14. Currently banding is used by the Home Office Inspectorate to help in the cost benefit analysis and to identify projects which must be submitted to the APC for its consideration. Both of these functions can be achieved by the proposals in the next paragraphs (Criteria as defined on the APC web site[33]) The actual banding process is not essential to them.

15. The provision by licensees of information predicting the degree of suffering and the numbers involved would assist licensees, Ethical Review Processes/Committees and the Inspectorate in assessing the likely harms to animals. Moreover if retrospective reporting is adopted, the predicted suffering could be matched against the actual suffering experienced by animals at the end of the project, thus providing an indication of the accuracy of predictions of suffering. This proposal differs from the House of Lords Committee's proposal in that these figures would be estimates only, and would not form part of the conditions of the licence.

16. This could be achieved for instance by modifying table 19a. There is currently a column in this table for the Severity limit. This could be replaced with a table in which applicants describe what they visualise as the estimated prospective suffering [ie for each protocol, the numbers of animals expected to experience each limit of suffering].

17. Since the House of Lords report was issued, licensees can, under the present legislation, be requested on a voluntary basis only to provide project licence abstracts which are prospective narratives and provide much "prospective" information. Furthermore Revisions to EC 86/609 Article 40 also recommends the publishing of non-technical summaries, suitably redacted to preserve appropriate confidentialities. Though the Directive does not specify details of severity the Sub-Committee believe that the publication of such an 'abstract' would provide information that would underpin accountability.

18. The information in the proposed table 19a would be reported in the abstracts which licensees currently produce and which are on the Home Office website.

19. Such a system would be more transparent than the present system, as licensees and the Inspectorate could account for the costs and benefits of procedures while the existing limits would remain as a control system.

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

ANNEX H

Sara Nathan OBE
Chairman
Animal Procedures Committee
Home Office

13 August 2009

Dear Sara

ANIMAL PROCEDURES COMMITTEE ADVICE ON THE CLASSIFICATION AND REPORTING OF ANIMAL SUFFERING AND SEVERITY

I have been asked to respond to the letter and report sent to Lord West on 3 July, and to convey his thanks to the sub-committee for the work that it has done and the advice that has now been offered.

The speed of my response is not a sign that the consideration given to the report has been superficial – rather it indicates the need to react and respond quickly to make the best use of the Committee advice in the context of the current European negotiations and Home Office Better Regulation Programme.

The high level objectives and requirements set out at paragraph 5 of your report, which relate to transparency and accountability, are consistent with other policy objectives and work in progress. It is agreed that information is required both prospectively for assessment, and retrospectively both to validate the decision making process and the display outcomes in practice – and the advice offered by the Committee is relevant to those points.

The main criticism of elements included in the current system relates to the purpose and utility of the project severity bands, and some components of your advice are based on opportunities to use other elements of the regulatory system to provide increased transparency and more informative outcomes. The main technical issue I would take a different view on is the use you assume is made by the Inspectorate of severity bands for the purposes of cost-benefit assessment – we have always maintained and practised that it is the full narrative and detailed technical content of the application and the clinical training of inspectors, not the severity band label, that is required for that purpose.

I note the reservations expressed about offering specific advice on sub dividing protocol severity limits at this time: but it is to be expected that forthcoming outputs from our formal consultation on the proposal to revise the Directive, and a very recent Commission workshop on severity classification systems, will allow the Committee to revisit this issue in the near future if necessary.

Although some potential revisions to the current system based on your recommendations are likely to be developed and evaluated both within the Better Regulation Programme (which includes information requirements and forms design and content) and the revision of Directive 86/609/EEC (which is likely to include prospective and retrospective classification, and related presentational and reporting requirements) there are three main considerations which are likely to delay formal full-scale changes until work on the revised Directive is more advanced.

The first of these is that dropping an established element of the current system, regardless of its perceived limited value, will be regarded by some as ‘creative accounting’ and an attempt to conceal what is being done, rather than being part and parcel of a desire and series of changes to provide better information.

The second is that the project licence abstracts, the development of which is probably a key component of any revised system, can under the present legislation only be requested on a voluntary basis (paragraph 17 of your report states in error that they “are now required”).

And the third is in Better Regulation terms the price to be paid for improved retrospective reporting will probably be a general retreat from the current statistical reporting requirements based on work started during the reporting year – something that is again dependent on revising the current European reporting requirements.

Although the definitive UK negotiating position with respect to the revision of the directive has yet to be finalised, the advice offered by the Committee seems generally consistent with views expressed by other key stakeholders and Member States.

The Committee's advice has already informed input by the UK representative to technical discussions on future severity classification systems at a workshop hosted recently by the European Commission; and will be forwarded to others involved with discussions within the Council of Ministers on the proposal in order to inform and influence their position, and to the Steering Committee overseeing the relevant UK Better Regulation initiative (setting the scene for piloting some of the ideas in advance of making substantive changes to the national processes).

I will update the Committee regularly on the feedback received and the progress being made, and would invite the Committee to offer further advice to Ministers as required as the European and Better Regulation processes progress.

Yours sincerely

Jon Richmond
ASPD
Head of Division

ANNEX I

Meg Hillier MP
Parliamentary Under Secretary of State
Home Office
2 Marsham Street
London
SW1P 4DF

01 October 20109

Dear Meg,

The Animal Procedures Committee (APC) has been following progress with the revision of Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes, as you know. We have previously made submissions in response to requests for information from both you and the House of Lords inquiry.

The APC believes that there are some significant, positive elements to the draft Directive. These include the increase in scope; explicit reference to the Three Rs and requirements for their implementation; clearer requirements for staff competence; requirement for inspections by the Member State; and detailed requirements for authorisation. All of these are welcome improvements and have the potential to contribute to better animal welfare and science throughout the EU.

Notwithstanding this, the APC also has some serious concerns regarding the way in which the Directive proposal has developed. We understand that the trialogue discussion between the Council of Ministers, European Commission and European Parliament is already under way, and that there is very limited scope for substantive amendments to the Articles within the proposal. However, we believe that, as currently written, some elements of the Directive could have negative consequences for both animal welfare and science throughout the European Union, in addition to potentially undermining UK legislation.

The Committee has therefore set out its major issues with the proposal below, not only to register the most pressing concerns, but also because these issues will have a bearing on the drafting and implementation of the new UK legislation and accompanying Codes of Practice. Note that these comments refer to the draft dated 5 October 2009.

The use of non-human primates (Article 8)

Committee members hold different views on the ethical acceptability of primate use and the particular welfare issues that are involved. Some would prefer to see restrictions on primate use over and above that of other species, while others are concerned that such restrictions would negatively affect scientific research.

However, all are in agreement that the draft Directive lacks clarity and is highly open to interpretation with respect to permissible purposes of primate use. The term “basic research” in Article 5(1) is undefined and can be taken to mean any experiment that generates new knowledge, however trivial. Similarly, the term “debilitating” as defined in Article 8 could have a number of different interpretations that could be legally challenged and, in the view of some members, could prevent the development of essential medicines. All of this does little to allay the concerns of those who are concerned about primate welfare and/or those whose research depends on primate use.

Some members believe that Article 8 does not set clear limits on primate use that balance the very specific needs and capacity to suffer of these animals against the current scientific requirement for their use, nor does it take into account the legitimate ethical concerns.

The supply of non-human primates (Article 10)

We question why it is envisaged that the proposed feasibility study into the supply of F2+ non-human primates should take five years to accomplish. This has been an issue of concern and debate for some years now and no reason has been given for the proposed timescale. Any such study should also differentiate between species of non-human primate; for example, there are some highly specific issues that apply to macaques.

Re-use (Article 16)

The Committee accepts that there is a case for carefully controlled re-use, taking the cumulative lifetime experience of each animal into account. However, we are deeply concerned that the Directive would permit animals to be re-used following a severe procedure. This is not acceptable.

Classification of severity of procedures (Article 15)

The Competent Authority (CA) is now permitted to authorise the use of a procedure involving severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated for "exceptional and scientifically justifiable reasons". We cannot think of any instance where such pain, suffering or distress could not be ameliorated in some way, including through sympathetic husbandry or therapeutic support such as heat pads. This addition is thus not necessary.

It is not clear what types of procedures would be covered by "severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated", nor is there guidance as to which animal models might involve severe and long-lasting pain, suffering or distress. Some members are concerned that, without clear examples of what is or is not permitted, certain animal models of pain research may be challenged and prevented.

Animal Welfare Body (Article 25)

As you are aware, the APC has reviewed the function of the local Ethical Review Process (ERP) in the UK. We found that the ERP is generally accepted to be a reasonable and potentially helpful aspect of policy, providing useful and structured institutional review of licence applications pending Home Office submission. It also provides informed and considered advice to Certificate Holders on a range of issues relevant to the management of animal use in their establishments[34].

The Committee was hoping that the new Directive would include a requirement for a body to perform an equivalent role to the UK ERP, so is deeply concerned by the progressive reduction of the role and composition of what was the Permanent Ethical Review Body (PERB). In particular, the change of name to "Animal Welfare Body" (AWB) immediately removes the concept that the body should provide ethical advice[35]. Furthermore, the disengagement from project proposals could well lead to a lessening of involvement and interest by scientists, resulting in the process being sidelined and down-graded to the status of a discussion group. In our view, the PERB/AWB should play the leading role in ensuring that animal use is justified, that the Three Rs are fully implemented, that training standards are high, and that the local "culture of care" is good, all taking local expertise and views into account. All of these have ethical dimensions as well as practical, scientific or animal welfare ones.

Another issue of concern relating to the AWB is the extraordinarily minimal membership that is now specified. We do not see how this reduced membership could fulfil the tasks for the AWB as set out in Article 26.

[34] APC (2007) *Summary report of the APC Working Group on the Ethical Review Process*.

[35] The apparent intention to remove the word "ethical" throughout the document is also inappropriate in our view.

Authorisation and retrospective assessment (Articles 36, 38, 41A)

The Committee believes that every project involving animals should require a project proposal, non-technical project summary, ethical evaluation, prior authorisation by a CA and retrospective review.

This is essential to ensure good science and adequate protection for experimental animals and to ensure that these are properly balanced, as well as to address public concerns about animal use. However, the current proposal contains worrying exemptions for the authorisation of procedures that are necessary for regulatory requirements, production or diagnostic purposes provided that these are either non-recovery, up to mild or moderate, and they do not use non-human primates. Such projects would not require a non-technical project summary, nor would they require the opinion of independent parties as part of the ethical evaluation. In addition, these projects may be authorised by "tacit approval" (Article 41A).

The APC understands that the exemptions would not apply to procedures conducted for other purposes (i.e. those that were not for regulatory requirements, production or diagnostic purposes) or to any procedures that were severe or used non-human primates. However, those studies that would be exempt account for a significant proportion of animal use. We do not believe that there is any justification for relaxing control, in effect dropping below current UK standards for these procedures, or for reducing the information made available to the public about them.

Article 38 of the Directive proposal requires retrospective assessment of all projects using non-human primates and projects involving severe procedures. The reviews should evaluate whether the objectives were achieved, the actual harms that were caused, and elements that may contribute to further implementation of the Three Rs. In the view of the APC, restricting such mandatory review to a small minority of procedures would present serious problems for animal welfare, scientific quality and public trust in the authorisation process.

Unless actual harms are reviewed following all projects, there will be no recognised mechanism for checking the accuracy of predictions of both direct and cumulative suffering. There is a risk that procedures predicted to be moderate could actually result in substantial suffering, for example, yet this would go unrecognised. Conversely, "moderate" procedures could result in mild suffering, in which case it makes sense from the aspect of public accountability to record and disseminate this information accurately.

We believe that reviewing whether objectives were achieved, and whether the Three Rs could be implemented more effectively in future projects, is important and relevant for all levels of suffering. "Even" mild projects can be of doubtful benefit, present significant ethical dilemmas and involve loss of animals' lives, all of which are of public concern. The requirement should therefore be for all projects to undergo retrospective assessment. It is our view that the establishment should conduct retrospective reviews, and not the CA as proposed, since the outcomes should help to inform future projects locally. The outcomes of retrospective reviews should be made available to the CA, however.

To conclude, the APC was pleased to note that Lord Brett, when examined by the House of Lords Select Committee on the European Union on 14 October of this year, did not believe that the Directive would threaten the present UK standards. He also explained that the UK representatives have been actively promoting the view that good science and high animal welfare are compatible[36]. We hope that they are successful and we look forward to working with the Home Office on developing and implementing the new UK legislation.

Yours

Penny Hawkins
Chair of the APC 86/609 Working Group.

[36] House of Lords European Union Committee (2009) 22nd Report of Session 2008-09, *The revision of the EU Directive on the protection of animals used for scientific purposes, Volume II: Evidence*, answer to Q465

ANNEX J

OMAND REVIEW RECOMMENDATIONS

Summary of Recommendations

***Recommendation 1:** The work on a rolling 3 year strategic plan should involve a consultation process culminating in an annual discussion with the Home Office Minister.

***Recommendation 2:** The Chair and Secretary use the mechanism of the planning process to ensure that there are matters of substance to be discussed for each of the scheduled APC Meetings.

***Recommendation 3:** The APC and Home Office work up a fuller public explanation for use by Ministers and on the relevant web – sites to explain the relative roles at tactical and strategic levels of the ASPI and the APC.

***Recommendation 4:** Consideration should be given to ways in which members of the APC can be involved in giving advice on the handling of issues following cases of alleged malpractice. Greater weight should be given to the role that the APC can play to provide independent oversight of the implications following investigation of alleged malpractice, and thereby providing reassurance to the public.

****Recommendation 5:** The practical interpretation of the remit of the APC be reconsidered jointly by the Chair, ASPD and ASPI when it becomes clear what will be the demands will be of the new EU Directive for an expanded role for the proposed 'National Committee for the Protection of Animals Used for Scientific Purposes'.

****Recommendation 6:** Steps should be taken when setting up the new 'National Committee for the Protection of Animals Used for Scientific Purposes' (in response to the revision of EU Directive 86/609) to ensure that there is no unnecessary overlap in consulting or and engaging with stakeholders between the Home Office and the national committee.

***Recommendation 7:** The Chair agrees a protocol with ASPD over setting target turn round times at the point of submission of APC advice, in the expectation that unreasonable failure to meet these times would be taken up directly with the Minister by the Chair.

***Recommendation 8:** The APC Secretary agrees with the Head of Animals Scientific Procedures Division a procedure that tracks the follow-up of a recommendation being taken forward and a reporting mechanism to the Committee. The Secretary should also consider whether it would be possible to word the APC's recommendations more carefully to make it easier for the Home Office to identify who should be responsible for overseeing the action, and thus provide a clearer line of sight for implementation.

***Recommendation 9:** The value of holding joint conferences with ASPI should be considered as potentially helpful to build relations between both bodies and I recommend that idea is further explored.

***Recommendation 10:** The Chair of APC should consider the possible need on occasion to seek wider and more diverse advice when it is judged necessary in the interests of upholding the statutory independence of the APC.

****Recommendation 11:** Clarification is provided by the Home Office to stakeholders of the channels of future advice and of the APC's ability (or that of any successor body) to advise both the Home Office and other bodies before the revision of EU Directive 86/609 becomes law.

* **Recommendation 12:** The Home Office and officials in the Department for Business, Innovation and Skills agree a process with the Chair of the APC for appropriate input into the review of non-human primate use.

***Recommendation 13:** The EU dimension is likely to occupy a significant part of the APC agenda in the coming years and this must be factored into the APC strategic work-plan and into its negotiation with the Home Office over resources.

***Recommendation 14:** The APC should develop ideas for how it could add leadership across Europe on issues such as animal welfare for which there would likely be widespread public support.

***Recommendation 15:** The Secretary of the APC should review, in consultation with the ASPD and ASPI, the material that is available to stakeholders to explain and keep them informed of their respective roles and relationships.

***Recommendation 16:** The Chair of the APC should re-examine with the Secretary the contents of the next annual report to see if there is more information that can be provided in that format on the work of the APC.

***Recommendation 17:** The APC Secretary and ASPD/ASPI work together on their web-sites to ensure that the information presented meets the highest Hampton standards and that there are user-friendly cross-links between them.

****Recommendation 18:** When the UK policy direction on the final EU Directive is clear, the APC Chair should establish, with Home Office Ministers, an agreed strategy for wider engagement.

****Recommendation 19:** The Home Office reviews the future resource needs of the APC, including for consultancy, when the revised EU Directive nears completion in time for the necessary adjustments to be made.

****Recommendation 20:** There should be no change for the present in the remuneration practice in respect of the APC. This might naturally be re-examined ahead of the forming the 'National Committee for the Protection of Animals Used for Scientific Purposes' as proposed by the revision of the EU Directive 86/609.

***Recommendation 21:** The NC3Rs and the APC Chair agree a mechanism so that the APC can feed in independent advice on 3Rs research priorities when it judges it appropriate.

***Recommendation 22:** The overall outcome of this quinquennial review and subject to the points of detail above, that the APC should continue to be the means by which the statutory requirement in the ASPA is discharged, and should become the 'National Committee for the Protection of Animals Used for Scientific Purposes' under the proposed revised EU Directive.

* – Recommendations for immediate consideration and implementation

** – Recommendations to be considered in light of the transposition of the revision of the EU Directive 86/609

ANNEX K

APC WORK PROGRAMME FOR 2010 onwards

OBJECTIVE	TARGET DATE
Primates Sub-Committee	
Horizon scanning of current situations/trends in the use of primates in medical research and the understanding of diseases, excluding regulatory toxicology.	On going
Consideration of overseas centres supplying non-human primates to UK laboratories.	As required
Education & Training Sub-Committee	
Finalise report on module 5 to present to main APC.	On going
Publish report on accreditation of training courses, including clarification of expectations and roles, assessment of trainees.	On going
Explore whether training exemptions could be granted and what qualifications/experience/ assessment would merit such exemptions.	April 2010
Infringements	
Analysis of recent infringements data.	April 2010
Applications Sub-Committee	
Consider and advise on applications for project licences referred to the Committee by the Home Office.	As required
Schedule 1 Working Group	
Review latest research about the use of CO2 and inert gases for humane killing.	On going
86/69 Working Group	
Advise on and evaluate revisions to the European Directive and their transcription into UK legislation, guidance and Codes of Practice.	On going
Housing and Husbandry sub-committee	
Oversee the pilot study on the Release of GA animals from the Act.	2010
The outcome of APC recommendations past and present.	2010

GLOSSARY

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

Embryonated egg – an egg which contains an embryo.

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

Ethology – the scientific study of animal behaviour.

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

In vitro – literally "in glass", i.e. experiments conducted using cells, tissues or organs in an artificial environment, outside a living organism.

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

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

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

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

List of Acronyms

APC – Animal Procedures Committee

ASC – Applications Sub Committee

ASPA – Animals (Scientific Procedures) Act 1986

CRO – Contract Research Organisation

LASA – Laboratory Animal Science Association

LAVA – Laboratory Animal Veterinary Association

NACWO – Named Animal Care and Welfare Officer

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

NDPB – Non Departmental Public Body

NVS – Named Veterinary Surgeons

PSC – Primate Sub-Committee

SAC – Scientific Advisory Committee

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