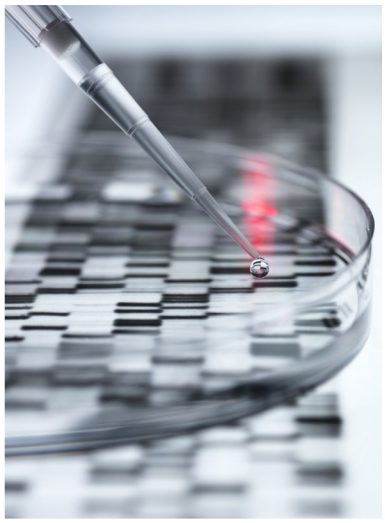
Home Office

Animals in Science Regulation Unit
Annual Report 2013



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Ministerial foreword

The Home Office Animals in Science Regulation Unit plays an essential role in overseeing the rigorous and proper regulation of animals involved in science. The regulatory framework is central to the UK's strong support for animal welfare and ensuring the quality and rigour of the science. From 1 January 2013 the Home Office, through the work of ASRU, implemented the transposed European Directive.

In 2010 the Coalition Government made a commitment to work to reduce the use of animals in scientific research. Essential to delivering the plan is the UK's continuing development of new technologies that replace animal use and I was pleased earlier this year to help launch the Coalition's delivery plan to reduce the use of animals in scientific research. I am very keen to encourage investment in this area and strengthen the UK growth agenda through industry-linked initiatives. The scientific and economic arguments to use alternative methods are now as strong as the moral one. I therefore fully support the drive to develop alternative methods to deliver fast, high-quality research that also boosts economic growth. The drive to reduce animal use is also a drive to increase the UK's cutting-edge competitiveness.

This drive is being delivered through a science-led programme. In addition to the work of ASRU, it involves a wide range of contributors from other government departments and agencies, the research community in both academia and industry, and animal welfare organisations. Much of the programme is being led by the National Centre for Replacement, Refinement and Reduction of Animals in Research (NC3Rs), an internationally recognised leader in the field. ASRU has played a leading role in drafting the Commitment Delivery Plan – a forward-looking strategy that seeks to harness scientific and technological advances for the UK to maintain its world-leading position.

The Coalition Government expects the highest standards of welfare for animals used in research. The provision of a licence entrusts duty holders to uphold their legal obligations and behave in ways that ensure the highest standards of animal care and welfare at all times.

Norman Baker MP
Minister of State

2013: A year for greater openness and transparency

It is difficult to exaggerate the hard work which has gone into the implementation of the new ASPA regulations during 2013 – not only from the ASRU Team but also from all our external stakeholders. I would therefore like to take this opportunity to thank everyone for their efforts in 2013 and I look forward to an equally productive 2014.

Amongst all this hard work, a consistent theme throughout the year has been to increase openness and transparency about all aspects of our work.

Whilst the new regulations looked remarkably similar to those before, there were subtle differences that caused confusion and needed to be clarified. We recognised the importance of our inspectors understanding the changes so that they could provide the most current advice with confidence whilst also helping us all to be aware of the questions being asked. We addressed these questions as early as possible in drafts of our Guidance which we finally published in 2014[1] (see page 10). I am personally proud that the UK was the first to publish such detailed guidance. As well as supporting our own stakeholders, it is already proving a useful point of reference for our EU partners.

We also took the opportunity to explain more clearly how we work. For example, in Appendix I of the Guidance we describe how we apply the harm–benefit analysis to project licence applications. This is helpful not only to those applying for licences but also to those concerned about the types of work we are authorising. Taken together with the detailed non-technical project summaries we now publish, we offer far greater insight into our decisions than in the past. I believe this is important for building public confidence in our regulatory system.

A further pledge towards greater openness was our commitment to review the Animals (Scientific Procedures) Act 1986 (ASPA) section 24, the so-called 'confidentiality clause'. I was greatly encouraged by the workshops and consultations we held with all interested parties during 2013. This is a challenging example of how government can develop 'open policy' that addresses a diversity of interests yet should result in a workable and widely supported solution (see page 24). I am confident that this increased transparency on our part will be

1 Guidance on the Operation of the Animals Scientific Procedures Act 1986, published in March 2014: https://www.gov.uk/government/publications/operation-of-aspa

complemented by the science community's Concordat[2] and will lead to far greater access to information instead of the previously perceived 'veil of secrecy'.

Transparency was also a key theme as we developed a plan that would deliver the Coalition Government's commitment to "work to reduce the use of animals in scientific research". The Delivery Plan[3] drawn up during 2013, publicly commits all delivery partners to a range of actions with key milestones (see page 21). I look forward to reviewing a year of progress towards the end of 2014.

We have also used this Annual Report to increase our transparency about non-compliance with ASPA. In Appendix 1 (see page 34) you will find, in detail greater than previously provided, a description of each case of non-compliance investigated during 2013. I hope this will enable our largely compliant community to benefit from the lessons of others. It also allows us to explain publicly this important aspect of our work. We have also been considering ways to increase our transparency going forward and, on page 31, we outline our plans for the future.

Through increased openness and transparency such as this, I believe we can continue to deliver the benefits that science can bring whilst we assure the welfare of our protected animals and the contribution of the life sciences to the UK's economic growth.

Dr Judy MacArthur Clark CBE
Head, Animals in Science Regulation Unit

2 Concordat on Openness in Animal Research, published in May 2014: http://www.understandinganimalresearch.org.uk/policy/concordat-on-openness-on-animal-research

3 Working to reduce the use of animals in scientific research, published on 7 February 2014: https://www.gov.uk/government/publications/working-to-reduce-the-use-of-animals-in-research-delivery-plan

Section 1: What the Animals in Science Regulation Unit does

"We regulate the use of animals in scientific research for the benefit of people, animals and the environment through the provision of impartial licensing procedures and evidence-based advice, and by encouraging the development and use of the 3Rs (Replacement, Reduction and Refinement) both nationally and internationally"

The Animals in Science Regulation Unit (ASRU) is a part of Home Office Science. It is responsible for regulating the operation of the Animals (Scientific Procedures) Act 1986 (ASPA).

The Unit is led by the Senior Leadership Team (SLT), comprising the Head of Unit, the Head of Policy & Administration and the Chief Inspector.

Two groups make up ASRU: Policy & Administration and the Inspectorate, which work closely together in collaboration to deliver ASRU's purpose.

The Policy & Administration Group's role

The Policy & Administration Group is based at the Home Office in Marsham Street, London and in Swindon. The Group comprises three teams: Policy; Licensing; and Business Support. They fulfil the following functions.

Policy and legislation

The Policy Team provides direct support to Ministers to develop and deliver policy objectives. In addition, the team supports all legislative matters as required and has been central to the transposition of the EU Directive and associated matters. The Policy Team has a key role in supporting the operation of ASPA and therefore works closely with all other parts of the Unit for example, in the development of the Guidance on the Operation of the Animals (Scientific Procedures) Act 1986.
The Policy Team also responds to Parliamentary Questions, Freedom of Information requests and all correspondence (Ministerial and official).

At the end of 2013 the Policy Team comprised one Senior Policy Manager and one executive fast-streamer. They were routinely supported, as appropriate, by others from ASRU including inspectors with expert knowledge.

Licensing

A key function of ASRU is licensing, which is carried out jointly by the Licensing Team and the Inspectorate. The purpose of the Licensing Team is to act on behalf of the Secretary of State in operating the licensing and regulation system. Its core functions within this remit are:

- issuing establishment, personal and project licences, and amendments;
- dealing with appeals against decisions taken;
- taking action in cases of non-compliance; and
- leading on the technology for e-licensing.

At the end of 2013 the Team comprised two Senior Licensing Managers, five Licensing Managers and nine Licensing Officers, some working part-time.

Business support

The ASRU Business Support Team is a dedicated resource providing business support to all operational staff and management. This includes:

- general support to inspectors and management;
- gathering and analysis of management information;
- secretariat function;
- internal and external recruitment;
- organising ASRU training, events and conferences including external stakeholder events;
- risk management including health and safety;
- collecting and administering the annual Return of Procedures exercise;
- procurement and general finance;
- collecting licence fees;
- managing the regional office closure project including relocation of inspectors;
- assisting with the roll-out of the e-Licensing system, ASPeL.

At the end of 2013 the Team comprised one Senior Manager supported by one Executive Officer.

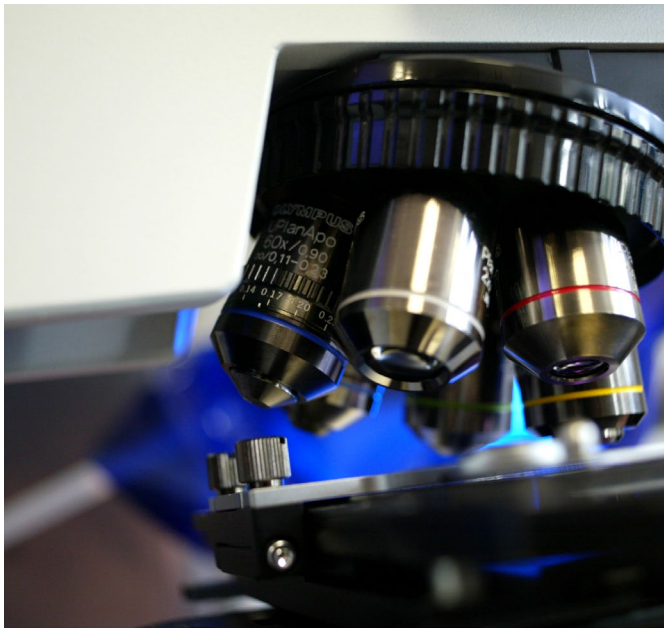
The Inspectorate's role

Inspectors act as professional advisers to the Secretary of State. They play a key role in the implementation of the controls of scientific procedures on animals covered by ASPA. Their work is split broadly into thirds between their commitments to inspection, licence assessment, and providing operational and strategic advice.

All inspectors are registered veterinary or medical practitioners who have first-hand experience of biomedical research and possess higher scientific or clinical postgraduate qualifications.

At the end of 2013 the Inspectorate comprised 23 individuals, including the Chief Inspector. However, during 2013 the average resource assigned to normal inspection duties (including licence assessment) was 15.7 FTEs (full-time equivalents). This was somewhat lower than the 17.7 FTEs in 2012 due to the departure of a number of inspectors and a time lag before replacements could be recruited. We expect to return to pre-2012 levels during 2014 once new inspectors have completed their training.

See **Figure A1** in **Appendix 2** for further related historical data.



The Business Reform Programme

ASRU has now come to the final phase of restructuring and reorganisation as part of its Business Reform Programme. The purpose of the programme has been to centralise ASRU operations as far as possible through the decommissioning of regional offices and centralisation of all activities in London, apart from some inspectors who need to be close to those they inspect at a distance from London.

The Dundee office was closed in October 2013 and the Shrewsbury office is due to close at the end of March 2014. To accommodate the displacement of inspectors, work locations were found at other government offices in Dundee and Glasgow and greater provision was made for home working. The closure of the regional offices will result in significant cost savings in 2014 and future years, both in terms of accommodation and staff costs. All licensing work is now undertaken in the centralised Licensing Team co-located in London and Swindon. This will also contribute to greater consistency in processes across ASRU.

ASRU and Home Office IT services are continuing to improve processes and technology to ensure that inspectors can work effectively when based in remote locations. Further benefits will be realised with the roll-out of the e-licensing system, ASPeL, during 2014. To ensure that inspectors have opportunities to share information and best practices, new communication processes have been put in place. In particular, virtual meetings through tele-conferences have been arranged to cover specific topics such as those relating to legislation, inspection and assessment of licence applications. It is expected that the use of video-conferencing will emerge during 2014 with the possibility of reducing travelling time for inspectors whilst further improving communications.

Section 2: Implementing new regulations

Implementation of European Directive 2010/63/EU on the protection of animals used for scientific purposes

We completed work to implement Directive 2010/63/EU in UK legislation in December 2012 and this was transposed into the Animal (Scientific Procedures) Act 1986 (ASPA) on the 1 January 2013.

The UK was one of only seven Member States to receive the EU Commission's 'green flag' by January 2013 as evidence of the successful implementation. However, there was, and still is, considerable work to be done to embed fully the amended Act.

In support of such embedding, the Animals in Science Regulation Unit (ASRU) consulted during 2013 on a range of topics including the proposed European Data Collection Scheme, codes of practice and guidance on the operation of ASPA. Responses to these consultations helped to inform our next steps and the outcomes will be seen during 2014.

Guidance on the operation of the Animals (Scientific Procedures) Act

Following the implementation of European Directive 2010/63/EU and its transposition into UK legislation, we continued our work to produce comprehensive guidance on the operation of the amended Animals (Scientific Procedures) Act (ASPA).

The Guidance is issued under the terms of section 21(1) of ASPA and provides information about the way in which the Secretaries of State for the Home Department and for Northern Ireland propose to exercise their powers under the Act and how they expect those working under ASPA to fulfil their duties. We expect to publish the new Guidance early in 2014[4].

The Guidance provides information and advice on:

- the scope and main provisions of the amended Act;
- the responsibilities of those with roles under the Act;
- licences granted under the Act, including the terms and conditions of their issue;
- severity classification, humane killing and the accommodation and care of animals, including the status of Annex 3 to the Directive and current UK Codes of Practice.

The Guidance is intended to be a reference document that explains how ASPA is administered and enforced and replaces the previous guidance issued in March 2000.

The new Guidance is for everyone involved with animals that are bred for, supplied for, or used in scientific procedures, including:

- holders of establishment licences, project licences and personal licences;
- those killing animals;
- named persons such as Named Veterinary Surgeons (NVSs);
- members of an establishment's Animal

4 Guidance on the Operation of the Animals (Scientific Procedures) Act 1986, published in March 2014: https://www.gov.uk/government/publications/operation-of-aspa

Welfare and Ethical Review Body (AWERB);

- others working in licensed breeding, supplying and user establishments;
- new licence applicants and prospective named persons;
- Home Office inspectors;
- members of the Animals in Science Committee (ASC); and
- others with an interest in this area.

Non-technical project summaries

The Directive introduced a requirement for a non-technical summary (NTS) to be provided by the applicant for each project authorised. The NTS should provide information about the objectives of the project, including predicted harms and benefits, and details of the animals to be used. It should also demonstrate how the 3Rs (Replacement, Refinement and Reduction) are being implemented in the project. The NTS submitted by the applicant forms part of the 'complete and correct' application and should not contain any intellectual property or confidential information.

Since 2005 UK project licence applicants had already been providing an abstract of their projects on a voluntary basis. This change required more specific details as well as making the NTS mandatory.

The UK agreed with other EU Member States a format for NTSs and published the form on the gov.uk website[5]. Where an application was well advanced in January 2013, we initially accepted an abstract in the old style but licence holders subsequently provided an NTS in the prescribed format. Inspectors assess the clarity and accuracy of the NTS as part of their overall assessment of the application.

During the transfer of our website to the gov.uk website during 2013, a new location needed to be found where we could publish anonymised NTSs. Our intention is that all projects authorised since January 2013 will therefore have an NTS, as submitted in the prescribed format, published on the website[6].

We recognise that these constitute an important aspect of our move towards greater openness and transparency about work being authorised. The current gov.uk website structure does not make the NTS publications readily searchable and we consider that a deficiency. We will therefore, during 2014, press for a more searchable and user-friendly option so that all stakeholders can locate work of interest to them.

5 Project licence application form – NTS section: https://www.gov.uk/research-and-testing-using-animals
6 Non-technical summaries: https://www.gov.uk/government/collections/non-technical-summaries-granted-during-2013.

Actual severity of procedures

Reporting of actual severity

EU Directive 2010/63/EU requires collection of data on the actual severity of procedures. Each animal that undergoes scientific procedures must be allocated a severity classification indicating the level of harm actually suffered due to those procedures. There are four categories:

- up to and including mild (which in the UK has been subdivided into sub-threshold and mild);
- moderate;
- severe; and
- non-recovery (for animals where the first procedure undertaken is anaesthesia from which they do not recover).

As in the past, a prospective classification that predicts the likely harms is assessed by inspectors and is used as part of the harm–benefit analysis of a proposed project.

The intention behind introducing recording actual rather than just prospective harm is primarily to increase transparency on the real harms of animal use. Collecting these data will also have the potential to aid in the targeting of refinement initiatives by identifying areas of high severity. This information will be collected in the UK, and in the rest of the EU for the first time for procedures completed from January 2014 onwards and will be published for the first time in 2015.

Actual severity pilot study 2013

Background: As an aid to ensuring a smooth implementation of the new requirement for reporting actual severity, a pilot study was carried out over a two-month period in August and September 2013. The aim was to test the process of collecting and reporting actual severity data using an electronic report form similar to that designed by the EU Commission for use from January 2014 onwards. This pilot involved a group of volunteer users from across the range of licensed establishments (see Table 1).

Purpose: The primary purpose was to test the newly drafted guidance notes intended to facilitate the accurate and consistent classification of actual severity. Additionally, data on actual severity in a sample of procedures were obtained. Although this sample was not intended to be entirely representative of the distribution of procedures performed in the UK, it provides a preliminary snapshot of the distribution of actual severity by sector and species for those project licences (PPLs) from which data were provided.

Results: Table 1 summarises the type of establishments participating in the pilot study and their response rate. In total, data on 35,409 procedures were supplied from 75 PPL holders at 21 establishments. Hence the pilot study covered 2.8% of all PPLs active at the end of the year and involved 12% of all licensed establishments.

When compared with the distribution of procedures reported in Statistics of Scientific Procedures on Living Animals in Great Britain 2012, broken down by species and purpose, it is apparent that the pilot sample differed in relative proportions for some species and some purposes.

With respect to the species, mice made up 72% of the pilot study data compared with 74% in the 2012 data, i.e. a very similar proportion. However, some other species such as fish, the next most commonly used species group in 2012, were under-represented in the pilot study (1% compared with 12% in 2012). See Figure 1.

Table 1: Volunteer organisation by type and response rate

Establishment type	Number of establishments recruited	Number of granted PPLs within recruited establishments	Number of PPL responses	Number of procedures reported
Academia	9	651	29	2,838
Government agencies	5	93	15	13,032
Independent research institutes	2	35	3	13,860
Pharmaceutical companies	3	43	17	4,325
Contract research organisations	2	28	11	1,354

Figure 1: Distribution of pilot data by species in 2013 pilot study compared with 2012 data

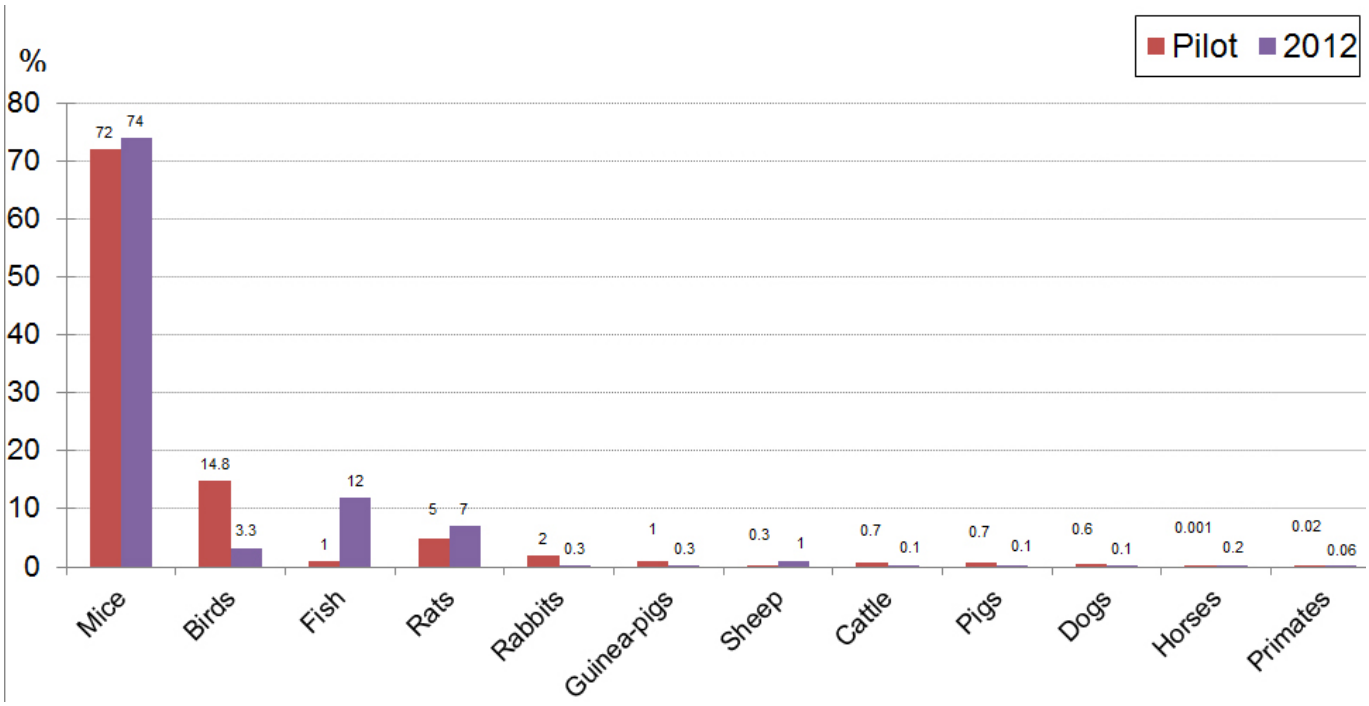
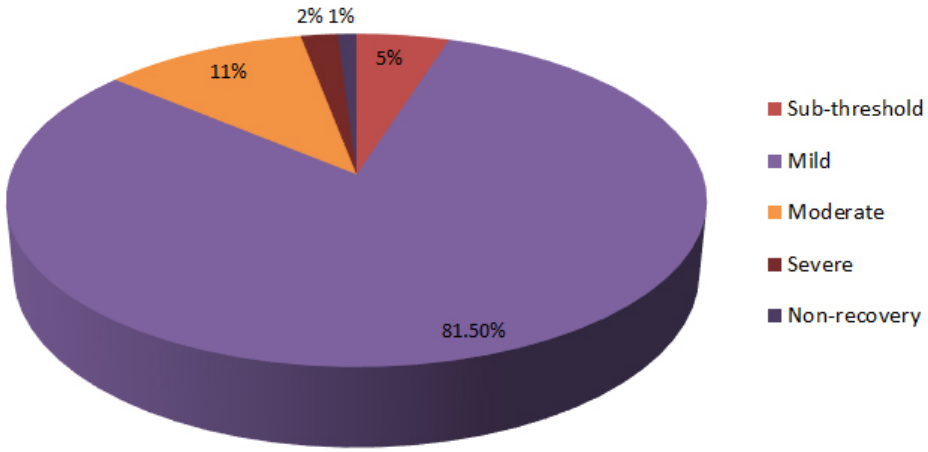


Figure 2: Distribution of pilot data by purpose of procedure compared with 2012 data

*Maintenance of colonies of established genetically altered animals, not used in other procedures

Figure 3: Distribution of 2013 pilot data by severity of procedure



With respect to the purpose of animal use, the number reported as "breeding and maintenance" (of genetically altered animals) was low in the 2013 pilot sample (see Figure 2), probably reflecting an under-representation of the academic sector. Similarly, the number reported as "regulatory testing and routine production" was high, probably reflecting an over-representation of the commercial sector. However, all of the major purposes (uses) were represented in the data received.

Any conclusions from the 2013 pilot data should therefore be drawn with caution especially in relation to the full-year results that will become available in due course.

Nevertheless, the results are interesting in that, after correction of any obvious misclassification (see below), 5% of the 35,409 procedures reported were determined to be sub-threshold, 81.5% were reported as mild, 11% were reported as moderate and only 2% were reported as severe. Just over 1% were non-recovery procedures (see Figure 3).
The severe procedures involved mainly mice, rats and fish. Severe outcomes were reported for both basic and applied research procedures, and also for routine production, but not for regulatory testing.

Misclassification of procedures: Of the species afforded special protection, only dogs were reported to have suffered severe procedures (in 3 out of 199 procedures). On further investigation of this report, it was found that this was a misclassification based on a misinterpretation of the guidance notes. The correct classification was mild.

There were other instances where animals had obviously been misclassified. For example, zebra fish that had fin tissue biopsied in order to assess genotype were allocated an actual severity of sub-threshold. Genotyping in these circumstances is a regulated procedure and should be classified above threshold based on the response of the animals (usually mild in this example).

Following the 2013 pilot project

Following completion of the pilot data collection and analysis, our volunteer users were given the opportunity to give feedback on the draft advisory notes, including at a meeting of experienced licensees in December 2013. This included considering areas of misclassification or difficulty experienced by the volunteers during the pilot study.

In addition, inspectors were consulted about areas where they considered that licensees might have difficulties in assessing or allocating an actual severity classification.

The advisory notes have subsequently been revised in the light of all this feedback and will be published on the gov.uk website[7] early in 2014. It is hoped these will minimise misunderstandings and improve consistency for the collection of actual severity data and will thus contribute significantly to the accuracy of data collected during 2014 for publication in 2015.

We are very grateful to all those who have provided help and feedback on the pilot study and on the subsequent revision of the Home Office advisory information.

Working with the EU Commission

The Directorate-General for the Environment in the EU Commission is responsible for ensuring the Europe-wide implementation of Directive 2010/63/EU. During 2013 senior representatives from ASRU, as the UK competent authority, attended a number of meetings in Brussels.

There were two National Contact Point (NCP) meetings, one each in January and September

7 Advisory notes on recording and reporting the actual severity of regulated procedures https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/276014/NotesActualSeverityReporting.pdf and Advice on severity assessment of genetically altered animals https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/276015/AdviceSeverityAssessmentGA.pdf, both published in January 2014.

2013. Updates were provided by all of the Member States on their transposition of the Directive. In addition, issues of interest to the Member States' regulators were discussed, and formal agreement reached on documents emanating from various expert working groups (EWGs). One of the key decisions taken was agreement on the format of, and mechanisms for, the annual reporting on the use of animals in regulated procedures, as required by Article 54 of the Directive.

In addition, three EWGs were convened during 2013. These covered the following topics:

- 19 and 20 March: Project evaluation and retrospective assessment of projects
- 3 and 4 July: Education and training, mainly for Named Persons
- 3 and 4 December: Inspection

Members of ASRU, together with UK stakeholders, attended all these meetings and provided active input to the written material that set the scene at the meetings, as well as contributing to the outcomes and reports. For project evaluation, mechanisms were explored for ensuring provision of sufficient good quality information, with evidence that the applicant has considered and understood all the relevant issues, to facilitate a well-informed harm–benefit analysis. The final document covering education and training for all of those with roles under the legislation was agreed by Member States at the NCP meeting in September 2013. A Principal Inspector from ASRU has taken a lead in developing the outcome documents on inspection covering both aide memoires for inspectors as well as broader advice on the inspection and enforcement processes. Details of the documents emerging from these EWGs can be found on the Commission's website.[8]

Working with the Animals in Science Committee

The Animals in Science Committee (ASC) is an independent, non-executive, non-departmental public body convened by sections 19 and 20 of ASPA (as amended).

The ASC was established by the Home Office on 1 January 2013, replacing the Animals in Procedures Committee (APC). Members of the new committee were recruited during 2013 and include relevant individuals with an animal welfare background, researchers, academics, legal and medical experts. All are appointed in a personal capacity.

8 Education and Training Framework: http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_E-T.pdf
Project Evaluation and Retrospective Assessment: http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_PE-RA.pdf

The ASC is responsible for providing impartial, balanced and objective advice to Ministers on issues relating to the 1986 Act. At all times, the Committee must 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.

A Working Protocol has been drafted that provides a framework under which the Government and the ASC will engage with each other on matters relating to the use of animals in scientific procedures and, once agreed, will be published early in 2014.[9]

The Home Office intends to commission advice from the ASC on an annual basis. The first commissioning letter was sent to the ASC on the 26 June 2013.[10] The commission is for matters of particular importance to the Department, and therefore the priority areas for ASRU. In addition, the ASC may consider areas of work as it deems as appropriate. The ASC is progressing this work and will report on many of these areas in the forthcoming year.

A role of the ASC is to review project licence applications received by ASRU that involve the highest level of permissible harm (severe procedures) and involve one or more of the specially protected species. During 2013 the ASC reviewed three project licences. The ASC may also consider other licence applications as it deems appropriate.

The Minister and ASRU received, from the APC Primate subcommittee working group, a report on cumulative severity. This report had a primary consideration of neuroscience procedures on non-human primates which tend to extend over a prolonged period of time, often several years. The report considered how these may be assessed, including consideration of the whole lifetime (cumulative) experience of an animal. The report has been referred to the ASC for further consideration over the coming months.

ASRU engages regularly with members and the chair of ASC. During 2013, we assisted with the recruitment of members and attended committee meetings and ad-hoc meetings on particular issues to provide advice. We also took part in regular meetings with the ASC Chair to assist in agenda setting and to ensure that the committee has the most current understanding of issues being dealt with by ASRU and the regulated community. ASRU is keen to develop this close and productive working relationship whilst assuring the ASC's independence of thought is retained in relation to its advice.

9 Working Protocol between the Home Secretary and the Animals in Science Committee: https://www.gov.uk/government/publications/working-protocol-between-the-home-secretary-and-the-animals-in-science-committee

10 Minister's letter to the Chair of the Animals in Science Committee: https://www.gov.uk/government/publications/ministers-letter-to-the-chair-of-the-animals-in-science-committee

Animals containing human material

In recent years the creation of animals that contain varying amounts of human material (so-called 'animals containing human material', ACHM) has played an increasingly important role in biomedical research. The scale of the changes now possible is such that genes, cells and tissues can retain significant aspects of their 'human' functionality in the animal environment and are of increasing value to scientific discovery.

Although the realistic possibilities in this area are currently limited to relatively simple functions, scientific advances may extend the boundaries in the future.

In 2010 the Academy of Medical Sciences (AMS) reported on ACHM and their great potential for biomedical use. The many uses of ACHM include:

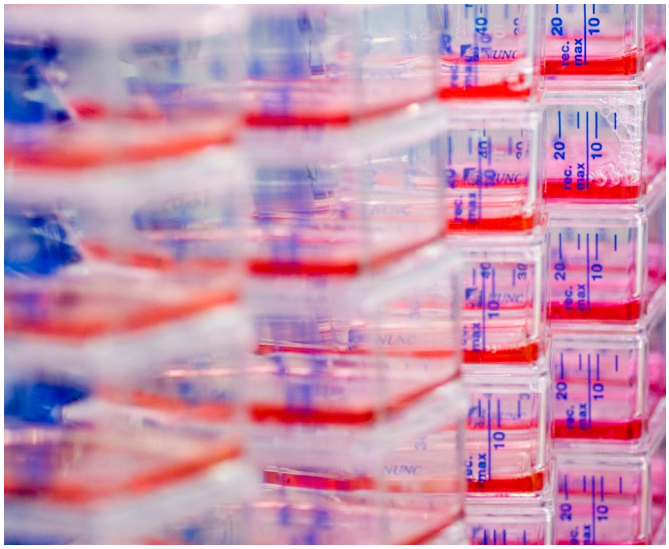
- understanding human bodily functions and disease – to determine the role of a specific piece of human DNA by seeing what effect it has in a living animal; and
- testing and developing methods of diagnosis, drugs and other treatments for disease.

In addition to the AMS, various religious, ethical and animal welfare bodies have expressed concerns over the future development of ACHM as the research seeks to push the boundaries and take on increasingly sophisticated 'human' functions. This use of animals has the potential to probe the limits of what is acceptable, both from a moral and ethical perspective and from the adverse welfare consequences that may be caused. However, any regulation needs to be constructed so as to continually balance these issues with the delivery of scientific and biomedical advances for the public benefit.

This is a publicly and politically contentious area in which a high standard of regulation is needed to achieve a balance of benefit whilst retaining confidence in the regulatory system through transparency. It also involves regulators in several government departments to avoid the risk of a regulatory gap. ASRU has been leading co-ordination of the responses of the relevant regulators – ASRU itself in the Home Office with ASPA and the Department of Health with the Human Embryology and Fertilisation Act and the Human Tissue Act.

During 2013 in consultation with these other regulators, we have drafted guidance aimed at helping scientists to understand the legal and regulatory requirements. This aims to facilitate contact with the relevant regulator or regulators when planning work in this contentious, complex and fast-developing area.

We expect to finalise guidance on ACHM in summer 2014 and publish it in conjunction with the other regulatory authorities.



Section 3: Licensing

The framework

The UK has a rigorous three-tier licensing system to ensure that animal research and animal testing are only carried out where no practicable alternatives exist and under stringent controls where suffering must be kept to the minimum.

- People carrying out procedures must hold a 'personal licence' (PIL), which ensures that those working with the animals are qualified and suitable, and are supervised until competent.
- The programme of work in which the procedures are carried out must be authorised in a 'project licence' (PPL).
- The place at which the work is carried out must hold an 'establishment licence' (PEL).

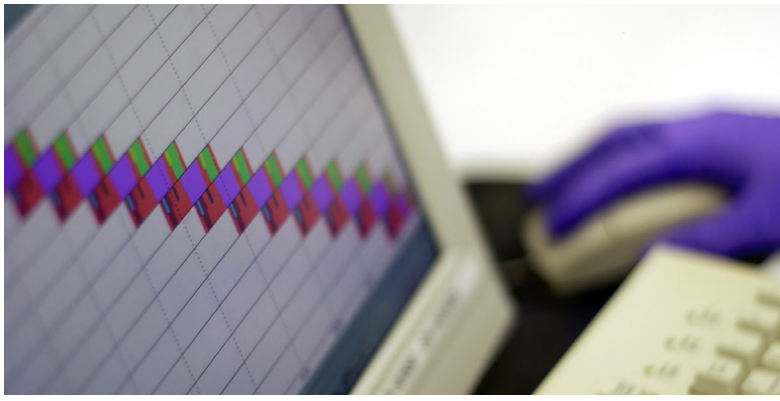
The Home Office avoids any conflict of interest in this regulatory role since it neither sponsors scientific research involving the use of animals, nor does it set any requirements for data generated by such procedures. The Animals in Science Regulation Unit (ASRU) within the Home Office administers the licensing function under the Animals (Scientific Procedures) Act 1986 (ASPA). The main threshold for authorising work using animals lies in a satisfactory harm–benefit analysis of the proposal. Hence, the overall level of scientific procedures that we license is determined by a number of factors including the quality of applications received, the availability of suitable alternatives, the economic climate for funding research, and global trends in scientific endeavour. We aim to maintain a flexible resource to provide a responsive licensing capability.

Animals in scientific procedures e-licensing (ASPeL)

It is essential that the regulatory system is underpinned by a modern and efficient licensing system. Since the regulatory system was introduced, the Home Office has operated a paper-based system. During 2013 the paper-based system has supported work carried out under approximately 15,000 personal licences, 2,500 project licences and 180 establishment licences. (See **Table A1** in **Appendix 2**.)

In 2012 we took the decision to invest in developing a web-based animals in scientific procedures e-licensing system (ASPeL). This will provide a modern approach to licensing that will significantly reduce the time, space and additional administrative work involved in handling paper files for the benefit of both duty holders and ASRU staff.

Development of the system progressed well during 2013 and towards the end of the year we took the decision, in consultation with duty holders, to roll out the system in a phased approach starting in early 2014. Phase one will involve all personal and establishment licences and phase two, targeted to start at the end of 2014, will involve the project licences.



We believe that, central to ASPeL, is the experience of users (both internal and external) and the security of documentation. We trialled the system with six 'early adopter' establishments prior to 'going live'. This collaboration provided us with constructive feedback on the system and enabled us to make improvements to reflect user requirements. Our grateful thanks go to those establishments that participated in the trials and gave us helpful feedback. In addition, we are developing effective guidance, which has benefited from this feedback and will be put in place before full roll-out.

ASPeL provides a platform for us to process personal licence applications well within the 20-day target. The conversion to e-licensing means that we will shortly phase out paper-based licences; from February 2014 all personal licences (new and amendments) will be electronic and establishments must be signed up to ASPeL for their personal licence applications to be processed.

Until we launch the project licence part of the system, we will continue to process applications for these licences on paper. Once the project licence part of ASPeL goes live, all new licences and substantial amendments to existing licences will be processed electronically. However, existing licences that do not require amending will normally be retained in paper format for the duration of their lifespan.

Licensing performance

Table A1 in **Appendix 2** summarises the ASRU licensing performance during 2013 compared with 2012. It is notable that the number of PIL amendments was significantly lower than in previous years but the total number of PILs granted increased by about 5%. The number of PPLs granted was slightly lower than the previous year but remained higher than the average for the previous five years. As a consequence of the reduced inspector FTE numbers in 2013, the number of PPLs granted and amended per inspector increased by about 13%.

Figure A2 in **Appendix 2** shows the historical trend in project licences granted between 2006 and 2013. **Figure A3** shows the trend in time taken to process project licence applications over the same period. In 2013, our performance target for granting successful applications changed. Previously our aim has been to grant 85% of applications within 35 working days. We have routinely achieved this standard and did so in 2013. However, the Directive brought in a new target – to grant most applications within 40 working days with the option to extend this for complex applications to a maximum of 55 working days. In 2013, we granted 94% of applications within 40 days and 98% within 55 days.

With regard to performance in relation to personal licences, this was significantly impacted by the unfortunate delay with the launch of our e-licensing system. In spite of this our Business Reform Programme (see page 9), which included centralising our licensing operations and closing our regional offices, had to continue to schedule since we had made commitments to departing staff.

The combination of losing staff before the e-licensing system came into use presented significant challenges to the Licensing Team, particularly in relation to personal licences where we were unable to routinely meet our target to grant a licence or amendment within 20 working days of receiving the application.

We have always set ourselves challenging delivery targets to meet our duty holders' needs and expectations and it was very disappointing for staff as well as applicants when we fell short. With the launch of ASPeL we are confident we will have a robust system that will deliver for our stakeholders, now and into the future.

Section 4: Promoting the 3Rs

Coalition commitments

In May 2010 the Coalition Government made a commitment to work to reduce the use of animals in scientific research. The Animals in Science Regulation Unit (ASRU) was tasked by Ministers to work with colleagues in the Department of Business Innovation and Skills (BIS) to develop a framework of measurable actions to progress the commitment and a narrative of rationale for the use of animals in scientific research. Early on it was announced that the National Centre for Replacement, Refinement and Reduction of Animals in Research (NC3Rs), an organisation with a strong record in reducing animal use, was ideally placed to play a leading role in the delivery of the commitment.

ASRU and BIS then sought further input from across Whitehall and independent scientific organisations to develop a Commitment Delivery Plan. The Plan is the first time that government has set out how the commitment is being met. The document also contributes to achieving wider openness, transparency and public understanding about this area of work. The Plan is the first publication of its kind to seek to argue the case for this crucial part of science which, taken together with our other regulatory functions, is critical to our engagement with the life sciences sector and growth of the economy.

The Delivery Plan will set out a science-led programme that has the 3Rs (Replacement, Reduction, Refinement) at its heart. In collaboration with BIS and the Department of Health, ASRU has developed the Plan which will be delivered through three strategic priorities:

- advancing the use of the 3Rs by putting them at the heart of science-led programmes;
- influencing the uptake and adoption of 3Rs approaches globally; and
- promoting an understanding and awareness about the use of animals where no alternatives exist.

The NC3Rs continues to be a key contributor and closely involves our Inspectorate, other government departments and agencies, the research community in both academia and industry, and others with relevant animal welfare interests. ASRU works closely with, and supports the work of, the NC3Rs which is an internationally recognised leader in the field (see below).

The Commitment Delivery Plan is due to be published in early 2014.[11] In conjunction with BIS, ASRU will lead and support an update report to be published in early 2015.

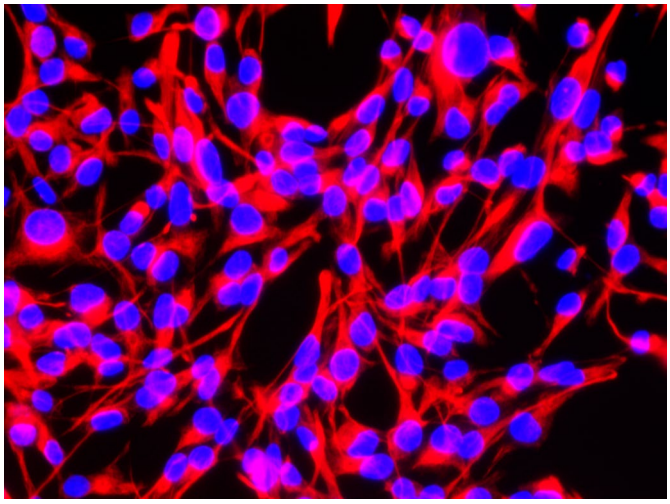
11 Working to reduce the use of animals in scientific research, published on 7 February 2014: https://www.gov.uk/government/publications/working-to-reduce-the-use-of-animals-in-research-delivery-plan

Work with the National Centre for Replacement, Refinement and Reduction of Animals in Research

In addition to our engagement over delivery of the Coalition commitment, ASRU inspectors also meet regularly with the NC3Rs Chief Executive and other staff to share knowledge on 3Rs initiatives. Such engagement enables inspectors to be fully apprised of developments and therefore influence the uptake of the 3Rs in establishments as part of their inspection duties. The meetings also provide a forum for inspectors to flag areas of interest, gained through inspection, that the NC3Rs may wish to take forward. A prime example of the mutual benefit of such engagement is inspectors being able to refer to the NC3Rs Procedures with Care microsite and ARRIVE guidelines during inspection and assessment. Likewise, inspectors triggered an initiative to drive aseptic standards in surgery, which inspired Newcastle University to obtain sponsorship from NC3Rs to produce a video on this topic, and which inspectors now actively promote.

Members of ASRU attended the NC3Rs Annual Science Review Meeting in February 2013. It was here that the Chief Executive from the Wyss Institute received the NC3Rs 3Rs Prize for his 'Lung-on-a-Chip' technology, a microdevice lined by human cells that models the complex functions of the living lung. This is a potential alternative to pre-clinical drug testing in animals. The Head of ASRU subsequently visited the Wyss Institute in Boston, USA with Lord Taylor (then Minister with the Animals in Science portfolio) to learn more about this technology.

The Chief Executive of the NC3Rs and its Head of Innovation and Translation attended our ASRU conference in May 2013 at which they described their current initiatives. Inspectors also had the opportunity to report their views on the most important areas of concern with regard to the 3Rs in UK animal research.



At ASRU's November 2013 conference, presentations were given by two NC3Rs-funded scientists. A researcher from Newcastle University discussed refined alternative strategies in liver research and a researcher from Nottingham University discussed developing an ex vivo model to investigate asthma and reduce animal usage in respiratory research.

Several inspectors also attended the NC3Rs primate welfare meeting in November 2013. This meeting was on the topic of Primate neuro-imaging: Tools for animal welfare and science and has provided sound recommendations that inspectors take into their everyday discussions with licensees.

The meetings and engagement with the NC3Rs are a further opportunity for ASRU:

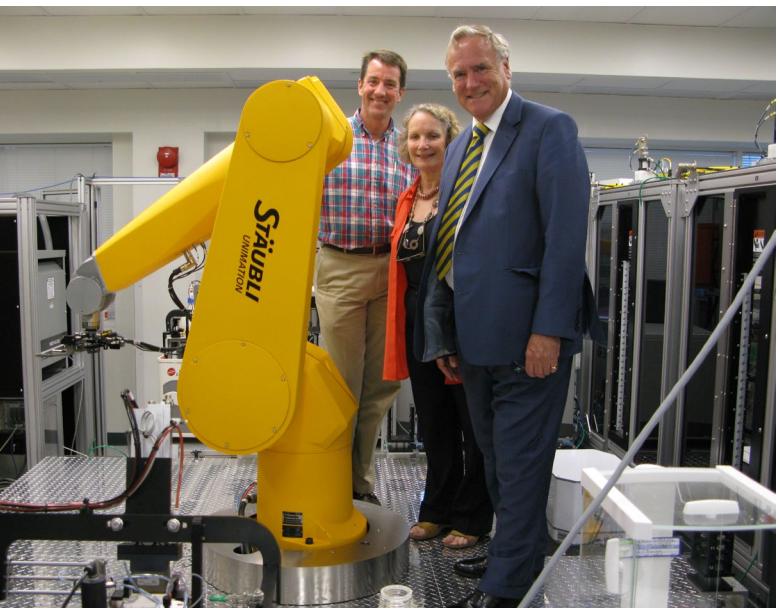
- to engage with the science community;
- to build key relationships with those working in the 3Rs;
- to understand new developments; and
- to promote the work of the regulator.

Through such engagement, the benefits of new technologies can be realised by the Inspectorate disseminating to the sector it regulates. Over the coming year, ASRU will be looking to exploit ways in which it can even better provide a conduit of 3Rs learning from individuals to the research community.

Global promotion of the 3Rs

As part of the delivery of the Coalition commitment, we are aiming to influence the uptake and adoption of 3Rs approaches globally. Towards this end, members of ASRU made presentations at a number of international conferences. These have included countries where the use of animals in science is growing, such as Brazil and China, as well as more traditional animal-using countries such as Japan and the USA. On all these occasions, the opportunity has been taken to emphasise the importance of the 3Rs, as well as effective harm–benefit analyses, in rigorously assessing project proposals.

In July 2013 Lord Taylor (then Minister with the Animals in Science portfolio) was accompanied by the Head of ASRU on a week-long visit to the USA to discuss implementation of the 3Rs in both academia and industry, and to meet other regulators. Topics including the use of non-invasive imaging, organs-on-a-chip (see above) and stem cell technologies were explored as well as opportunities to share information on animal models and reporting of animal studies, and to harmonise approaches to regulatory testing.



Dr Chris Austin, Director of the US National Center for Advancing Translational Sciences, shows Lord Taylor and Dr MacArthur Clark the robotic facility for in vitro screening of environmental chemicals.

This is the first time that a UK Minister has embarked on such an overseas initiative. It was apparent that, where non-animal alternative methods can be shown to be valid, they usually lead to better, faster and cheaper scientific advances. It was also an excellent opportunity to promote the UK's leadership in implementing the 3Rs.

Refinement and replacement of batch testing of botulinum toxin products

International and UK regulations relating to the safety and efficacy of medicines require that many biological products are tested for potency to assure the safety of manufactured batches intended for clinical use. We therefore continue to authorise such testing under the Animals (Scientific Procedures) Act 1986 (ASPA).
In the case of batches of botulinum toxin, this involves a very severe test in mice in which animals become paralysed and will die if not humanely killed. We became aware in 2012 that one company manufacturing botulinum toxin products had successfully validated a non-animal alternative test to replace at least some of this potency testing for their particular product. However, since this is a biological product it is not possible to apply that validation to botulinum toxin produced by other companies.

As part of the Coalition commitment to promoting the 3Rs globally, we actively worked throughout 2013 to ensure that those other companies were rigorously pursuing the validation of alternative tests. We also collaborated with the Medicines and Healthcare products Regulatory Agency (MHRA) of the Department of Health in this initiative to ensure that validation can be approved as rapidly as possible within the requirement to ensure consumer safety.

Good progress is being made and, in line with our legislation, we will cease to authorise the animal test as soon as these alternative tests are validated and accepted by regulators. In

the meantime we have agreed a number of measures to reduce the severity of the mouse test as far as possible. This includes checking mice at least once every hour throughout the day and night to ensure that they are observed as soon as they show clinical signs and are humanely killed wherever possible.

We are often asked why the testing is allowed to continue when the UK has had a ban on the testing of cosmetics in animals since 1998. The answer is that botulinum toxin products tested under ASPA are all covered by marketing authorisations for use as a medicine. These products are prescribed by medical practitioners for a range of clinical conditions. They are thus not cosmetics as defined in the EU Cosmetics Directive and are tested under legislation relating to medicines.

Refinement of severe animal models

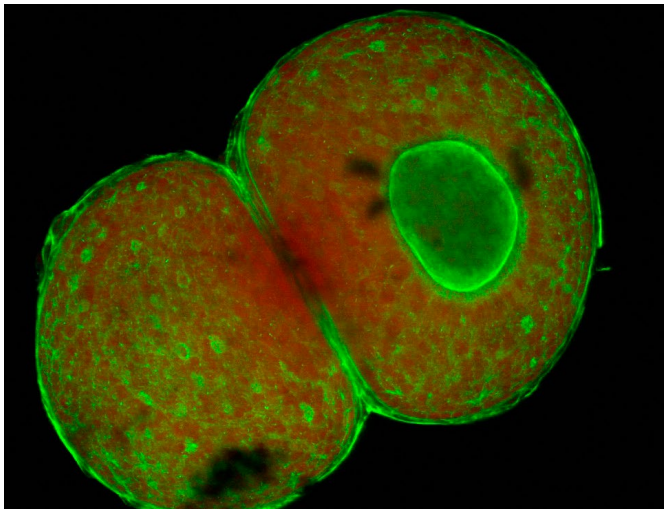
As another aspect of delivering the Coalition commitment, we are working with a number of stakeholders to refine some of the most severe models to avoid or reduce animal suffering.

One such example is sepsis, a serious medical condition caused by infection and resultant widespread inflammation. It may lead to organ failure, septic shock and death. It is a major cause of human illness and death worldwide. Given that antimicrobial-resistant infections are becoming more common globally, it is likely that the number of serious and hard-to-treat infections will increase, resulting in more sepsis cases. Further research remains essential, in order to improve the prevention and treatment of the condition. Because of the complexity and seriousness of sepsis and the allied conditions, it is not yet possible to study all aspects without using live animal models. In some cases these can be very severe.
In 2013 the Royal Society for the Prevention of Cruelty to Animals (RSPCA)'s Research Animals Department set up an expert working group on animal models of sepsis. The objectives were to identify the welfare issues associated with these models, and set out practical refinements that can be used to reduce suffering and thus improve welfare and scientific outcomes. The intention is to produce and publish a report and guidance, aimed at the users of sepsis models and those involved in ethical review.

The Home Office Inspectorate is represented on the group along with RSPCA staff, Named Veterinary Surgeons, and scientists who are experienced in using, reviewing and refining sepsis research models. Inspectors have contributed practical knowledge of the assessment, use, and refinement of sepsis models and the ethical considerations. The publication of the group's report is likely to occur in spring/summer of 2014. However, inspectors are already aware of refinements being made to sepsis experiments as a result of expertise flowing from participating in the working group.

Review of section 24

The Coalition Commitment Delivery Plan will include a strategic priority to promote an understanding and awareness about the use of animals where no alternatives exist. Section 24 of ASPA, the so-called 'confidentiality clause', provides for the protection of confidential information given in connection with our regulatory activities under the Act. We have a long-standing commitment to review section 24 since the broad and inflexible confidentiality requirements do not accord with this desire for openness and transparency. Further it does



not align well with the approach taken in other legislation such as the Freedom of Information Act 2000 (FOI).

Our challenge is to design a framework that will provide greater transparency to assist public understanding, whilst protecting people, places, proprietary rights and intellectual property and not harming the competitiveness of the UK life sciences.

Options for the review of section 24 have been developed through extensive early consultation and collaboration with our wide range of stakeholder groups and assisted by the Design Council as an independent facilitator. The next step is public consultation to be launched in spring 2014. Replies to the public consultation will help to shape the thinking on the Government's future policy.

We are committed to maintaining the principles behind open and shared policy making when taking forward the final option, collaboratively working with our diverse range of stakeholders.

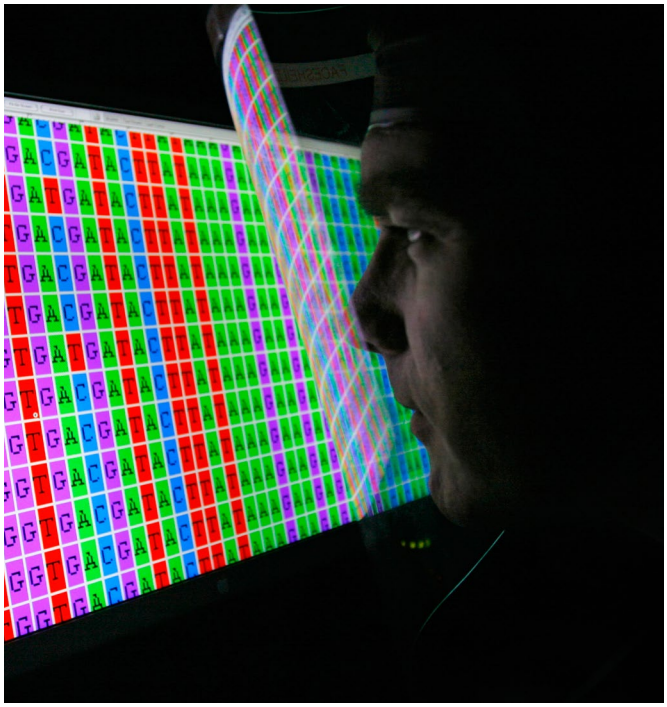
Potential changes, such as ways of communicating information, will be implemented through collaboration with end-users and stakeholders. Developing the policy delivery mechanisms in the same way that we have developed our policy options – through continuous engagement with end-users and stakeholders – will contribute to achieving the best outcome.

Household products

The Coalition Government made a commitment to ban the testing of household products on animals. Although superficially straightforward, this issue has not been easy to resolve. Any solution we propose has to be legally viable since a ban on testing cannot be implemented where that testing may be required under UK or EU law. In addition, we are mindful of unintended consequences. For instance, we must not develop a solution that precludes research that is essential or drives necessary research overseas where welfare standards may be lower.

A key issue for this commitment is whether ingredients should be included in the ban. The inclusion of ingredients was not in the original commitment and has led to conflicting views among stakeholders. Ministers have requested that ASRU actively considers options to develop a solution that is viable and does not generate a chain of unforeseen consequences.

ASRU prioritised the commitment to 'reduce the use of animals in scientific research' in 2013. ASRU will provide advice and will support Ministers to deliver the commitment on household products during 2014.



Section 5: Engaging with stakeholders

Communications

The Animals in Science Regulation Unit (ASRU) has a key role to support Ministers in providing well-evidenced and fully considered responses to Parliamentary Questions (PQs), Freedom of Information Act 2000 (FOI) requests and correspondence from the general public on any issue related to the use of animals in science. PQs and correspondence are an important way in which government communicates current policy and thinking.

Correspondence

During 2013 we answered just under 800 pieces of correspondence. These covered a wide range of the issues on the use of animals in science and related subjects. Broadly, the two main topics were the Coalition commitment to work to reduce the number of animals used in scientific research and the review of section 24 of the Animals (Scientific Procedures) Act 1986 (ASPA), see pages 20 and 23.

Parliamentary Questions

PQs represent a means by which Ministers can be held to account and provide an opportunity for scrutiny of operations. Since the answers become official Ministerial statements, it is of paramount importance to ensure their accuracy. Answers must also be provided within a very tight timeline – often less than 24 hours.

Members of Parliament tabled 46 questions during the year, covering a broad range of issues. Among the popular topics were questions that asked for a statement on:

- statistics on animals used in testing following the publication of the 2012 statistics;
- non-human primates; and
- questions about Imperial College London following allegations made in the Sunday Times.

Freedom of Information requests

ASRU received 62 FOI requests on a variety of topics during 2013. In line with the Government's policy on openness and transparency our approach is to release as much detail as the legislation permits. In responding, we seek to provide greater transparency to assist public understanding whilst also balancing this against protecting personal details and information given to the Home Office in confidence including proprietary rights and intellectual property.

Requests ranged from asking for:

- specific details on research that had been undertaken;
- information on specific statistics other than those collected in the published annual return; and
- more general information on the import of dogs and their re-homing.

Again accuracy is critically important and we are subject to strict timelines – though not generally as short as for PQs.

Consultations

During 2013 we held formal public consultations on the following topics:

- a draft code of practice for the care and accommodation of animals, setting out standards to be applied by all users, breeders and suppliers of animals from 1 January 2013 to 31 December 2016;
- proposals for the collection (from January 2014) and publication of annual statistics on the use of animals for scientific purposes required under Directive 2010/63/EU.

In addition, we informally consulted with our established stakeholder groups (see below) on a number of issues including the final drafting of the Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 and the review of section 24 of ASPA. We are grateful to all who provided responses to our consultations which have informed our policy going forward.

Meetings with stakeholders

In support of our objectives, the ASRU leadership held regular meetings with a wide range of stakeholders during the year. These covered matters related to progress with implementation of the revised regulations, updates on operational matters, and other general policy issues including delivery of Coalition commitments. The meetings included representatives from:

- industry, academia, government research institutes, medical research charities and research funders;
- animal welfare and alternatives (3Rs – Replacement, Reduction and Refinement) groups;
- animal protection groups; and
- ASPA named persons and other professionals performing functions under the Act.

We also met periodically with other government departments and agencies including: Department for Business, Innovation and Skills (BIS); Department for Environment, Food and Rural Affairs (Defra); Ministry of Justice (MoJ); Medicines and Healthcare Products Regulatory Authority (MHRA); Food Standards Agency (FSA); Veterinary Medicines Directorate (VMD); Health and Safety Executive (HSE); Human Fertilisation and Embryology Authority (HFEA); Human Tissue Authority (HTA); Medical Research Council (MRC); and with a range of non-governmental organisations (NGOs) and charities including National Centre for Replacement, Refinement and Reduction of Animals in Research (NC3Rs); Wellcome Trust; Royal Society for the Prevention of Cruelty to Animals (RSPCA); Safer Medicines Trust and the Dr Hadwen Trust. These meetings were generally to discuss specific issues of mutual interest.

ASRU staff also routinely joined the Minister in meetings with stakeholder groups to provide advice as appropriate.

Duty holder engagement

Engagement with those who hold a licence is an important aspect of our work. It allows us to explain our policies and plans, and to receive feedback on the quality of our work and our delivery. During 2013 the ASRU Licensing Team took steps to maintain and improve its dialogue and availability to duty holders by establishing a dedicated telephone help line and email address with direct access to a Licensing Manager throughout normal working hours.

Cascading information throughout establishments, especially those with complex structures, has been particularly important this year with the legislative changes as well as the introduction of ASPeL. We will continue to refine our modes of communications through direct communications, newsletters, the e-licensing system and presentations as well as this Annual Report.

Society of Biology

Our meeting organised in partnership with the Animal Sciences Group of the Society of Biology has become a regular annual event. In December 2013 topics covered included:

- severity and actual severity recording;
- improving communications between those involved in animal research; and
- promoting transparency and openness.

In addition, our Minister, Norman Baker MP, recorded a video message that outlined his early views, having recently acquired the portfolio, and was well received.

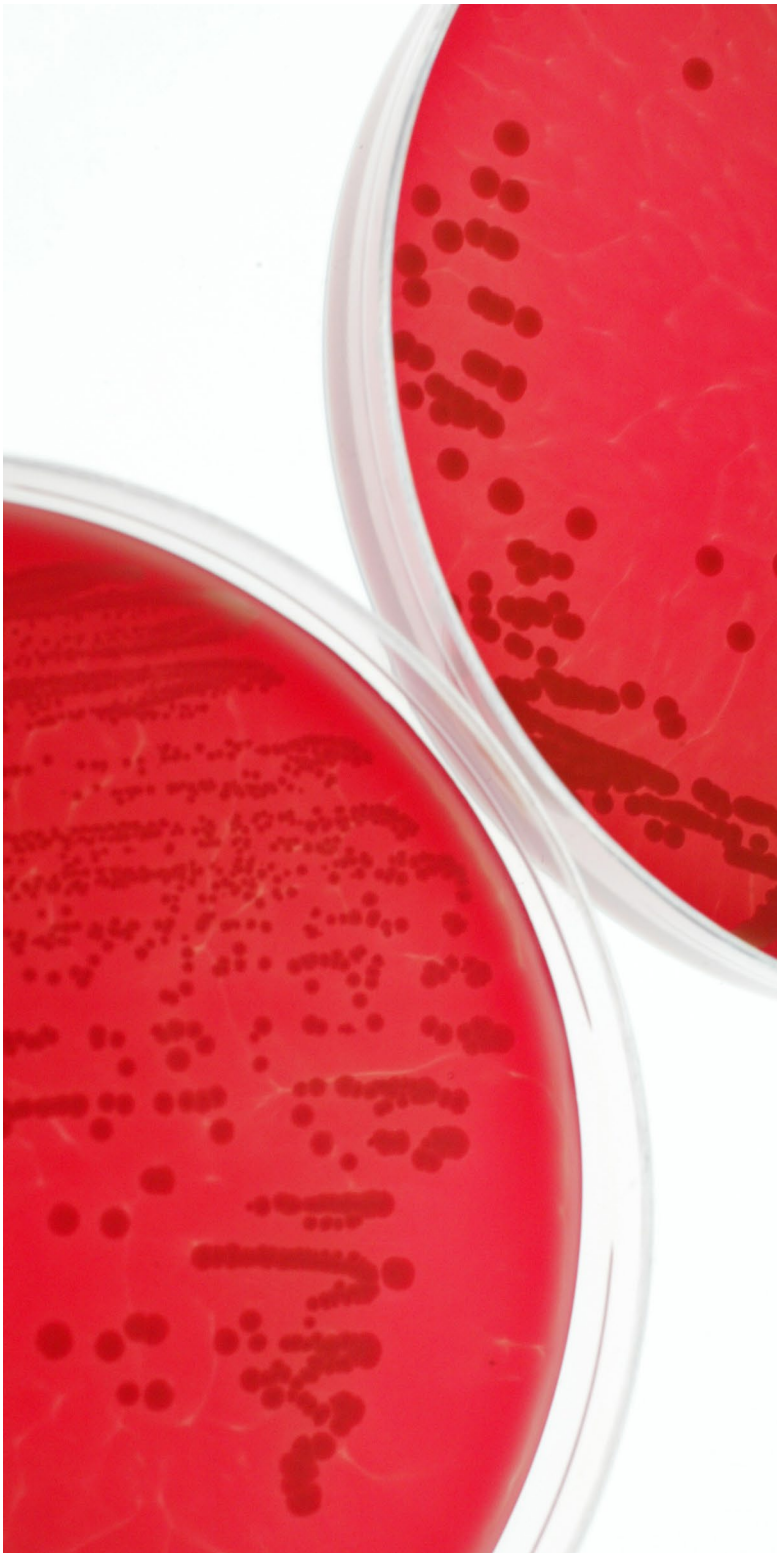
This meeting provides an excellent opportunity to engage face to face with duty holders and to discuss matters of mutual importance. It has proved a very popular event.

Laboratory Animal Science Association (LASA)

ASRU has a representation on the Laboratory Animal Science Association (LASA)'s Education, Training and Ethics Section Committee and also attends LASA Council meetings. During 2013, we were involved in two LASA initiatives.

- Developing guidelines to help licensees to appreciate the complexity of behavioural tests in animals by providing an overview of what licensees should consider when planning and undertaking such procedures on animals in biomedical experiments. This resulted in the publication, Guiding Principles for Behavioural Laboratory Animal Science.
- Developing guidelines to help licensees and trainers to understand key principles and responsibilities to ensure compliance with ethical and legislative requirements and to facilitate good science and animal welfare. This led to the publication of Guiding Principles for Supervision and Assessment of Competence as required under EU and UK legislation, which summarises what is required when developing processes to deal with these issues at establishment level.

Attendance at LASA Council meetings also allowed ASRU to provide the most current advice on other relevant matters being considered.



Section 6: Compliance

Those with a licence under the Animals (Scientific Procedures) Act 1986 (ASPA) are responsible for ensuring that they comply with the legislation and the conditions of their licence. Significant responsibility is placed upon the Establishment Licence (PEL) holder (or, in the case of a corporate entity, the Named Person Responsible for Compliance). It is essential that the PEL holder has put in place robust systems and frameworks that prevent unauthorised procedures from being carried out at their establishment, and ensure that all licensees comply with the terms and conditions of their licences (personal and project licences) when working at their establishment.

A key function of inspection visits is to determine whether establishments and licensees are complying with the provisions of ASPA and with the conditions of their licences. This is a statutory requirement under section 18 of ASPA. Inspectors report any non-compliance and make appropriate and proportionate recommendations for the action required, which is generally aimed at the prevention of repeated faults. Inspectors also advise licensees and others how to comply and generally promote a culture of compliance.

The Animals in Science Regulation Unit (ASRU) Compliance Team consists of a Principal Inspector and a Senior Licensing Manager. The Compliance Team provides support and advice to inspectors during the investigation of potential non-compliance with the aim of promoting a robust, efficient and consistent national approach to cases. The purpose of the team is to ensure that cases are investigated appropriately and the sanctions imposed are applied fairly, accurately, consistently and proportionately. A member of the team may accompany the assigned inspector during the investigation process – particularly where a more serious case is under investigation. The team reports directly to the Chief Inspector and the Head of ASRU.

In most cases of non-compliance, an inspector submits an initial report to the Senior Licensing Manager within five working days of discovery. A full investigation report is then submitted within 30 working days of discovery, together with a recommendation for action. Those involved in the case will normally be notified by the inspector and, in writing, by the Senior Licensing Manager and will be given the opportunity to provide any information that they wish to be considered before a decision is taken regarding the appropriate sanction. There is also the opportunity for appeal against some sanctions. In rare cases, an inspector may take a view early in the investigation that an offence has been committed that is sufficiently serious to merit referral for prosecution.

Details of the process for dealing with non-compliance will be included in the new guidance to the operation of the Act, which will be published early in 2014.[12]

Compliance advice

Inspectors often provide advice to assist licensees to comply. Examples of compliance advice are recorded in inspectors' visit reports and are collated and reported annually to the Secretary of State. In 2013 there were 90 recorded examples of compliance advice given by inspectors.

12 See Guidance on the Operation of the Animals (Scientific Procedures) Act 1986, published in March 2014: https://www.gov.uk/government/publications/operation-of-aspa

Non-compliance cases and key messages

During 2013, we categorised cases of non-compliance according to their severity and the sanction applied. The main characteristics of the categories can be found in **Appendix 1** but it is clear that the boundaries between categories are ill-defined. We therefore propose to cease assigning cases to categories in 2014. Instead, each case will be considered with regard to the severity of the non-compliance. The relevant sanction will be applied with the aim of deterring or preventing recurrence, and will take account of both aggravating and mitigating circumstances.

Appendix 1 provides summaries of all the non-compliance cases in 2013. Thirty-four cases of non-compliance were investigated and completed during the year. Twenty-two of these (65%) were self-reported. **Table A2** in **Appendix 2** shows the history of non-compliances from 2006 to 2013.

A common cause of non-compliance was that the details of the authorities granted in the personal or project licences had not been adequately checked. Failure to check authorities is not a mitigating factor. It is therefore imperative that licensees are fully familiar with the details and authorities given in their personal licence and in the relevant project and establishment licences under which they are working.

Compliance, and failures to comply, can often be traced back to behaviours, cultures and attitudes. The capacity of the establishment to comply often lies in the attitude of the licensees and named persons as well as the engagement of the Animal Welfare and Ethical Review Body (AWERB).

It is clear that a 'culture of care' at an establishment starts with an expectation of compliance, which must be communicated from the top and must pervade all the work being carried out throughout the establishment. In establishments with a good culture of care, it is often the Establishment Licence holder, their staff, or the licensees themselves, who report a non-compliance.

ASRU inspectors seek to enhance the ability of Establishment Licence holders to ensure compliance by advising and influencing, and by clarifying the regulatory requirements and enhancing knowledge through our published Guidance.

Transparency going forward

We have routinely reported summary details of all cases of non-compliance in our Annual Report for several years (see Appendix 1). ASRU also initiates a number of more substantial investigations each year. These may be triggered by a number of factors including:

- an exposé making allegations in the public domain;
- a cluster of non-compliances or 'near-misses' triaged by an inspector to ASRU management;
- a non-compliance apparently involving significant animal harm;
- a published paper that appears to describe unjustified pain, suffering or distress; and
- concern raised by inspectors or others that a particular procedure may not optimally implement the 3Rs.

Such investigations are normally led by inspectors and result in a detailed investigation report to ASRU management.

In the interests of transparency and openness, we intend to start publishing anonymised summaries of such investigation reports on the gov.uk website once they are completed. This will be in addition to our usual reporting in our Annual Report. We believe that this will help ensure that all stakeholders can learn from the outcomes of these investigations as early as possible and enable them to address any potential weaknesses in their own management systems, creating a cycle of continuous improvement. These reports will also provide the public with an insight into this important aspect of ASRU's work.

In determining which investigation reports to publish, we will apply a public interest test. All reports involving significant compromise to animal welfare, or those in which there is evidence of deliberate intent to deceive, will normally be published. In cases where the Establishment Licence holder is found to have failed to comply, it is likely that the issues will be wide-ranging within the establishment and we will normally also publish those reports. In the interests of transparency, we expect that a decision to not publish an investigation report to be the exception.

We intend to commence publishing such summaries of investigation reports during 2014 and will also provide links and summarise the lessons learnt each year in our Annual Report.

Section 7: Inspection

During 2013 the Inspectorate met its target for risk-based inspections. Inspectors conducted a comprehensive programme of visits, mainly unannounced, to places licensed under the Animals (Scientific Procedures) Act 1986 (ASPA) to assess whether statutory requirements were being met, including proper safeguards for the welfare of animals, and that establishments had effective management systems to meet their obligations under the Act. See 2012 Annual Report Appendix 3 for a detailed description of our risk-based inspection system.[13]

During 2013 the Inspectorate carried out 1,390 visits to places where scientific work on animals was conducted. Of the visits made to animal units, 70% were made without notice and 41% of all visits were unannounced. These inspections amounted to 4,264 hours of contact time with those holding licences under ASPA. Inspectors spent 3,729 hours travelling.

The overall number of visits was higher compared with 2012 (8%), and the total contact hours increased by 5%, indicating that the average visit in 2013 was slightly shorter. Time spent travelling also increased by 9%, see **Figure A4, Appendix 2**. The average number of visits per full-time equivalent (FTE) also increased (89 in 2013 compared with 73 in 2012, up 22%) as did contact time per FTE (273 hours in 2013 compared with 228.4 hours in 2012, up 20%), see **Figure A5, Appendix 2**.

The increase in inspection activity was, in part, due to prioritisation of inspection and assessment over other Inspectorate activities such as attending conferences and acting as observers in stakeholder initiatives. In addition, a review of the risk ratings of smaller establishments suggested that a higher minimum level of inspection was needed in some cases. Increased inspection activity following the British Union for the Abolition of Vivisection (BUAV) exposé at Imperial College also contributed to the overall increase. Additional visits for training purposes followed the appointment of three new inspectors during 2013. The overall increase in inspection activity was despite a reduction in FTEs to 15.7, some 11% lower than 2012.

The amount of time spent travelling is related to the geographical distribution of inspectors and the locations of the establishments they inspect. As there were fewer FTEs in 2013 than in 2012, and they maintained the risk-based programme of visits, the amount of travelling per FTE was increased. Whilst we make every effort to reduce travelling time to a minimum to ensure value for money in public expenditure, decisions on inspection responsibilities are not based solely on geographical proximity.

13 Animals in Science Regulation Annual Report 2012: https://www.gov.uk/government/publications/animals-in-science-regulation-unit-annual-report-2012

Section 8: Assessment

Harm–benefit analysis

All project licence applications (and applications for amendments) must specify the required regulated procedures for the programme of work, the likely adverse effects that may occur as a result of those procedures, and the humane endpoints that will be applied. Applicants must also explain what benefits are likely to accrue as a result of their project. The Inspectorate then uses this information to undertake a harm–benefit analysis as part of the project evaluation process. While assessing and minimising the harms, inspectors evaluate the extent to which the 3Rs have been applied.

Only once the harms and benefits (including both impact and likelihood of delivery) have been fully explored is a judgement made as to whether the likely harms are justified by the likely benefits. Inspectors then provide advice, based on the harm–benefit analysis, to the Licensing Team who then will issue the licence acting on behalf of the Secretary of State.

To ensure a high quality and consistent approach across the Inspectorate, inspectors use a number of processes including:

- regular communication and referral between inspectors with particular expertise;
- continued professional development to keep up to date in specialist areas;
- joint consideration of cases that may have set a precedent; and
- seeking external views, for example, consulting the Animals in Science Committee (ASC) and external experts.

During 2013 inspectors assessed and recommended the authorisation of 604 new project licence applications in addition to 1,157 applications for amendments to existing project licences. Details are provided at **Appendix 2**. The assessment of project licence applications occupies about 30% to 35% of Inspectorate time.

The process for performing this harm–benefit analysis is one in which the Inspectorate has great experience and we are widely recognised as a world-leader. We have described it in some detail and will include this in the new guidance to the operation of the Act due to be published early in 2014.[14]

14 Guidance on the Operation of the Animals (Scientific Procedures) Act 1986, published in March 2014: https://www.gov.uk/government/publications/operation-of-aspa

Appendix 1: Categories of non-compliance

The gravity of a non-compliance will depend upon its origins, scale and any consequential animal suffering. Thus, deliberate non-compliances will be viewed more seriously than those due to ignorance, confusion or adherence to inappropriate instructions from those in authority. Repeated failures will generally be viewed more seriously than single incidents; and any unnecessary animal suffering or attempts to conceal the facts will increase the perceived gravity of any non-compliance. A view may be taken on whether or not the licensee is likely to observe their legal and administrative obligations in the future.

A range of sanctions is available to Ministers, including measures aimed at deterring or otherwise preventing a recurrence. These include:

- letters of reprimand, with or without requirements for further action to correct perceived deficiencies which might include:
  - requirements for formal training or retraining;
  - requirements for altered management practices; and
  - addition of special conditions to licences;
- revocation, suspension or amendment of licences;
- requirements specified in a Compliance Notice; and
- referral to the prosecuting authorities.

A non-compliance may also trigger more frequent inspection of an establishment if this is deemed to be appropriate.

Those involved in non-compliances, either directly as the personal licensee or as the relevant project or establishment licensee, will be notified that the Inspectorate has made a report and will be informed of the nature of the breach. Once a non-compliance has been investigated, those involved will be invited to provide any information which they may wish to be considered in mitigation before a decision is taken regarding the appropriate sanction. If this includes variation or revocation of authorities, the rights to appeal under section 12 of the Animals (Scientific Procedures) Act 1986 (ASPA) will be explained.

Once dealt with, non-compliances are reported to the Animals in Science Committee (ASC). The number of non-compliances each year and summary details are published in an anonymised form in our Annual Report.

Compliance advice

Inspectors advise on a case-by-case basis how to ensure compliance with licence conditions and the requirements of ASPA. They also advise on how to avoid non-compliance. Typically, compliance advice may be given by an inspector to ensure compliance with licence conditions and the requirements of ASPA. Occasionally, upon discovery of a trivial breach of licence conditions, an inspector may give compliance advice clearly indicating the actions needed to ensure that such a trivial breach does not recur. Details of such compliance advice may be recorded in the inspector's visit report, with no further formal action being taken by ASRU.

Compliance Notice

The regulations approved in 2012 introduced Compliance Notices as a new sanction. We may issue a Compliance Notice in the event of a breach of a licence condition or a provision of ASPA where we require action to be taken within a specified period to prevent further non-compliance. It will specify the licence condition(s) or ASPA provision(s) that have been breached and will also specify:

- the action that must be taken to ensure that the failure is not continued or repeated; and
- any action that must be taken to eliminate or reduce any consequences of the breach.

The Compliance Notice will also explain what will happen in the event of failure to comply, including possible revocation of a licence or licences.

Category A non-compliance

The characteristics of a category A non-compliance include some or all of the following:

- no, or minimal, animal welfare implications;
- no evidence of intent to subvert the controls of ASPA;
- resolved, or remedy is in place, immediately or within days of discovery.

Typically, in the event of a category A non-compliance, we will send a written reprimand to the person or persons involved. We may also require further action, such as additional training or altered management practices, if we consider this will address the underlying cause of the non-compliance. We will record details of the non-compliance on the relevant licence files (in case of a future recurrence).

Category B non-compliance

The characteristics of a category B non-compliance will include some or all of the following:

- some animal welfare implications but not involving significant avoidable or unnecessary pain, suffering, distress or lasting harm;
- no evidence of intent to subvert the controls of ASPA;
- not resolved within days of discovery, and further action may be needed;
- not sufficiently serious for revocation of licences to be considered.

Typically, in the event of a category B non-compliance, we will send a written reprimand to the person or persons involved and are likely to require further appropriate action, such as additional training or altered management practices. We will also record details of the non-compliance on the relevant licence files (in case of a future recurrence) and may apply an additional condition to the licence.

Category C non-compliance

The characteristics of a category C non-compliance will include some or all of the following:

- serious animal welfare implications involving significant avoidable or unnecessary pain, suffering, distress or lasting harm;
- evidence of untruthfulness or attempts to evade responsibility;
- future compliance concerns and further action required;
- not sufficiently serious for referral for prosecution to be merited.

Typically, in the event of a category C non-compliance, we will amend, revoke or suspend the relevant licence(s) of the person or persons involved. We will normally require further appropriate action, such as additional training

or altered management practices. We will also record details of the non-compliance on the relevant licence files (in case of a future recurrence) and, if appropriate, we will apply an additional condition to the licence.

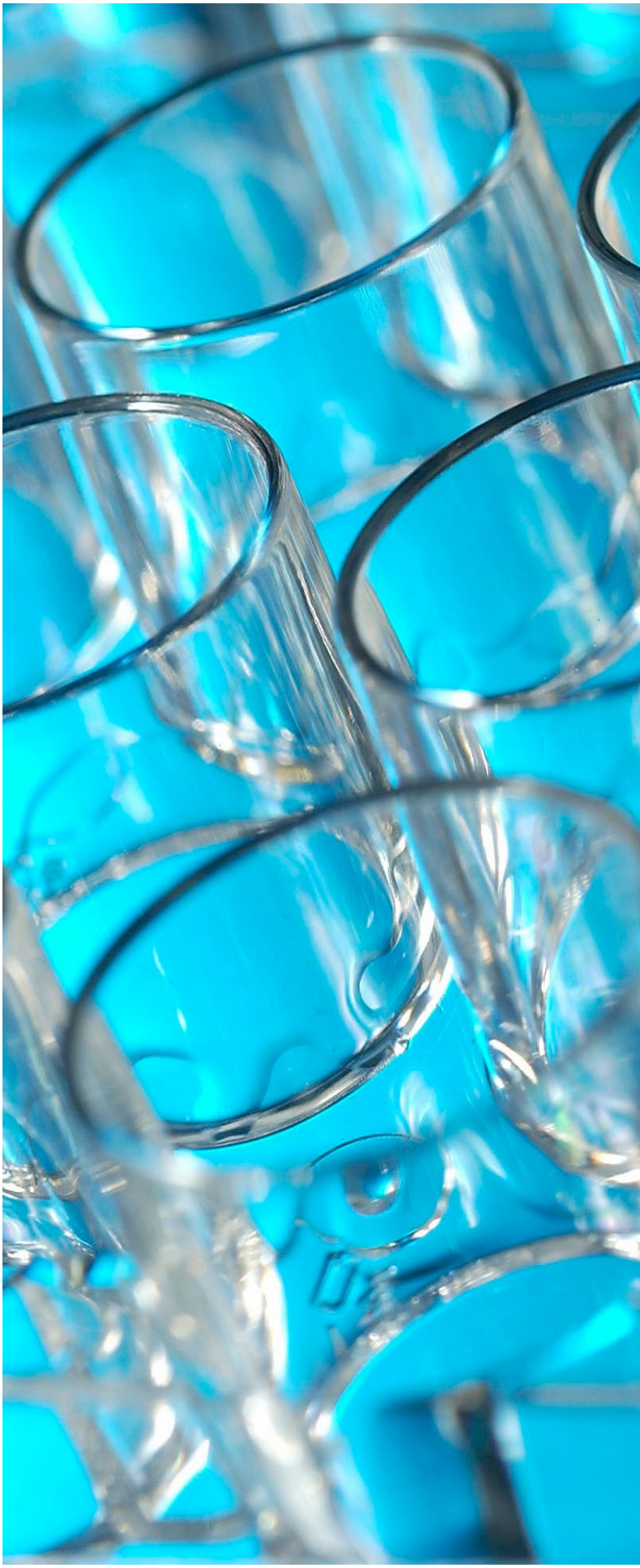
Category D non-compliance

The characteristics of a category D non-compliance will include some or all of the following:

- serious animal welfare implications involving avoidable or unnecessary pain, suffering, distress or lasting harm;
- evidence of significant untruthfulness or attempts to evade responsibility;
- serious contraventions which merit referral for possible prosecution.

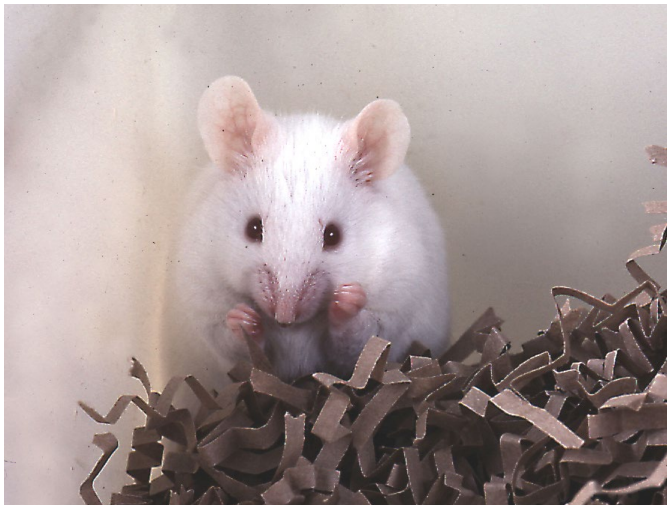
In such circumstances, the Inspectorate will undertake a preliminary investigation only, sufficient to establish whether prosecution should or should not be considered. If prosecution is contemplated, further investigation is then undertaken by the police with assistance from the Inspectorate.

Typically, in the event of a category D non-compliance, we will refer the case to the Crown Prosecution Service (in England and Wales) or the Procurator Fiscal (in Scotland) to consider prosecution. Whether or not the decision is taken that prosecution is in the public interest, it is likely we will revoke the relevant licence(s) and require significant further action before any re-application for a licence will be considered. We will also record details of the non-compliance on the relevant licence files in case of a future re-application.



Wellcome Library, London

Cases reported and completed in 2013



Compliance advice

In 2013 there were 90 reports of compliance advice recorded (for example, the fabric of a building was falling significantly below the Code of Practice guidance, the records of a project licence were not fully up to date, or a cage label had not been fully completed).

Cases of non-compliance

In addition to one non-compliance leading to a Compliance Notice, there were 33 further cases of non-compliance which were investigated and completed during 2013 of which 22 (65%) were self-reported. Of the 19 category A cases, 16 were self-reported. Three of the eight category B cases were self-reported and three of the six category C cases were self-reported. No investigations into cases of Category D non-compliance were concluded during 2013.

Compliance Notice

In 2013 we issued one Compliance Notice. An animal rights organisation submitted a report containing numerous allegations about individuals working at a university. Further documentary material was provided together with a video that purported to show work being undertaken in breach of ASPA. We identified and investigated 18 cases of potential non-compliance involving 30 individuals.

The majority of the allegations were not substantiated; however, we confirmed four cases of non-compliance involving six individuals. These involved a failure to adhere to the authorised endpoints permitted in a project licence and failure to inform us. All were dealt with as category B non-compliance cases. One further case was discovered during the investigation and involved two individuals in inadequate record-keeping. This was dealt with as a category A non-compliance. All these cases are reported in more detail in the relevant category below.

The number of non-compliant individuals was small in proportion to the total number of licences held at the establishment. However, there was evidence of widespread poor understanding of responsibilities under ASPA which led us to conclude that there was a poor culture of care at the establishment. Communication between the Establishment Licence holder and licensees and others with responsibilities under ASPA was generally poor. Additionally, there was a failure to maintain local systems that make all reasonable efforts to prevent the performance of unauthorised procedures.

The Establishment Licence holder was therefore found to be in breach of a number of licence conditions and was served with a Compliance Notice, which required the

instigation of an immediate short-term response together with a longer-term improvement in the culture of care. This Notice included the following requirements:

1. to provide evidence of improvement in the training of all working under ASPA, demonstrated through records of training, supervision and competence;
2. to demonstrate how those involved in animal care are actively involved in experimental design and in the adoption of refined models and good practices;
3. to demonstrate improvements in local systems of management to effect the reporting of likely or potential breaches of severity and to prevent the application of unauthorised procedures;
4. to explain improvements in record-keeping including: experimental records; training and supervision of competence records; and actual severity recording;
5. to demonstrate how the AWERB will be effective in promulgating the 3Rs; and
6. to demonstrate how communication with ASRU has been improved.

Inspectors continue to visit the establishment on a regular basis to assess the improved culture of care and to assess the improved empowerment of staff under ASPA. The Establishment Licence holder has been required to conduct regular reviews and will have to demonstrate the continued impact of these improvements after a further 12 months, in February 2015.

Category A non-compliance

In 16 of the 19 cases, procedures (for example, blood sampling, intraperitoneal injection, cannulation, re-use) were carried out competently but without the necessary authorisation. In all cases authority would have been granted had it been applied for. Of these cases, 11 were at universities, 2 at commercial organisations and 3 at research institutes.

In addition, in one case at a university there was a breach of the authorised severity limit. Three groups of seven mice underwent surgery and six days later seven of the animals died and a further two were euthanised due to weight loss. It was concluded that this was due to a genuine error on the part of the personal licensee. Nevertheless, the death rate exceeded that permitted in the project licence protocol and was not reported due to confusion on the part of the personal and project licence holders who each thought the other had made the report. There were no other adverse welfare consequences.

In another case, at a commercial organisation sheep were subjected to bilateral surgery when the current project licence authorised only unilateral surgery. The previous licence had authorised bilateral surgery but an error in drafting the new licence had led to this omission. The surgery was conducted competently and no animal welfare concerns were evidenced. The project licence has subsequently been amended to permit bilateral surgery.

Finally, there was a failure at a university by the holder of a project licence, and a personal licensee working on that project licence, to maintain adequate records.

Category B non-compliance

1. At the conclusion of a series of regulated procedures on rats at a commercial organisation, the holder of a personal licence failed to kill one rat properly. As a consequence, the animal regained consciousness and suffered adverse effects as a result of the procedure, and unnecessary distress as a result of being deprived of food and water. The case was self-reported and improved standard operating procedures were promptly put in place by the Establishment Licence holder concerned. The personal licensee was sent a written reprimand.

2. At a university, 31 mice were either found dead or had to be killed due to unexpected adverse effects following what was intended to be sub-lethal irradiation and reconstitution with spleen cells. This was a failure to adhere to the authorised endpoints and a failure to report the breach. This incident occurred due to an apparent misunderstanding by the project licence holder who did not appreciate that the increased death rate is considered to be a breach of the severity limit of the protocol in his licence and that this should have been notified to the Home Office. The project licence holder was sent a written reprimand and required to undergo retraining in modules 1 and 5. The personal licence holder was also sent a written reprimand and required to undergo retraining in modules 1 and 2.

3. At a university, 3 out of 12 (25%) rats died during anaesthesia but the project licence authorised an upper limit of just 1%. The project licence holder thus failed to adhere to the authorised endpoints and also failed to inform the Home Office of the breach. The licence holder was sent a written reprimand and required to undergo retraining in modules 1 and 5.

4. At a university 14 out of 37 rats died under general anaesthesia and a further 1 rat died within 24 hours. This represented a death rate of 40% of the cohort while the project licence authorised an expected mortality of between 20 and 25%. The project licence holder thus failed to adhere to the authorised endpoints and also failed to inform the Home Office of this breach. The licence holder was sent a written reprimand and required to undergo retraining in modules 1 and 5.

5. At a university following anaesthesia of three mice, fur was shaved and depilatory cream applied to remove remaining hair. The mice were then washed, injected with antibodies and then imaged. Two of the mice were subsequently placed in one cage and the third mouse was housed on its own. The mice were left over the weekend and the two mice housed together were found in a distressed state on the Monday morning with skin lesions. It was established that the shaving of the mice was conducted to a poor standard, and the depilatory cream was not washed off adequately from the animals resulting in skin lesions. The project licence holder was sent a written reprimand and required to undergo retraining in modules 1 and 5. The personal licence holder was also sent a written reprimand and required to undergo retraining in modules 1 and 2.

6. At a university animal numbers used on a protocol in a project licence were exceeded by 65% (660 mice as opposed to 400). Furthermore, the protocol included a mandatory step that dictated the severity of the protocol. However, experiments were conducted without using the mandatory step with the intent to develop a modification to a different model. This meant that this work was undertaken without proper licence authority. Further investigation revealed that record-keeping of a running tally of animals used was confusing and it was difficult to reconcile the number of animals actually used against the number recorded. All procedures were otherwise competently performed. The incident was self-reported and authority to increase the numbers of animals used would have been granted had it been applied for. In view of these circumstances, additional training was not considered appropriate and the project licence holder and two personal licence holders were each sent a written reprimand.

7. At a university the holder of a personal licence carried out a regulated procedure on 20 rats under project licence authority. During an unannounced inspection, it was discovered that one rat had been found to have chewed three digits off its left hind paw. Furthermore, it appeared that two

more phalanges had been chewed off. In another cage one rat had also chewed approximately half of its left hind foot off and the remaining stump was swollen and reddened.

The laboratory manager immediately culled the two animals concerned. However, remedial action should have been taken earlier by the personal licence holder. The remaining animals all appeared fine. The breach resulted in exceeding the project licence endpoint. The project licence holder and the personal licence holder were each sent a written reprimand. Further training was not considered appropriate because the establishment concerned instigated changes in their standard operating procedures to minimise the possibility of any recurrence of this type of incident.

8. At a university 30 mice were anaesthetised and weighed by a personal licence holder without project licence authority. Ten of the mice were also anaesthetised using isoflurane in the absence of sufficient oxygen and eight of these failed to recover from anaesthesia. The incident was self-reported. Improved standard operating procedures for anaesthesia were put in place by the Establishment Licence holder. The project licence holder and the personal licence holder were each sent a written reprimand. The personal licence holder would have been required to undergo retraining in anaesthesia had this not already been mandated by the Establishment Licence holder.

Category C non-compliance

1. At a university a group of 20 mice were injected with parasites and the holder of a revoked personal licence subsequently assumed responsibility for the experiment. This included daily monitoring and blood sampling of the animals and was all done without appropriate personal licence authority or supervision.

Two days later, 8 of the 20 mice were found dead and 1 further mouse had to be humanely killed. Further investigations established that this group of mice had exceeded the authorised moderate severity. Additionally, it was confirmed that the personal licence of the individual who had assumed responsibility for these animals had been revoked eight months earlier but that the individual concerned was not aware of this revocation. Carrying out regulated procedures without holding a personal licence constitutes a breach of section 3(a) of ASPA. In this instance, the inspector concluded that there was no deliberate intent to breach the regulatory controls. Nevertheless, by failing to provide an appropriate level of supervision, the project licence holder was considered to have failed to discharge his responsibilities.

The case was self-reported and the Establishment Licence holder introduced a series of rigorous procedures to ensure that incidents like this could not happen again. The Establishment Licence holder and project licence holder were each sent a written reprimand. The former personal licensee was sent a letter of censure. The individual was due to leave the UK in March 2013 and in the interim was prohibited by the Establishment Licence holder from undertaking any work with animals at the establishment. Neither retraining nor additional conditions on the relevant project licence were considered appropriate because the licensee terminated any further work on the licence as soon as the problems became apparent and submitted the licence for revocation.

2. This was a complex investigation at a university involving many elements. The holder of a personal licence, working under the supervision of a project licence holder, kept 6 rats in metabolic cages for a total of 8 periods of 24 hours and also administered a general anaesthetic to 5 further rats without appropriate project licence authority.

For this breach, the licensee received a written reprimand.

During this investigation, it was discovered that 2 undergraduate personal licence holders, working under the supervision of the same project licence holder, undertook behavioural tests on 30 rats without appropriate project licence authority. A further two undergraduate personal licence holders, also acting under the supervision of the same project licence holder, re-used four of these animals without appropriate project licence authority. The four undergraduates all left the establishment before conclusion of the investigation by the inspector and their personal licences were revoked.

A further personal licence holder, acting under the instruction of the same project licence holder, undertook regulated procedures on 2 rats and decapitated a further 30 rats, all without appropriate project licence authority. This personal licensee received a written reprimand. Finally, the holder of the project licence under which all this work had purportedly been carried out, had failed to report unexpected adverse effects observed in a further five rats.

At the end of a lengthy investigation, it was concluded that the project licence holder had not knowingly permitted the personal licensees to carry out unauthorised regulated procedures but had demonstrated a severe lack of knowledge and understanding of ASPA, the Guidance, and the project licence conditions. Taken in their totality, it was considered that this failure reached the level of category C non-compliance and the project licence holder received a written reprimand and was required to retake training in modules 1 and 5.

In addition, one personal licence breach was dealt with as category B non-compliance and five as category A. All six were reported in our 2012 Annual Report.

3. The holder of both a project and a personal licence at a university exceeded the number of animals stated in a protocol, miscalculated dosing levels causing the deaths of 26 mice, and then failed to notify us of this. The same individual also exported abroad multiple batches of animals undergoing regulated procedures on the project licence without authorisation, failed to maintain adequate records of procedures carried out, and was found to have signed the sponsor's declaration for his own personal licence application without the authority of the Establishment Licence holder. All these non-compliances were discovered by an inspector.

   The Secretary of State informed the holder of her intention to revoke both the project and the personal licence. The licensee appealed against this decision under section 12 of ASPA. However, the appeal was delayed due to the repeated failure by the licensee to respond to communications both from the Home Office and our solicitors. In due course, the person appointed by the Secretary of State to hear the appeal advised that the appeal should be closed. This advice was accepted and both the project and personal licences were summarily revoked.

4. Surgical procedures were performed on ten mice at a breeding establishment prior to being moved to a university for further procedures. However, three of the mice had to be euthanised after they arrived at the university. Concerns were raised about the standards of the aseptic surgery technique used at the breeding establishment and inadequate care of these mice following their arrival at the university.

   The incident came to light at a meeting of the breeding establishment's AWERB, attended by an inspector, at which

concerns were expressed about the poor aseptic technique of the personal licensee conducting the surgical procedures. Using powers in section 13(1) of ASPA, we suspended the individual's personal licence for a period of three months. The personal licensee subsequently requested revocation of the personal licence one month after the date of suspension. Establishment Licence holders at both the breeding establishment and the university instigated a series of seminars on aseptic technique for their licensees to improve their standards. The former personal licensee received a letter of censure. The project licence holder at the university received a written reprimand and was required to undergo retraining in module 5 due to the failure to ensure adequate care of the surgically prepared animals following their arrival.

5. At a research institute, seven wild-type mice were weaned and discovered three days later without any food. One mouse was found dead and the other six were in a weak and emaciated condition. All were humanely killed without further delay. A number of checks had failed to detect either the lack of provision of food or the deteriorating condition of the animals. The non-compliance was self-reported. A detailed internal investigation was undertaken by the Establishment Licence holder and an action plan was put in place to minimise the chance of a recurrence. Disciplinary action was taken against five members of staff.

   A written reprimand was sent to the Establishment Licence holder and three special conditions were added to the Establishment Licence requiring, within one month, the following to be completed:

   - a thorough review and action plan detailing the steps the establishment intended to take to ensure that this type of incident would not recur; and
   - a review of the training of all animal care staff, with details of the outcome of this review to be sent to Home Office.

   Finally, quarterly updates on the review of, and progress with, the action plan over the next year were required. The Secretary of State also wrote to the Director of the Establishment's parent company to reinforce the concerns.

6. At a breeding establishment, the failure of an air-conditioning unit led to the death of 787 rats and mice and the culling of another 345 for welfare reasons. The equipment breakdown resulted from a failure by the Establishment Licence holder to ensure adequate investment in plant and other equipment, and inadequate routine maintenance. The incident was self-reported.

   A written reprimand was sent to the Establishment Licence holder and two special conditions were added to the Establishment Licence requiring, within one month, the following actions to be completed and reported to the Home Office:

   - a list of measures taken to remedy the immediate issues which caused the failure; and
   - an action plan detailing other measures being taken to ensure that all facilities authorised under the Establishment Licence would operate in accordance with ASPA and any associated Home Office Codes of Practice, and would be maintained in such a way that ongoing compliance would be assured.

   The action plan was to be prioritised, unequivocal and have clear deadlines. Adherence to it would be monitored during future inspections. The Secretary of State also wrote to the Chief Executive Officer of the parent company to reinforce the concerns.

Category D non-compliance

There were no cases of Category D non-compliance during 2013.

Appendix 2: Tables and figures

Table A1: Licence and certificate applications and amendments, 2013 and 2012

	Total			Per inspector FTE		
	2013	2012	Change	2013	2012	Change
PILs granted	2,770	2,639	+5%	176.4	149.2	+18%
PILs amended	2,025	2,858	-29%	129.0	161.6	-20 %
PILs in force at year-end	16,112	14,875	+8%	1,026.2	841.0	+22%
PELs granted	3	3	0%	-	-	-
PELs amended	247	247	0%	15.7	14.0	+13%
PELs in force at year-end	174	176	-1%	11.1	10.0	+11%
PPLs granted	604	626	-4%	38.5	35.4	+9%
PPLs amended	1,157	1,156	0%	73.7	65.4	+13%
PPLs in force at year-end	2,672	2,698	-1%	170.2	152.5	+12%
Inspectors FTE	15.7	17.7	-11.1%			

Note: FTE = full-time equivalent; PIL = personal licence; PEL = establishment licence; PPL = project licence

Table A2: History of non-compliances, 2006-2013

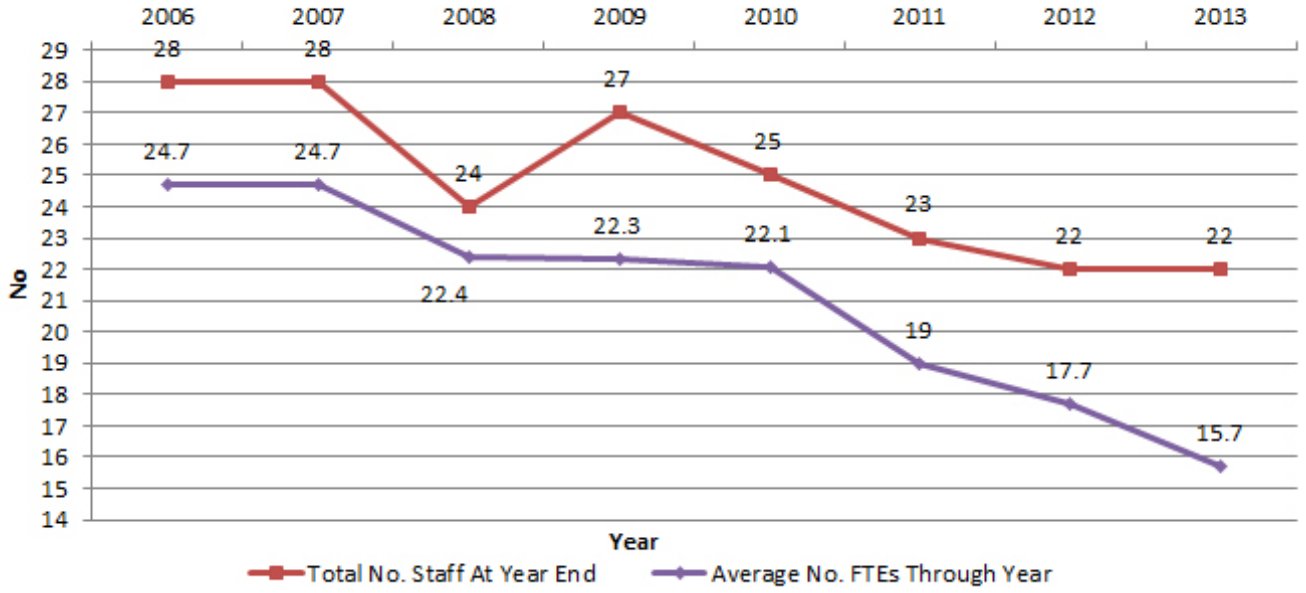
Year	Compliance advice**	Total non-compliances	Compliance Notices	Category A	Category B	Category C	Category D
2006*	n/a	29 (17)					
2007*	n/a	30 (15)					
2008*	n/a	37 (24)					
2009	36	29 (26)		18 (15)	8 (8)	3 (3)	0
2010	108	33 (18)		10 (6)	14 (6)	9 (6)	0
2011	155	39 (25)		21 (14)	11 (8)	6 (3)	1 (0)
2012	131	26 (16)		13 (9)	10 (5)	3 (2)	0
2013	90	33 (22)	1(0)	19 (16)	8 (3)	6 (3)	0 (0)

Note: Figures in brackets indicate self-reported non-compliances (versus those discovered by inspectors).

* For these years, non-compliances were categorised differently and therefore only total numbers can be compared.

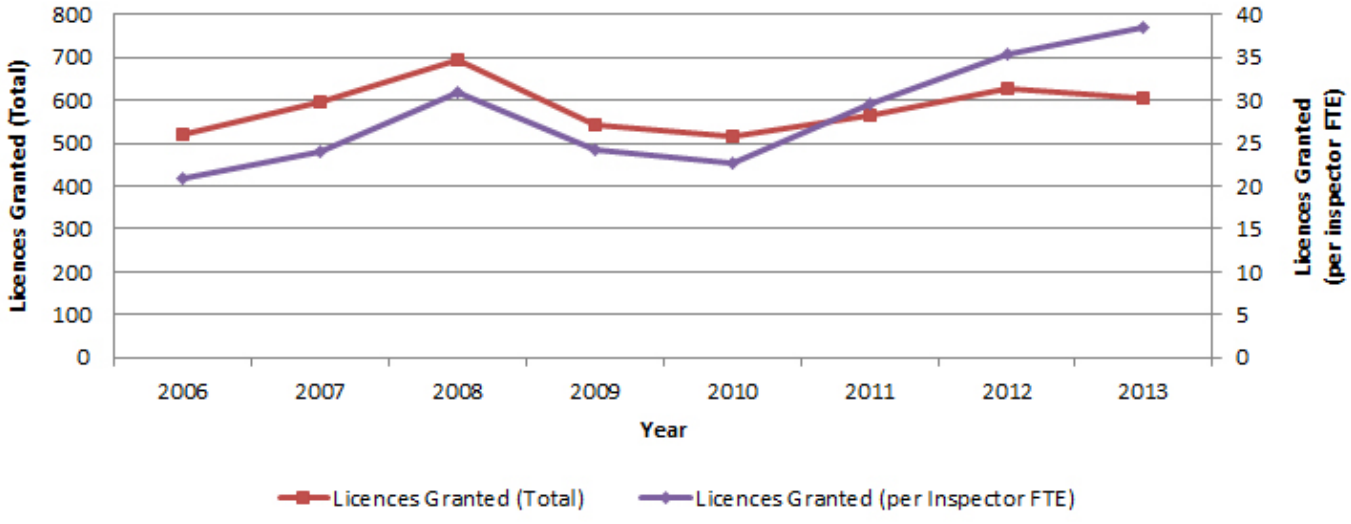
** Frequency of providing compliance advice was not recorded prior to 2009

Figure A1: Inspectorate staff, 2006-2013



FTE = full-time equivalent

Figure A2: Project licences granted, 2006-2013



FTE = full-time equivalent

Figure A3: Project licence application processing, 2006-2013

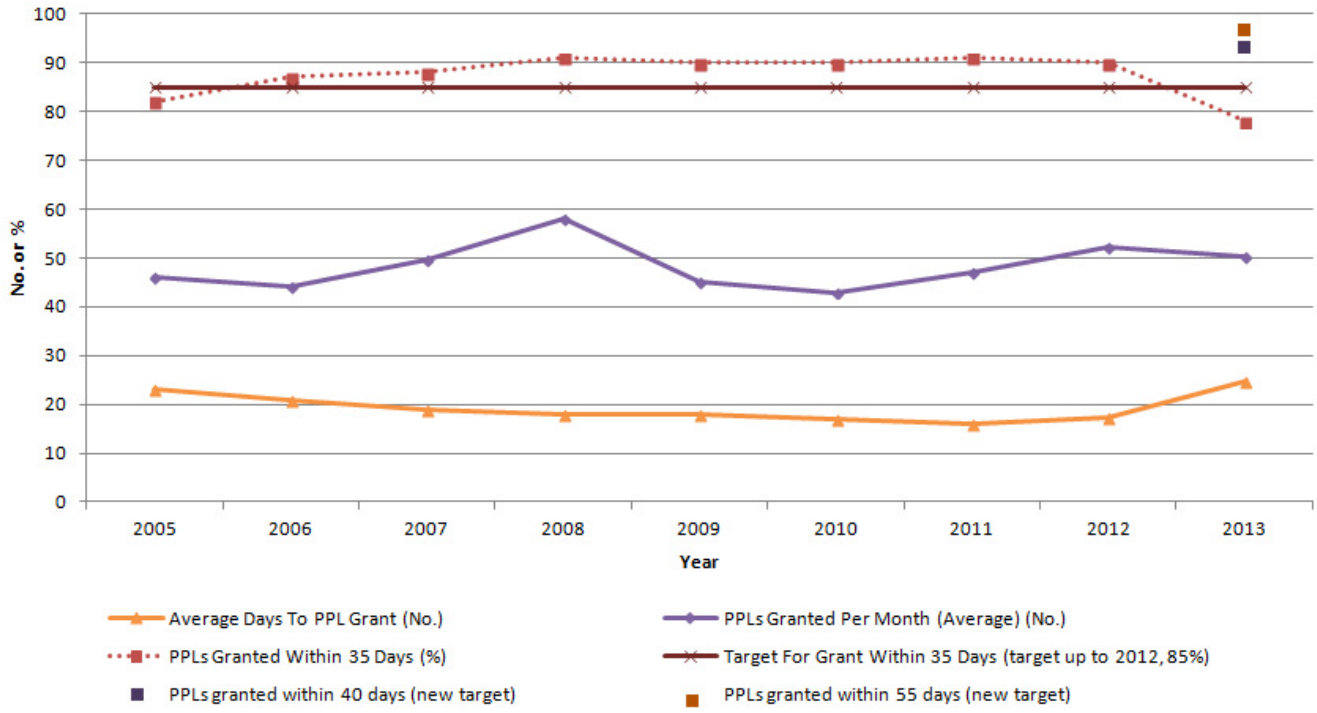


Figure A4: Total inspections, 2006-2013

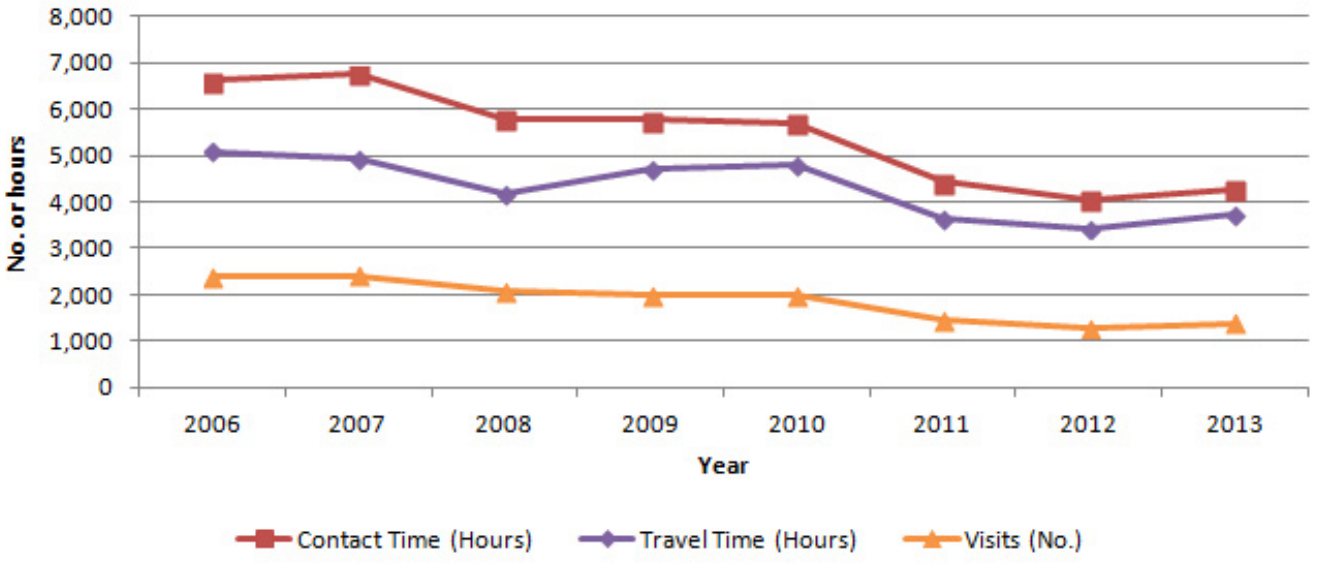
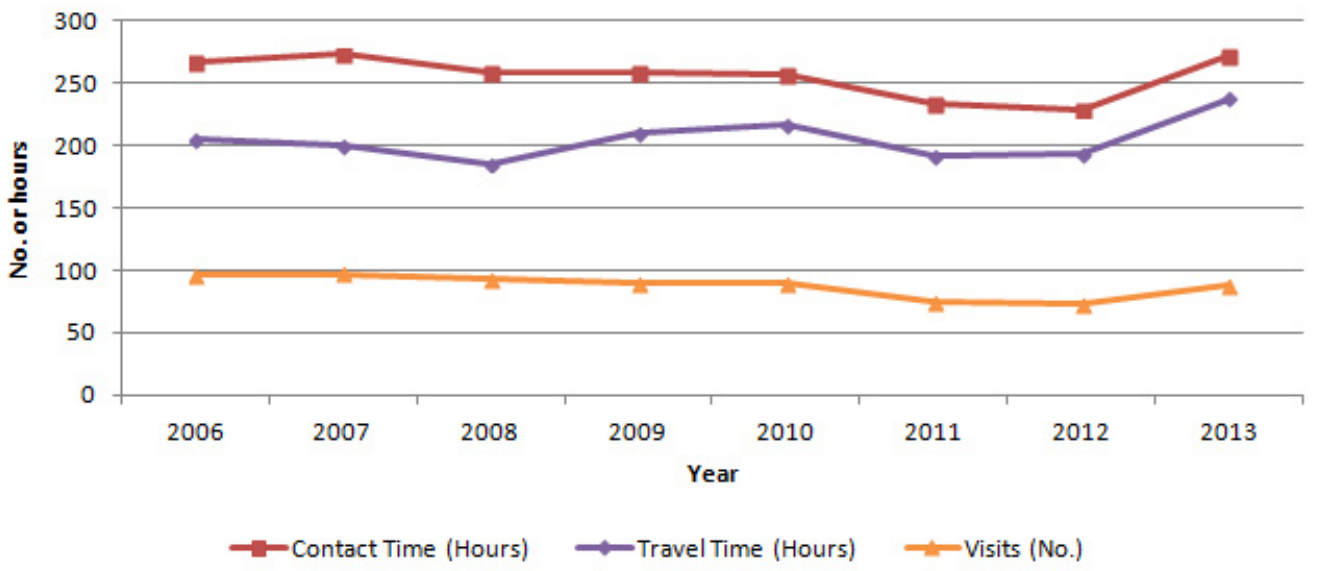


Figure A5: Inspections per FTE, 2006-2013



FTE = full-time equivalent

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