The **A S C**

Animals in Science Committee

Animals in Science Committee

Review of the ASC January 2013 – December 2014

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CHAIR'S FOREWORD

As Chair of the Animals in Science Committee (ASC), I am pleased to introduce the ASC's first Annual Report.

The ASC was established in 2013 and much of that year was taken up by the recruitment of members, determining the terms of reference and parameters within which it would operate, and putting in place its standing subgroups. This report therefore reviews the Committee's work over its first two year period; henceforth we shall publish Reports annually.

The ASC's membership is drawn from a diverse range of professional backgrounds. Roughly half were appointed on the basis of specific technical competences and the remainder as 'lay' members. Some of the Committee's members are employed in research using animals and in the animal protection sector, but all were recruited as individuals and required to act as such, and not as representatives of any interest or pressure group whether formally or informally constituted.

I have been impressed by the way in which my colleagues have been able to fulfil this requirement and to engage constructively as members of a team, notwithstanding a diversity of backgrounds and perspectives on the issues raised by the use of animals in research and testing. I am very grateful to them for this, and for the time and effort they have dedicated to the work of the ASC since the time of their appointment.

This work falls into two categories; some continuing responsibilities assigned to the Committee under legislation, and a requirement to provide advice to Ministers on specific issues as and when required or at the ASC's own initiative.

The ASC's continuing responsibilities chiefly comprise the provision of advice on such Project Licence applications as are referred to it by the Home Office's Animals in Science Regulation Unit Inspectorate (ASRU-I), and advice to Animal Welfare and Ethical Review Bodies (AWERBS) at the establishments licenced to conduct work with animals under the Animals (Scientific Procedures) Act 1986 (A(SP)A). Each of these responsibilities is discharged by one of the two standing subgroups reporting to the main ASC.

The Report also details a number of pieces of specific advice, prepared on behalf of the ASC by specially constituted 'Task and Finish Groups' in response to Ministerial requests. Amongst these was our advice consequent to the allegations made by the British Union for the Abolition of Vivisection (BUAV) in respect of Imperial College London. In this advice we stressed the importance of the role that A(SP)A assigns to Establishment Licence Holders, and the issues raised for Inspectors by what we termed 'patterns of low-level concerns'. I am pleased to say that the ASRU-I is currently taking this matter forward. The advice, reported here, on Harm-Benefit Analyses has also generated a work-stream which is currently on-going.

In conclusion, I should like again to thank my colleagues on the Committee for the time and effort they have committed to the ASC as well as those in the Animals in Science Regulation Unit , with whom we have established a fruitful and constructive working partnership. I am also most grateful to the many people and organisations I have met through visits, conferences, and other events, and who have willingly shared their experiences and contributed ideas in the promotion of our work.

Dr John Landers,
Chair of the Animals in Science Committee

Chapter 1

THE ROLE, REMIT AND MEMBERSHIP OF THE ANIMALS IN SCIENCE COMMITTEE

Legislation

The use of animals in research and testing is regulated under the Animals (Scientific Procedures) Act 1986 (A(SP)A). A(SP)A was recently amended to transpose European Directive 2010/63/EU on the protection of animals used for scientific purposes. The revised legislation came into force on 1 January 2013[1].

Article 49 of that EU Directive requires that each European Member State establish a National Committee for the Protection of Animals used for Scientific Purposes. In the United Kingdom, this Committee is known as the Animals in Science Committee (its predecessor being the Animal Procedures Committee (APC)).

Established under Sections 19 and 20 of A(SP)A, the Animals in Science Committee (ASC) is a non-executive, non-departmental public body sponsored by the Secretary of State for the Home Department. The ASC is responsible for providing impartial, balanced, and objective advice to the Home Secretary on issues relating to the 1986 Act and her functions under it. This especially relates to any experimental or scientific procedures applied to a protected animal that may have the effect of causing that animal pain, suffering, distress, or lasting harm.

Whilst Ministers commission key elements of its work, the ASC has scope to determine its own work streams and offer advice on issues within its remit.

In undertaking its work, legislation requires that the ASC take into account both the legitimate requirements of science and industry and the protection of animals against avoidable suffering and unnecessary use in scientific procedures.

There are four key requirements of A(SP)A that relate to the ASC:

- the ASC must provide advice to the Home Secretary and the Animal Welfare and Ethical Review Bodies (AWERBs) on such matters relating to the acquisition, breeding, accommodation, care and use of protected animals as the ASC may determine, or as may be referred to the ASC by the Secretary of State;

- in its consideration of any matter under its remit, the ASC has 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;

[1] https://www.gov.uk/government/publications/consolidated-version-of-A(SP)A-1986

- the ASC must take such steps as it considers appropriate to ensure the sharing of best practice in relation to the acquisition, breeding, accommodation, care and use of protected animals; and

- the ASC must take such steps as it considers appropriate to share the following information with other EU Member State committees:
  (a) information on the manner in which the Secretary of State evaluates applications for project licences; and
  (b) information on the operation of the Animal Welfare and Ethical Review Bodies.

Ministers

The function of the Animals in Science Committee is to provide the Home Secretary and the Northern Ireland Minister of Health, Social Services, and Public Safety with impartial, balanced, and objective advice on issues relating to A(SP)A.

The ASC receives, on an annual basis, a commissioning letter from the Home Office Minister with portfolio for animal regulation that sets out matters of particular importance to the Department, and the priority areas for the ASC to take forward across the coming twelve months, and, potentially, beyond.

The Ministerial commissioning letters are covered later in this report under Chapter 2 (Activities and Work streams).

Membership

Membership of the Committee is based on required skills, expertise, and experience based upon fulfilling its work objectives. Membership can be found at ANNEX A

The ASC therefore draws upon a diverse range of expertise from within its membership in order to effectively perform its function. Relevant areas of expertise include, but are not limited to, pharmaceutical research, statistics, animal welfare, veterinary science, and neuroscience (listed in the Home Secretary's/ASC Working Protocol, at Annex B).

Appointment of Committee Members

Members are appointed as individuals on the basis of their expertise, not as representatives of any organisation by which they are employed, nor as representatives of any particular employer, profession, organisation, or interest group.

The recruitment process and subsequent appointments for the current membership was carried out in accordance with the rules of the Office of the Commissioner for Public Appointments, with the decision on appointments of Committee members taken by the Home Secretary.

While it is likely that most of the expertise required by the ASC to fulfil its remit will be available from within its membership, the ASC is able to consult, or co-opt, outside experts if, for any reason, it needs to draw on expertise not covered by current membership.

When providing advice, the names of experts who are not Committee members, and have contributed to the evidence base is made clear.

Recommendations and final advice remain the responsibility of the ASC itself.

Guidance to members (guiding principles)

On appointment, members receive guidance about matters such as working procedures, guiding principles and representing the ASC. Principle to this is the Code of Practice for Science Advisory Committees (CoPSAC)[2], the Cabinet Office Code of Conduct for Board Members of Pubic Bodies[3], and the Seven Principles of Public Life (identified by the Nolan Committee on Standards in Public Life (within CoPSAC). Members are at all times expected to act in accordance with, and in the spirit of, these codes of conduct and practices.

Register of members' interests

Where members activities and interests might be in competition with matters under consideration, and which could be seen, or misinterpreted to be seen, to likely influence any advice provided by the ASC, there is a requirement for members to register all as conflicts of interest. Such interests could be either personal or business, and may be perceived, potential, or actual.

The Secretariat is required to compile and maintain a register of members' interests; the register is published on the ASC's website[4].

[2] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/278498/11-1382-code-of-practice-scientific-advisory-committees.pdf
[3] http://www.bl.uk/aboutus/governance/blboard/BoardCodeofPractice2011.pdf
[4] https://www.gov.uk/government/publications/animals-in-science-committee-members-register-of-interests

Chapter 2

ACTIVITIES AND WORK STREAMS OVER THE REPORTING PERIOD

Over the reporting period, there were six general meetings of the ASC, two in 2013, and four in 2014. The minutes of those meetings have been published and can be found on the ASC's website.[5] The ASC additionally held an extended meeting (24-25 March 2014) that included a retrospective assessment of its work, and to consider its future work streams for the coming year and beyond.

Working Protocol between the Home Secretary and the Committee

An early key piece of work was the development of a working protocol between the Committee and the Home Secretary (at Annex B).

The Protocol formally:

a. sets out the relationship between, and expectations of, the ASC and Ministers;
b. supports the ASC in discharging its duty under A(SP)A, both to provide advice on matters referred to it by Ministers and to consider relevant issues of its own volition;
c. provides a point of reference for those areas of expertise most likely to be relevant to the ASC; and
d. places the ASC's independent provision of scientific and ethical advice on a firm footing within the Home Office

Ministerial commissioning letters

At its meeting in October 2013 the ASC considered and discussed its first Ministerial commission (from then, Lord Taylor), which outlined the ASC's priority work streams for 2013[6], and beyond. These were:

- advice on the reporting of actual severity;
- advice on the review of Section 24 of the Act, which relates to openness and transparency;

[5] https://www.gov.uk/government/organisations/animals-in-science-committee
[6] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/243722/Lord_Taylors_letter.pdf

- consider the recommendations of the Animal Procedures Committee's (APC) Primate Subcommittee's Working Group's review on the assessment of cumulative severity – the Pickard report[7];
- commitments relating to animal use made by the, then, Coalition government;
- advice on animal project licence applications referred to the ASC; and
- advice on lessons identified and the broader issues following completion of reports into allegations of non-compliance following an undercover investigation by the British Union for the Abolition of Vivisection (BUAV) into Imperial College.

The ASC subsequently received a commissioning letter from the then Minister, Norman Baker[8], built on the earlier commissioning letter from Lord Taylor and including a number of new key areas of work for the Committee. These were:

- to consider and provide advice on the Home Office's Animals in Science Research Unit (ASRU) Inspectorate's harm-benefit analysis process, and consideration of whether this might be improved;
- the consideration of the APC's Primate Subcommittee's Working Group's report on cumulative severity;
- consideration and provision of advice on the revised version of the Animals (Scientific Procedures) Act Code of Practice for the care and accommodation of protected animals; and
- consideration and advice on the proposed revision of Section 24 of A(SP)A.

The areas of work within both Ministerial commissioning letters are reflected within this review document.

Committee Sub and Task and Finish Working Groups

To take forward the Ministerial commissioned work the Committee convened three subgroups:

- the Project Licence Applications Subgroup;
- the Animal Welfare and Ethical Review Bodies Subgroup; and
- the Harm-benefit Assessment Task and Finish Group.

Memberships of the Subgroups are listed at Annex C.

Project Licence Applications Subgroup

This Subgroup is chaired by Dr Landers, and is made up of specialist and lay members drawn from the main Committee.

Under A(SP)A (section 9(1)), the Secretary of State may refer certain animal project licence applications to the ASC for advice. The Guidance on the Operation of A(SP)A provides that advice will be sought on applications involving

[7] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/261687/cs_nhp_review_FINAL_2013_corrected.pdf

[8] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/350407/NB_to_John_Landers_ASC_annual_commission_11-08-2014.pdf

- the use of wild-caught non-human primates;
- the use of cats, dogs, equidae or non-human primates in severe procedures;
- use of endangered species;
- projects with major animal welfare or ethical implications;
- projects involving the use of admixed embryos falling into category 3 of the Academy of Medical Sciences report on Animals Containing Human Material[9] and category 2 where the predominance of an admixed embryo is unclear or uncertain (Section 5.18.2);
- projects which may invoke any of the 'safeguard clauses' in the Directive with respect to the purpose of primate use, proposals for the use of a great ape, or proposals to cause long-lasting pain, suffering or distress that cannot be ameliorated; or
- projects of any kind raising novel or contentious issues, or giving rise to serious societal concerns.

In examining the applications referred to it and in dialogue with the applicant and the Inspectorate, the Subgroup explores:

a. the purpose and principle objectives of the project;
b. the expected benefits as set out in the application[10], e.g. in terms of to man, animals or the environment;
c. how effectively the 3Rs (Replacement, Reduction and Refinement) have been implemented;
d. the predicted harms and ethical issues relative to the proposed benefits;
e. the level and nature of suffering that might be experienced by the animals (during the whole life-time of the project);
f. whether the project relates to progress made under previous or current project licences
g. whether unnecessary duplication of previous work been avoided
h. the study and programme design,
i. standards of housing and husbandry; and
j. the extent to which pain, suffering, distress and lasting harm can be avoided, managed or ameliorated.

The findings are then used to offer advice as to whether, in the ASC's view, the project licence is justified and if it should be granted and, if so, on the provision of particular conditions being applied. All of this information is used when deciding whether a project is justified, and advising the Home Office of the Subgroup's considerations and recommendations on the licence application.

Over the reporting period, the Home Office referred seven licence applications to the Committee for advice – three in 2013 and four in 2014.

In all of the licence applications considerations, the ASC Application Subgroup met with the applicant, and the associated assigned Inspector, to discuss in detail the individual procedures within the applications. In all cases – but with two having to be subject to a

[9] http://www.acmedsci.ac.uk/policy/policy-projects/animals-containing-human-material/

[10] Under A(SP)A the Secretary of State is required to carry out a harm-benefit analysis of the proposed programme of work to assess whether the harm that would be caused is justified by the expected outcome.

majority agreement - the Subgroup was satisfied that the licences for the proposed procedures be approved. However, this was subject to the acceptance (by the applicant and the Animals in Science Regulation Unit Inspectorate (ASRU-I) to any proposed amendments to licence applications made by the Subgroup.

In summary:

I. The first referral concerned a programme of work involving a special species, in neuroscience studies to investigate the nature of the interactions that exist between the different sub-areas in the prefrontal cortex, and between prefrontal and extra-prefrontal regions that are directly connected to the prefrontal cortex.

The Subgroup examined several aspects of this application including the likely suffering of the animals, the number of animals that proposed to be used, housing and husbandry, and operative and post operative care. Overall, the Subgroup agreed that the application provided clear, helpful, and well written information, particularly on the 3R's and on the adverse effects. Following consideration of the potential benefits of the proposed work, the Subgroup recommended that the application be approved, with an overall severity limit of severe on one protocol.

II. The second application concerned a programme of work involving a special species in neuroscience studies to investigate the role of the ventral visual pathway in the perception of stereoscopic depth.

The Subgroup was asked particularly to consider whether the benefits likely to proceed from this project outweighed the harms to the animals, and whether the severity limit of severe was appropriate.

Although the Subgroup noted that the application provided clear, helpful and well written information particularly on the 3R's and on the adverse effects, there remained a number of matters that the Subgroup sought clarification from the applicant. These were, predominantly, around areas of the techniques proposed in the preliminary training stages of the animals.

With the Subgroup encouraging use of positive reinforcement techniques and reducing the requirement for fluid control to achieve the same objectives, and a number of possible amendments to the licence application, the Committee recommended that the application be approved, with an overall severity limit of severe on the MRI and neurophysiology protocol.

III. The third application involved the use of a special species to examine neural control of movement, and to use the information to inform novel diagnostics and interventions in diseases of motor control, such as stroke and spinal cord injury.

The Applications Sub-Committee was asked to consider whether there was any scope for improvement in the application of the 3Rs to the proposed

work/application, and to consider whether the benefits likely to proceed from this project outweighed the harms to the animals.

The Subgroup felt that use of the 3Rs had been well reflected, and welcomed the use of reward motivation to encourage the animal to accept restraint. However, members of the Subgroup had a number of reservations about the overall severity of suffering that may be experienced by the animals. The Subgroup therefore sought from the applicant further detail regarding periods of restraint the animals would be subject to while under procedure and the proposed (potential) use of food and water restrictions as motivation, and discussed how to lessen these.

With a Subgroup majority in agreement to recommend the application (one member considered that the project could not be justified), the application was supported with a severity limit of 'severe'; this was subject to a number of Subcommittee recommendations being taken forward within the application.

IV. In January 2014, the ASC considered an application involving the use of a special species in procedures of severe severity, in chemical agent studies.

The Subgroup examined whether the expected benefits of this programme of work are sufficient to justify the harms in terms of animal welfare and whether the proposed species is the only suitable species for use.

The Subgroup considered that the application was comprehensive with the use of the 3Rs well reflected. In understanding the need and the aims of the project, and with further clarifications provided by the applicant, the Subgroup recognised the requirement for the use of the requested species in the project.

Following the consideration and examination of the potential benefits of the proposed work, one member considered that the project could not be justified. However, there was a majority agreement recommending that the application be approved with a severity limit of 'severe'. However, this would be subject further to a number of conditions being added to the application prior to it being granted.

The Subcommittee was encouraged to note from the application, and from discussion with the applicant, that the results from the research will be published and disseminated in open peer-reviewed scientific literature, wherever possible.

V. In July 2014, the ASC considered an application involving the use of a special species in neuroscience studies. The overall aim of the proposed programme of work was to explore how cognitive processes are mediated by neuronal network interactions and delineate the neurotransmitters involved.

The ASC considered several key aspects of the proposed project. This included whether the potential benefits were justified by the harms, whether

there was a contribution to fundamental knowledge and whether the protocols involved should be, as set out in the application, classified as moderate severity.

The Sub-group agreed that the fundamental knowledge accrued would contribute to a better understanding of cognition and receptor systems relative to neurodegenerative diseases beyond the life of this project. However, in view of the surgical interventions, the fluid restrictions proposed and length of time the animals may be restrained, the Subgroup recommended that the application should be re-categorised as severe; subject to this and compliance with a further number of the recommendations, the application was supported by the Subgroup.

VI. In October 2014, the ASC considered an application involving the use of a special species in neuroscience studies to test various hypotheses regarding the structure and function of cerebellar modules.

The application, as presented to the Subgroup, set out that the protocols should be classified as moderate.

The Subgroup carefully considered the procedures within the licence application, particularly with respect to the likely effects of those procedures on the animals involved, the potential harms to the animals (in terms of pain, suffering and distress) and the justification and the proposed scientific benefits of the project.

In discussion with the applicant, there was clarification that, in order to meet the objectives, there is a need to obtain high quality recordings from single cerebellar cells during natural behaviour; and, currently, this is possible in special species but not in, for example, rodents.

Following the Subgroup's consideration of the fundamental benefits to be gained from the proposed work, and being satisfied with the evidence presented that this work can only be done with the use of a special species (and that any other species would not yield adequate results), and that the potential benefits of the project licence were sufficiently focused and achievable, the Subgroup was satisfied that the application met the requirements of A(SP)A and accorded with a favourable harm-benefit assessment. However, this was subject to two (by majority agreement) Subgroup conditions; that one of the protocols within the application be re-categorised from 'moderate' to a category of 'Severe', and that the applicant will review the application stating clearly that the use of special species will only be undertaken when the use of rats is not possible.

VII. Also considered, in October 2014, was an application involving the use of a special species in neuroscience studies to examine mechanisms of movement generation and inhibition, including cortical and subcortical structures.

The Subgroup noted that the application demonstrated a clear commitment to the 3Rs, and the considerable efforts demonstrated to minimise the cost to the animals under procedure. Additionally, the Sub-group noted that the training

regime would use only positive reinforcement, where animals are rewarded for the desired behaviour, which is good practice.

Members deliberated on whether any other species could be used. In discussion with the applicant, there was clarification that the requested species have similar motor systems to humans; and that other species do not have that motor system.

In weighing the harms and the benefits, the Subgroup examined: the scope for translational benefits; the fundamental benefits to be gained from the proposed work; that the work could only be undertaken with the use of the requested species (and that any other species would not yield adequate results); that objectives as described are sufficiently focused and achievable; the duration that the animals would be under restraint; and that the proposed severity limits set out in the application were appropriate.

Following consideration, and discussion with the applicant, the Subgroup recommended that the application be approved; however, this would be subject to compliance with a number of conditions recommended by the Subgroup.

In consideration of an application, and provision of any subsequent advice or recommendations, the ASC has no executive powers to grant, revoke, or vary (amend) licences granted under A(SP)A – that rests with the Secretary of State.

Animal Welfare and Ethical Review Bodies (AWERBs) Subgroup

The Subgroup was convened to lead in the delivery of the Committee's functions regarding AWERB's, as set out under Section 20 of A(SP)A, in that:

> *'The Committee must provide advice to the Secretary of State and the Animal Welfare and Ethical Review Bodies on such matters relating to the acquisition, breeding, accommodation, care and use of protected animals as the Committee may determine or as may be referred to the Committee by the Secretary of State.'*

The Subgroup is chaired by Dr Landers, membership of the Subgroup can be found at Annex C.

A core requirement of the Committee (set out in A(SP)A) includes the sharing and promotion of best practice with, and between, AWERBs on matters relating to the acquisition, breeding, accommodation, care, and use of protected animals.
As an initial step, the Subgroup convened a one-day workshop on 13th November 2014. The workshop provided the first opportunity for a number of AWERB Chairs, from across the UK, to meet the Home Office's independent body responsible for advising on the care and use of animals under experimental or scientific procedures.

The workshop included both presentations and facilitated discussion sessions and provided an initial forum to: discuss the associated roles of the ASC and AWERBs, share experiences, identify challenges (and opportunities) and identify good practice (as well as its most effective indicators) and how these can be shared.

With extremely positive feedback from participants, a workshop report was produced. The published report[11] embodies the main points arising from the day's deliberations, and provides the foundation for the work strands of the Subgroup.

Harm-benefit Assessment Task and Finish Subgroup

Ministers tasked ASRU with conducting a review of the Harm-benefit assessment (HBA) process and requested that the ASC contribute to this review, with the first phase concentrating on the HBA process currently used for Project Licence (PPL) applications.

In early October 2014, the ASC was asked by the Home Office's Animals in Science Regulation Unit to review Appendix I of the Home Office Guidance Notes (which dealt with the HBA process) and, in consideration of the current process, to review and identify areas where further clarification, or change, of the HBA process might be useful.

The HBA Subgroup responded with its initial commentary on the Home Office's Harm Benefit Analysis Review on 31 October 2014. The Home Office welcomed the advice provided, accepting a significant number of the proposed revisions. [12]

Committee visits

Across the review period, Committee members made a number of visits to establishments licensed under A(SP)A. The purpose of the visits was to increase the outreach and raise awareness of the ASC, and to further develop understanding of establishments' processes and practices. The Committee is grateful to the establishments for the open approach they have shown in facilitating these visits.

[11] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/431907/ASC_AWERB_13_Nov_2014_Report.pdf

[12] Following that initial advice, the ASC Harm-Benefit Assessment is continuing its work in the analysis of the harm-benefit procedures and also the effect of cumulative severity and lifetime experiences in non-human primates used in neuroscience research.

PROVISION OF ADVICE

The following is a summary of the work of the Committee's subgroups and working groups.

Lessons to be learnt, for duty holders and the regulator, from reviews and investigations into non-compliance at Imperial College London

In April 2013, the British Union for the Abolition of Vivisection (BUAV) issued a report making a series of allegations concerning animal care and welfare at Imperial College London (ICL).

On 23 December 2013[13], the Committee was requested by the then Home Office Minister, Norman Baker, to carry out a review of both the Home Office's Animals in Science Regulation Unit Inspectorate report, and the independent report by Professor Brown, on the incidents of non-compliance at Imperial College. The terms of the review would be to provide advice on lessons learned and the broader issues, and to provide detailed recommendations for improvements toward improving the standards of animal care and welfare.

To take forward the review, the Committee convened a working group chaired by Dr Landers, with Anna Rowland and Ken Applebee as members.

In general, the Committee expressed concern, based on the findings of the ICL independent review, that there had been significant management, communication, training and procedural issues within the establishment. Additionally, it found no evidence of omission on the part of the Home Office Inspectorate in its oversight of ICL over the period in question. It recognised, however, that there were difficulties for the regulator in addressing a pattern of low-level concerns, which may be individually insufficient to require action, but when taken together are symptomatic of an establishment management and welfare regime falling short of expected standards.

The ASC's report recommended a number of improvements to the Home Office's Animals Inspectorate procedures that would introduce greater rigour into their mechanisms for dealing with patterns of low-level concerns. The recommendations were accepted, with work on the area of low-level concerns now being examined by ASRU.

The full report of the review, endorsed by the Committee, was presented to Ministers and published on 2 July 2014[14]. The recommendations within the report are listed below:

- **Recommendations to the Minister**

A. That the Home Office Inspectorate (HOI) is given a clear mandate to identify and remedy failings of the kind identified in the reports with respect to establishments' standard of provision, AWERB and overall institutional culture regarding animal welfare and the 3Rs, including the exercise of effective strategic leadership.

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13 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/321476/Letter_from_NormanBaker_to_John_Landers.pdf

14 https://www.gov.uk/government/publications/lessons-to-be-learnt

B. In order to ensure consistency of approach and appropriate standards in the HOI's response to patterns of low-level concerns in these areas, guidance should be produced for HOI staff on the process to be followed when dealing with them. This guidance would focus on HOI procedures rather than specific solutions to the concerns identified; these must be individually tailored to each facility and driven extensively by input from the facility itself. The guidance should promote transparency regarding the HOI's approach to these types of concerns.

C. The HOI should review its process for recording the outcome of inspection visits to ensure that follow up of low-level concerns identified on inspection visits is clearly recorded to ensure that patterns of concerns are picked up appropriately and to improve transparency in relation to how these concerns are dealt with.

D. That the HOI reviews its system of risk assessment to ensure that establishments where there may be an unacceptable risk of non-compliance and/or inadequate provision are rapidly identified.

E. The HOI should ensure that the ELH's responsibility to promote a culture of care throughout their establishment is properly understood and discharged.

F. The accountability of the ELH to the Home Office is given concrete expression through the application of appropriate sanctions in cases of serious failure to discharge their responsibilities.

G. That the Minister should consider whether he can continue to have confidence in the current ELH at ICL retaining this role.

- **Recommendations to the institution**

H. Licence holders should ensure that all those involved with work under A(SP)A have a readily accessible means of raising 'causes for concern' with the management of their establishment, and the HOI's mandate should extend to monitoring these arrangements.

I. In order to promote the wider involvement of biomedical staff in animal-based research, licence-holding academic institutions should be encouraged to provide wider financial support to their biomedical services – beyond routine 'basic husbandry and welfare duties' – from their central budget outside the provisions of fEC.

ASC response to Pickard report on the assessment of Cumulative Severity

In November 2013, the former Animal Procedures Committee's (APC) Primate Subcommittee Working Group published its report on the Review of the Assessment of Cumulative Severity and Lifetime Experience in Non-human Primates Used in Neuroscience – the Pickard report[15]. This work had been started by the APC Primate Subgroup, prior to the establishment of the Animals in Science Committee.

Leading up to the publication of the Pickard report, the ASC was, at the request of Lord Taylor (then Home Office Minister for the regulation of animals in science), asked to consider and comment on the findings and recommendations of the report[16].
The ASC responded to Ministers on 15 July 2014 with its initial considerations and recommendations[17]. The ASC, overall, welcomed the report as a thought provoking

[15] https://www.gov.uk/government/publications/animal-procedures-committee-cumulative-severity-review
[16] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/243722/Lord_Taylors_letter.pdf
[17] https://www.gov.uk/government/publications/cumulative-severity-review-response-by-animals-in-science-committee

contribution around the assessment of cumulative severity and lifetime experiences of non-human primates used for scientific purposes. However, it also noted that the report was largely based on qualitative data, which were used to describe the respondents' perceptions of the animals' welfare. The ASC felt it would be valuable to accumulate more data on emotional and psychological indicators of distress as a critical component of the assessment of animal welfare.

In acknowledging the contribution that the Report makes in taking an initial step towards a framework for identifying, monitoring and collating information for evaluating cumulative severity, the ASC convened a Harm-benefit Task and Finish Subgroup (membership can be found at Annex C); the terms of reference include examining how the recommendations within the Pickard report can be effectively taken forward. This work is ongoing.

ASC advice and consideration of options for the review of Section 24 of the Animals (Scientific Procedures) Act 1986

In July 2014, the ASC was asked by the Home Office to provide its considerations and advice on the analysis of the public consultation on options to review Section 24 of A(SP)A (protection of confidential information and intellectual property rights), and proposals therein. The ASC welcomed the opportunity to make such a contribution and provided its advice on 14 August 2014 (see Annex D); the advice provided was well received by the Home Office.

ASC advice on the revised Code of Practice for the Housing and Care of Animals Bred, Supplied or Used for Scientific Purposes

In September 2014, the ASC responded to a request from the Home Office to provide advice on the, then, draft revised Code of Practice for the Housing and Care of Animals Bred, Supplied or Used for Scientific Purposes.

The ASC provided initial advice on four specific areas of the Code, as asked by the Home Office (see annex E). The advice included proposed amendments to the draft Code to ASRU and a small number of pragmatic and forward looking recommendations. A number of amendments were made to the draft code to reflect the comments made by ASC.

ASC advice on the draft Guidance on the Operation of A(SP)A

In November 2013, the ASC provided the Home Office with advice on the Draft Guidance on the Operation of the A(SP)A and the Draft Guidance on the use of Human Material in Animals (see Annex F).

Chapter 3

RESOURCES

Costs

The ASC is funded by the Home Office. Budget allocations for the accounting years 2013/14 and 2014/15 were £18,677 and £12,836 respectively.

Costs were associated with recruitment and the provision of facilities for meetings, and expenses properly incurred by members in the undertaking their Committee duties.

Members are unremunerated for their activities on behalf of the ASC.

Secretariat

The ASC's administrative support has been provided by the Home Office Science Secretariat, with costs for the Secretariat met from the Home Office Science Secretariat budget.

MEMBERSHIP & BIOGRAPHIES[18] OF ASC MEMBERS

Chairman

Dr John Landers, was formerly Principal of Hertford College, Oxford where he is now a Senior Research Fellow. Before this he was Lecturer in Biological Anthropology at University College London, and subsequently University Lecturer in Historical Demography and a Fellow of All Souls College, Oxford. He is a member of the International Union for the Scientific Study of Population and a Fellow of the Royal Historical Society. His academic speciality is Historical Demography with particular reference to the history of infectious disease mortality.

Members

Ken Applebee, a former chair of the Institute of Animal Technology Council and is currently Director of Biological Services at King's College London. Ken has over 30 years experience in biomedical science and research. His career includes valuable experience as a professional animal technologist in a number of academic institutions. He is a long serving and active member of the Council of the Institute of Animal Technology (IAT), serving for a number of years as Chair and currently Chair of the IAT Board of Educational Policy. Ken is taking the lead in advanced discussions to develop a new BSc in Laboratory Animal Science and Technology.

Professor Gail Davies, is Professor in Human Geography at the University of Exeter, and was previously Senior Lecturer in Geography at University College London. Professor Davies' academic work explores the global cultures of science and technology, with specific reference to biotechnological and biomedical sciences, and the place of animals in contemporary societies. She has carried out long-term research interests in facilitating public and critical artistic engagements with science and technology.

Dr Sophie Dix, is a senior research scientist at Eli Lilly and Co. Dr Dix's principal research interest is the development of models of rodent cognition that applies directly to human disease conditions such as those affected in Alzheimer's disease and schizophrenia.

Professor Simon Glendinning is Reader in European Philosophy at the London School of Economics. Professor Glendinning has a long standing research interest in the idea of the difference between human beings and other animals, and the history of Western conceptions of animal life. He is currently Chair of the British Horseracing Authority Ethics Committee.

[18] ASC members' biographies within this Report relate to the reporting period 2013-2014. Current biographies can be found on the ASC's website.

Dr Huw Golledge, is Senior Scientific Programme Manager at the Universities Federation for Animal Welfare and the Humane Slaughter Association, charities which work towards the welfare of animals through scientific knowledge. Trained as a neuroscientist, Dr Golledge was formerly an animal welfare researcher at Newcastle University, where he had specific research interests in assessing the welfare impacts of anaesthesia and humane killing techniques for rodents.

Dr Penny Hawkins, is Head of the RSPCA's Research Animals Department, which works to achieve effective ethical review of animal research and the replacement of animal experiments, reductions in numbers and suffering and improvements in welfare while animal use continues. Dr Hawkins has been involved in the revision of European legislation regulating animal experiments and is currently a member of two Animal Welfare and Ethical Review Bodies in the UK.

Professor Malcolm Macleod is Professor in Neurology and Translational Neuroscience at the University of Edinburgh and Consultant Neurologist at Forth Valley Royal Hospital. Professor Macleod's clinical research includes trials of brain cooling for stroke. He has pioneered the use of systematic review and meta-analysis to analyse data from animal experiments in the neurosciences, and is a staunch advocate of improving experimental rigour and of evidence based clinical trial design.

Dr Matthew Parker, read psychology at the University of Southampton and received his PhD in animal behaviour and welfare in 2009. Since then his research has focused on animal behaviour, first at the Royal Veterinary College in Hertfordshire where he studied farm animal welfare, and now at Queen Mary, University of London, where he studies molecular markers of human psychiatric disease using zebra fish as a comparative model. He has published widely on animal behaviour and welfare, and has presented papers at both national and international conferences.

Anna Rowland, is Assistant Director of Policy for Fitness to Practice at the General Medical Council (GMC). She qualified as a solicitor, leaving the practice to specialise in legal policy. She has an extensive background in legal and medical policy having held senior policy positions at the Law Society prior to joining the GMC in 2008.

Dr Gerlinda Stoddart, is Science Adviser, People for the Ethical Treatment of Animals (PETA) and gained her PhD from the Welsh School of Pharmacy in 2002. Dr Stoddart has several years experience working in the R&D industry developing transdermal products. Dr Stoddart is now the Science Advisor for an animal protection organisation where she works with regulators, policymakers, industry and other scientists to reduce the use of animals in experiments, improve their welfare and ultimately eliminate animal experimentation altogether.

Professor Sarah Wolfensohn, is Professor of Animal Welfare at the University of Surrey School of Veterinary Medicine. She is a veterinary surgeon and is a European specialist in both laboratory animal medicine and in animal welfare, ethics and law, and has a background in general practice. Professor Wolfensohn has over 25 years' experience in both academia and the pharmaceutical industry working with a wide range of species and experimental models. Her particular areas of expertise are ethical evaluation of projects, training of those involved in the use of animals in science, and primate management and welfare.

Professor Gavin Woodhall, a professor of Neuropharmacology and Director of Biomedical Sciences School of Life and Health Sciences, Aston University. Professor Woodhall gained his PhD in neuroscience at the University of Southampton in 1991 and this was followed by post-doctoral research at the Universities of Montréal and Bristol. Since 2004, he has been based at Aston University and Birmingham Children's Hospital, studying mechanisms underlying drug-resistant epilepsy in children and developing 3Rs-based, refined animal models of the epilepsies.

WORKING PROTOCOL BETWEEN THE HOME SECRETARY AND THE ANIMALS IN SCIENCE COMMITTEE

1.0 Background and scope

1.1 The use of animals in regulated scientific procedures raises ethical, animal welfare and scientific issues. It is essential that animal welfare ethical review bodies, practitioners, policy makers, and ministers have access to the best available evidence and advice to inform their interests in this field. For this reason, the Government values the work and independent advice of the Animals in Science Committee (ASC).

1.2 The ASC is an independent, non-executive, non-departmental public body set up under Sections 19 and 20 of the Animals (Scientific Procedures) Act 1986 as subsequently amended, hereinafter referred to as "the Act". The ASC is responsible for providing impartial and objective advice to the Home Office and the Department of Health and Social Services for Northern Ireland, and to the animal welfare and ethical review bodies, on issues relating to the 1986 Act and their functions under it. It is also responsible for exchanging information and exploring possibilities for collaboration with 'national committees for the protection of animals used for scientific purposes' in other European Union (EU) member states, and for sharing good practice within the EU on the operation of animal welfare bodies (animal welfare and ethical review bodies in the UK) and project evaluation.

1.3 This working protocol supports the ASC in discharging its duty under the Act, both to provide advice on matters referred to it by Ministers, and matters considered under its own volition. The working protocol also provides a point of reference for those areas of expertise most likely to be relevant to the ASC.

1.4 The Home Secretary has entered into this protocol with the ASC, as the Secretary of State who sponsors the ASC as an advisory non departmental public body and discharges the responsibility for making appointments to the body. The Home Secretary will generally delegate responsibilities in this area to a designated Minister, referred to in this protocol as "the Minister". This document will be reviewed as appropriate.

2. Engagement

The key principles set out below intend to support effective engagement between the ASC and the Government.

2.1 The ASC and Ministers are committed to ensuring that the best evidence-based advice is available to Government on the use of animals in science, working together with the common purpose of the effective application of ethical review and the "3Rs" (the Replacement, Refinement and Reduction of animals in research and testing), taking into account the legitimate requirements of science and industry, the protection of animals against avoidable suffering and unnecessary use in scientific procedures, and the Government's commitments to end the testing of household products (including their ingredients) on animals and to work to reduce the use of animals in scientific research.

2.2 In discharging their respective responsibilities:

i. The ASC and its members will work under the Code of Practice for Scientific Advisory Committees[19], incorporating the Seven Principles of Public Life (the Nolan Principles[20]). In particular, the ASC Chair and its members will act in the public interest and observe the highest standards of public office, including impartiality, integrity, and objectivity, whilst being accountable through Ministers to Parliament and the public.

ii. Ministers will continue to work under the Guidelines on the Use of Scientific and Engineering Advice in Policy Making[21] and the Ministerial Code[22], which states that Ministers "should have regard to the Principles of Scientific Advice to Government."

2.3 In continuing to provide its advice on the available evidence to the Minister:

(i) The ASC will work with best endeavours to the Government's priorities for the ASC that will be communicated by the Minister in writing at appropriate intervals, including any "in year" requests for advice. The ASC will also consider and take forward work of its own volition which it considers appropriate within available resources.

(ii) The ASC will be guided by the relative priority given by the Minister to each of the specific commissioned areas of work to inform its programme of work, taking into account work that it may wish to undertake of its own volition.

(iii) The ASC will inform the Minister how it intends to take forward commissioned work and will set out putative timelines. With due regard to the ASC's duty to consider any matter referred to it by the Minister, and matters of its own volition, in the event that the ASC foresees or encounters difficulties in providing advice or prioritising that advice in the manner requested, the Chair of the ASC will discuss the ASC's reasons with the Minister.

(iv) The ASC will publish its advice concurrent with its presentation to the Minister, unless there are pressing reasons for not doing so. (Such reasons

[19] http://www.bis.gov.uk/assets/goscience/docs/c/11-1382-code-of-practice-scientific-advisory-committees.pdf
[20] https://www.gov.uk/government/publications/the-7-principles-of-public-life
[21] http://www.bis.gov.uk/assets/goscience/docs/g/10-669-gcsa-guidelines-scientific-engineering-advice-policy-making.pdf
[22] https://www.gov.uk/government/publications/ministerial-code

might include, for example, issues of national security or the safety of individuals, prevention of crime or the protection of property (including intellectual property or commercially sensitive information), or other sensitivity of documents or information.)

(v) The Chair of the ASC will report to the Minister on progress against each of the priorities on a six-monthly basis when they meet. It is expected that the ASC's annual report will reflect the ASC's on-going commitments and priorities as above. It shall be the duty of the ASC Chair to bring to the attention of the Minister any substantive matter pertaining to the use of animals in science, considered by him/her or the ASC, before making public statements thereof; this is exclusive of those matters under formal consideration by the ASC, whether requested by the Government or of its own volition, where there is an expected publication procedure.

2.4 In commissioning work of the ASC, the Minister will take account of the ASC's current work programme, including any work that it is undertaking of its own volition. In continuing to give careful consideration to all of the ASC's advice:

i. The Minister will not pre-judge the ASC's advice in advance of receiving it;

ii. The Minister should meet with the ASC Chair on a regular scheduled basis, at least twice a year, and either the Minister or the Chair may request additional meetings at other times;

iii. Before issuing a response, the Minister will give appropriate consideration to the ASC's advice;

iv. If the Minister is minded not to accept the ASC's advice, the Minister will, before making a final decision, offer the opportunity for a discussion with the Chair of the ASC, or nominated representative;

v. If key recommendations are not to be accepted, the Minister will write to the ASC setting out the reasons for rejection in advance of any public comment by the Home Office on the matter;

vi. The Minister will look to provide a decision on all ASC recommendations, and to give a response (published subject to the same provisos as the advice itself) within 3 months of receipt. If a response is unlikely to be published within 3 months, the ASC will be informed of the reasons and a prospective date given; and,

vii. The Home Office will provide the ASC with the resources and support required to carry out its functions under the Act and the programme of work commissioned by the Minister, without in any way constraining the committee in the way it chooses to carry out its work.

3. Expertise and the Membership

3.1 The ASC needs to draw on a diverse range of expertise from within its membership in order to fulfil its duties. The relevant areas of expertise will vary according to issues under consideration at any time. The list below sets out what these are likely

to include. This is not, nor is it intended to be, an exclusive or exhaustive list of likely relevant areas of expertise, but will be given due regard when appointments are made to the ASC.

3.2 The ASC should inform the Home Office of desired expertise based upon fulfilling the Minister's and its own work objectives. The Home Office will seek the views of the ASC to inform any recruitment campaign for ASC members before any recruitment process is undertaken. The Home Office Chief Scientific Adviser will advise the Minister on the balance of membership requirements appropriate to the available resource and the need for effective functioning.

3.3 For recruitment panels for new members (excluding the Chair), the ASC Chair, or nominated representative chosen from among the membership of the ASC, should sit on the panel. The final decision on appointments remains with the Home Secretary. The Code of Practice for Ministerial Appointments to Public Bodies, including the Seven Principles of Public Life, applies to all appointments to the ASC. All members of the ASC are appointed as individuals on the basis of their expertise, not as representatives of any particular profession, employer, or interest group.

3.4 While it is likely that most of the expertise required by the ASC to fulfil its remit will be available from within its membership, the ASC is always able to consult, or co-opt, outside experts if for any reason it needs to draw on expertise not covered by current committee members. When advising Government, it will make clear to the Minister (and, if the advice is published, to the public) the names of outside experts that have contributed to the evidence base. However, recommendations and final advice remain the responsibility of the ASC itself.

3.5 The relevant areas of expertise are likely to include:

a. the use and welfare of non-human primates in scientific procedures;
b. the use of animals in the pharmaceutical industry, including the work of contract research organisations in a regulatory environment;
c. animal welfare[23];
d. approaches and technologies for the replacement of animals in scientific procedures by non-animal alternatives;
e. statistics and experimental design;
f. veterinary science and practice;
g. ethics;
h. law (including the legislative process and an understanding of public policy);
i. the breeding, care and acquisition of animals;
j. the form, function and working of the local animal welfare and ethical review body;
k. clinical experience, with an understanding of the patient experience; and
l. the creation and use of animals containing human material.

[23] Animal welfare in general, as well as specific to the use, breeding and supply of animals protected under the Animal (Scientific Procedures) Act.

3.6 It is anticipated that the ASC membership will be drawn predominantly from those with expertise as listed above. The list of likely relevant expertise will be kept under periodic review by the ASC and the Government, acting in concert.

4.0 AGREEMENT

4.1 This working protocol was agreed between the Minister and the Chair and members of the ASC.

1 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/278498/11-1382-code-of-practice-scientific-advisory-committees.pdf
2 https://www.gov.uk/government/publications/scientific-and-engineering-advice-guidelines-for-policy-makers
3 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/61402/ministerial-code-may-2010.pdf

ANNEX C

Memberships of Sub and Working Groups (as at 31 December 2014)

Project Licence Applications Subgroup
Dr John Landers (Chair)
Mr Ken Applebee
Dr Huw Golledge
Professor Malcolm Macleod
Dr Matt Parker
Professor Gavin Woodhall
A lay member of the Committee (on a rotating basis) attends.

Animal Welfare and Ethical Review Bodies Subgroup
Dr John Landers (Chair)
Mr Ken Applebee
Dr Sophie Dix
Professor Simon Glendinning
Dr Penny Hawkins
Dr Gilly Stoddart
Professor Sarah Wolfensohn

Harm Benefit Assessment Task and Finish Subgroup
Professor Gail Davies (Chair)
Dr Huw Golledge
Dr Penny Hawkins
Ms Anna Rowland
Professor Sarah Wolfensohn
Professor Dominic Wells (Co-opted member)
Dr Kate Chandler (Home Office observer)

ANNEX D

The A S C

Animals in Science Committee

Dr John Landers, Chair of the Animals in Science Committee
1st Floor, Peel Building NE, 2 Marsham Street, SW1P 4DF
Email: asc.secretariat@homeoffice.gsi.gov.uk
Tel: 020 7035 4776

14 August 2014

Animals in Science Regulation Unit
2 Marsham Street
London
SW1P 4DF

Animals in Science Committee response to the review of Section 24

Thank you for your letter of 29 July seeking advice on your proposals for the review of section 24.

Your letter sets out your proposals to review S24 through secondary legislation under S75 FOI which provides for the removal or relaxation of prohibitions to the disclosure of information including consequential, incidental or transitional provision.

I note that while it is suggested that, in light of the options consulted upon, the only viable option under S24 is to repeal S24 in its entirety, your letter proposes a partial repeal of S24. Is there any difficulty moving forward with a partial appeal as proposed in your letter, in view of the fact that this option was not contained in the consultation?

I note that there was very little support for a new criminal offence of 'malicious intent' and that this is not included in your recommendations (and is not viable under s75 FOI). We agree that a criminal offence is problematic. I note the biosciences sector was concerned about an offence that required intent in order to secure conviction. Members of the committee also had concerns about a strict liability offence where intent would not be required for liability to arise.

Your letter sets out two alternative proposals:

1. Use FOI to relax S24 by keeping protection only **for information that is confidential at the time that it is given**, rather than any and all information that was provided in confidence; or alternatively

2. To use FOI to relax S24 by keeping protection only for information that it is **intellectual property**, rather than any and all information that was provided in confidence.

From the report there appeared to be wide support for a repeal of S24 with a significant concern being registered by the biosciences sector and academic community specifically in relation to the protection of intellectual property. We note the minority view from some respondents from industry in relation to the need for a direct threat to be demonstrated before sensitive information can be exempted under FOI. However, the majority view, including from industry was that FOI was adequate in this respect.

Given the clear concerns expressed by the biosciences sector specifically about protection of IP, we support the proposal to relax s24 in such a way that protection is maintained for IP while all other information becomes subject to disclosure unless exempt under FOI. Although there was significant support for repeal of s24, the report demonstrates a significant concern expressed by the Biosciences sector and in particular academia for the need for clear protection for intellectual property that does not involve organisations in complex and burdensome assessments of FOI exemptions that would need the significant involvement of lawyers.

It would be useful to understand what arrangements operate where there is a dispute about whether information falls into the category of IP. Under option 2, if an information holder identifies non-IP information as IP under the definition in that section in order to avoid disclosure, we presume this would be a breach of the FOIA and therefore the requestor could make a complaint to the Information Commissioner.

We note your concerns about whether option 2 can be achieved by way of a relaxation of S24 because it would require a definition of IP to be included. If, for that reason, your preference is to progress option 1 then the wording of that option needs further clarification.

Firstly, we assume that under this option, the definition of IP would be governed by the FOIA and therefore any dispute about whether information falls within the definition of IP in the FOIA could be referred to the Information Commissioner.

Secondly, you described that option as seeking to relax S24 to protect only information that is inherently confidential as opposed to all information that is provided in confidence. By inherently confidential we assume you mean information that is protected from disclosure by law (other than by s24). If so, we consider that the relevant time period is not **‘when the information is provided’,** but **‘when a request for disclosure is made’**. We would envisage that if the law is changed to remove protection from a category of information it would not be desirable to prevent its disclosure indefinitely because the law protected it at the time it was provided, particularly because in this scenario the information is likely to be in the public domain. Conversely, if the law is changed to protect a new category of information (probably in light of evidence of a need for protection) it would not seem desirable for that information to fall outside the terms of s24 indefinitely because it was not a legally protected category of information when it was provided.

If you have queries about this advice then I would be happy to take your call or meet to discuss this further.

Yours sincerely

Dr John Landers, Chair, Animals in Science Committee

ANNEX E

The A S C
Animals in Science Committee

Direct Line 020 7035 4776 email: asc.secretariat@homeoffice.gsi.gov.uk
Website: https://www.gov.uk/government/organisations/animals-in-science-committee

4 September 2014

From the Chairman
Dr John Landers

Home Office
Animals in Science Regulation Unit
2 Marsham Street
London
SW1P 4DF

Animals in Science Committee (ASC): Animals in Science Regulation Unit (ASRU) Draft Codes of Practice

The ASC has now considered, by e-mail correspondence, the four questions which ASRU put to it in respect of the draft Code of Practice, and I am attaching a document setting out the Committee's response. I am very grateful to my colleague Dr Huw Gollege who acted as co-ordinator in this and was the document's principal author.

You will see that there was a division of view on one issue in particular, but the attached has been adopted by a majority vote of the Committee and should be taken as our collective view on these issues.

In the course of the correspondence, it became clear that some members had concerns on issues beyond those incorporated in the four ASRU questions – principally as regards the application of 'performance' or 'engineering' criteria to housing and environmental variables. We are currently engaged in formulating a Committee view on this matter and I hope to let you have the result in the next week or so.

Dr John Landers
Chair of the Animals in Science Committee

ASC response to questions raised by ASRU on the draft Code of Practice

The ASC has considered the four questions raised by ASRU regarding the new Code of Practice and its responses are provided below.

1. Retention of higher UK standards in force prior to 2010 (Introduction P1 L11-12)
Q 1.1 Does the ASC concur with this position?

On the retention of higher UK standards in force prior to 2010; the Committee agreed that these standards should be retained and that where deviation from the standards was sought (because they were suggested to impede science or industry) that a robust and adequately evidenced justification, accompanied by a harm/benefit analysis, would be required before any derogation from UK standards was permitted.

2. Definition of to whom and where the code of practice applies (Introduction P1 L16-18).
Q 2.1 Does the ASC agree with this definition?

The committee agreed with the definitions of the scope of the Code of Practice.

3. Mandatory and advisory standards (Introduction P1 L26-31, P3 L89-101, P5 L106-107, P5 L132-143).

Q 3.1 Does the ASC agree with this structure (mandatory and advisory sections)?
There was general support in principle for this two-part structure, although some members felt that the term 'advisory' was inappropriate, given the wording of section 8.3 of the introduction, and would have preferred 'expected' (see answer to Q 3.3 below).

Q 3.2 Does the ASC agree with the intent of section 3 standards?
The Committee supported the intention of section 3 in so far as this was to encourage practices which went above the 'bare minimum' standards required to comply with Sections 1 and 2.

Q 3.3 Does the ASC feel that this intent has been adequately communicated in the Introduction?
The Committee does not believe that the Introduction adequately communicates the intent of the section 3 standards, at least as regards the interpretation of the term 'advisory' and the consequences of an establishment's failure to meet them. The text is ambiguous as to: (i) whether these standards are simply desirable, or whether establishments would be expected to comply with them in the absence of strong reasons for not doing so, and; (ii) if the latter, whether failure to comply would attract sanctions, what these would be, and how they would be applied. The Committee was divided as to which of the two approaches was preferable, but believed that greater clarity was essential in either case.

4. Definition of breeding animals (Introduction P5 L152)

Options:

a) Maintain the status quo
b) Breeders adopt *user* standards
c) Users adopt *breeder* standards

The ASRU preferred option is option (c)

Q 4.1 Does the ASC concur with this position?
This was a difficult topic for the Committee, which recognises that it is required to have regard to both the legitimate requirements of science and industry and to the protection of animals against avoidable suffering. When considering this question, members identified economic, animal welfare and scientific implications associated with each option, and individuals differed as to the relative weighting that they believed ought to be afforded to these.

There was thus a division of views among the Committee with some members favouring (b), on the basis that this option promoted higher standards of housing, with benefits for both animal welfare and science. These members did not accept arguments that welfare improvements would be insignificant, or that costs would be disproportionate. Other members preferred (a), since this at least precluded the possibility of standards being reduced.

By a majority, however, ASC concurred with ASRU's preference for (c), on the basis that most members accepted the advice provided by ASRU and other bodies that:
(i) any additional welfare benefits gained from larger 'user-standard' enclosures were small since 'diminishing returns' set in beyond a certain enclosure size (though some members thought that this case had not been adequately made out);
(ii) the imposition of user-standards across the board would force increases in costs disproportionate to any welfare gains, which could also risk increasing the scale of imports and the associated transport stress on the animals involved; and
(iii) the maintenance of the *status quo* placed an unfair economic burden on user establishments engaged in breeding, putting them at a disadvantage relative to commercial breeders.

Animals in Science Committee
4 September 2014

ANNEX F

The A S C
Animal in Science Committee

3rd Floor, South West Quarter, Seacole, 2 Marsham Street, London SW1P 4DF
Direct Line 020 7035 3053 email: asc.secretariat@homeoffice.gsi.gov.uk
web-site: https://www.gov.uk/government/organisations/animals-in-science-committee

24 October 2013

Animals in Science Regulation Unit
Home Office
2 Marsham Street
London SW1P 4DF

Dear Colleague

You will recall that the ASC discussed, at its meeting of 14 October, the Draft Guidance on the Operation of the ASPA and the Draft Guidance on the use of Human Material in Animals (ACHM). I would like to thank you, and your ASRU colleagues, for finding the time to come along to that meeting to discuss both guidance documents. Although a number of considerations were put forward by ASC members, it was agreed that any additional thoughts could be forwarded by email. Accordingly, for your note, please see the undernoted comments.

1) ASC comments on the Draft Guidance on the Operation of the ASPA (as amended)

a) The draft ASPA Guidance has the potential to say more about data sharing and international contexts to research. This could be something to develop with the potential for further review in several years' time.

b) It would have been valuable to see the text on the likely benefits in the Guidance on the operation of ASPA. An indication of the nature of the criteria through which benefits are evaluated would be helpful. The question of potential 'translate-ability' of certain animal models is an issue raised between different model organism communities and by publics too. It would be good to see how this question might be creatively and directly addressed for the future.

c) Replace 'man' in the ASPA documents with humans where possible (i.e. when not required by the original wording of ASPA or referring to questions of species identity). There are two issues here; (**NOTE -** These comments similarly apply to the Draft Guidance on ACHM Item 2 below)

- Consistency between AHCM and ASPA guidance, e.g. when referring to the sequence of say clinical trials from animals to man etc. Members consider the term 'humans' is more appropriate in most cases; and

- The plural is important, especially as personalised medicine gathers pace and therapeutic developments may raise different issues for different groups; the use of the singular ‘man’ obscures questions about the distribution of risks and benefits.

d) Extending the language around fire precautions (standard condition 19) to include flood risks. Bearing in mind recent laboratory flooding events in New York and Houston, and the potential for increased future flood risks, this seems an issue that could benefit from flagging for more precautionary vigilance.

e) There is a blurring of the singular and plural forms in the ASPA Guidance.

f) In the glossary there is a brief explanation about some of the organisations referred to but not all. It would be useful to briefly explain them all.

g) Is there a need to clarify the threshold for the need for an establishment licence on page 25? The guidance says 'you may not carry on an undertaking involving any of the activities listed below unless you are authorised to do so in an 'establishment licence' granted under ASPA section 2C.' Further down it says 'An establishment engaging in two or more of the activities listed above must be authorised accordingly. There is a contradiction in relation to whether 'any' or only 'two or more' of the activities trigger the need for a licence.

h) There is a typo on page 27 - the word 'be' missing from line 35. The sentence should say “it is considered to ‘***be***’ at least as humane as a method listed in Schedule 1 as being appropriate for the type of animal.”

i) On page 34 (3.13.8) the guidance refers to care or conditions for an animal must be 'appropriate for its health and wellbeing'. It may be obvious what that means, but is there an objective standard and if so it could be referred to?

2) ASC comments on Draft Guidance on the use of Human Material in Animals (ACHM)

a) The comments in 1c) on ASPA Guidance above also apply to ACHM Guidance.

b) Page 5, and the rest of document:

- ‘Foetal’ is incorrect; the correct spelling is ‘fetal’ (e.g. as used by the HFEA).

c) Page 6, second section:

- Should be ‘harms’ not ‘costs’.

d) Page 7, paragraph on AWERBs:

- This does not give much of an impression of the roles of the AWERB – suggest cross refer to page 19.

e) Page 17, first paragraph:

- Wording ‘should be permissible’ is inappropriate, as the ASPA is an enabling piece of legislation with a presumption against animal use unless justified. More appropriate wording would be ‘*may be permissible, subject to a positive harm/benefit assessment and additional specialist scrutiny by a national expert body*’.

f) Page 17, last line:

- How ‘regular’ would the review be?

g) Page 18, line 5:

- An animal can never be a ‘donor’ ‘*Source*’ is more accurate.

h) Page 18, at end of ‘Regulation of category 2’:

- This says advice may be sought from the ASC, but the first line on page 17 and the last paragraph on page 18 both say that it will – so should change from ‘may also be sought’ to ‘will also be sought’.

i) Page 19,

- Should say ‘The roles of the AWERB include the following: providing … and reviewing…’

I hope you find the comments helpful, and thank you for inviting the ASC to comment on the documents.

Yours sincerely

ASC Secretariat