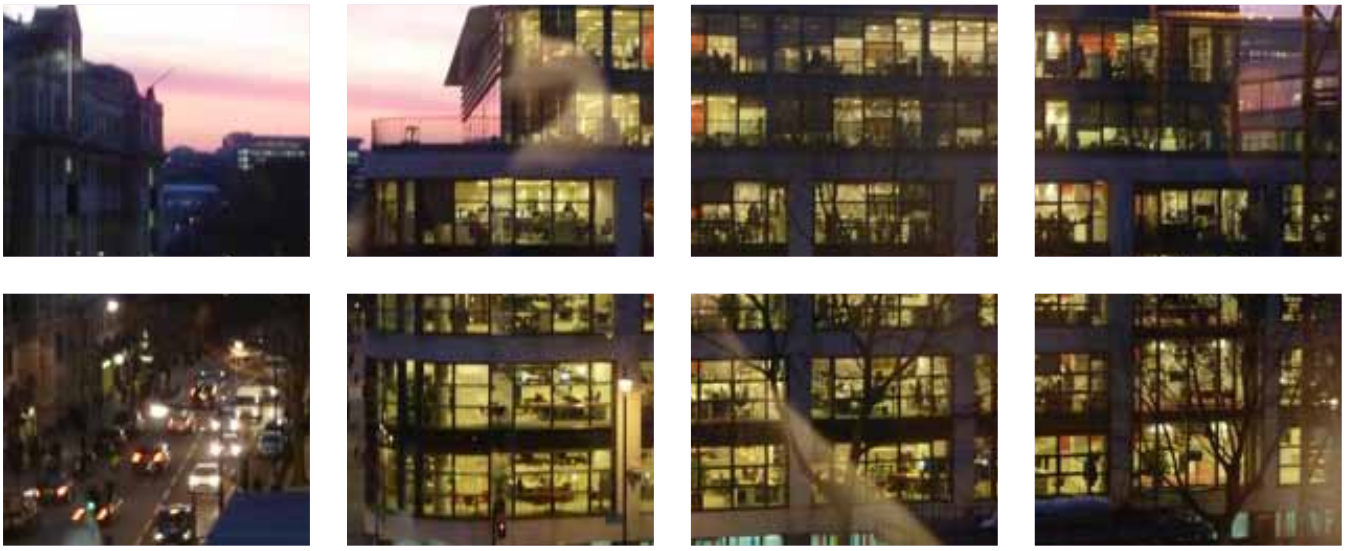
Home Office

Animals in Science Regulation Unit
Annual Report 2012



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Foreword

I am very pleased to introduce the 2012 Home Office Animals in Science Regulation Unit (ASRU) Annual Report.

2012 was a challenging year. Of particular significance was ASRU's work to implement Directive 2010/63 in UK legislation which was successfully completed in December 2012. ASRU is now pressing ahead with implementing the revised UK legislation.

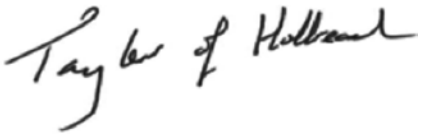
ASRU also started a major business reform programme involving reorganisation and restructuring the unit and the development of an e-Licensing IT system. Both projects were making significant progress by the year end. Plans to centralise the Licensing Team to improve efficiency, and to roll out the new e-Licensing system – known as ASPeL – will move towards completion this year.

At the same time, the routine work of licensing and inspection continued unabated and to established high standards, amply demonstrating the professionalism and commitment of our staff.

ASRU continues to work closely with the Department for Business, Innovation and Skills to deliver the Coalition Agreement commitment to work to reduce the use of animals in scientific research. Key areas of activity will include exploiting the latest developments in science and technology to reduce animal use and facilitating data sharing and collaboration across industry and academia.

ASRU is also taking forward initiatives to deliver greater transparency regarding the use of animals under the Animals (Scientific Procedures) Act 1986, through a review of section 24 – the so-called 'confidentiality clause' – and a project to develop arrangements for reporting on the actual severity of the procedures applied to them.

Everyone deserves to be congratulated on a busy and successful year and I look forward to another challenging and productive year ahead.



Lord Taylor of Holbeach
Lords Minister and Minister for Criminal Information

Introduction

For ASRU colleagues and for our stakeholders across the diversity of interests, this has been a year to remember and 2013 promises to be equally challenging.

Transposition of Directive 2010/63/EU into UK legislation was a major task, led by our Policy Team but with essential support from our inspectors and licensing staff. We became very practised at briefing Ministers for debates in both houses of Parliament. Our Impact Assessment attracted a green rating from the Regulatory Policy Committee leading the way for us to implement regulations which retained higher UK standards whilst avoiding unnecessary bureaucracy. The UK was one of only seven EU Member States to have fully implemented the revised regulations by January 2013.

We continued to develop e-Licensing but needed to take a brave decision half way through the year to change horses and develop a new web-based system, ASPeL. We are confident that ASPeL will be ready for roll-out during late 2013 and will benefit both our stakeholders and ourselves by allowing quicker processing of applications and simpler access to information within a secure environment.

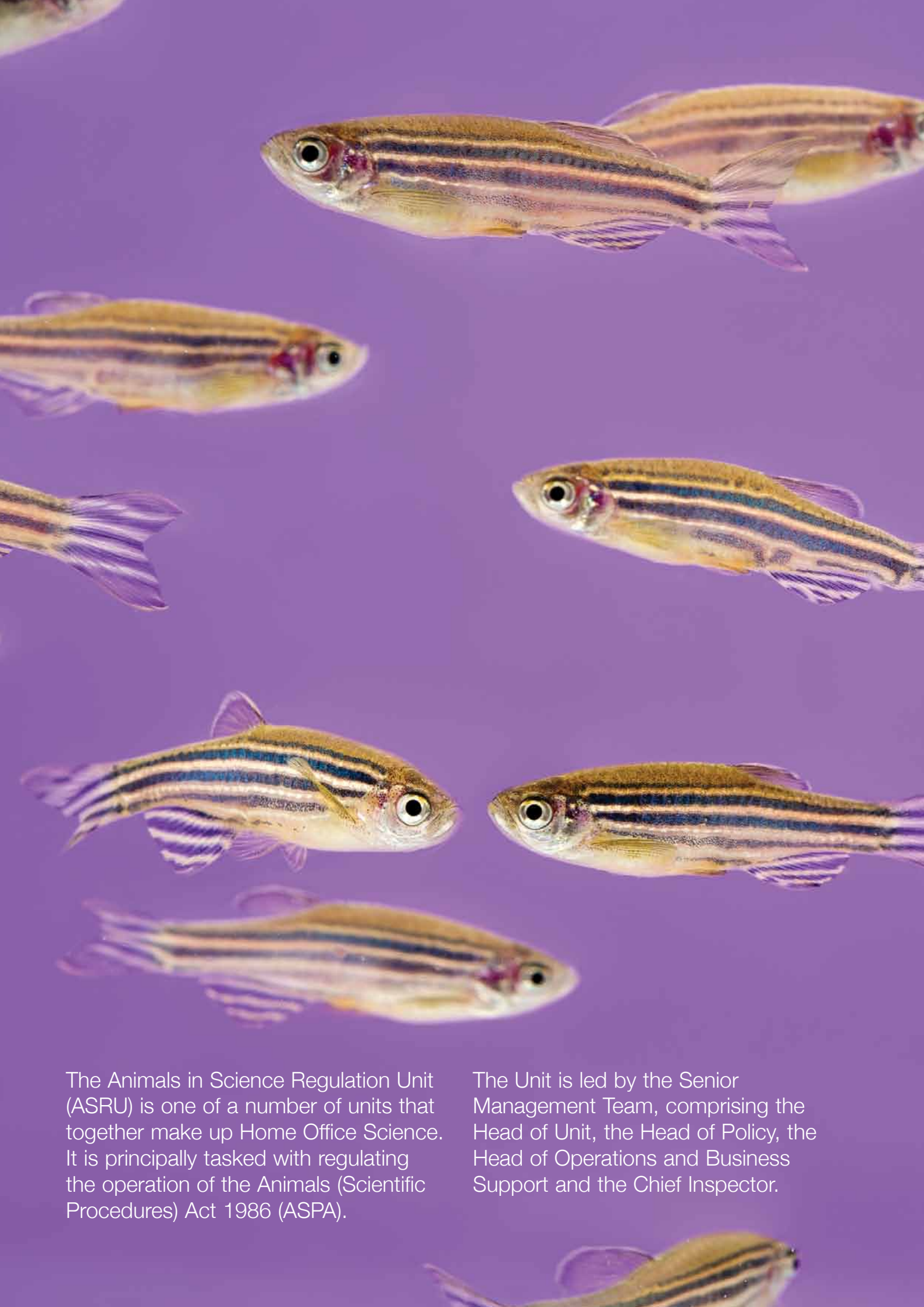
As part of our re-organisation and restructuring, we continued to move towards centralised licensing based in London. Decommissioning the first of our regional offices, in Cambridge, in late 2012 demanded significant resource. We will learn from this lesson as the other regional offices close.

Delivering our two coalition government commitments has also been a priority during 2012. In this report we describe the way in which inspectors promote the 3Rs (Replacement, Reduction and Refinement) and how we have partnered with the UK National Centre for the 3Rs in a science-led approach to alternatives. We also did further work in 2012 on the proposal to ban the testing on animals of household products.

We have continued to refine our risk-based approach to inspection. The formal Risk Management Meetings between inspectors and establishment licence holders, held at least annually, are appreciated by both sides as a critical element in mitigating risks and developing action plans to ensure an appropriate culture of care.

It is important that we make use of all our resources as efficiently and effectively as possible. The life sciences will undoubtedly make a major contribution to UK economic growth over the next few years. We recognise the need to deliver the social benefits that science can bring whilst we also fulfil our role in ensuring that the welfare of animals is safeguarded. It is this balance that gives the public confidence in our regulatory system.

Judy MacArthur Clark CBE
Head, Animals in Science Regulation Unit



The Animals in Science Regulation Unit (ASRU) is one of a number of units that together make up Home Office Science. It is principally tasked with regulating the operation of the Animals (Scientific Procedures) Act 1986 (ASPA).

The Unit is led by the Senior Management Team, comprising the Head of Unit, the Head of Policy, the Head of Operations and Business Support and the Chief Inspector.

Section 1: Operations – Licensing and Business Support

A key function of ASRU is licensing which is carried out jointly by the Licensing Team and the Inspectorate. They, in turn, are supported in their operations by the Business Support Team.

The Licensing Team's role

The Licensing Team is part of ASRU Operations and is managed within that line. It is based at the Home Office headquarters at 2 Marsham Street, London, as well as at three Regional Offices that are located in Dundee, Shrewsbury and Swindon. A fourth regional office located in Cambridge was closed during 2012 and inspectors have been relocated into alternative government office accommodation near Bedford. At the end of 2012 the Team comprised two Senior Licensing Managers, three Licensing Managers and 15 Licensing Officers.

The purpose of the Licensing Team is to operate the licensing and regulation system for scientific procedures using living animals. Its core functions within this remit are:

- issuing personal and project licences;
- issuing establishment licences (before January 2013 known as certificates of designation);
- collecting statistics on procedures;
- administering fees from establishments;
- dealing with non-compliance.

The Inspectorate's role

Throughout 2012 the Inspectorate comprised 22 individuals, including the Chief Inspector. All inspectors are registered veterinary or medical practitioners who have first-hand experience of biomedical research, and possess higher scientific or clinical postgraduate qualifications.

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

During 2012, the average resource assigned to normal inspection duties (including licence assessment) was 17.7 FTEs (full-time equivalents). This was somewhat lower than the 19 FTEs in 2011. See **Figure 1, Appendix 4** for further related historical data.

Licence assessment

Inspectors assess detailed research proposals to advise on whether they meet a satisfactory harm–benefit analysis to merit licence authorities. Time is spent discussing these proposals with scientists to reach a clear understanding of the requirements of the scientific aims and how these can be accommodated whilst ensuring implementation of the 3Rs (Replacement, Reduction, Refinement) for that particular piece of work. Inspectors also assess and advise on the suitability and competence of applicants to perform the techniques set out in applications for personal

licences, and of places to be licensed as scientific procedure establishments, or breeding or supplying establishments.

In 2012 advice was provided to the Licensing Section for the granting of 626 project licence authorities. This work involved a number of internal referrals between inspectors to benefit from our collegiate expertise in reaching conclusions on applications. In addition nine of these licences were referred to the Animal Procedures Committee, including seven involving non-human primates in procedures of potentially substantial severity. Inspectors subsequently advised officials on whether and on what terms such licences might be granted.

Licensing performance

Table 1 in **Appendix 4** summarises the ASRU licensing performance during 2012. It is notable that the number of applications for amendments of all types of licences was significantly lower than in previous years. This may, at least partially, have been due to licence holders choosing to delay changing their authorisations until the new regulations had been passed. This is perhaps particularly the case for personal and establishment licences which do not expire.

In the case of project licences, there was a higher number of new project licences granted in 2012 than had been expected. It may be that applicants who might have considered amending their old project licence chose instead to apply for a new project licence under the old regulations This was something we encouraged to hopefully decrease the number of applications for project licences in 2013 when we will all be getting used to the new regulations. The quality of applications for project licences has also improved with the new project licence application form which was introduced in 2010 and it may be that this is now resulting in a reduced need for amendments to authorities.

Establishment licences

Some details of the characteristics of an establishment licence (certificate of designation prior to January 2013) are described in **Appendix 1**.

Table 1, Appendix 4 summarises our performance in terms of certificates of designation for 2012.

Three applications for new certificates of designation were granted compared with five in 2011.

Project licences

Some details of the characteristics of a project licence are given in **Appendix 1**.

Table 1, Appendix 4 shows our performance in terms of project licences for 2012.

The assessment of project licence applications is by far the most time-consuming activity for inspectors and licensing staff. In total, inspectors advised that 626 project licence applications should be granted, see **Figure 2**, **Appendix 4**. The number of project licences granted increased by 11% between 2011 and 2012. Inspectors also gave advice on 1,156 requests for amendments to existing project licences, a decrease of 17% on the 1,391 requests in 2011.

The performance target for project licence applications is for licensing decisions to be made within 35 working days of receipt in at least 85% of applications. **Figure 3, Appendix 4** shows the performance trends against targets for the last seven years. Average processing time in 2012 was 17.3 days, slightly higher than the 16 days achieved in 2011. However, the proportion of licences granted within 35 days (90%) continued to exceed the target.

Personal licences

Some details of the characteristics of a personal licence are given in **Appendix 1**.

Table 1, Appendix 4 summarises our performance in terms of personal licences for 2012.

During 2012 we granted 2,639 personal licences. This was an increase of 2% in assessments leading to granted licences compared with 2011.

We also granted 2,858 personal licence amendment requests and reviews. This was a decrease (-6%) of 182 compared with the number granted in 2011 (3,040).

The Business Support Team's role

The Business Support Team was formed in June 2012 to centralise all tasks and responsibilities not directly related to licensing, inspecting establishments or assessing licences. ASRU now has a dedicated resource providing business support to all operational staff and management. This includes:

- collecting and administering the annual Return of Procedures exercise;
- managing the regional office closure project including relocation of inspectors close to those they inspect;
- internal and external recruitment;
- secretariat function;
- gathering and analysis of management information;
- general support to inspectors and management and the regional offices;
- procurement and general finance;
- risk management, including health and safety; and
- organising ASRU training, events and conferences, including external stakeholder events.

During 2013 the team will also be taking over the collection of licence fees and assisting with the roll-out of the e-Licensing system, ASPeL.

Section 2: Inspection and Advice

Inspection

Inspectors conduct a risk-based programme of visits, mainly unannounced, to places licensed under ASPA to ensure that statutory requirements are being met, including proper safeguards for the welfare of animals and that establishments have appropriate management systems to meet their obligations under the Act. See **Appendix 2** for a detailed description of our risk-based inspection system.

During 2012 the Inspectorate carried out 1,285 visits to places where scientific work on animals was conducted. Of the visits made to animal units, 77% were made without notice and 44% of all visits were unannounced. These inspections amounted to 4,051 hours of contact time with those holding licences or certificates under ASPA, in addition to 3,430 hours spent travelling. The overall number of visits was lower compared with 2011 (11%), but the total contact hours were not reduced by as much (9%), indicating that the average visit in 2012 was longer. Time spent travelling also decreased (6%), see **Figure 4, Appendix 4**. The average number of visits per FTE also decreased slightly (73 in 2012 compared with 75 in 2011) as did contact time per FTE (228.4 hours in 2012 compared with 232.0 hours in 2011, down 2%), see **Figure 5, Appendix 4**.

These changes reflect a number of factors including the on-going application of the risk-based approach to inspection based on objective measures of risk, see **Appendix 2**. In addition, the high number of applications for project licences and the need for referrals proved to be a significant proportion of the inspectors' workload in 2012.

The amount of time spent travelling is related to the geographical distribution of inspectors and the locations of establishments that they inspect. 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.

Operational and strategic advice

Involvement in the casework and policy formulation of ASRU is also an important component of the inspector's role. In 2012 a significant proportion of time was spent on these tasks. One inspector was seconded full time to support the ASRU Policy Team in implementing the EU Directive and including negotiations with Parliamentary Counsel and further analysing public consultation responses. Other inspectors also provided significant support to these processes, whilst maintaining an inspection and assessment workload. In addition the equivalent of 0.5 FTE was committed to the development of the e-Licensing system.

Continuing professional development

Participating in continuous professional development (CPD) events is essential to ensure that Inspectorate knowledge and skills are maintained and developed. As well as bi-annual internal conferences, internal meetings and regular teleconferences, inspectors also attend external learning events. Their role at these is often a mixture of representation for ASRU and personal CPD – for example, inspectors attended the National Centre for Replacement, Refinement and Reduction of Animals in Research (NC3Rs) workshop on surgical implants and also the 2012 European Congress on Immunology in Glasgow.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Section 3: Compliance

Introduction

A major function of visits is to determine whether establishments and licensees are complying with the provisions of the Animals (Scientific Procedures) Act 1986 (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 promote a culture of compliance.

A key aim of the reorganisation and restructuring of ASRU which commenced in 2011 has been to develop more integrated working practices across the business. As part of this, a Compliance Team was created in 2012 consisting of a Principal Inspector (PI) and a Senior Licensing Manager.

The Compliance Team provides support and advice to ASRU inspectors during the investigation of potential non-compliance with the aim of promoting a robust, efficient and consistent national approach to cases. This includes ensuring that cases are assigned to the appropriate category and that any sanctions imposed are applied fairly, accurately, appropriately, and proportionately. A member of the team may accompany the local 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.

Advice is often provided by inspectors to assist licensees to comply. These cases of compliance advice are recorded in the inspector's visit report and are collated and reported annually to the Secretary of State. In category A to D cases of non-compliance, formal reports are submitted to the Senior Licensing Manager as soon as the inspector's investigation is complete, together with a recommendation for action. The main characteristics of the categories, as they were applied during 2012, can be found in **Appendix 3**.

In 2012 there were 131 reports of compliance advice given (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), and 26 cases of non-compliance were investigated and completed (13 category A, 10 category B, and 3 category C cases). In establishments with a good culture of compliance, it is very often the licensees, the establishment licence holder or their staff who report suspected non-compliance. In 2012, 16 of the 26 cases were self-reported. Inspectors discovered the remaining 10 cases: four in category A, five in category B, and one in category C.

Category A cases

In eight of the 13 cases, procedures (for example, blood sampling, intraperitoneal injection, cannulation, re-use) were carried out competently but without the necessary authorisations. In two cases there was a breach of the authorised severity limit. In the first, a tumour growth exceeded the size permitted in the project licence protocol, while in the second mortality amongst a number of rats exceeded that permitted in the project licence protocol. In both cases there were no

obvious adverse welfare consequences as a result of the non-compliance. In one case there was a failure to monitor daily, as required, a number of rats. In one other case there was a failure to provide feed and water to a number of mice for several hours. Finally, there was one instance where a regulated procedure, blood sampling, was performed competently on one cow without the necessary licence being in place.

Category B cases

1. Following an ectopic heart transplant in a mouse, the animal was not observed over the weekend following which it was found dead. The licence holder believed that responsibility for monitoring of the animal had been passed over to a surgical technician. The technician believed that there were no animals in the recovery room and so did not enter that part of the establishment over the weekend. This case was self-reported. The personal licence holder had breached standard conditions 12 and 15 of his personal licence. Following this incident a number of improved standard operating procedures were put in place by the establishment licence holder. The personal licence holder was formally reprimanded.

2. Eight mice were identified as having exceeded the limit on tumour growth authorised in the project licence, and a further two mice had lost more weight than was authorised by the licence. The animals had been identified as approaching the permitted limits but, at that time, the licence holder was taken ill and failed to make suitable arrangements for the mice to be monitored. As a consequence, the problem was not discovered for a further four days when technicians alerted the Named Veterinary Surgeon who immediately culled the animals. The incident was self-reported. The personal licence holder had breached standard conditions 12 and 15 of his licence, and the project licence holder had breached standard condition 6 of his licence. Following this event the establishment licence holder put in place a number of improved operating procedures for the internal monitoring of study animals. Both the project licence holder and the personal licence holder were formally reprimanded and the latter was also required to review all the standard conditions of his personal licence and consider, in practical terms, how he would ensure future compliance with each condition.

3. Eight zebra fish were used in a procedure that was not authorised in the project licence and six of these fish died. The incident was self-reported. The licence holder held both a personal and project licence; he claimed to believe initially that authority for this work was permitted in the project licence, but then discovered this was in error. He had breached standard condition 3 of his personal licence and standard conditions 1(i) and 6 of his project licence. Following this incident the establishment licence holder undertook an extensive review of local operating practices, and the local animal welfare committee undertook to prospectively review all new studies to ensure that the most refined approach was being taken and that the relevant authorities were in place prior to commencement. The licence holder was formally reprimanded.

4. As a result of a dosing miscalculation, 2,730 birds received an overdose of a compound that resulted in the project exceeding the permitted protocol severity limit. As a consequence, one bird died and 28 were culled on humane grounds. The overdose was a result of a failure to check dilution calculations carefully. The incident was discovered during a visit by an inspector to the establishment. The project licence holder had breached standard condition 6 of his licence. Following this incident the licence holder was formally reprimanded and his project licence was amended to require him to undertake and pass a module one training course within three months. The aim was to improve his understanding of his responsibilities under ASPA.

5. Two groups of mice, comprising six and 18 mice respectively, were placed on dietary restrictions and were found to have exceeded the severity limit permitted in the project licence. The project licence holder failed to ensure that the full details were known to the personal licensees performing these procedures. Consequently he had breached standard conditions 6 and 8 of his project licence. A personal licensee also failed to check the project licence authority before commencing the study and, as a result, was found to have breached standard conditions 13 and 20 of his personal licence. The incident was discovered during a visit by an inspector to the establishment. The inspector concluded that there was no intention to circumvent the regulations. Following this incident the project licence holder was formally reprimanded and had his licence amended to require him to undertake and pass a module one and a module five training course within six months. The personal licence holder was also formally reprimanded and had his licence amended to require him to undertake and pass a module one training course within six months. The aim was to improve the understanding of both individuals of their responsibilities under ASPA.

6. During a routine inspection, an inspector was informed of a number of unexpected adverse effects that had occurred within a group of rats. Further investigation by the inspector revealed that a study had been undertaken that was not in accordance with the programme of work authorised in the project licence. Additionally, the project licence holder failed to maintain full records and to provide an appropriate level of supervision for personal licensees carrying out the study. The holder breached standard conditions 1, 9 and 14 of the project licence. The incident appeared to have arisen through a genuine, though avoidable, mistake. A number of very similar studies had been undertaken over the years, and there was a failure on the part of the project licence holder to appreciate and distinguish the factors that made this study different from the others. Following the incident, the establishment licence holder instigated a number of tighter controls to minimise the likelihood of any recurrence. The project licence holder was formally reprimanded and required to review all the standard conditions of her licence and consider, in practical terms, how she would ensure future compliance with each condition.

7. During a routine inspection, an inspector discovered that five rats had undergone spinal surgery two weeks earlier with no indication that post-operative analgesia had been administered. The personal licence holder who had undertaken the procedures was asked to explain why no analgesia had been given. He admitted that it was an oversight on his part. The inspector found that, two weeks after surgery, the wounds were healing well and the animals appeared to be in good condition. The licence holder had nevertheless breached standard conditions 12, 19B and 20 of his personal licence and was formally reprimanded.

8. An inspector was informed by a project licence holder that two types of regulated procedures had been carried out by two individuals in the absence of the necessary personal licence authority. In the first instance, the individual had no personal licence but had carried out cardiac perfusion and maternal separation (the early separation of pups from their mother) in rats. She had been on a number of recent training courses and had mistakenly believed that a personal licence had been issued to her. The second individual held a personal licence and similarly carried out early maternal separation of pups. Although early separation was authorised in the project licence it was not authorised in her personal licence. All these procedures were competently performed and authority would have been granted for both had it been sought. The first individual has since been granted a personal licence. These non-compliances constituted a breach of section 3(a) of ASPA by the non-licensee, and a breach of section 3(a) of ASPA and of standard condition 1 by the personal licence holder. Furthermore, the establishment licence holder was in breach of standard condition 16 of his authority. All were formally reprimanded.

9. An inspector was informed by a project licence holder that the holder of a personal licence had performed regulated procedures (injections) on two occasions without the necessary project licence authority. The procedures were competently performed and the necessary authority would have been granted had it been applied for. The holder of the personal licence had breached section 3(b) of ASPA, and also standard condition 3 of his licence. The establishment licence holder was in breach of standard condition 16. They were each formally reprimanded.

10. An inspector discovered that a personal licence holder had carried out a number of procedures on animals that had previously been used in other procedures. However, the project licence did not give authority for re-use. The licensee had also performed a number of procedures the purpose of which was not authorised by the project licence. The licensee had failed to check that the necessary authorities were in place and, when the non-compliance was discovered, he immediately enrolled on a module one training course to improve his understanding of his responsibilities under ASPA. These cases constituted a breach of sections 3(b) and 14(3) of ASPA, and also a breach of standard conditions 3 and 9 of his personal licence. He was formally reprimanded.

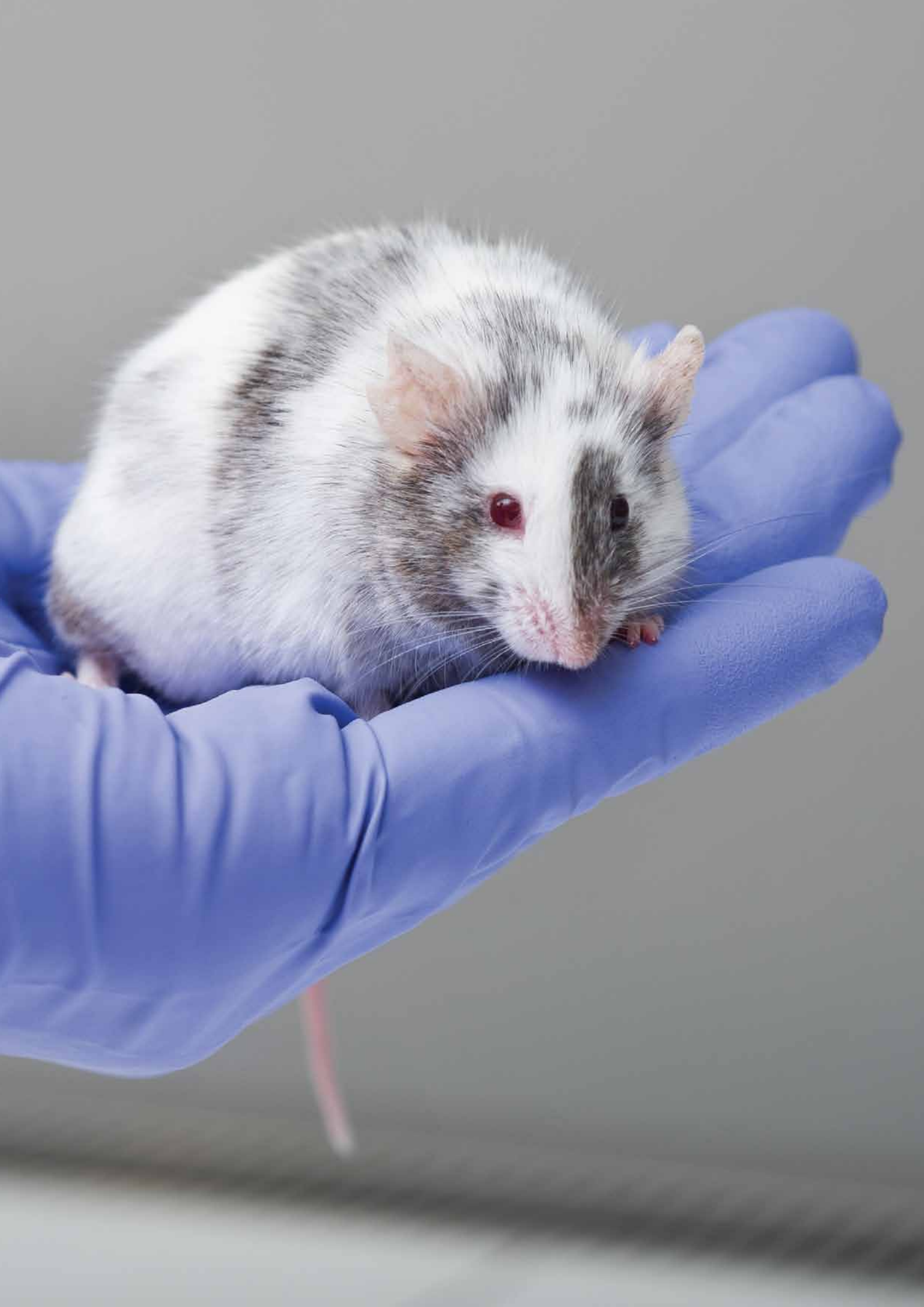
Category C cases

1. Five recently weaned stock mice at an establishment were left without food for a period of nine days although water was available throughout. Four of these animals were found dead, while one was humanely killed. The case was self-reported. The animals had initially been placed by an animal technician into an empty cage with a water bottle and a handful of pellets scattered on the cage floor. No feed was placed in the food hopper and further checks carried out by a number of technicians over the following days failed to note the absence of food pellets in the hopper. No satisfactory explanation could be provided for this failure. Following the incident, the establishment licence holder arranged for the relevant standard operating procedures to be thoroughly reviewed and re-written and staff responsibilities re-assessed and reinforced. The three animal technicians involved (all non-licence holders) were each given a written warning. The establishment licence holder was in breach of standard condition 9 of his authority and was formally reprimanded.

2. An individual deputising for a project licence holder was supervising a personal licensee who started a procedure using mice under the project licence. However, the procedure continued beyond the expiry date of that project licence. After the project licence expired, the individual changed the cage labels to show a different project licence that had not expired. However, the second project licence did not authorise the procedure that was underway. This was done without the knowledge and consent of either project licence holder. Furthermore, several of the mice died during the procedure, and the rest needed to be humanely killed. In view of the severity of the non-compliance, the personal licensee's licence was revoked, and an application for a project licence from the deputising individual was refused under ASPA section 12 on the grounds that the individual's knowledge and understanding of ASPA 1986 and the responsibilities of a project licence holder, were inadequate to take overall responsibility for a licensed programme of work. The individual was also formally reprimanded, and required to retake and pass a module one training course, the aim being to improve understanding of her responsibilities under ASPA. The case was discovered by an inspector.

3. A personal licensee carried out a number of regulated procedures on mice, under the authority of a project licence, following which he then intended to kill the animals using a method listed in Schedule 1 of ASPA. However, one mouse was found alive the following day. The animal was in poor condition and was immediately euthanased. The personal licence holder was

not included on a register of those competent to perform Schedule 1 killing and, in respect of the animal that was found alive, he had also failed to perform the killing competently. The holder of the project licence was found to have failed to keep records of the personal licensee's training and failed to provide an appropriate level of supervision. None of the facts was disputed, and the establishment licence holder subsequently instituted a number of improvements in standard operating procedures to minimise the likelihood of any recurrence. The incident was self-reported. The personal licence holder was in breach of section 3(a) of ASPA and standard conditions 8, 12 and 20 of his personal licence. The project holder was in breach of standard conditions 14 and 16 of his project licence. Furthermore, the failure of the establishment licence holder to maintain a register of people competent to perform Schedule 1 killing constituted a breach of standard condition 17 of his authority. All three were required to undergo a programme of retraining and were formally reprimanded.



Section 4: Initiatives and progress

Improving information technology

Work towards improving our information technology (IT) and data-handling systems for both licensing staff and inspectors in ASRU, and for our external stakeholders, continued throughout 2012.

We previously announced that ASRU would deliver an IT project to introduce an electronic licence application system (CBP e-Licensing) on which we worked closely with colleagues in the UK Border Agency (UKBA). It became clear in mid-2012 that external factors meant that this system was likely to have a very short lifespan. The decision was made to terminate that project and to proceed with a new project to deliver a web-based application system. New contracts were let and development commenced during September 2012. The new system, called ASPeL, will be delivered and launched in 2013.

From ASRU's perspective, the new system will significantly reduce the time, space and additional administrative work involved in handling paper files. It will provide universal access to electronic versions of current applications and, in due course, details of all current licences. This can be used as reference material to inform better, consistent and prompt decision-making about new applications. The new IT system also reflects the new processes and incorporates the new forms that resulted from the changed legislation.

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. This was achieved by amending the Animals (Scientific Procedures) Act 1986 (ASPA). The relevant amending regulations (SI 2012/3039) were laid before Parliament on 29 October 2012 and were debated first in the House of Commons Delegated Legislation Committee on 3 December[1] and then in the House of Lords Grand Committee on 13 December[2]. We then published a 'Quick Start Guide' to the revised legislation on 19 December.

The revised legislation retains stricter UK standards. These include:

- special protection for cats, dogs and horses;
- protection for immature forms of birds and reptiles;
- larger enclosure and cage sizes for dogs and a number of other species; and
- methods of killing animals that are more humane.

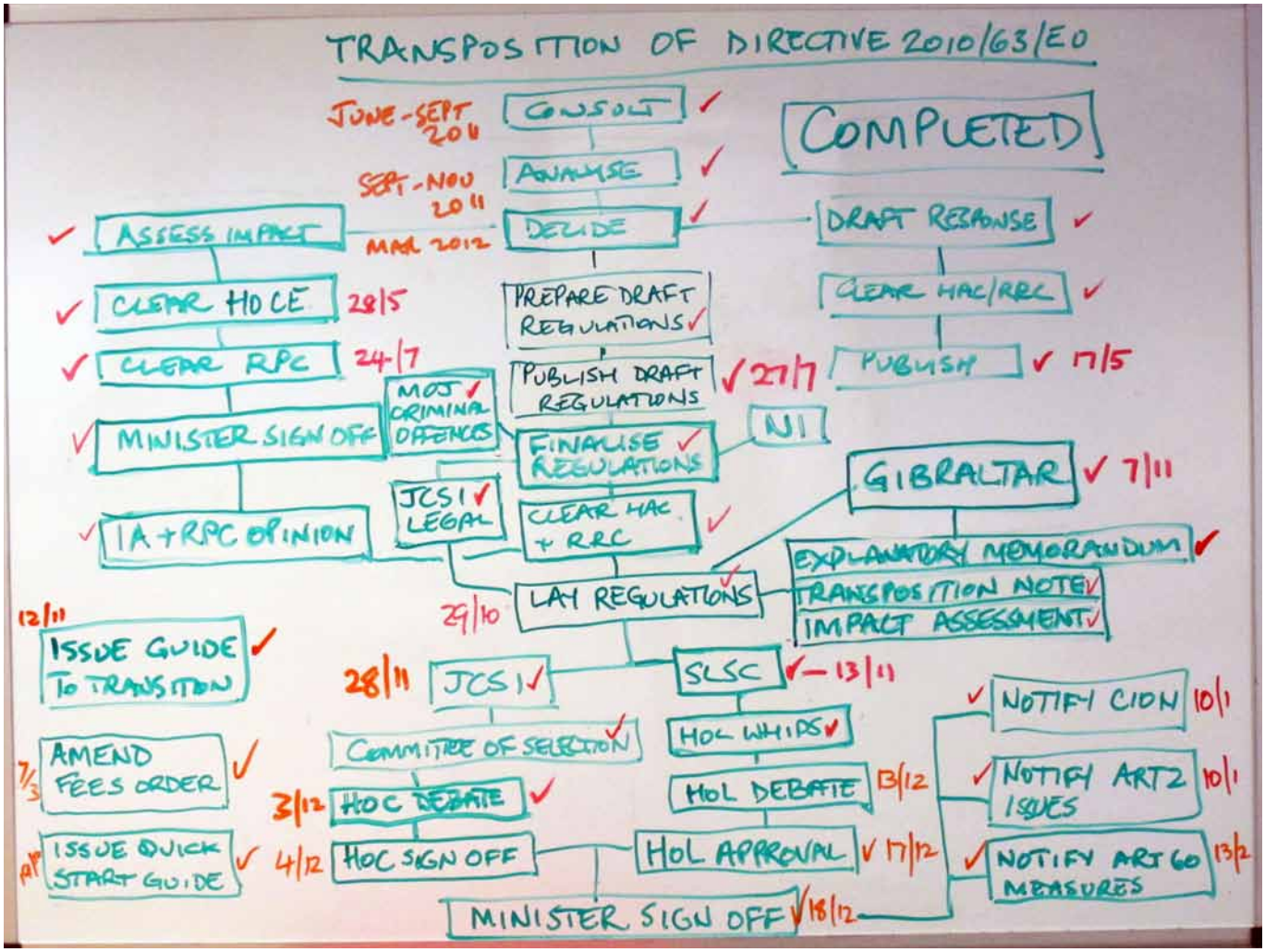
1 http://www.publications.parliament.uk/pa/cm201213/cmgeneral/deleg6/121203/121203s01.htm
2 http://www.publications.parliament.uk/pa/ld201213/ldhansrd/text/121213-gc0001.htm#12121339000271

We also placed absolute bans on the use of great apes and stray animals of domestic species on the face of the legislation. We believe that including and retaining these and other stricter standards in the legislation is necessary and justified on animal welfare grounds and to maintain public confidence that animals used in experiments and testing will continue to be properly protected.

At the same time, we have simplified our system of personal licences authorising individuals to apply procedures to animals. A system of personal licensing is essential to ensure that procedures causing pain and suffering are only applied to animals by individuals who are properly trained and competent. However, it is also important that the system should not be overly bureaucratic. We have, therefore, made some small, but important changes to simplify the detail required in personal licences and the way that we process applications for these licences.

Another important change is a requirement to collect and publish statistical information on the actual severity of the procedures applied to the animals. Publication of this information will be a major step forward in terms of transparency and, combined with the mandatory requirement to publish non-technical summaries of authorised projects, will help to inform the debate on the use of animals in research and testing.

On the issue of severity classification, although the Directive requires procedures to be classified by their severity, there is no requirement to ensure that these classifications are subsequently adhered to. Under current UK arrangements, licence holders are required to inform the Home Office if a severity limit is breached or likely to be breached. We have retained this requirement in a project licence condition which sets a clear obligation to adhere to the severity limit and to notify the Secretary of State if the severity limit appears to have been or is likely to be breached.



The Coalition Agreement and the 3Rs

The commitment to work to reduce the use of animals in scientific research is being delivered through a science-led programme headed by the UK National Centre for Replacement, Refinement and Reduction of Animals in Research (NC3Rs).

The NC3Rs has pioneered a first-class science-led programme involving many others in its delivery. This provides opportunities to replace and reduce animal use and to refine the welfare of those animals that continue to be used (principles commonly known as the 3Rs)

Our inspectors work closely with the NC3Rs to promote the 3Rs. For example, an initiative pioneered by inspectors in 2011 to improve the uptake of aseptic technique in rodent surgery has led to the development of an online video resource. The video provides guidance that can be adopted at any establishment carrying out surgery on rodents. The production was funded by the NC3Rs and led by the University of Newcastle. The resource is available on the Procedures with Care website (www.procedureswithcare.org.uk).

How ASRU promotes and delivers the 3Rs

1. Requirements under the Animals (Scientific Procedures) Act 1986

Section 5(5) of ASPA 1986, reproduced below, defines the circumstances under which a project licence may be granted with regard to the 3Rs.

> The Secretary of State shall not grant a project licence unless he is satisfied –
>
> a) that the purpose of the programme to be specified in the licence cannot be achieved satisfactorily by any other reasonably practicable method not entailing the use of protected animals; and
>
> b) that the regulated procedures to be used are those which use the minimum number of animals, involve animals with the lowest degree of neurophysiological sensitivity, cause the least pain, suffering, distress or lasting harm, and are most likely to produce satisfactory results.

During the project licence assessment process, the inspector determines whether an application satisfies section 5(5). If not, the inspector advises what changes are required to address the 3Rs satisfactorily. However, application of the 3Rs must not prejudice the generation of satisfactory results.

2. Project licence application process

The following, specific questions are asked of the applicant on the project licence application form. The answers to these questions assist the inspector to determine if section 5(5) has been satisfied.

a) **Replacement**
Why is it not possible to achieve the objectives of your project without using animals? What alternatives have you considered and why are they not suitable? What alternatives will be used in achieving your objectives?

b) Reduction

What measures have been or will be taken to ensure that the minimum number of animals will be used in this project?
Explain the principles of experimental design you will use and sources of advice you will consult e.g. on statistics.

c) Refinement

Explain your choice of species, model(s) and method(s). Explain why they are the most refined for the intended purpose.
How will you minimise animal suffering in order to achieve your objectives?
Provide specific justification for any substantial severity protocols.

In addition, in describing their protocols applicants are asked to indicate:

- the adverse effects that may result from each procedure;
- the likely incidence of adverse effects;
- how those adverse effects will be recognised and monitored; and
- the measures they will take to prevent or control the severity.

They must also identify practicable and realistic humane end-points. Hence, the required humane end-points are clearly specified in the licence. This information helps the inspector to determine if refinement is being adequately addressed both before the licence is authorised and throughout the life of the licence.

3. Further information

Inspectors will ask other questions of project licence applicants to gain additional information. Examples of these are listed below.

- What, if any, in silico, in vitro or ex vivo techniques will you use and how will they integrate into this project?
- What principles are followed when selecting between options of different severity?
- Why can't further reductions in the intensity or duration of adverse effects be achieved?
- Do you intend to refine the studies during the course of this project? If so, how?

4. Additional roles of inspectors with regard to the 3Rs

Inspectors advise on the most refined models or methods using their veterinary or medical expertise, their scientific, veterinary or medical area of specialisation, and their knowledge of methods used by others in the research community.

From their day-to-day work of inspection of facilities and assessment of licence applications, inspectors develop an overview of the range of disease models and methods used across the UK, and they actively encourage researchers to work together on 3Rs issues.

Inspectors ask applicants to state that surgery will be undertaken using appropriate aseptic practices, and they inspect surgical procedures to ensure that this occurs.

Once a licence is granted, inspectors make visits to assess compliance with the licence authorities. This includes inspection of animals under study to check that severity limits are being complied with. Inspectors will advise on implementation of the 3Rs during these visits and this may result in amendment of licence authorities with resultant 3Rs gains.

Inspectors generally advise that reducing the severity of adverse effects in individual animals should take precedence over reducing the numbers of animals exposed to adverse effects. Hence whilst the total number of animals used may go up, the suffering of each individual, and the overall level of suffering, may be driven down.

Outreach

Outreach to our stakeholder community in the UK and internationally is an important aspect of ASRU's work, delivered by staff in all parts of ASRU including the senior management team, inspectors, licensing and policy staff.

Representation

Four inspectors worked with members of the Animal Procedures Committee (APC) and external stakeholders to develop an APC 'Report on Cumulative Suffering in Non-Human Primates' during 2012. This will be published during 2013.

Inspectors represented the UK Government on three of the Expert Working Groups arranged by the European Commission in Brussels during 2012. These were focused on Severity Assessment, the Application of the 3Rs and planning for the EU Statistics. The Head of ASRU and the Chief Inspector also represented the UK at two meetings of National Competent Authorities as part of our on-going European engagement.

The Chief Inspector worked with the Royal College of Veterinary Surgeons to support the development of advice to the profession on the need for ethical review of practice-based research. The resulting 'Ethical Review for Practice-based Research' was published in February 2013 and is available at: www.rcvs.org.uk/publications

An inspector attended the Acute Toxicity Task Force of the European Partnership for Alternative Approaches to Animal Testing (EPAA) Round Table on acute toxicity testing for chemicals and agrochemicals in Brussels. This provided an opportunity to ensure Home Office representation in this forum, as well as facilitating forging key contacts for our work in this area going forward.

Presentations

Members of ASRU presented updates on progress with the proposed changes to the legislation, and general presentations covering various aspects of the use of animals in research at a number of national and international meetings. These included:

- the Danish Department for Innovation International Conference on Research Infrastructures (as part of the Danish EU Presidency);
- the Annual Conference of the Laboratory Animals Veterinary Association (LAVA);
- the Third International OIE Conference on Animal Welfare in Kuala Lumpur;
- a conference on animal welfare law held at Northumbria University School of Law;
- the Laboratory Animal Science Association (LASA) Winter Meeting;
- a regional seminar of OIE Eastern European national contact points for animal welfare in Kiev, Ukraine;
- the Institute of Animal Technicians (IAT) Annual Conference; and
- a meeting of the Certificate Holders Forum.

Collaborations

We arranged our regular joint annual meeting with the Society of Biology at Marsham Street in December 2012. The programme included the use of genetically altered animals (jointly with the RSPCA), transposition of the Directive, and the new e-Licensing system, ASPeL. Lord Taylor addressed the meeting and mixed with delegates over lunch.

The Inspectorate has formalised ASRU's relationship with the British Trust for Ornithology (BTO) establishing channels for regular communication. The aim of this is to reduce the duplication of enquiries to both ASRU and BTO regarding the potential need for licence authorities under ASPA and wildlife legislation. Scientific research on wild birds requires licence authorities from the BTO for the capture and identification of these birds. BTO's processes include a similar harm–benefit analysis to ours covering consideration of the need for the research in terms of its scientific validity and relevance, the likelihood that relevant data will be gathered by virtue of the experimental design and the level of harm that might accrue.

We now meet annually to review research using wild birds and the BTO regularly advises researchers to contact us for advice, where it appears that the proposal might also need licence authorities under ASPA.

Stakeholder engagement

Senior staff of ASRU meet regularly with four stakeholder groups:

- the Bioscience Sector Coalition (comprising representatives of industry, academia and funders);
- a group of professionals involved in laboratory animal care (including veterinarians, animal care staff, breeders and trainers);
- a group representing animal welfare and alternatives; and
- a group of animal protection organisations.

During 2012, we met with each stakeholder group on at least five occasions – over 20 meetings in total. In addition, a number of meetings of stakeholders with Ministers were arranged, especially during the period leading up to implementation of the new regulations.

Publications

On 10 July 2012 we published Annual Statistics on the use of animals under ASPA during 2011. The Head of ASRU and Head of Policy participated in a media briefing organised by the Science Media Centre which was also attended by a representative of the National Centre for the 3Rs. There was a great deal of press interest in this publication as well as the simultaneous publication of ASRU's Annual Report for 2011.

Communications

The ASRU Policy Team has responsibility for replying to correspondence from the general public or from Members of Parliament. Replies may be made directly by the Policy Team or through the Departmental Communications Unit. These include requests made under the Freedom of Information Act. During 2012 we directly answered 789 letters and emails and 27 requests received under the Freedom of Information Act.

We also responded to 46 parliamentary questions tabled during the year.

The main topics of the correspondence and parliamentary questions related to the implementation of the European Directive and the coalition commitment to work to reduce the use of animals in scientific research.

Newsletters

During 2012 there were 10 dedicated newsletters about the transposition and implementation of European Directive 2010/63/EU. These newsletters reported on progress with the transposition process, explained what would change under the new legislation and sought the help of stakeholders in preparing for the changes before the end of the year.

In addition, there were a further 16 newsletters covering other issues that impacted on, or were of interest to, our stakeholders.

Abstracts of project licences

We continued to publish abstracts of authorised project licences until the end of 2012 and these can be accessed through the archived Home Office website. In total 467 abstracts were published during 2012. Over 3,330 abstracts have been posted on the Home Office website since their introduction in 2004.

The new European Directive requires that an application for a project licence must be accompanied by a non-technical project summary.

ASPA section 5A (2) sets out what is required in the summary:

> A project summary is a statement, in non-technical language, which:
>
> a) describes the proposed programme of work and states the objectives of the programme, the predicted harm and benefits of the programme and the number and types of animal to be used in the programme;
> b) demonstrates that the proposed programme of work would be carried out in compliance with the principles of replacement, reduction and refinement.

During 2012 we have agreed a suitable format for these summaries in association with other EU Member States. These will be published on the new GOV.UK website during 2013.

Appendix 1: Background to the Animals (Scientific Procedures) Act 1986 (ASPA) as amended in 2012

Throughout this report we have used terminology relating to the amended regulations wherever appropriate. For example, we refer to establishment licence holders although formerly these were called certificate holders during 2012, the period of this report. The following text describes the main provisions of the Animals (Scientific Procedures) Act 1986 (ASPA) after transposition of European Directive 2010/63/EU. These provisions apply from 1 January 2013.

What does ASPA cover?

ASPA regulates procedures that are carried out on 'protected animals' for scientific research and testing that may cause pain, suffering, distress or lasting harm.

ASPA also regulates the breeding and supply of certain species of animals for use in regulated procedures, and the breeding of animals for the use of their organs or tissues in procedures.

What licences are required?

ASPA has a three-level licensing system:

- those carrying out procedures must hold a **'personal licence'**, which ensures that they are qualified and suitable;
- the programme of work in which the procedures are carried out must be authorised in a **'project licence'**;
- the place at which the work is carried out must hold an **'establishment licence'**.

Places breeding and/or supplying the species of animal listed in ASPA Schedule 2 must also hold an establishment licence.

Procedures may be authorised at places other than licensed establishments (POLEs), and these will be specifically identified in the relevant project licences.

Personal licences

The personal licence shows that a person is qualified and suitable to carry out specified regulated procedures, under supervision if necessary.

Under ASPA, a person is not allowed to apply a regulated procedure to an animal unless all three of the following requirements are met:

- they hold a personal licence authorising them to apply a procedure of that description to an animal of that type;
- the procedure is applied as part of a programme of work authorised in a project licence; and
- the place where the procedure is carried out is specified in that project licence.

Project licences

A project licence specifies a programme of work and authorises the application, as part of that programme, of specified regulated procedures to animals of specified descriptions at a specified place or specified places.

A place may not be specified in a project licence unless it is a place where a person is authorised by an establishment licence to apply regulated procedures to protected animals.

Establishment licences

A person may not carry out any of the following activities unless authorised to do so in an 'establishment licence' issued under ASPA section 2 (c):

a) applying regulated procedures to protected animals (**a user establishment**);
b) breeding protected animals listed in ASPA Schedule 2 with a view to (i) their use in regulated procedures, or (ii) the use of their tissues or organs for scientific purposes (**a breeding establishment**);
c) breeding other animals (not listed in ASPA Schedule 2) primarily for the same purposes (also **a breeding establishment**);
d) keeping Schedule 2 animals that have been bred elsewhere and are to be supplied with a view to (i) their use elsewhere in regulated procedures, or (ii) the use elsewhere of their tissues or organs for scientific purposes (**a supplying establishment**).

A user establishment may also be authorised as a breeding establishment if it breeds animals for use in procedures there or somewhere else.

A breeding establishment must also be a user establishment if any of the animals bred there are genetically altered and of a potentially harmful phenotype.

Who issues licences?

ASPA licences are issued by the Home Office in England, Scotland and Wales and by the Department of Health, Social Services and Public Safety (DHSSPSNI) in Northern Ireland.

What is a protected animal?

ASPA protects **all living vertebrates, other than man, and any living cephalopod**.

Embryonic and foetal forms of mammals, birds and reptiles are protected during the last third of their gestation or incubation period or from an earlier stage of development if they are going to live beyond the last third of their gestation or incubation period and the procedure is likely to cause them pain, suffering, distress or lasting harm after they have developed to that stage.

What is a regulated procedure?

A procedure is regulated if it is carried out on a protected animal and may cause that animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by inserting a hypodermic needle according to good veterinary practice. This is called the 'lower threshold'.

Procedures may be regulated if they involve doing something, such as dosing or sampling, or not doing something, such as withholding food or water.

Permissible purposes

Procedures have to be for one of the following permissible purposes:

a) basic research;
b) translational or applied research with one of the following aims:
   (i) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality, or their effects, in man, animals or plants;
   (ii) the assessment, detection, regulation or modification of physiological conditions in man, animals or plants; or
   (iii) the improvement of the welfare of animals or of the production conditions for animals reared for agricultural purposes;
c) the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs or any other substances or products, with one of the aims mentioned in paragraph b);
d) the protection of the natural environment in the interests of the health or welfare of man or animals;
e) research aimed at preserving the species of animal subjected to regulated procedures as part of the programme of work;
f) higher education or training for the acquisition, maintenance or improvement of vocational skills;
g) forensic inquiries.

Further information

The Home Office Animals in Scientific Procedures page on the GOV.UK website:
https://www.gov.uk/research-and-testing-using-animals

Draft guidance on the Operation of the Animals (Scientific Procedures) Act 1986:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/116843/aspa-draft-guidance.pdf

National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs):
http://nc3rs.org.uk

Appendix 2: Risk-based inspection

As part of the Hampton Implementation Review of the Inspectorate, the external reviewers commented that, although stakeholders understood the reasons behind inspections in general, the rationale behind the risk assessments had not been fully shared with them and they would welcome further clarity on the risk basis.

The risk basis behind inspections is one of the important aspects that contributes to public confidence in the regulatory system and, when applied consistently across all inspections with stakeholders, may help to allay any concerns over perceived inconsistency between inspectors. Our approach considers both the likelihood that non-compliance may occur and the potential impact of such non-compliance in terms of both adverse animal welfare and the resultant public concern.

Table 3 in **Appendix 4** sets out a comparison between the criteria that should be considered to comply with Directive 2010/63/EU and those incorporated into the Inspectorate's approach. It is clear that the Inspectorate approach includes all aspects required under the Directive as well as additional information which is deduced through inspectors' regular contact with establishments.

Factors considered in determining levels of risk

Number of regulated procedures undertaken

Undertaking increasing numbers of regulated procedures under ASPA raises the risk profile for any establishment as a result of the likely incidence of any errors or lapses occurring during such procedures. There is a wide and variable – year-on-year – range for the number of procedures completed at each establishment, from zero to many tens of thousands and a similar wide range in the type of regulated work that is undertaken. For example, breeding of phenotypically normal transgenic mice may represent many thousands of essentially similar procedures whilst surgical procedures may be undertaken on only a few occasions each year.

The number of project licences alone held at each establishment is, however, a relatively poor indicator of risk as each licence is unique and may comprise either a single protocol or several protocols within a broad programme of work.

Severity of procedures undertaken

Undertaking regulated procedures of increasing severity under ASPA raises the risk profile for an establishment as a result of the likely consequences to protected animals of any errors or lapses occurring during such procedures. The current banding of severity ranges from Unclassified (all work under terminal general anaesthesia) through 'Mild', to 'Moderate', to the upper limit of 'Substantial'.

Each project licence is assigned an overall Severity Band, with a typical range classifying licences as 3% Unclassified, 35% Mild, 60% Moderate and 2% Substantial. Those establishments conducting a higher proportion of their work in the Substantial category will generally be considered to carry a higher risk rating than those conducting work which is Unclassified or Mild.

Species

Undertaking regulated procedures on any of the species specially protected under ASPA (cats, dogs, equidae and non-human primates) also raises the risk carried by any establishment. Currently, no establishment carries out procedures in all four of these species groups, but a small number do have licence authorities for work in more than one of the species.

Overall, the use of these specially protected species is a very small proportion of the total regulated work conducted in the UK, with data for 2011 showing that the total for all regulated use of all these species was just less than 0.5% of all regulated work in the UK.

Compliance history of an establishment

One of the most important factors to be considered in assessing the risks posed by any establishment is whether it has previously failed to comply fully under ASPA. Such failure raises the risk profile. Compliance history includes records of non-compliance (as reported under ASPA) as well as evidence from visits of inspection when specific compliance advice may have been given.

Non-compliance cases are classified according to the gravity of each occurrence (see Appendix 3), with an appropriate weighting applied to reflect adequately the nature and seriousness of the lack of compliance.

Management factors at the establishment

Inspectors consider a number of aspects about an establishment which are known to them through their regular contact throughout the year. These include:

- the efficiency with which the Ethical Review Process functions across its breadth of responsibilities;
- the roles played by the Named Persons – Named Veterinary Surgeon (NVS) and Named Animal Care and Welfare Officer (NACWO);
- the focus on housing and care including environmental enrichment;
- whether proactive attention is being given to facilities issues; and
- the training and supervision of personal and project licence holders and those responsible for day-to-day care.

Setting and amending the risk basis for each establishment

As an outcome of each of their visits, inspectors review the risk status for each establishment, noting whether there has been any significant change in the relevant factors as outlined above. The three possible outcomes – increased, decreased or unchanged risk profile – are considered along with any recommended changes to control measures; to the frequency of inspections; or to particular aspects of work at that establishment.

Inspectors also discuss the risk profile with key individuals at the establishment, particularly the establishment licence holder, at least once per year. Other factors that may be useful in managing down the risks, including those listed above as management factors, are discussed and this meeting will normally result in an agreed action plan to enable the establishment to mitigate their risk wherever possible.

Changes to the risk factors may significantly alter the risk rating of an establishment and, more importantly, offer an opportunity for establishment licence holders and others to manage actively the perceived risks carried at their establishment.

Appendix 3: Categories of non-compliance

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

- referral to the prosecuting authorities;
- revocation, suspension or amendment of licences;
- addition of special conditions to licences;
- requirements for formal training or re-training; and
- letters of admonition, with or without requirements for further action to correct perceived deficiencies (such as additional training or altered management practices).

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 negligence, 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 significantly increase the perceived gravity of any non-compliance. A view may be taken on whether or not the licensee is likely to observe legal and administrative obligations in the future.

Those involved in non-compliances, either directly 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. They will then have the opportunity to provide any information they wish to be considered before the decision on the action to be taken is conveyed by the Animal Procedures Licensing Section. Those involved in the non-compliance will be notified of the action that the Secretary of State proposes to take. If this includes variation or revocation of authorities, then the rights to make representations under section 12 of the Act will be explained.

Once dealt with, non-compliances are reported in an anonymous form to the Animals in Science Committee. The number of non-compliances each year and summary details are published by the Home Office.

Compliance advice

The characteristics of compliance advice will include some or all of the following:

- trivial breach of licence conditions;
- no disputed facts;
- no evidence of intent to subvert the controls of ASPA ;
- no evidence to suggest that an offence has been committed;
- no adverse animal welfare consequences;
- resolved immediately or within day(s) of discovery.

Typically, compliance advice may be given verbally by an inspector upon discovery of a trivial breach of licence conditions. The outcome of compliance advice will be to note and record details of the advice in the visit report, with no further action being necessary.

Category A non-compliance

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

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

Typically, the outcome of a category A non-compliance will be to note and record details of the non-compliance, with no further action being necessary.

Category B non-compliance

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

- no disputed facts;
- no evidence of intent to subvert the controls of ASPA 1986;
- animal welfare implications that do not necessarily involve avoidable or unnecessary pain, suffering, distress or lasting harm;
- future compliance concerns;
- no likelihood of representations being made over the course of action proposed;
- not sufficiently serious for referral for prosecution or revocation of licences to be considered;
- not resolvable within days of discovery and further action needed;
- recurrent or persistent instances of category A non-compliance.

Typically, the outcome of a category B non-compliance will be to send a letter of admonition (i.e. a warning) to the person or persons involved, although in some cases the Home Office may require further action (such as additional training, or altered management practices) or 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 avoidable or unnecessary pain, suffering, distress or lasting harm;
- future compliance concerns;
- disputed facts;
- evidence of untruthfulness or attempt to evade responsibility;
- variation, suspension or revocation of licence is merited;
- referral for prosecution is not merited;
- recurrent or persistent problems of a lower category.

Typically, the outcome of a category C non-compliance will be to amend, revoke or suspend the licence, and to send a letter of admonition to the licensee.

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

Typically, the outcome of a category D non-compliance will be for the Home Office to refer the case to the Crown Prosecution Service (in England and Wales) or the Procurator Fiscal (in Scotland) to consider prosecution.

Appendix 4: Tables and figures

Table 1: Licence and certificate applications and amendments, 2011 and 2012

	Total			Per inspector FTE		
	2012	2011	Change	2012	2011	Change
PILs granted	2,639	2,584*	2%	149.1	136	10%
PILs amended	2,858	3,040*	-6%	161.5	160	-1%
PILs in force	14,875	15,403	-3%	841.0	810.7	4%
PCDs granted	3	5*	-40%	-	-	-
PCDs amended	247	335*	-26%	14	17.6	-20%
PCDs in force	176	181	-3%	10.0	9.5	5%
PPLs granted	626	564	11%	35.4	29.7	19%
PPLs amended	1,156	1,391*	-17%	65.3	73.2	-11%
PPLs in force	2,698	2,624	3%	152.5	138	11%

* These figures have been reviewed and accordingly revised from those reported in the 2011 Annual Report.

Note: FTE = full-time equivalent; PIL = personal licence; PCD = certificate of designation; PPL = project licence.

Table 2: History of non-compliances, 2006–2012

Year	Compliance advice**	Total non-compliances	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

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.

Table 3: Comparison of EU and ASRU criteria for risk-based inspection

Directive 2010/63/EU inspection risk criteria – Article 34	ASRU risk-based inspection criteria
• Number and species of animals housed	• Number of regulated procedures undertaken annually • Species used
• Compliance record	• Compliance history
• Number and types of projects	• Number and severity of projects • Species used – specially protected species
• Any information that might indicate non-compliance	Management factors: • Effectiveness of licence holder, Named Persons, Ethical Review Process (ERP) • Quality of working relationships at all levels • Maintenance of facilties and environmental enrichment • Quality of training plans, supervision and records • Policies and practice for surgical and breeding procedures where relevant

Figure 1: Inspectorate staff, 2006–2012

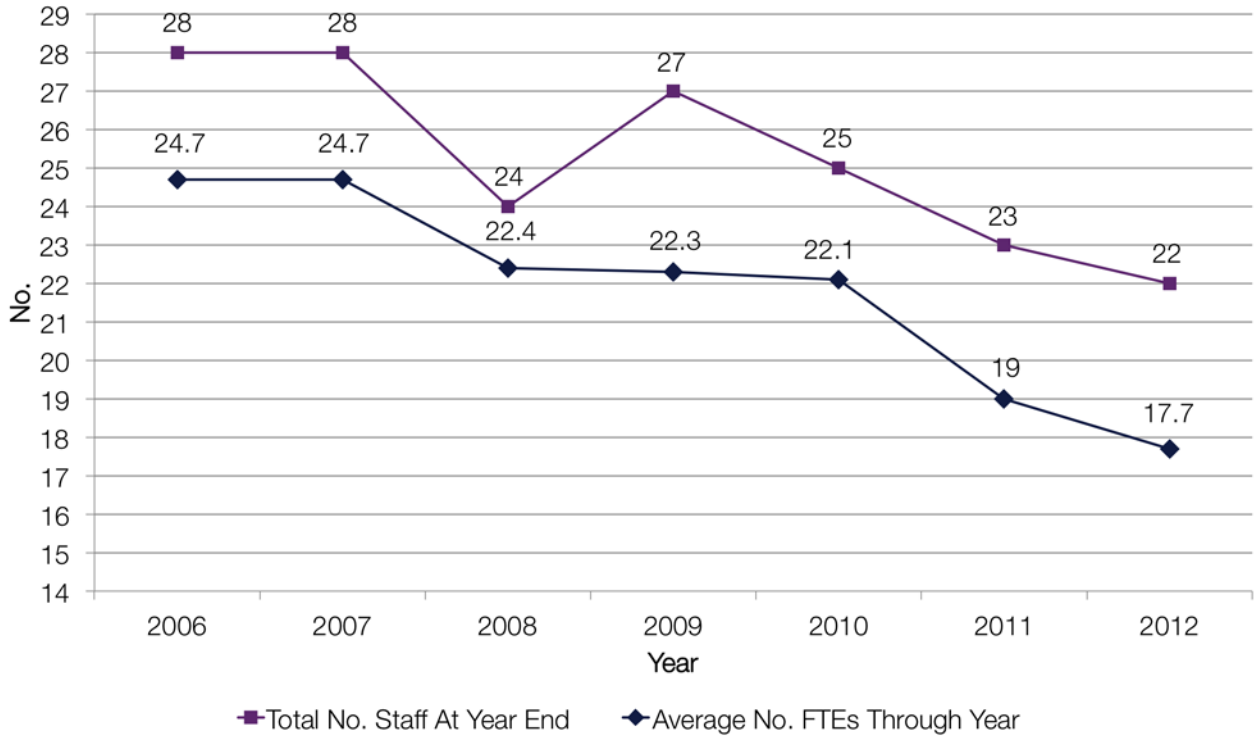


Figure 2: Project licences granted, 2006–2012

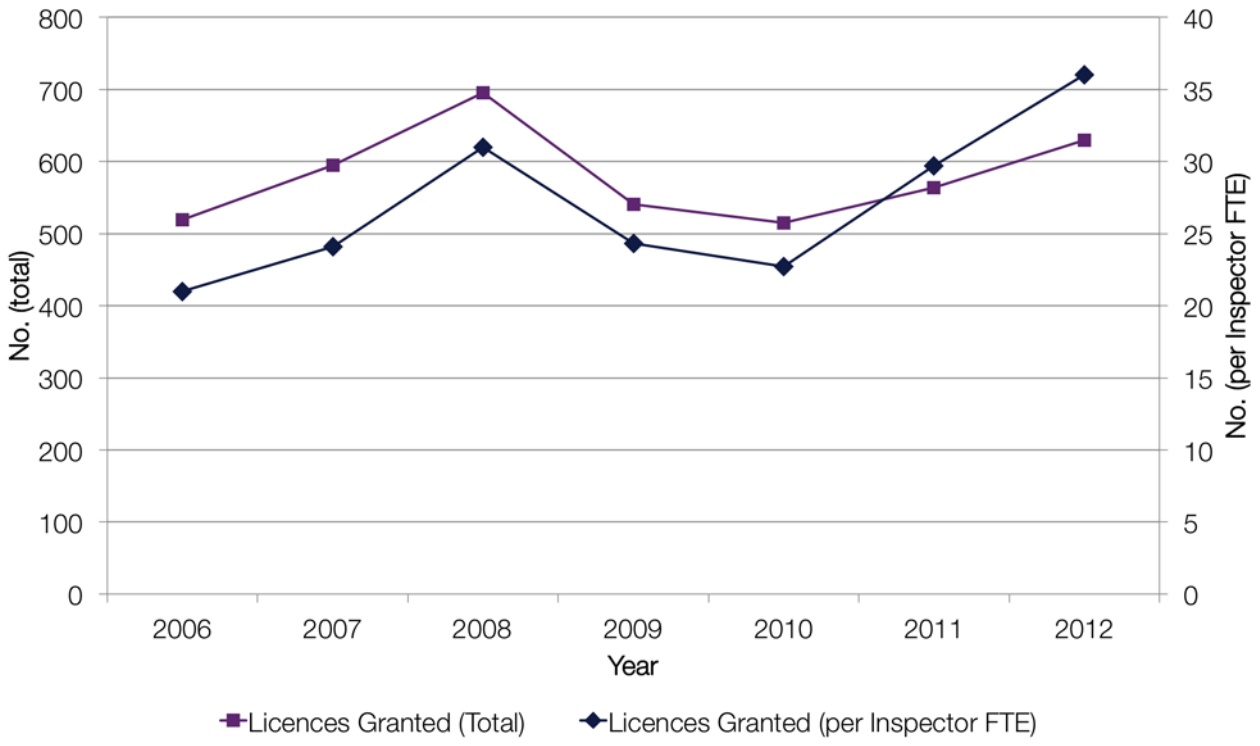
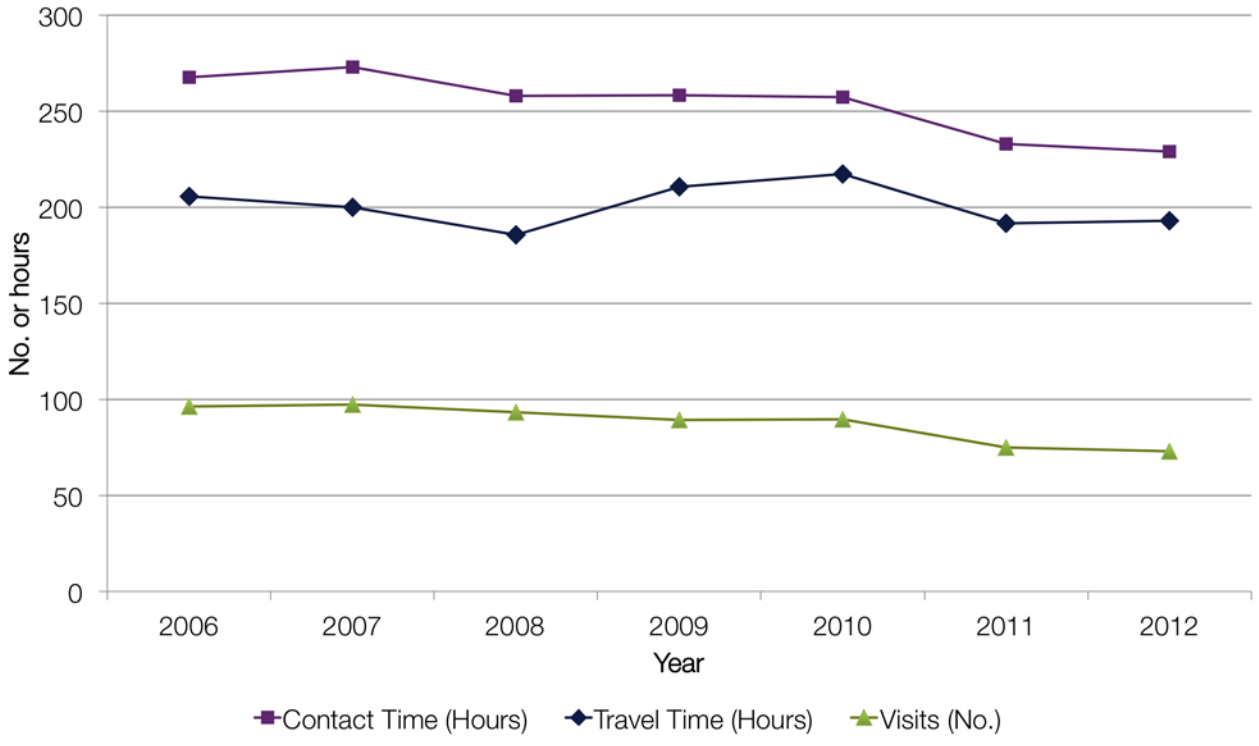


Figure 3: Project licence application processing, 2006–2012

Figure 4: Total inspections, 2006–2012

Figure 5: Inspections per FTE, 2006–2012



ISBN: 978-1-78246-160-9
Published by Animals in Science Regulation Unit, Home Office