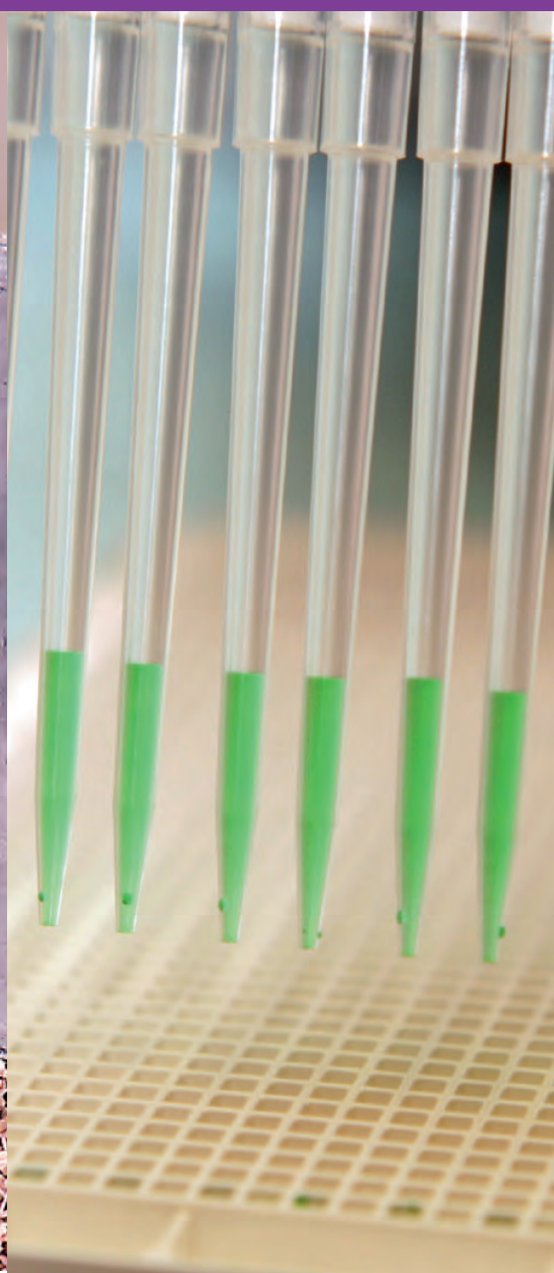
Home Office

Animals in Science Regulation Unit
Annual Report 2014



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Ministerial foreword

The UK has one of the most sophisticated regulatory regimes for animals in science worldwide. I believe we should maintain and seek to develop this capability to deliver high quality science and high standards of animal welfare. We have a robust framework of regulation in the Animals (Scientific Procedures) Act 1986 (ASPA), underpinned by a rigorous inspection process. A cornerstone of our regulation is our commitment to ensure animal research is carried out only where the harms are justified by the expected benefits, where no practicable alternatives exist and where any suffering is kept to a minimum.

The properly regulated use of animals in science provides benefits to society, the environment and to animals. These benefits include greater understanding of how biological systems work and support for the development of new medicines and new technologies among others.

The UK is a global leader in supporting the 3Rs (Replacement, Refinement and Reduction). Further advances in science and technology continue to present ever growing opportunities for 3Rs advances and the development and validation of alternatives. In 2015 we intend to share our frameworks with international partners, thereby seeking to effect change and deliver benefits well above what can be achieved just in the UK.

In the forthcoming year I will implement a policy ban on the testing of finished household products in animals and apply restrictions to the testing of ingredients. In implementing this policy, I want to avoid simply exporting work overseas where standards may not be as rigorous as in the UK. Instead, this policy will play an important role in improving the lives of humans and animals and safeguarding the safety and sustainability of the environment. I also want to promote and support innovation and, in the coming years, to make further advances as we work with our UK stakeholders and as we share our experience with our EU partners and colleagues further afield.

The Rt Hon Lord Bates
Minister of State

2014 A year of commitments: Better regulation and the 3Rs

The challenges and successes of 2014 can be neatly summarised as commitments to 'Better Regulation' and to 'The 3Rs'.

To deliver Better Regulation, we have significantly improved the way we communicate our expectations for the delivery of the legislation. We published two key documents during 2014: the *Guidance on the Operation of the Animals (Scientific Procedures) Act 1986* and the *Code of Practice for the Housing and Care of Animals Bred, Supplied or Used for Scientific Purposes*.

Both these documents represent a milestone in our commitment to firmly embed the European Directive (2010/63). They serve different purposes: the Guidance concerns how the Act is being administered and enforced; the Code is about setting standards. Nevertheless, both documents have a common aim of allowing all who work under the Act to support and share in a commitment to the 3Rs, to high standards of animal welfare, and to developing a culture of care at least partly delivered through a culture of compliance.

In addition to the Guidance and the Code we have been developing Advice Notes on specific topics. These explain particularly complex aspects of the legislation and aim to assist establishments in ensuring they understand and can comply. In due course, these Advice Notes may be included in subsequent revisions of the Guidance. Currently, our aim has been to be as transparent as possible whilst consulting with stakeholders to ensure our advice is helpful and clear; we will retain the flexibility to amend them if appropriate.

The launch of our e-Licensing system (ASPeL) for personal licences in February 2014 was a landmark in our commitment to move away from paper-based licensing. We plan to further develop ASPeL during 2015 for Phase Two roll-out in late summer. This will include project licences and further improvements in the personal licensing functionality that stakeholders have requested.

ASPeL demonstrates how working in collaboration with stakeholders can help us to deliver Better Regulation in a modern, fit-for-purpose manner. ASPeL supports greater efficiency (for both establishments and ASRU colleagues), greater transparency (by the ability to more readily search records), greater security (by protecting confidential information) and greater cost-effectiveness.

In relation to our commitment to the 3Rs, during 2014 we launched the Government's plan to "work to reduce the use of animals in scientific research". This Delivery Plan is a first of its kind internationally and allowed ministers to be clear of their intention to drive forward a science-led programme built around all the 3Rs (Replacement, Refinement and Reduction). To meet this challenge, we worked across Whitehall and our various partners and agencies to deliver a coherent programme of work.

The Delivery Plan struck a chord with our stakeholder groups – setting out how we could reconcile support for animal welfare in tandem with progressing the UK's leading position in science and innovation.

The UK is internationally recognised as a leader in the regulation of the use of animals in science. We recognise this brings responsibilities to deliver benefits to animal welfare and good science and to embed the 3Rs, not only with our Directive partners in Europe but also on a global stage.

We have worked alongside colleagues in the Foreign and Commonwealth Office (FCO) to particularly support China to develop standards in research animal welfare and ethical use. An international seminar in Beijing in March was followed by further discussions culminating in a Chinese visit to the UK in December. We are supporting our partners in embedding the 3Rs in their science, thus supporting collaborations between UK and Chinese scientists. We are also together exploring ways to avoid unnecessary testing of cosmetics and duplicative testing of medicines in animals. In addition, we have initiated similar activity with Brazil.

I am constantly aware that we deliver our work in partnership with an array of talented individuals and organisations and we rely on their commitment to support our challenging programme. During 2015, we will further consolidate many initiatives commenced in 2014. In particular, we will continue to support the delivery of two key commitments. Firstly, we will continue to promote the 3Rs and achieve greater openness and transparency in all our work. Secondly, we will conclude our efforts to deliver a ban on the testing of finished household products in animals. Our ambition is to also deliver controls on the testing of ingredients, ensuring that no such testing is carried out unless it is required by law or is profoundly justifiable. And in keeping with our commitment to transparency, we will be open about any such testing which we may authorise.

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

Photo credit: Wellcome Photo Library, Wellcome Images

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, Refinement and Reduction) 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 and Administration and the Chief Inspector.

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

The Policy and Administration Group's role

The Policy and 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 2014 the Policy Team comprised one Senior Policy Manager and one executive fast-streamer, both of whom report to the Head of Policy and Administration. 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 by the Licensing Team on advice from 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 to these;
- 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 2014 the Team comprised the Head of Licensing (reporting to the Head of Policy and Administration), two 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 2014 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 including the application of the 3Rs (Replacement, Refinement and Reduction). Their work is split broadly into thirds between their commitments to inspection, assessment of applications for licences, and providing operational and strategic advice.

Inspectors are fully registered veterinary or medical practitioners and usually have higher scientific or clinical postgraduate qualifications and first-hand experience of biomedical research.

At the end of 2014 the Inspectorate comprised 24 individuals, including the Chief Inspector. During 2014 the average resource assigned to normal inspection duties (including licence assessment) was 17.0 FTEs (full-time equivalents).

See **Figure A1** in **Appendix 3** for further related historical data.

The Business Reform Programme

One of the aims of the Business Reform Programme (BRP) was to centralise ASRU's operations through the decommissioning of regional offices and bringing activities together in London. Nevertheless, we recognised the need for ASRU inspectors to be located close to those they inspect. Therefore we have maintained hub locations in Scotland, Bedford and Swindon for inspectors as well as providing facilities to enable inspectors to work from home.

The BRP started in 2012 and was formally drawn to a close in 2014. Regional offices in Cambridge and Dundee were closed in 2012 and 2013 respectively, and closure of the office in Shrewsbury followed in 2014. These changes represent substantial cost savings for ASRU (and our fee-payers) both in terms of accommodation and staff costs. This reduced capacity and capability has been balanced by the progress ASRU has made in developing efficiencies through new IT, including e-Licensing (ASPeL), and new ways of working.

Section 2: The regulatory framework

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

In 2014 the Animals in Science Regulation Unit (ASRU) completed work to implement the European Directive through the publication of comprehensive *Guidance on the Operation of the Animals (Scientific Procedures) Act 1986*[1] and a *Code of Practice for the Housing and Care of Animals Bred, Supplied or Used for Scientific Purposes*[2] under ASPA.

Both documents were drafted with invaluable input from many sources including: the biosciences sector; representatives of licensed establishments; animal welfare and protection groups; subject-matter experts; the ASRU Inspectorate; other government departments; and the Animals in Science Committee.

The documents support establishments to understand ASPA and how to be compliant. They also provide a point of reference to all stakeholders, including the public, as to the intent of ASPA.

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

The Guidance was published in March 2014 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 ASPA and how they expect those working under ASPA to fulfil their duties.

The Guidance is intended to be a reference document for everyone involved with animals that are bred for, supplied for, or used in scientific procedures. Over the coming years, as the amended ASPA fully embeds, there will be further Advice Notes issued to complement the Guidance – providing further explanation where required. It is envisaged that these Advice Notes will be consolidated into a future edition of the Guidance.

Code of Practice for the Housing and Care of Animals

The *Code of Practice for the Housing and Care of Animals Bred, Supplied or Used for Scientific Purposes* ("the CoP") was laid before Parliament in December 2014 and is now being used by all licensed establishments. It contains standards for the care and accommodation of animals, and its purpose is to ensure that the design, construction and function of the installations and equipment of licensed establishments – along with their staffing, care and practices – allow procedures to be carried out as effectively as possible.

The key outcomes driven by this CoP are:

- to promote good animal welfare through the provision of consistent, high-quality care and accommodation;

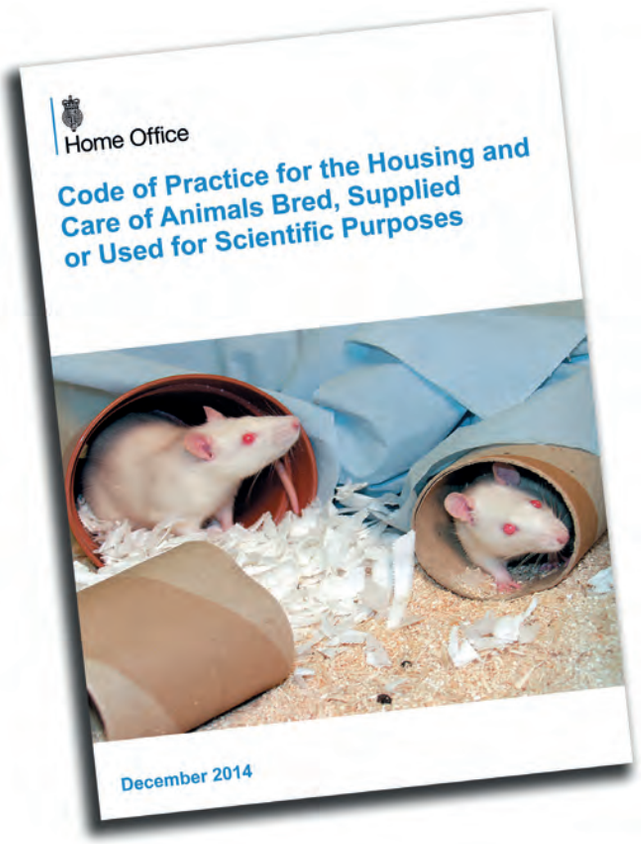
1 https://www.gov.uk/government/publications/operation-of-aspa

2 https://www.gov.uk/government/publications/code-of-practice-for-the-housing-and-care-of-animals-bred-supplied-or-used-for-scientific-purposes

- to support the generation of high-quality, reliable scientific results through the reduction of environmental variables;
- to implement the principles of the 3Rs through using the minimum number of animals and causing the minimum degree of pain, suffering, distress or lasting harm.

The CoP is split into three sections.

- Section 1 describes the legal minimum standards applicable now.
- Section 2 describes the legal minimum standards applicable from 1 January 2017.
- Section 3 provides non-mandatory advice covering a broader range of subjects than Sections 1 and 2, and aims to promote a shared understanding between establishments and Home Office inspectors of the manner in which the requirements of Sections 1 and 2 might be met. Section 3 aims to encourage the application of up-to-date evidence-based 3Rs approaches to accommodation and care as leading practice evolves.



Through 2015 we will be holding workshops to help establishments to adopt this CoP. A review of Section 3 of the CoP is being considered for approximately five years' time so, as stakeholders become familiar with both the Guidance and the CoP, we would welcome feedback. Please send your comments to ASRUBusinessSupport@homeoffice.gsi.gov.uk

Actual severity of procedures

Following the pilot study reported last year, we have published advice on how to classify severity in accordance with Annex 8 of the Directive and data on actual severity for procedures completed in 2014 have been collected for the first time.[3] These data will be published with the statistics on animal use in the UK in autumn 2015.

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 2014 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 February and October in 2014. Updates were provided by all EU 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).[4] In 2014 EWGs provided the NCPs with guidance for endorsement on the following.

3 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/276014/NotesActualSeverityReporting.pdf
4 http://ec.europa.eu/environment/chemicals/lab_animals/interpretation_en.htm

- Inspections and enforcement to fulfil the requirements under Articles 34 and 60 of the Directive. The EWG met on 3–4 December 2013 and the resulting document was endorsed by the National Competent Authorities for the implementation of Directive 2010/63/EU at their meeting of 9–10 October 2014 (with the exception of Annex V: List of elements referred to in Article 23 (3)).
- Animal Welfare Bodies and National Committees to fulfil the requirements under Articles 26, 27 and 49 of the Directive. The EWG met on 11–12 June 2014. The objectives of the EWG were to develop guidance and principles of good practice for Animal Welfare Bodies and National Committees to facilitate the implementation of the Directive. The EWG guidance was endorsed by the NCPs at their meeting of 9–10 October 2014.
- A common education and training framework for the EU to fulfil the requirements under Articles 23 and 24 of the Directive. The EWG met on 22–23 February and 19–20 September 2012, and 3–4 July 2013. The objectives of the EWG were to develop a common framework to meet the requirements for competence of all those involved in the use and care of animals for scientific purposes and free movement of personnel. The EWG guidance was endorsed by the NCPs at their meeting of 19–20 February 2014 (with the exception of Annex V: List of elements referred to in Article 23 (3)).

Members of ASRU, together with UK stakeholders, attended EWG meetings and provided active input to preparation, discussion and decision-making.

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 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.

The ASC is commissioned by the Minister both annually and on an ad hoc basis as well as having the ability to commission its own work. In 2014 the Minister wrote to the ASC on 11 August setting out matters of particular importance to the department, and therefore the priority areas for ASRU[5]. In addition, the commission provided the ASC with headspace to consider areas of work it deems as appropriate.

A standing role of the ASC is to review project licence applications received by ASRU that involve the highest level of permissible harm (severe procedures) and one or more of the specially protected species. During 2014 the ASC reviewed four of these project licences.

In December 2013 the Minister requested that the ASC review the Home Office's ASRU Inspectorate report on compliance with ASPA, and the independent report by Professor Brown on the incidents of non-compliance at Imperial College, London. The review focused on, and evaluates, the inspection regime both at the time of the non-compliance at Imperial College and for the future. The review provided nine recommendations: seven on the regulatory framework and two for institutions. The Home Office fully accepted the recommendations and published a response[6].

In 2014 the Home Office requested that the ASC review harm–benefit assessment, for which it established a working group. As part of its review, the Home Office requested the ASC to consider the recommendations of

5 https://www.gov.uk/government/publications/ministers-commissioning-letter-to-the-chair-of-the-animals-in-science-committee

6 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/336030/Government_response_to_the_ASC_Review.pdf

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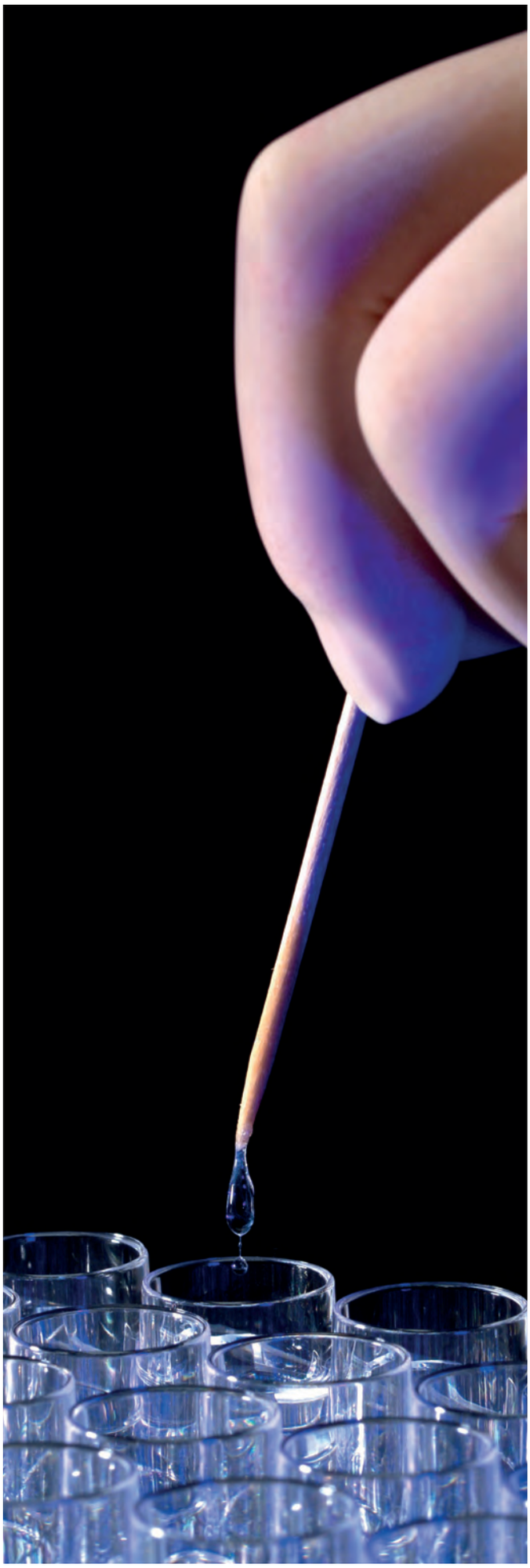


the *Review of the Assessment of Cumulative Severity and Lifetime Experience in Non-human Primates Used in Neuroscience Research* as they pertain to harm–benefit assessment.

In 2014 the ASC also provided ASRU with advice on the CoP and contributed to reviewing responses to the consultation on section 24 of ASPA.

ASRU engages regularly with members and the Chair of the ASC. During 2014, we 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 continues to develop this close and productive working relationship whilst assuring the ASC's independence is retained in relation to its advice.

Advice Notes in development

The purpose of Advice Notes is to support the operational guidance where further detail would support better delivery. During 2014 ASRU has commenced development, with internal and external stakeholders, of Advice Notes on: re-use; re-homing and setting free; and use of wild animals. These Advice Notes are scheduled to be finalised and published during 2015.

Re-use

The Advice Note, *Use*, *Keeping Alive and Re-use* aims to explain the interpretations of the terms 'use', re-use' and 'continued use' under ASPA and to provide further guidance on the criteria that must be satisfied to keep animals alive at the end of their use in order that they may be re-used. Although section 15 of ASPA (which deals with killing animals at the end of a series of regulated procedures) has not materially changed with the amendment of the Act in 2013, section 14 (which provides the legislative framework for re-use) has changed. The new interpretations were presented in a series of stakeholder meetings and a wide

range of external stakeholders commented on the final draft document.

Re-homing and Setting Free

The Advice Note, *Re-homing and Setting Free* expands on the information already provided in the Guidance on the operation of ASPA.

The intention of the Advice Note is to provide good practice principles for licensed establishments on the re-homing and setting free of protected animals bred, supplied, kept, or used in research. Consideration must be given to:

- the state of health of the animal;
- whether the animal poses a risk to public health, animal health and the environment;
- the requirements for an effective socialisation scheme or rehabilitation programme; and
- any other appropriate measures to safeguard the animal's well-being such as the suitability of the new owner or location to provide for the individual animal's needs.

A draft Advice Note was circulated to ASRU's external stakeholder groups and establishments for comment in addition to face-to-face meetings held with individual groups to discuss best practice approaches to re-homing and setting free.

Use of wild animals

Some of the changes to ASPA following transposition of EU Directive 2010/63EU have particular relevance to work using wild animals; for example, capture for an experimental or scientific purpose can only be carried out by a competent person using a method that does not cause the animal avoidable pain, suffering, distress or lasting harm.

Work on an Advice Note clarifying how these changes are being implemented was started in 2014. The Advice Note is intended to explain the regulatory framework surrounding the use of animals taken from the wild in the UK for scientific purposes, both at licensed establishments and where such work is performed at a place other than a licensed establishment.

It is primarily intended to provide operational guidance to:

- those working or applying for authorities to work under ASPA;
- Animal Welfare and Ethical Review Body (AWERB) members, as well as veterinary surgeons and others who are involved in the decision-making process regarding the use of animals taken from the wild; and
- inspectors within ASRU.

The aim is to aid appropriate and consistent interpretation of ASPA requirements.

Many wild animals are protected by other legislation such as the Wildlife and Countryside Act (1981). During the process of drafting the Advice Note, other regulators have been consulted with the intention of clarifying the interface with ASPA. In addition, internal and external stakeholders have been invited to comment.

ASRU's Head of Policy, Will Reynolds, speaks to Establishment Licence holders at their Annual Forum.

Section 3: Licensing

The framework

The UK has a rigorous three-tier licensing system to ensure that animal research and animal testing is only carried out where no practicable alternatives exist and under stringent controls where suffering must be kept to the minimum. The Home Office neither sponsors scientific research involving the use of animals, nor does it set any requirements for data produced by such procedures.

The licensing framework comprises:

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

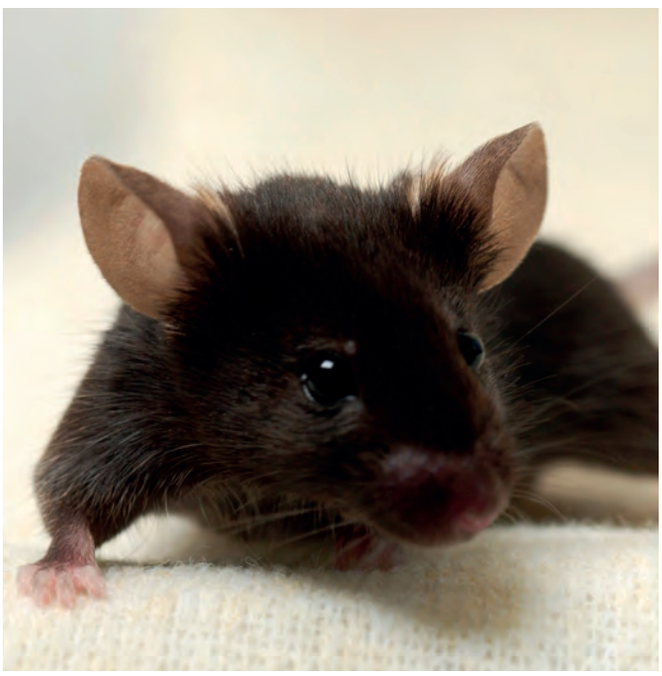


Photo credit: Wellcome Photo Library, Wellcome Images

The Animals in Science Regulation Unit (ASRU) administers the licensing function under the Animals (Scientific Procedures) Act 1986 (ASPA). The overall level of scientific procedures that we license is determined by a number of factors including the economic climate and global trends in scientific endeavour. We currently license 176 establishments with approximately 2,700 project licences and 17,500 personal licensees. The pharmaceutical, biotechnology and contract research industries and major academia (universities and research institutes) are the main organisations regulated under ASPA.

Performance

Establishment licences – During 2014, four new applications were received with six establishment licences granted and issued (a carryover of two from 2013).

Project licences – During 2014, 94.3 per cent of project licences were granted within the 40-day target and 98 per cent within 55 days.

Personal licences – With the launch of the Animals in Scientific Procedures e-Licensing (ASPeL) for PILs in February 2014 (see below), we achieved an overall rate of 98 per cent in granting new PIL applications within our 20-day target. During April and August there was some slippage owing to the Easter and summer holiday periods. Contingencies were put in place to cover the Christmas period which ensured that performance standards were maintained. We have received positive feedback from our duty holders regarding the speed with which these applications are being processed and authorised in comparison to the previous paper-based system.

Animals in Scientific Procedures e-Licensing (ASPeL)

It is essential that the ASPA regulatory system is supported by a modern and efficiently functioning licensing system; the development of e-Licensing has therefore been central to ASRU's future planning. During 2014, we successfully rolled out the ASPeL for the processing of new applications from all licensed establishments for personal licences and for amendments. ASPeL has significantly reduced the administrative work involved in handling paper files which has benefitted both our stakeholders and our staff. The ASPeL PIL functionality supports the efficient processing of licences and will, in the long term, allow better management of licences for establishments with appropriate safeguards. (See Table A1 in Appendix 3.)

To move swiftly to e-Licensing we have undertaken a conversion programme of paper-based PILs to e-licences. The programme got under way during 2014, with the mammoth task of converting all 16,500 paper-based PILs onto ASPeL. We are scheduled to complete the process by the end of 2015.

Phase Two for new and complex amendment PPL applications will be launched in summer 2015 (scheduled for late September). When we 'go live' with the PPL part of ASPeL, all new licence applications will be processed electronically, but current licences can be retained as paper-based for up to the duration of their five-year lifespan. We will trial the system prior to 'go-live', with 'early adopter' establishments as we did for the PILs conversion. Again, this collaboration will provide us with constructive feedback on the system and matching it to requirement. We will develop effective guidance that will be put in place for the full roll-out.

We are optimistic that, in due course, PPL holders will opt to convert their licence to an e-licence, particularly if they are applying for an amendment, in order to benefit from the convenience of having an e-licence. If they opt to apply for a renewal of their project licence before its scheduled expiry date, they will benefit from the extended new licence duration of up to five years. However, we do not propose to apply pressure on licence holders to take any of these steps.

The development of ASPeL, within ASRU's centralised operations, is helping to ensure we deliver a modern, fit-for-purpose licensing system utilising the best of technology in a secure and reliable environment.

Licence holder engagement

The engagement of licence holders with the Licensing Team is important. In 2014 we further developed this relationship with the introduction of a Single Point of Contact (SPoC) in the Licensing Team for each establishment, and through a new stakeholder forum.

The purpose of the SPoC role is to simplify the contact that establishments have with the Licensing Team and reduce the number of ASRU staff they need to liaise with. The role should drive efficiencies in the way we undertake licensing activities. Feedback from across establishments has been positive, enhancing our delivery of service, and we are addressing those areas where we could further improve.

The year 2014 saw a greater engagement between ASRU and the Home Office Liaison Contacts (HOLCs) through the launch of a forum that uses the existing Home Office Liaison and Training Information Forum (HOLTIF). We have hosted quarterly meetings to meet and discuss areas of interest with members of ASRU staff. The aim is to encourage a greater understanding of the regulatory environment and to build effective working relationships to deliver better outcomes for our duty holders.

Section 4: Promoting the 3Rs and wider projects

The previous Government's commitment

The previous 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 this commitment and a narrative of rationale for the use of animals in scientific research.

The Delivery Plan, published on 7 February 2014,[7] set out how the commitment would be met. The Plan was based on three strategic objectives:

- advancing the use of the 3Rs (Replacement, Refinement and Reduction) 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 strategic objectives were delivered through a science-led programme with the 3Rs at its heart. During 2014 ASRU worked in collaboration with BIS and the Department of Health to manage the programme of work set out in the Plan. The National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) was a key contributor to the Plan, which also closely involved our Inspectorate, other government departments and agencies, the research community in both academia and industry, and others with relevant animal welfare interests.

In early 2015, a Delivery Report[8] was proposed which would describe the progress made during the first year on actions set out in the Delivery Plan.

In addition to achieving the overall aim, the Plan contributed to wider openness, transparency and public understanding about this area of work. Importantly, the Plan balanced the need for the UK drive to stay at the forefront of alternatives to animal testing, while continuing to make clear the benefits that animal research brings to society.

7 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/277942/bis-14-589-working-to-reduce-the-use-of_animals-in-research.pdf

8 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/417441/Delivery_Report_2015.pdf

Influencing the uptake of the 3Rs globally

The UK scientific community is a global leader in promoting and implementing the 3Rs. ASRU is committed to using this expertise to influence the uptake and adoption of 3Rs approaches globally through international engagement. Our work focuses on realising benefits for the UK in three areas:

- **ethical** benefits of reduced animal testing globally and increased global animal welfare standards;
- **scientific** benefits of enhanced opportunities for international collaboration and more streamlined studies (for example, accelerated drug approvals);
- **economic** benefits that come from breaking down barriers to trade (for example, in cosmetics).

We have had a particular focus on China where animal testing is mandated for imported cosmetics and data are not readily accepted from Organisation for Economic Development (OECD)-based pharmaceuticals research, resulting in the duplication of studies. Over the past year we have continued to build relationships with the China Food and Drugs Administration (CFDA) and the Chinese Association for Laboratory Animal Sciences (CALAS). In December 2014 we welcomed two delegations of Chinese officials from CFDA and a delegation from CALAS. During these visits we showcased UK expertise in the 3Rs and our world-leading regulatory system.

In March 2014 we partnered with CALAS to co-run a UK–China International Seminar in Beijing aimed at promoting the uptake of the 3Rs in China. The Seminar brought together expert speakers from the UK, EU, USA and China to explore difficult areas ranging from delivering training and assessing competence through to practical approaches to harm-benefit analysis.

We have also worked closely with the CFDA and the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) to explore the possibility of China joining the OECD Mutual Acceptance of Data (MAD) programme, which would significantly reduce the duplication of animal testing in pharmaceutical development.

In 2015 we plan to co-run a further international seminar in Beijing to include ethical review and harm–benefit analysis. We then plan to follow the seminar with a workshop in Beijing on Cosmetics Safety Assessment with experts from the UK, EU and China aimed at familiarising officials in China with non-animal cosmetics safety testing methodology.

Through this work, China has redoubled its commitment to develop laboratory animal welfare standards and regulatory procedures with the 3Rs at their core. We will cement the UK as the partner of choice to influence the uptake and adoption of 3Rs approaches in China, and will support the development of collaborations between UK and Chinese scientists by providing a compatible ethical framework within which they can work.

The first UK–China seminar aimed at promoting the uptake of the 3Rs in China brought together expert speakers from the UK, EU, USA and China.

Section 24

Over the last year ASRU has continued its work to promote understanding and awareness of the use of animals where no alternative exists. A key element of achieving this was the review of section 24 of the Animals (Scientific Procedures) Act 1986 (ASPA).

Section 24 limits the openness on information held in connection with the regulation of the use of animals in science. It has remained unchanged since 1986, but since that time the Freedom of Information Act 2000 (FOIA) has come into effect, supporting the public right of access to information held by public bodies. Reforming section 24 demonstrates the Government's accountability, strengthening people's trust in government and ensuring that the public are informed about the use of animals in science. The objective of the section 24 review was to create a better approach that provides greater transparency and assists public understanding, whilst not damaging the UK's scientific and economic success, nor compromising personal data or safety.

The review began with our bringing together stakeholders from across the spectrum of opinion, including members of animal welfare and protection organisations and people working in the life sciences. Working with the Design Council we investigated what openness meant to differing groups, points of difference and areas where all sides agreed.

Following this discussion, the previous Government published a public consultation on options for reforming section 24. The consultation offered consideration of three options that ranged from the complete repeal of the section through to no change. Almost 5,000 responses were received, the majority from the online survey. Almost without exception, respondents expressed a desire for increased openness and transparency in this field whilst recognising the need to protect the identities of people and places, as well as information that is academically or commercially sensitive.

Taking the public's views into account, we have continued discussions with stakeholders on the best way forward and intend to continue our work on improving openness in the regulation of animal research in the coming year. This will be the first step in moving to a more open system where information is published that helps people to understand ASRU's work and hold us to account.

Household products

The previous Government made a commitment to ban the testing of household products on animals. During 2014 we engaged closely with key stakeholders to understand the issues. We considered a range of options and worked with stakeholders from all sectors to ensure that there were not unforeseen or unintended consequences if the ban was introduced.

Three key issues needed to be considered and resolved:

- to consider whether ingredients could be included in the ban;
- the ban must be legally viable since a ban on testing would not be feasible where such testing is required under UK or EU law; and
- the solution should not preclude research that is importantly innovative, or simply drive such research overseas where welfare standards may be lower.

This extensive consideration led to the development of a solution that will result in:

- a ban on the testing of finished household products on animals; and
- a qualified ban on the testing of ingredients which are primarily intended for use in household products.

Where the testing of such ingredients is required for regulatory purposes, we propose to permit this and require retrospective notification shortly following the start of such testing. Where the testing is not required for regulatory purposes, we propose to require a prospective authorisation, specific to the

particular proposal. For such applications, which we would expect to be few, ASRU would apply a rigorous harm–benefit analysis.

In addition, there is no internationally accepted definition of a household product and we have therefore needed to develop one as well as to indicate clearly what we will consider to be an ingredient which is primarily intended for use in a household product.

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

As the UK national organisation for the discovery and application of new technologies and approaches to replace, reduce and refine the use of animals for scientific purposes, the NC3Rs is an important stakeholder organisation for ASRU, in its capacity as the regulator, to engage with.

In 2014 we had a key collaboration with the NC3Rs in the development and delivery of the Coalition Commitment: 'Working to reduce the use of animals in scientific research'. The NC3Rs made significant progress in delivering the first of the strategic priorities: 'Advancing the use of the 3Rs in the UK', and supported the international priority of 'Influencing the uptake and adoption of 3Rs approaches globally'. ASRU's ongoing activities with the NC3Rs offer opportunities for ASRU to engage more closely with key stakeholders in the scientific community and to continue to build on key relationships with colleagues at the NC3Rs so that expertise can be shared to achieve even greater 3Rs gains.

ASRU inspectors meet regularly with the Chief Executive and other staff of the NC3Rs to share knowledge and expertise. This enables inspectors to be well informed to drive 3Rs improvements as part of their role. In turn, inspectors suggest areas of interest they have identified that the NC3Rs may be interested to take forward. The Inspectorate is thus well placed to disseminate 3Rs knowledge to the science community and through engagement with the NC3Rs we seek to make best use of this national resource.

During their inspection and assessment activities in 2014, engagement with the NC3Rs has encouraged ASRU inspectors to refer duty holders to the NC3Rs' Procedures with Care microsite, the ARRIVE guidelines, and the NC3Rs' online resource for reducing and refining the use of genetically altered mice. This supports both the requirements of ASPA and our shared intent of putting the 3Rs at the heart of our commitment to work to reduce the use of animals in research. In this context, ASRU supports the NC3Rs' initiatives including the annual prize giving in February 2014 which was attended by several members of ASRU.

An important part of ASRU's work is supporting and embedding the uptake of the NC3Rs' work as it moves from concept to realisation. In 2014 members of ASRU supported the publication of a review of the NC3Rs' very impressive work with the pharmaceutical industry over several years, as well as attending a workshop on Adverse Outcomes Pathways.

The launch of the NC3Rs' ten-year vision was an important event during the year and focuses on five key areas:

- **practice** in the biosciences;
- **procedures** on animals;
- **people** in the biosciences;
- **places** where animal research is carried out; and
- **policy** related to animal research.

ASRU shares these focuses and looks forward to supporting the delivery of this vision. NC3Rs speakers attended ASRU events during the year to describe their vision to inspectors and other staff. In addition, we invited Dr Sam Jackson, the programme manager for disease models, efficacy and safety pharmacology, to an inspectors' conference to discuss the relevance and importance of age in murine disease models.

Section 5: Engaging with stakeholders

Communications

The Animals in Science Regulation Unit (ASRU) has a key role in supporting Ministers in providing well-evidenced and fully considered responses to Parliamentary Questions (PQs), Freedom of Information (FOIA) 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 the Government communicates current policy and thinking.

Correspondence

During 2014 we handled 794 pieces of correspondence. This comprised 32 FOI requests, 54 PQs, 327 items of Ministerial correspondence and 381 other pieces of correspondence.

Correspondents were concerned with a breadth of issues. The main topics included:

- the Government's commitment to work to reduce the use of animals in research; and
- the extent of the use of dogs, cats and horses in procedures.

Parliamentary Questions

PQs represent a means by which Ministers can be held to account by politicians, often acting on behalf of their constituents. They 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. We responded to 54 Parliamentary Questions during 2014.

Freedom of Information requests

The 32 FOI requests received during 2014 covered a variety of topics. 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.

Consultations

Public consultations, and more informal mechanisms of seeking views from stakeholder groups, are important to assist us in our consideration of issues. They help us to develop policies and to understand the impacts, consequences and suitability of our proposals. They give us the opportunity to reconsider issues and to recognise where there is support for particular options. In 2014 we held one formal consultation and consulted on numerous occasions with key stakeholder groups. We also implemented the outputs of previous consultations.

Public consultation

In May 2014 we held a formal public consultation on the review of section 24 of the Animals (Scientific Procedures) Act 1986 (ASPA) (see page 18). Broadly, we consulted on three options:

a) keep section 24 unchanged;
b) limit section 24's scope to cover only sensitive personal information and intellectual property;

c) repeal section 24 entirely and rely on the exemptions in the Freedom of Information Act to protect sensitive information.

Stakeholder consultation

In 2014 we consulted stakeholder groups on a number of issues.

- The Code of Practice for the care and accommodation of animals under ASPA (see page 9). Following consultation, the Code was laid in Parliament and published in December 2014.
- The development of guidance on animals containing human material. We consulted with establishments, Department of Health bodies[9] and the Academy of Medical Sciences. The guidance will be published in 2015.
- The implementation of full cost recovery (FCR) for ASRU (see page 37). FCR will be implemented from April 2015.
- The development of various Advice Notes, including: re-use; re-homing and setting free; the use of wild animals and return to the wild. We consulted with numerous stakeholder groups to gather feedback on the Advice Notes which will be published in 2015.
- The development of a policy to implement a ban on testing of household products. ASRU engaged with various industry associations, government departments, establishments and stakeholder groups, including the animal welfare and protection sectors, to develop the policy. An announcement will be made in 2015.

Implementation and outcome of previous consultations

During 2013, we consulted on the following topics.

- The draft Code of Practice for the care and accommodation of animals under ASPA, setting out the standards to be applied by all users, breeders and suppliers of animals from 1 January 2013 to 31 December 2016. The outcome of the consultation was the publication of a draft code, which was maintained until we completed the final code that was published in December 2014 (see above).
- 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.

During 2014 we implemented the process for the collection of statistics and provided instructions online. Guidance specifically on actual severity and severity assessment of genetically altered animals was published in 2014 and is available on the ASRU website.[10]

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 on implementing the revised regulations, updates on operational matters, and other general policy issues. The meetings included representatives from industry, academia, government research institutes, medical research charities and research funders; animal welfare and alternatives groups; animal protection groups; ASPA named persons and organisations representing other professionals performing functions under the Act.

We also met periodically with other government departments and agencies including: the Department for Business, Innovation and Skills (BIS); Department for Environment, Food and Rural Affairs (Defra); Ministry of Justice (MoJ); Medicines and Healthcare Products Regulatory Agency (MHRA); Food Standards Agency (FSA); Health and Safety Executive (HSE); Human Fertilisation and Embryology Authority (HFEA); Human Tissue Authority (HTA); Medical Research Council (MRC); Veterinary Medicines Directorate (VMD); and with a range of non-governmental organisations (NGOs) and charities including the National Centre for the Replacement, Refinement and Reduction of

9 The Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority.

10 https://www.gov.uk/research-and-testing-using-animals

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 routinely join the Minister in meetings with stakeholder groups to provide advice as appropriate.

Duty holder engagement

Engagement with those who hold a licence, and those in establishments who assist with applications for licences, 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. The ASRU Licensing Team developed engagement with the Home Office Liaison and Training Information Forum (HOLTIF) (see page 15) during 2014, and this is on-going.

External representation

External representation and engagement with our stakeholders, both in the UK and internationally, is an important aspect of ASRU's work. This has been delivered by staff in all parts of ASRU including the Senior Leadership Team and inspectors.

Some highlights for 2014.

International attendance and presentations included:

- American Association for Laboratory Animal Science, San Antonio;
- III Brazilian Congress on Bioethics, Curitiba, Brazil;
- Federation of European Neuroscience Societies Forum, Milan, Italy;
- UK–China 1st International Seminar on Laboratory Animal Welfare and Ethical Use;
- Laboratory Animal Science Meeting, Switzerland;
- Pan-Asian Veterinary Conference, Bangalore, India;
- The FELASA-AALAS European Forum on Harm–Benefit Analysis, Bergen, Norway;
- 9th World Congress on Alternatives, Prague;
- Norwegian Research Council Panel Review on Fish Research.

UK presentations, workshops and working groups included:

- Institute of Animal Technologists Annual Conference;
- Laboratory Animal Science Association Winter Meeting;
- Laboratory Animal Veterinary Association Annual Conference;
- Royal College of Veterinary Surgeons Workshop on Evidence Based Veterinary Medicine;
- Royal Society of Biology;
- Workshop on refining regulated procedures in the dog, Stirling University.

In addition, inspectors routinely made presentations to staff at their assigned establishments, explaining the regulatory system and new and emerging policies. We welcome these interactions.

Faculty for the first UK–China International Seminar on Laboratory Animal Welfare and Ethical Use held in Beijing in March 2014.

Royal Society of Biology

Our meeting organised in partnership with the Animal Sciences Group of the Royal Society of Biology has become a regular annual event. In December 2014 topics covered included openness and its implementation and improving animal research. This meeting provides an excellent opportunity to engage face to face with duty holders and to discuss matters of mutual importance.

ASRU's Head of Policy, Will Reynolds, addresses the IAT Congress in Blackpool.

Laboratory Animal Science Association

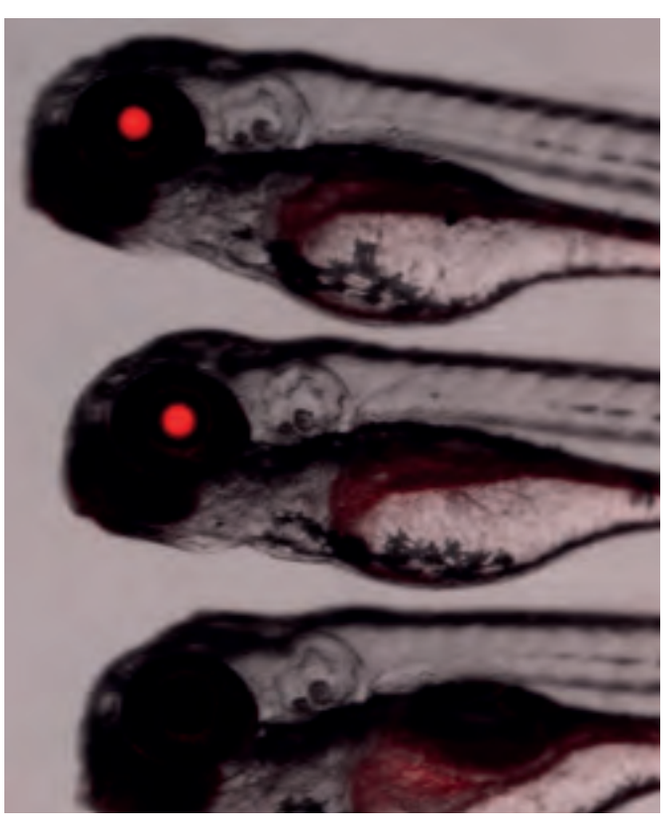
ASRU inspectors attend the Laboratory Animal Science Association (LASA) Council meetings and have had a significant involvement as part of the education, training and ethics (ETES) subsection of LASA. Inspectors have also facilitated an Animal Welfare and Ethical Review Body (AWERB) workshop at LASA's winter meeting, supporting LASA Council members.

Institute of Animal Technologists

The Senior Leadership Team and Inspectors have presented at Institute of Animal Technologist (IAT) meetings and supported a workshop on named persons.

Royal College of Veterinary Surgeons

Members of the Inspectorate liaised with working groups from the Royal College of Veterinary Surgeons to revise and update two chapters of the supporting guidance to the Code of Professional Conduct for Veterinary Surgeons on Named Veterinary Surgeons and Recognised Veterinary Practice.



Section 6: Compliance

A culture of care at an establishment starts with a culture of compliance. Significant responsibility is placed upon the establishment licence holder (ELH) (or, in the case of a corporate entity, the Named Person Responsible for Compliance) to deliver their role, thereby promulgating an appropriate culture of care in meeting both the letter and the spirit of the law. The ELH must have in place robust systems and frameworks that support and encourage compliance. By so doing, they can prevent unauthorised procedures from being carried out at their establishment and ensure all licensees comply with the terms and conditions of their licences (personal and project licences) when working at their establishment.

One 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 primarily aimed at the prevention of repeated similar failures. Inspectors also advise licensees and others how to comply and generally promote a culture of compliance.

The ASRU Compliance Team consists of a Principal Inspector, a Senior Licensing Manager and administrative support. The Compliance Team supports and advises 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. The Team reports directly to the Chief Inspector and the Head of ASRU.

In most cases of non-compliance, the assigned inspector consults with colleagues and gathers sufficient information to determine whether there is a case which merits investigation. An initial report is then submitted to the Senior Licensing Manager within five working days of discovery. A full investigation report is usually 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 which 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 can be found in the Guidance to the Operation of the Act which was published early in 2014.[11]

Compliance advice

Compliance advice may be given verbally by an inspector upon discovery of a minor breach of licence conditions. In such cases, there should be no disputed facts, no evidence of intent to subvert the controls of ASPA, no evidence to suggest that an offence has been committed, and no adverse animal welfare consequences.

11 https://www.gov.uk/government/publications/operation-of-aspa

The breach should be resolved immediately or within a few days of discovery.

In 2014 there were 127 recorded incidents of compliance advice given by inspectors (90 in 2013).

Non-compliance

Each case is considered with regard to the gravity of the non-compliance, and the relevant sanction is applied with the aim of deterring or preventing recurrence, and takes into account both aggravating and mitigating circumstances. The factors to be considered in any case of non-compliance include, but are not limited to, the:

- extent of unnecessary pain, suffering, distress or lasting harm;
- timeliness of resolution or remedy;
- risk of future similar non-compliances; and
- evidence of untruthfulness or attempts to evade responsibility.

In determining the sanctions to be applied, deliberate non-compliances will be viewed more seriously than those due, for example, to misunderstanding 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 may increase the gravity of any non-compliance sanction applied. A view will be taken on whether or not the licensee is likely to observe their legal and administrative obligations in the future.

As set out in the guidance, a range of sanctions is available to the Secretary of State:

- 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
  - amendments to licence authorities including the addition of special conditions;
- revocation, suspension or amendment of licences;
- requirements specified in a Compliance Notice (see below); and
- referral to the prosecuting authorities.

In addition to sanctions, a non-compliance may trigger more frequent inspection, or specifically focused inspection, of an establishment as appropriate.

Those involved in non-compliances, either 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 right to appeal under section 12 of ASPA will be explained. Once dealt with, non-compliances are reported to the Animals in Science Committee.

In the most serious circumstances the Inspectorate will undertake a preliminary investigation sufficient to establish whether prosecution should or should not be considered. If prosecution is contemplated, such cases will be referred to the Crown Prosecution Service (in England and Wales) or the Procurator Fiscal (in Scotland). In addition to other factors, these authorities will consider whether it is in the public interest to pursue a prosecution.

Compliance Notice

The amended ASPA provides for the issue of a Compliance Notice in the event of a breach of a licence condition, or a provision of ASPA, where we require particular action to be taken to prevent further non-compliance. Such a Notice will specify the licence condition(s) or ASPA provision(s) which have been breached and will also specify:

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

The Compliance Notice will explain what will happen in the event of failure to comply, including possible revocation of a licence or licences. There is no provision in ASPA for appeal against a Compliance Notice. However, should the licence holder fail to comply, they may then be sanctioned with suspension or revocation of their licence against which they can appeal under ASPA section 12.

Compliance in 2014, self-reporting and a culture of care

In 2014 63 cases of non-compliance were reported, fully investigated and completed; 43 (68%) occurred at universities, 10 (16%) at government research establishments, 6 (10%) at commercial organisations, and 4 (6%) at other types of establishments. Of the 63 cases dealt with in 2014, 49 (78%) were self-reported. In 2013 and 2012 66 per cent (21) and 58 per cent (15) of cases respectively were self-reported.

There were two cases in 2014 which were considered to be sufficiently serious to warrant referral to the prosecuting authorities. These cases were not concluded in 2014 and so will be reported at a later date. In neither case was it decided that prosecution was in the public interest and we are therefore reviewing our policy regarding such referrals.

Table 1 provides a summary of the discovery of the cases of non-compliance for 2013 and 2014 and Appendix 1 provides summary narrative for each case in 2014.

Self-reporting is generally indicative of an establishment making efforts to ensure compliance. It indicates that an establishment is aware of its responsibilities and is committed to building a good culture of care. Where appropriate, self-reporting should be a part of normal practice within establishments and embedded within good governance frameworks.

Most of the increase in non-compliance cases compared with 2013 is accounted for by the increased number of self-reported cases. In such cases, either the non-compliant licence holder or another named person within the establishment reported the non-compliance to the Home Office which was then investigated by an inspector. We believe there are a number of reasons for this increase in self-reporting. Firstly, in 2014 we published new Operational Guidance which has increased awareness among licence holders of their responsibilities under the amended ASPA. Likewise, ASRU colleagues have taken opportunities to present on the new regulations which has had a similar awareness-raising effect. Secondly, we are aware that the reports we now publish about major or high-profile investigations are being used by duty holders to implement positive changes in the way they approach compliance and establishing a culture of care. We fully support the trends in reporting and encourage duty holders to seek advice from ASRU.

Table 1 Discovery of cases of non-compliance in 2013 and 2014

	2014	2013
Cases reported by the establishment	49	21
Cases reported by others independent of the establishment	2	5
Cases discovered by an inspector	12	7
Total cases	**63**	**33**

We have been greatly encouraged that establishment licence holders (especially through the Establishment Licence Holders' Forum) are giving careful consideration to what a 'culture of care' means and how it can best be developed locally in establishments. The culture of an establishment, framed by behaviours and attitudes, is central to good compliance. The Act provides a framework of roles filled by named persons, as well as the Animal Welfare and Ethical Review Body (AWERB), all of whom are well positioned to support the ELH in delivering strong governance and leadership throughout even the most complex of establishments.

Key compliance messages

As in 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 be familiar with authorities cannot be considered a mitigating factor. Licensees must be 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.

Three common non-compliance themes emerged during 2014:

- procedures conducted without licence authority;
- the un-authorised re-use of animals;
- a failure to provide food and/or water.

Knowledge of these themes should be used to better understand how to avoid non-compliance and support establishments in their frameworks for delivering requirements under ASPA. The case summaries of all non-compliances during 2014 have, where appropriate, been grouped under these themes, and otherwise listed separately in Appendix 1.

1. Procedures conducted without a licence authority

Working without authority has occurred where either personal licence or project licence authorities were not in place. Causes included:

- a mistaken belief that project authority was in place;
- personal licensees were unaware that their licence had been revoked;
- a non-licensee was instructed, and allowed, to carry out a regulated procedure;
- a request by the holder to update a personal licence after the completion of modular training had not been submitted by the establishment to the Home Office for amendment.

This group included 31 cases (49%) of the total of 63 cases (see Appendix 1).

Root causes

The causes for these non-compliances were administrative lapses and error; inadequate or inappropriate record keeping, and a lack of communication amongst key personnel. Nevertheless, the primary responsibility for ensuring compliance with licence authorities rests with the individual licence holder. Licensees should be sure of their authorities before carrying out regulated procedures on animals.

2. The unauthorised re-use of animals

The 'use' of the animal involves one or more regulated procedures applied for a particular purpose and lasts from the time of the first regulated procedure on that animal until completion of observations or collection of data or products for a particular purpose. At the end of each 'use', a decision must be taken as to whether the animal can be kept alive. Any animal that, in the opinion of the personal licensee or the veterinary surgeon, is suffering or is likely to suffer as a result of the regulated procedures at the end of its 'use' must be killed. Re-use is explained in our Guidance as the use of a protected animal that has already

completed a series of regulated procedures for a particular purpose when a different animal on which no regulated procedure has previously been carried out (a naïve animal) could be used. It follows that the sole criterion for determining if an animal is being re-used is whether a naïve animal could be used for the second or subsequent use and still achieve the scientific objective. Of the total 63 cases, 4 cases (6%) fell under this theme (see Appendix 1). This reflects fundamental misunderstanding of animal use authorised under ASPA.

Root causes

The causes were typically: failings in communication between key personnel; staff and licensees who are unfamiliar with the controls and provisions of project licence authorities; and inadequate systems of record keeping.

3. A failure to provide food and/or water

Failure to provide food and water to animals as part of normal husbandry and care is unacceptable. It is therefore of utmost importance that establishments have robust procedures in place to ensure the provision of food and water to animals kept under the terms of ASPA. Of the total 63 cases, 9 cases (14%) fell under this theme (see Appendix 1) and in the majority of these incidents animals died as a result.

Root causes

The primary reasons for failure to provide food and water are related to the effectiveness of routine checks of animals. The ability of an establishment to conduct full and proper checks, as required by ASPA, is related to both staffing resource and the ease with which staff can readily view and assess the animals and their environment. Staff resource may be stretched during busy times and out-of-hours, such as at weekends. However, proper provision for training, competence assessment and supervision should be incorporated into management systems. It is also notable that checking the well-being of animals housed in cages on ventilated racks and ensuring food and water provision may take longer than for animals in open cages. Allowance must be made for this.

Solutions for non-compliance themes

There are number of common solutions to safeguard against the above themes related to non-compliance, which all establishments should have fully in place. These are:

- good channels of communication at all levels in the establishment;
- proper supervision;
- effective training, including competence assessments;
- good administrative practices;
- a culture of checking licence authorities before starting any new set of experiments; and
- sufficient time and resource allocated for daily, meaningful routine monitoring of all animals.

In the first instance, the Home Office Operational Guidance to ASPA should be used as a resource and routinely followed. In this way, establishments should be able to assure themselves they are conducting their work compliantly.

In relation to re-use under the new regulations, we have recognised that some confusion may exist and we are drafting further guidance for publication in 2015. Nevertheless, all duty holders should always fully check their licence authorities before starting any new work, and any queries or concerns should be fully explored and addressed with senior role holders and, if required, with the assigned inspector.

Transparency of major investigations

As well as investigating each non-compliance case, either self-reported or discovered by an inspector, we also initiate a number of more substantial investigations each year. These may be triggered by a number of factors including:

- an infiltration resulting in allegations in the public domain of poor practice;
- a cluster of non-compliances or 'near-misses' identified by inspectors;
- a non-compliance apparently involving significant animal harm;
- a publication which appears to describe unjustified pain, suffering or distress; or
- concern raised by inspectors or others that a particular procedure may be not be either the most refined or the most appropriate model for the purpose.

Such investigations are normally led by inspectors and result in one or more detailed investigation reports.

In the interests of transparency and openness, we have commenced publishing anonymised reports of such investigations on GOV.UK once they are completed. This is in addition to our usual reporting in this Annual Report. We believe 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 also provide the public with insight into this important aspect of ASRU's work.

In determining which reports to publish, we apply a public interest test. All reports involving significant compromise to animal welfare, or those in which there is clear evidence of deliberate intent to deceive, are normally published. In cases where the ELH is found to have failed to comply, it is likely that the issues will be wide-ranging within the establishment and we will normally publish those reports to offer useful lessons to others. In the interests of transparency, we expect a decision to not publish a major report to be the exception. We published details of three reports of such major investigations during 2014. Links to the reports and a summary of the lessons learnt can be found on GOV.UK.[12]

Photo credit: Wellcome Photo Library, Wellcome Images

12 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/360468/ASRU_-_25_09_14_v3.pdf
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/359747/C30_1_ASRUinvestigationCompliance.pdf
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/359749/C51_1_ASRUInvestigationCompliance.pdf

Section 7: Inspection

The inspection role of the Animals in Science Regulation Unit's (ASRU's) Inspectorate is key for the protection of animals used for experimental or other scientific procedures. Inspectors visit all establishments licensed to breed or supply animals, or to carry out regulated procedures on animals under the Animals (Scientific Procedures) Act 1986 (ASPA) in England, Scotland and Wales. The purpose of inspection is to provide reassurance to Ministers and the public that the care of animals, and the experiments carried out, comply with the requirements of ASPA and the relevant conditions specified in licences. The risk-based inspection programme for 2014 is described in this section. Also during the year, ASRU conducted an in-depth survey of the views of stakeholders as part of a general review of the inspection programme. The results from the survey and the conclusions from the inspection review are presented in Section 8 and Appendix 2.

Risk-based inspections

Inspectors conducted a comprehensive programme of visits, mainly unannounced. See ASRU's 2012 Annual Report, Appendix 3 for a detailed description of our risk-based inspection system.[13]

During 2014, inspectors carried out 1,495 visits to places where scientific work on animals was conducted. Of the visits made to animal units, 62 per cent were made without notice. Total inspections amounted to 4,994 hours of contact time with those holding licences under ASPA. The overall number of visits was 8 per cent higher compared with 2013 and the total contact hours increased by 17 per cent.

The average visit in 2014 was slightly longer (3.3 hours) compared with 3.1 hours in 2013. Time spent travelling amounted to 4,374 hours, an increase of 17 per cent (see Figure A4, Appendix 3). The average number of visits per full-time equivalent (FTE) inspector remained the same at 89; however, the contact time per FTE inspector increased from 273 to 296 hours, up 8 per cent compared with 2013 (see Figure A5, Appendix 3).

Approximately 200 of the 1,495 visits were carried out by two or more inspectors. The purpose of such joint visits is to foster consistency of inspection and advice as well as to contribute to the training of new inspectors. Joint visiting is an important part of continued professional development for all inspectors and encourages the sharing of good practice both between inspectors and between establishments. Joint inspection is also used to conduct in-depth investigations, when needed.

The increase in inspection activity was due to several factors. During 2014 five new inspectors were appointed to fill vacancies that had arisen during the previous 12 months. Visits were therefore increased for training and the transfer of establishments between inspectors. In addition, the average number of FTE inspectors rose to 17 during 2014 from 15.7 in 2013. Visits to investigate non-compliance are often done in addition to planned risk-based visits. Handover and non-compliance investigation visits are usually done by prior appointment to ensure that necessary meetings with key individuals are possible.

Following the identification of patterns of low-level concern by assigned inspectors, in-depth inspections were carried out at two

13 https://www.gov.uk/government/publications/animals-in-science-regulation-unit-annual-report-2012

establishments by a team of inspectors. One or more principal inspectors accompanied the assigned inspector(s) over several days, affording the opportunity for a joint review of compliance with licences and risk factors. In each case, at the end of the visit wide-ranging advice was provided to the establishment licence holder. This included suggestions about the ways in which processes and procedures could be strengthened to meet their responsibilities and to build their capability to comply with their licence requirements. This type of comprehensive inspection was generally welcomed by establishment licence holders (ELHs) and their named persons. It was seen as supporting their continuous improvement and the development of a culture of care.

A pilot was also started in 2014 to provide a structured analysis of the strengths and weaknesses of a compliance programme at a formal annual meeting between the assigned inspector and the ELH. The meeting agenda is based on the risk factors identified for risk-based inspection (see Appendix 3 of ASRU's *2012 Annual Report*). Constructive feedback is given on each of the factors as appropriate, for example, the effectiveness of named persons and the Animal Welfare and Ethical Review Body, training and competence outcomes and proactive approaches to accommodation and care requirements. In addition, the discussion will review the numbers of procedures carried out, numbers of animals used, use of special species and severity of procedures to ensure that the ELH is fully cognisant of their responsibilities. This has been widely welcomed by ELHs as well as being a helpful review for inspectors. We plan to use this approach more widely in 2015.

Animals in Science Regulation Unit conference programme

The Business Reform programme has resulted in many more inspectors working from regional hubs or home-working. Therefore, there was a recognised need for more interaction between inspectors and with other ASRU staff to provide scientific continuing professional development (CPD) and training in administrative and operational matters, policy and the legislation. The ASRU conference programme plays an important role in promoting such consistency and better cohesion between all members of the Unit. These outcomes were delivered through six meetings held in 2014.

Two three-day conferences in May and November covered a broad range of topics and were targeted mainly at inspectors. In February a two-day meeting, also mainly for inspectors, considered non-compliance. In March a business-planning meeting, spanning two days and involving the entire Unit, was held and led to the formulation of our detailed Business Plan for the 2014–15 year. In September we held a special meeting for inspectors run by external experts on managing breeding programmes for genetically altered mice. The Minister attended and addressed this meeting. In December, a one-day meeting for all ASRU staff included a fascinating introduction to the Crick Institute in Central London. These meetings contribute to several ASRU Business Plan and Home Office objectives and are central to ASRU's aspirations to promote the 3Rs.

The Chief Inspector, Sue Houlton, regularly addresses stakeholder conferences to explain the work of the Inspectorate and answer questions.

Section 8: Inspection review and stakeholder survey

Introduction

In 2014 the Chief Inspector initiated a review of the inspections carried out by the Animals in Science Regulation Unit (ASRU). The reasons for carrying out the review were as follows:

- the need to examine periodically the efficiency and effectiveness of processes, particularly in times of austerity;
- the requirement in the regulator's code to engage those it regulates, citizens and others to offer views and contribute to the development of its policies and service standards;
- to review how recent changes to the Animals (Scientific Procedures) Act 1986 (ASPA) had been implemented;
- to review the recommendations made by the Animals in Science Committee in its report of its investigation of the exposé at Imperial College regarding the inspection process;
- commitments to improve the transparency of the inspection process and outcomes.

The objectives of the review were to examine whether it would be possible to make recommendations for:

- a more efficient and effective inspection system;
- greater consistency of approach across inspected institutions and a more informed inspectorate with a wider breadth of experience;
- better promotion of best scientific practice and the reduction of suffering to animals through more systematic application of the 3Rs;
- more public confidence in the appropriateness of the use of animals in research through greater transparency in the inspection process and the publication of outcome-based results of inspections in addition to their absolute numbers.

The review will report in June 2015. A key part of the review, completed early, was a review of the views of stakeholders.

Views of stakeholders

Any review of a regulatory system needs to gather the views of those regulated and other stakeholders. To achieve this, an internet-based survey of all stakeholders on their views of the inspections and the non-compliance process was set up using the website Smartsurvey. This report will discuss the results of the survey with respect to inspections only. The results with regard to non-compliance will be used for a review of those processes. The results of the inspection survey are published at Appendix 2.

An invitation to complete the survey was sent to all licence holder distribution lists with a request to forward the survey to anybody else within their organisation who had contact with ASRU inspectors. In addition, members of the Animals in Science Committee and of the four advisory groups to ASRU (Animal Protection, Animal Welfare, the Biosciences and the Home Office Laboratory Animal Liaison Groups) were invited to take part.

In total 675 people filled in the survey. This was a very encouraging response rate and many times the number of replies originally expected.

The survey consisted of 19 questions on the inspections and 8 questions on the non-compliance process (with standard responses of Strongly Agree/Tend to Agree/ Neither Agree nor Disagree/Tend to Disagree/ Strongly Disagree and Don't Know) and 2

questions asking for other comments on the inspections and non-compliance process in a free text format.

Only those who had taken part in a non-compliance investigation were allowed to answer questions in that area.

The survey was, by default, anonymous with the opportunity for a respondent to voluntarily add their name and email address to allow follow-up to their comments.

Results

Purpose of inspections

The first three questions addressed the issues of the purpose and value of inspections. The first question asked whether ASRU inspections were an essential component in ensuring effective implementation of the Act: 66 per cent of respondents strongly agreed with this proposition and over 92 per cent either strongly agreed or tended to agree with this statement against only 3 per cent who disagreed with this statement. Strong support was found in subsequent questions on whether the inspections provided public reassurance (78% positive compared with 6% negative) and whether the inspection regime helped to prevent suffering to animals (65% positive compared with 17% negative).

Effectiveness of inspections

The next series of questions asked about the effectiveness of the inspections. There was strong support for unannounced inspections (82% positive and 6% negative). The competence and breadth of experience of inspectors was highly valued as was their ability to promote the 3Rs.

This section did, however, throw up the first concern around the inspection regime. There were concerns around the consistency of standards as applied to different institutions: 42 per cent of respondents disagreed with the statement that “the standards applied by inspectors are consistent across different institutions” while only 19 per cent agreed with this statement.

Relationships and reporting of inspections

Advice provided by inspectors was very highly valued (85% positive compared with 4% negative) and the licensees felt strongly that the relationship between inspectors and those being inspected was independent enough to allow objective and impartial regulation. Note, however, that these numerical results effectively mask the smaller number of replies from animal protection and welfare groups, who were concerned that the relationship was too close.

There was very strong support for the provision of inspection reports after inspections and that these should contain some sort of statement of compliance and agreed list of actions (90% positive compared with 3% negative, 85% compared with 3% and 92% compared with 2% respectively).

Organisation and administration of inspections

The results to the question of whether the administrative burden of hosting inspections was onerous resulted in an almost completely neutral result with a symmetric distribution around the most common answer (Neither agree nor Disagree) and similar numbers for Tend to Agree/Disagree and for Strongly Agree/Disagree.

Despite the respondents’ views of the administrative burden, there was strong support for the statement that the value of advice given by the inspector outweighed that burden (56% compared with 9%).

The concerns about the administrative burden did not seem to extend to concerns about the frequency of inspections with 54 per cent agreeing that the frequency of inspection was proportionate against 6 per cent who did not agree.

Individual comments

There was the opportunity to make individual comments on any matter around inspections in the survey. The themes from these comments need to be separated into comments from licensees and comments from welfare and protection groups.

The licensees' comments were on three major issues.

- Consistency – there were concerns that there was too much variation in the standards and practices between inspectors and across institutions.
- Reporting – a report to institutions containing a statement of compliance and agreed actions would be most helpful.
- Advice/policing and attitude of inspectors – licensees found the advice given by inspectors to be very valuable (as the survey results confirmed) and were concerned that there might be a drift from an advice culture to more of a policing/tick box culture (as they described it). A number had perceived a move in this direction. Coupled with this was a low-level concern around the attitude of some inspectors and a feeling that they were at times overbearing and intransigent.

The welfare and protection group's comments were on the following themes.

- Independence – concerns that the current lead inspector arrangements were leading to 'regulatory capture' without effective or independent regulation of animal research.
- Resources – that ASRU was insufficiently resourced to carry out its role, and that the increases in the numbers of animals used in research only exacerbated the situation.
- Scientific insight – that the range and sophistication of biological and life science research was such that it was becoming impossible for a generalist inspector to understand all of the projects that they were supposed to be regulating.

The views of stakeholders gathered in this survey will form a key source of evidence for the inspection review and will strongly influence the recommendations of the review.

Section 9: Assessment: Harm-benefit analysis

The harm–benefit analysis (HBA) is required under the Animals (Scientific Procedures) Act 1986 (ASPA). It is the process of assessing the likely harms that the animals will experience and the likely benefits to be delivered and then determining whether the likely harms to animals are justified by the benefits likely to accrue.

The HBA is undertaken, on behalf of the Secretary of State, by Animals in Science Regulation Unit (ASRU) inspectors. Other sources of similar advice may include the Animals in Science Committee (ASC) and independent assessors. The outcome of the HBA forms the basis of the recommendation to the Secretary of State either to grant a project licence or to refuse an application.

In the *Guidance on the Operation of the Animals in Scientific Procedures Act 1986*[14] Appendix I, we set out what we assess in the HBA and why. Members of the ASRU Inspectorate have developed an Advice Note describing how we currently conduct the HBA during evaluation of a project licence application.

The purpose of the Advice Note is twofold.

- It provides greater transparency about the process for applicants explaining the information that is required in an application.
- It provides a foundation for the review of HBA, which is scheduled to be conducted by the ASC in 2015–16.

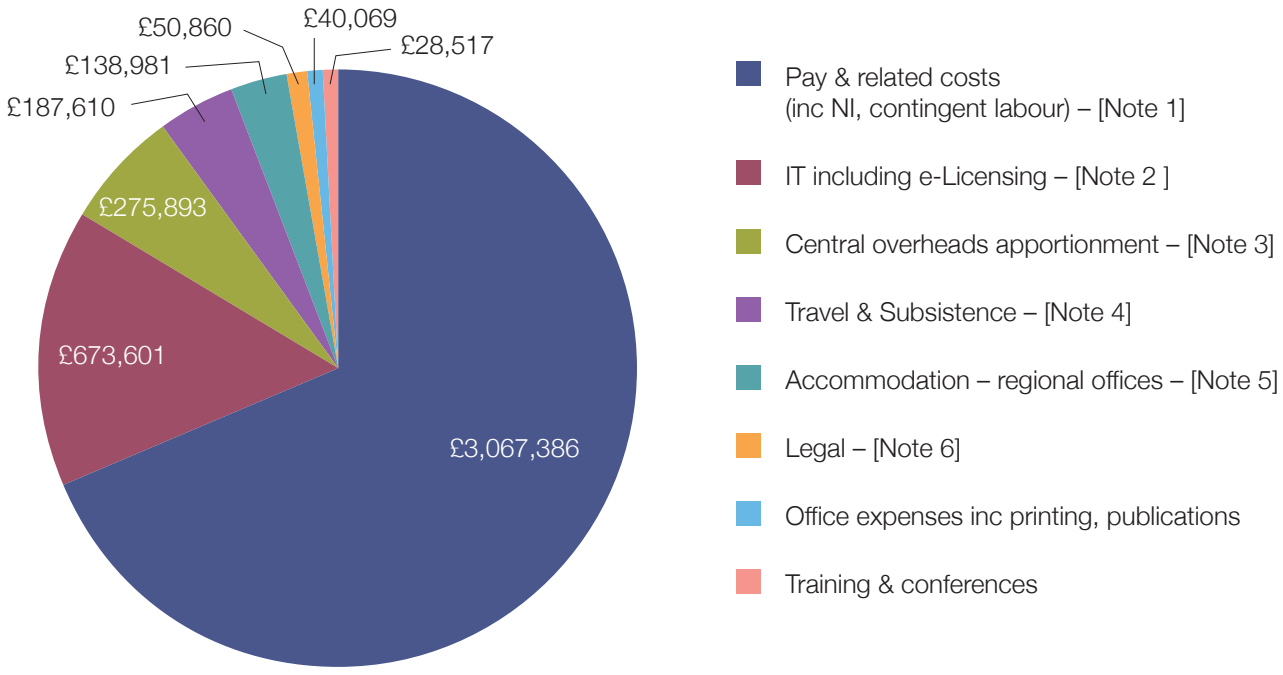
We aim to publish the Advice Note on our website in 2015.

14 https://www.gov.uk/government/publications/operation-of-aspa

Section 10: Financial report

ASRU's fee-funded expenditure during 2014/15 can be broken down as follows:

Income was received in 2014/15 but relates to licences held in 2013/14.



Notes:

1. Of the £3,067,386 of pay costs approximately £2.15 million was salary costs, £677,000 was NI/superannuation and £224,000 was for agency and locum staff to temporarily increase staff resource in the Licensing Team and the Inspectorate.

2. The IT costs include approximately £630,000 spent on the Animals in Scientific Procedures e-Licensing system (ASPeL). This includes development, testing, hosting and service support during 2014/15.

3. Central overheads are calculated on a headcount basis and cover core Home Office services such as IT delivery, HR and finance. It also covers an apportionment of the accommodation and facilities costs of the London Head Office at 2 Marsham Street.

4. The majority of the travel and subsistence costs are incurred by inspectors during their visits to establishments.

5. During 2014/15 ASRU paid rent, rates and service charges in the Shrewsbury and Swindon offices and a transfer to other parts of the Home Office or other government departments for the use of office space in Glasgow, Dundee and Bedford.

6. Includes legal costs of defending Judicial Reviews, and handling appeals against licensing decisions taken. ASRU claims costs against litigants wherever possible in order to mitigate the overall legal costs to be covered by fees.

A fee for each establishment is invoiced and received in arrears each year based on licences held during the financial year (1 April to 31 March). A fee is charged for each personal licence held during the year, even if held for only part of the year. In addition, a single establishment licence fee is charged each year.

The fee rates from 1 April 2014 to 31 March 2015 were:

- personal licence £226;
- establishment licence (if a user establishment) £252;
- establishment licence (if a breeder and/or supplier only) £1,130.

Fee income received in 2014/15 was £4,111,570. This related to licences held in 2013/14. Fee-funded expenditure during 2014/15 was £4,367,029. Therefore there was a £255,459 deficit that was covered by the Home Office.

In addition to the fee-funded costs shown above, £250,000 was paid from central Home Office funds to the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs). This is with reference to our service agreement with NC3Rs which includes:

- provision of advice on implementing the 3Rs in applications;
- liaison with the European Commission on behalf of government in relation to aspects of implementation of Directive 2010/63/EU;
- supporting delivery of government policy to promote the 3Rs through science-led initiatives;
- support with developing ASPA Guidance and Advice Notes; and
- acting as a source of information and expertise on the 3Rs to ASRU (particularly to inspectors carrying out assessments of project licence applications) and to licence applicants and establishment staff (including Named Information Officers).

From 1 April 2015 ASRU will be operating on a full cost recovery basis. Our fees had not been increased since 2002 so an increase is essential to ensure that we cover all of ASRU's costs.

The new fees applicable from April 2015 will be:

- personal licence £242;
- establishment licence (all establishments) £631.

These fees will be invoiced in arrears in April/May 2016. In accordance with Treasury guidance ASRU will be reviewing the fees annually to ensure that fee income continues to cover costs incurred. Nevertheless, we will also continue to seek ways in which to achieve increased efficiencies without loss of effectiveness as a regulator. In this way, we hope to minimise any fee increases in future years.

Appendix 1: Non-compliance

This section provides summaries of all 63 cases of non-compliance that were concluded in 2014.

During 2013 we categorised cases of non-compliance according to their severity (these categories are explained in Appendix 1 of the 2013 ASRU Annual Report). Given the complexity of cases and the context in which they occur, we determined that such categorisation was broadly unhelpful in terms of deciding appropriate sanctions or in explaining the rationale for these decisions. In 2014 we therefore ceased assigning categories to cases and instead each case is considered on its own merits with regard to the severity of the non-compliance and hence the appropriate sanctions.

Section 1 of this Appendix describes those cases of non-compliance that are grouped under the three themes identified in Section 6:

1. Procedures conducted without licence authority
2. The un-authorised re-use of animals
3. A failure to provide food and/or water

The examples under these themes should be used to understand better how to avoid these types of non-compliance and support establishments in their frameworks for delivering the requirements under ASPA.

The other 19 more miscellaneous cases of non-compliance are described in Section 2 of this Appendix.

Section 1: Cases of non-compliance grouped under three common themes

Incidents of procedures that were conducted without a licence authority

1. A mouse was re-sutured twice by the holder of a personal licence following surgery when it was discovered that the mouse was over-grooming the surgical wound and had removed all its stitches. The project licence only authorised re-suturing on one occasion. The incident was self-reported to the Inspector. The personal licence holder claimed that reclosing the wound was done in the best interest of the animal but failed to realise the additional trauma the animal was put through by additional anaesthesia and surgery. The personal licensee was sent a written reprimand which was also recorded on their file.

2. Frog eggs were injected with genes and subsequently allowed to develop into tadpoles. The intention was to kill the tadpoles before they reached the age when independent feeding begins. However, 5 tadpoles and 10 froglets were kept alive beyond this point without the necessary project licence authority. The personal licence holder had overlooked the fact that once the tadpoles began to independently feed, the genetic manipulation that he had made would mean the tadpoles and later froglets would require project licence authority. An amendment to the project licence was being drafted to permit this work to continue but the personal licensee was unaware that the amendment had not been granted and failed to check. He therefore began the work before the project licence authorities were in place. The personal licensee was sent a written reprimand which was also recorded on their file.

3. Four groups of mice, totalling 35 mice, were placed on a protocol to act as non-tumour-bearing control mice. However, there was no licence authority for carrying our procedures without tumour implantation as it was not listed as an optional step in the protocol investigating tumour/bone interactions. No welfare issues were identified and the remaining non-tumour-bearing control mice were moved to an alternative protocol under the authority of the same project licence. The procedures were competently performed and no adverse effects were recorded in both the tumour and non-tumour-bearing mice. The project licence holder failed to adequately check the conditions of his licence. Had he requested an amendment to his licence to allow the use of non-tumour-bearing animals on his studies this would have been recommended for grant. The project licence holder, who was also the holder of a personal licence, was sent a written reprimand which was also recorded on their file.

4. Two rats that had undergone regulated procedures to assess a tendon repair process developed swellings in their shoulder area approximately 6–7 weeks post-surgical intervention. The project licence authority only allowed for the animals to be kept alive for a maximum of 21 days post surgery. Furthermore, a total of 88 rats were identified as having been kept past the 21-day post-operative time point. The incident was discovered as a potential breach after the project licence holder notified the inspector of the unexpected swelling at the shoulder of the two rats and, upon reviewing the authority in the protocol, it was discovered that the end point was defined at '[humane] killing at time points up to 21 days post operatively'. The authority of the licence had thus been exceeded. The project licence holder claimed that the non-compliance occurred as a result of a mismatch in wording between the project plan and the protocol which led them to believe that they could take the time points further than day 21 if scientifically indicated. The project licence holder was sent a written reprimand and required to undergo retraining in modules one and five. Three holders of personal licences were sent a written reprimand and required to undergo retraining in module one. The establishment licence holder was sent a written reprimand. All written reprimands were also recorded on the relevant individuals' files.

5. A group of 18 mice were subjected to general anaesthesia by a personal licence holder in order to measure the size of tumours that had been implanted superficially. Although the personal licence allowed administration of general anaesthesia to mice, the project licence did not authorise general anaesthesia for the purpose of measuring tumour size, and the personal licensee failed to check the authority permitted in the project licence. The procedure was competently performed. A letter of reprimand was sent to the personal licence holder which was also recorded on their file.

6. Two different establishments each requested revocation of a personal licence. In each case, failures in their internal administrative systems meant that that they did not notify the individuals concerned who each continued to perform minor regulated procedures on the assumption each still had a personal licence. Though not holding a licence, the work was competently performed in each case. Each establishment licence holder was sent a written reprimand as also was each non-licensee, and each reprimand was also recorded on the relevant file.

7. Following the expiry of a project licence, due to a failure in its internal administrative systems, an establishment continued to hold mice that were to be used in regulated procedures without any replacement licence in place. Upon discovery, and as an alternative to euthanasia, the Named Veterinary Surgeon agreed to take temporary care of the animals until a replacement licence could be granted. The personal licence holder was sent a written reprimand which was also recorded on their file.

8. A personal licence holder undertook a terminal procedure on one guinea-pig in the mistaken belief that project licence authority was in place when it had expired one day earlier. The error was due to an internal administrative oversight, and the procedure was competently performed. All staff involved were required to provide assurance that systems

would be put in place to prevent recurrence and the establishment licence holder, project licence holder and personal licence holder were each sent a written reprimand which were also recorded on the relevant files.

9. Three mice were inoculated intranasally by a personal licence holder. Two animals died immediately after inoculation and the third animal recovered normally. Intranasal administration of substances was not authorised in the personal licence, although the technique was authorised in the project licence. The personal licence holder was sent a written reprimand which was also recorded on their file.

10. Sixteen zebrafish underwent fin-clipping procedures for genotyping. The procedure was authorised by the project licence but the person performing the procedures did not hold a personal licence. A licence had been applied for at the time the procedures were conducted and the individual was mistakenly advised that it had been granted. The procedures were otherwise competently performed. Internal systems were revised for improved communication and the non-licensee was sent a written reprimand which was also recorded on their file when their personal licence was issued.

11. A personal licence holder was undergoing training in Schedule 1 killing of anaesthetised mice by cervical dislocation, under the supervision of an experienced personal licence holder. Twenty mice had been ordered for this purpose and 15 of these were killed as planned. However, part way through the training session it was decided to practise withdrawal of blood by cardiac puncture in the final five anaesthetised mice. This method is not an authorised Schedule 1 killing method and consequently project licence authority was necessary. No such authority was in place. The procedure was competently performed and, had the authority been applied for, it would have been granted. The establishment licence holder instituted a formal review of the management systems in place, the outcome of which resulted in the setting-up of more robust systems to prevent the occurrence of unauthorised procedures. All those involved in the incident were also required to undergo module one retraining. The establishment licence holder and the personal licence holder were each sent a written reprimand which was also recorded on their files.

12. A short-term project licence had been issued to allow the maintenance of genetically altered zebrafish lines. This was required because a five-year project licence authorising further regulated procedures on these fish had expired. The short-term project licence subsequently expired but the licence holder continued to maintain the fish without any authority in place. The incident arose due to the failure, by both the project licence holder and the establishment administrator, to ensure that the renewal application was submitted in a timely fashion. There were no animal welfare issues for the fish. The project licence holder and the establishment licence holder were each sent a written reprimand which was also recorded on their files.

13. A personal licence holder culled a 700 g guinea pig by cervical dislocation followed by a blow to the cranium. The weight limit for this type of killing under Schedule 1 is 500 g and the procedure was conducted without the necessary licence authority. The personal licence holder claimed to be unaware of the change in legislation in Schedule 1 killing methods. In addition, it was found that out-of-date documentation was kept in the animal unit with regard to Schedule 1 killing methods. The procedure was otherwise competently and humanely performed and the licence holder was sent a written reprimand which was also recorded on their file.

14. During an inspector's visit to an establishment, it was discovered that 27 mice had been administered streptomycin by oral gavage by a personal licence holder when the project licence authority only permitted the administration of antibiotics via the drinking water. The personal licensee had been instructed by the project licence holder to use oral gavage as the route of administration. The project licence holder and the personal licence holder were each sent a written reprimand which was also recorded on their files.

15. A project licence holder significantly exceeded the estimated number of genetically altered zebrafish authorised to be used for regulated procedures under his project licence. It was estimated that over 80,000 fish had been used without authority. The licence holder was unaware of this and failed to take action because record keeping at the time did not allow monitoring of a running total of animals used in regulated procedures. A number of changes were subsequently instituted by the establishment to address the failings and to further reduce the number of animals used in regulated procedures. Written reprimands were issued to the project and establishment licence holders including a requirement for the establishment licence holder to provide details of the additional measures that had since been put in place to ensure that the establishment effectively monitors and prevents the performance of further unauthorised procedures. The reprimands were also recorded on their files.

16. A personal licence holder supervised the training of the procedures necessary to inject frogs for a personal licence holder and two non-licensees at a time when none of these three individuals had personal licence authority to undertake this procedure. The training was undertaken in preparation for study of the frogs by a research group. There were no adverse welfare consequences and written reprimands were issued to the two non-licensees, and the personal licence holder who undertook the training and procedures. The personal licence holder who supervised the training was also sent a letter of written reprimand and was additionally required to undertake module one retraining within three months of the date of receipt of the written reprimand. The relevant project licence holder was issued with a compliance notice requiring them to undertake remedial action to fully check licences of those in their team to avoid any recurrence. A written reprimand was also issued to the establishment licence holder. The letters were recorded on the respective files of all six individuals.

17. On four separate occasions, up to 30 ml of blood was withdrawn from a pig for education and training purposes without the necessary project licence authority. The incidence occurred due to a misunderstanding of the project licence authorities. The procedures were competently performed and there were no welfare issues. A written reprimand was sent to the project licence holder which was also recorded on their file.

18. A personal licence holder performed a cardiac puncture on a mouse under terminal anaesthesia without having the necessary personal licence authority. The procedure was performed competently and there were no welfare issues as a result. The personal licence holder was issued with a written reprimand which was also recorded on their file.

19. A personal licensee removed carotid bodies from 25 terminally anaesthetised rats without the necessary project licence authority. The procedure had been permitted under a recently expired licence but was not authorised in the new replacement licence. The personal licensee volunteered to undertake retraining of module one and was sent a written reprimand. The project licence holder was also sent a written reprimand and both reprimands were also recorded on their files.

20. A project licence holder significantly exceeded the estimated number of fish that were authorised in their licence and did not notify the Home Office of this significant excess. The project licence authorised the use of 69,770 fish, yet a total of 96,012 fish had been used. Additionally, the record keeping of fish used was not linked to the establishment's central recording systems. Had it been so linked the excess would have been flagged up sooner. The project licence holder was sent a written reprimand which was also recorded on their file.

21. Three personal licence holders killed, between them, 177 mice by rapid thermal fixation (focused microwave irradiation). The procedures were conducted competently but without the appropriate personal licence authority. The three personal licensees and the establishment licence holder were all sent written reprimands which were also recorded on their files. The establishment licence holder

was also required to submit a report of the steps that were immediately taken, and a detailed plan of those measures being put in place to strengthen the establishment's in-house controls to prevent the performance of unauthorised procedures in the future.

22. A group of 15 mice comprising both genetically altered and wild type animals were injected intra-peritoneally with tamoxifen on 5 consecutive days and this led to the deaths and culling of 10 of the animals. However, the project licence stated that no deaths or other adverse effect were expected from this technique. Post-mortem examination of two animals provided evidence of inflammation and haemorrhage consistent with damage due to injection and/or infection. The personal licence holder was issued with a written reprimand and required to undertake retraining in modules one, two and three. The incident was also recorded on their file.

23. Tracking collars that had been fitted to two large wild mammals were found to have caused unexpected injuries to the necks of the animals. These were significantly more severe than provided for by the severity limits and the refinement control measures specified in the project licence protocol. The project licence holder also failed to ensure that the Home Office was notified promptly of the breach of the severity limit to these animals. A written reprimand was sent to the project licence holder which was also recorded on their file.

24. Anaesthetised animals were left unattended for short periods of time. In addition, procedures that required sterile techniques were performed in rooms scheduled for non-sterile procedures. The project licence holder also failed to adhere to the controls specified in the licence by allowing terminally anaesthetised animals to be kept alive for up to 12 hours when the licence permitted only 10 hours. The project licence holder was sent a written reprimand and was required to undergo retraining in modules one, four and five. The incident was also recorded on their file.

25. The maximum period that two mice undergoing procedures could be kept alive post surgery was exceeded by two personal licensees. This was because of a delay in the arrival of equipment so that it was necessary to kill the mice before a full data set could be obtained from them. The project licence holder also disregarded advice that the two mice could not be kept alive unless the project licence was amended. There were no adverse welfare consequences and the project licence holder and the two personal licence holders were each issued with written reprimands which were also recorded on their files.

26. A rat underwent cranial implant surgery. The following day it was found by animal care staff having removed the sutures; the wound had opened. Due to concern for the welfare of the animal, a personal licensee anaesthetised and re-sutured the wound without the appropriate project licence authority in place to do so. The procedure was competently performed and the animal made a full recovery. The establishment mandated retraining for the personal licence holder, which otherwise would have been required by the Home Office. The personal licence holder was sent a written reprimand which was also recorded on their file.

27. There was a failure to humanely kill two rats after the completion of their regulated procedures. The incident occurred due to the animals being moved to a new cage. This resulted in a new cage label being produced by the computerised system which re-set the 'start' date of the experiment. Animal care staff were thus unable to know that the animals had lived beyond the 12-month endpoint authorised in the project licence. The animals were discovered when they suffered general poor health that required humane killing. The incident was self-reported. A written reprimand was sent to the project licence holder which was also recorded on their file.

28. A project licence holder significantly exceeded the estimation of numbers of mice that were to be used on a mild severity breeding and maintenance protocol for

genetically altered mice. A total of 3,140 mice had been bred over 16 months when the licence authorised the use of only 1,800 mice over 5 years. Had the licence holder requested an amendment to breed this greater number of mice, it would have been granted. The project licence holder was sent a written reprimand which was also recorded on their file.

29. A skin biopsy was performed under local anaesthesia on five pigs by a personal licence holder who had successfully completed module four training. However, the individual had failed to submit their licence to the Home Office for amendment prior to performing the regulated procedures. The techniques were competently performed under the supervision of the Named Veterinary Surgeon. There was a detailed investigation which led to optimising practice to prevent similar incidents from occurring. Written reprimands were sent to both the establishment licence holder and the personal licence holder, and both were also recorded on their files.

30. A mouse was re-sutured twice following surgery when the project licence only authorised re-suturing by a personal licence holder on one occasion. Further closure of the same wound, if deemed necessary, should have been undertaken by a veterinarian and only if they considered it appropriate to do so. The personal licence holder was issued with a written reprimand which was also recorded on their file.

2. Un-authorised re-use of animals

1. Three male mice were subjected to unauthorised re-use on a breeding and maintenance protocol after undergoing irradiation using UV light to induce melanoma. The project licence holder believed that the movement of animals between protocols was permitted. He sought advice from the NVS and NACWO who considered this to be re-use. There appeared to have been a genuine misunderstanding about what constituted re-use of animals. The project licence holder (who also held the personal licence) accepted that they had made an error and offered to undergo modular training. They were sent a sent a written reprimand and voluntarily undertook module one retraining. The incident was also recorded on their file.

2. Animals underwent oral dosing with a test substance to investigate the mechanisms associated with glucose and insulin tolerance, and later underwent a glucose tolerance test involving the administration of glucose, followed by the withdrawal of several blood samples. These procedures were followed by the administration of a second test substance, and repetition of the glucose tolerance test, in the absence of the necessary project licence authority to re-use those animals. The re-use was apparently done inadvertently due to a lack of understanding of authorities. The project licence holder was sent a written reprimand which was also recorded on their file.

3. A personal licence holder used a non-Schedule 1 method of killing on a mouse which had previously been imaged under anaesthesia. However, the method of killing used was not authorised on the project licence on the imaging protocol. There were no welfare concerns and the technique was competently performed. The personal licensee was sent a written reprimand which was also recorded on their file.

4. A mouse that had previously been operated on was prepared for the same surgery (anaesthetised, shaved and an incision made) before it was discovered that the animal had already undergone surgery. The mouse should have been killed seven days after the previous surgery but had been kept alive. This was due to inadequate cage labelling compounded by the fact that animals that had been surgically prepared and naïve animals were kept in the same cage. The personal licence holder was sent a written reprimand which was also recorded on their file. They were also required to improve their housing and labelling practices.

3. Failure to provide food and water

1. Two mice out of a pre-study batch of 42 singly housed animals held on a reverse light cycle were not given food after having been placed in clean cages. The error was not detected during the health and welfare checks carried out later that same day, nor during routine checks on the following two (weekend) days. Upon discovery on the fourth day, approximately 72 hours after the error occurred, the animals were found hunched and lethargic, with signs of hunger distress. The two mice were immediately provided with supplementary heat and food and closely monitored by the NACWO. Within one hour both mice were showing positive signs of recovery and were eating. There was a major internal investigation, which found that the incident occurred as a result of human error. Staff had apparently concentrated on observing each mouse in the room rather than checking the provision of food and water. All three staff involved received retraining, and disciplinary measures were taken against them. The establishment licence holder regarded the non-compliance with considerable gravity, and made significant and relevant changes to their standard operating procedures. Had these changes not been voluntarily implemented, a Compliance Notice would have been served requiring them. The establishment licence holder was sent a written reprimand which was also recorded on their file.

2. A mouse and six recently born pups were left without food. The incident was not discovered until three days later when it was noted that all the pups had disappeared from the cage. It is surmised that the absence of food drove the dam to cannibalise her pups. The establishment took prompt and appropriate actions to prevent recurrence as well as disciplinary action against the staff involved. Management also instigated a longer-term in-depth review of management practices, consulting expertise from outside the establishment. All animal care staff involved were retrained and a written reprimand was sent to the establishment licence holder which was also recorded on their file.

3. On two separate occasions staff failed to give mice and rats food when sub-dividing groups of animals in stock cages. The design of the cages meant that food and water were not immediately visible at the cage front. Furthermore, the cages were not being pulled out from the rack to be checked. In one case the error was not detected for two days. In the other case, a mouse cannibalised its cage mate. Following these incidents, new procedures were put in place requiring more rigorous daily checks of food and water. In addition, an animal technician now routinely undertakes a second daily round of checks. The training, competency and supervision of all staff involved has been re-examined by the project licence holder, and the establishment had undertaken a detailed internal review and provided a full response to the Home Office. A written reprimand was sent to the establishment licence holder which was also recorded on their file.

4. Following the arrival of 31 female mice at an establishment, the animals were grouped and placed in cages by animal technicians. Four days after their arrival, six mice in one of the cages were found dead due to a failure to provide the animals with food though they had been provided with water. The normal procedure was to provide food and water for all animals on arrival and to then put the cages on the rack. The technicians involved could not recall why this one particular cage was missed and only provided with water. The establishment reviewed and significantly improved its internal practices and a number of staff underwent refresher training. The NACWO was suspended following this incident and subsequently left the company. The establishment licence holder was sent a written reprimand which was also recorded on their file.

5. A total of 64 mice were being assessed for their willingness to de-husk untreated cereal seed so they could be selected for use in a trial. On three consecutive days they had food removed overnight, then had four hours access to a measured volume of trial seeds before having approximately four hours with their normal diet. Late on the second day, two

mice were found dead, another was culled, and a further one died the next day. Post-mortem indicated starvation. The project licence authorised a maximum weight loss of 15 per cent. The remaining mice were weighed at the end of the 3-day trial and 8 out of 60 were found to have weight loss in excess of 15 per cent. The establishment licence holder was sent a written reprimand and his licence was varied requiring him to submit a detailed action plan on how it was intended to ensure effective liaison and communication channels between duty holders and named persons responsible for the welfare of protected animals kept at the establishment. The project licence holder amended the licence to transfer it to a new holder. Otherwise, the project licence holder would have been required to undergo formal retraining in all relevant modules. The individual was also advised that if they were to apply for a licence at a future date, the Secretary of State would take the circumstances of this incident into consideration in arriving at a decision whether to grant such an application. They were also informed that if a decision was taken to grant a licence, they would be required to first undertake all the appropriate modular training.

6. While conducting an inspection at an establishment, the inspector was advised by the NACWO that a personal licence holder left four genetically modified mouse pups in a cage after having removed the mother who was their source of food and fluid. As a result the pups died. The personal licence holder was alleged to have lied about the incident in order to cover up the error. The establishment licence holder ordered an internal enquiry which found the allegations were proved. The licensee resigned from his post prior to internal disciplinary measures and his licence was revoked at the request of the establishment. Had it not been revoked in this manner, it is likely it would have been revoked by the Secretary of State.

7. Two mice were found by an animal technician to be dead in their cages without adequate food and water. The animal technician did not follow the establishment's standard procedure for investigating and recording deaths and was suspended by the institution pending investigation. The establishment licence holder was sent a letter of written reprimand which was also recorded on their file. In addition, due to the nature of the incident, a number of additional conditions were added to the establishment licence to prevent recurrence and to assure the Home Office that standards required under ASPA would be upheld. The establishment licence holder was also required to submit detailed information of the systems to be put in place to ensure compliance with all the establishment licence conditions.

8. Eleven recently weaned transgenic mice, not under study, were discovered dead in a cage. A post-mortem examination undertaken on the mice by the Named Veterinary Surgeon revealed that the animals had empty stomachs and intestines. The person responsible for checking the cages, who was also the personal licence holder, failed to check for food. There was a detailed local investigation by the establishment which resulted in disciplinary action being taken against the personal licence holder. Both the personal licence holder and the establishment licence holder were issued with written reprimands which were also recorded on their files.

9. A mouse was found in a cage with access to food but no water. It was very dehydrated and was promptly humanely killed. The cage had no label, the day book records were incomplete, and all attempts to identify the animal and the cause of the error failed. A detailed investigation included meetings with key staff in order to optimise practices and prevent a similar error occurring. The most likely cause of the error was failure to deal with all the animals in a cage at a time of euthanasia. The particular mouse may have remained hidden among the enrichment items in the cage and was missed. The establishment licence holder was sent a written reprimand which was also recorded on their file.

Section 2: Other cases of non-compliance, not included in the three common themes

1. A project licence holder failed to ensure overall implementation of the programme of work under the licence authority, failed to adhere to the authorised number of animals permitted, and failed to notify the Home Office when a number of animals died unexpectedly. The individual had delegated much of the work to a personal licensee in the research group and spent significant periods away from the establishment where the work was being undertaken. The project licence holder was sent a written reprimand which was also recorded on their file, was required to repeat module five training, and was also required to amend the project licence to describe clear, unambiguous endpoints. The personal licensee voluntarily revoked their licence.

2. The failure to kill five mice before the onset of adverse effects resulted in the deaths of four of the mice and the need to euthanase the remaining mouse. Local systems failed to pick up the error. The establishment licence holder, project licence holder and personal licence holder were each sent a written reprimand, each of which was also recorded on their files.

3. A personal licence holder at an establishment failed to correctly complete animal cage labels following authorised regulated procedures on eight rats. When one of the animals was found dead six days later, the care staff did not realise that the unexpected death was due to the regulated procedures and therefore did not take actions that might have prevented further death and illness in the remaining animals. As a result a further rat died and four more animals became ill and had to be humanely killed over the next two days. The establishment licence holder reviewed and revised internal systems to prevent similar incidents from occurring. In mitigation, the personal licence holder claimed to have been suffering from increased stress which had resulted in them overlooking the cage labels. The individual was sent a written reprimand which was also recorded on their file.

4. An establishment was holding 1,500 stock fish prior to procedure. In view of rising ammonia and nitrite concentrations in the water, an attempt was made to alleviate this by undertaking an overnight partial water change. The following day, approximately 750 fish had died. Rescue procedures were attempted but approximately 450 more fish had died the following day and the rest were humanely killed by a Schedule 1 method. It was concluded that there had been a failure to provide adequate care and accommodation appropriate to the species, exacerbated by a failure to maintain appropriate staff levels at all times to ensure the well-being of the protected animals. The establishment licence holder instituted a number of changes at the establishment to prevent recurrence and developed a standard operating procedure to be followed on the observation of fish deaths. This included notification and involvement of the Named Veterinary Surgeon. The establishment licence holder was sent a written reprimand, which was also recorded on their file, and required to ensure that all licence holders at the establishment attended modular retraining courses suitable to the species with which they worked.

5. The severity limit on a project licence protocol was exceeded. While performing an experiment on 11 mice involving abdominal surgery, 3 of the mice had to be humanely killed during the surgery because of problems encountered as a result of inadequate planning. The remaining eight mice were returned to the animal unit after surgery without proper arrangements being in place for monitoring the animals in line with the controls stated in the project licence. Four of the mice died overnight and three needed to be humanely killed the following day. The remaining mouse, though apparently healthy, was humanely killed to terminate the experiment. Following these events, the project licence holder amended the licence to refine the model and prevent future recurrence. The establishment licence holder was sent a written reprimand, which was also recorded on their file, and required to submit detailed information on the systems and procedures to be put in place to ensure

compliance with establishment licence standard conditions. The project licence holder, who also held the personal licence, was sent a written reprimand, which was also recorded on their file, and required to complete retraining in modules one, four and five.

6. Six mice died unexpectedly following irradiation and administration of haematopoetic cells as part of a gene therapy and stem cell transplantation protocol. A further 13 mice were humanely killed before the end of the experiment due to unexpected adverse effects. None of this was reported to the Home Office until approximately five months later on the advice of the Named Veterinary Surgeon. The project licence holder was not aware that he was required to report such an incident of this nature to the Home Office, and was sent a written reprimand which was also recorded on their file.

7. While conducting regulated procedures, the holder of a personal licence left three anaesthetised mice unattended. The licensee had been called away for more than 25 minutes to deal with a human patient. Arrangements should have been made for such an eventuality and appropriate care provided for the mice. Although there were no adverse welfare consequences, this was in breach of his licence authority and the personal licence holder was sent a written reprimand which was also recorded on their file.

8. During an unannounced inspection at an establishment, an inspector discovered that eight groups of eight mice prepared for subcutaneous implantation of tumour cells were showing signs of having been irregularly shaved. Furthermore, approximately one-third of these animals had developed shaving injuries with associated inflammation. It was discovered that the personal licensee had experienced difficulties with the shaver but continued with the procedure without taking appropriate action to mitigate the injuries being caused. The personal licence holder was sent a written reprimand which was also recorded on their file.

9. The shaving of mice was conducted to poor standards, and depilation cream also not removed adequately, resulting in skin lesions. The regulated procedures were conducted by a personal licence holder. The project licence holder was sent a letter of written reprimand and required to undergo retraining in modules one and five. The personal licence holder was sent a letter of written reprimand and required to undergo retraining in modules one and two.

10. At an establishment, 350 stock fish were being held in a holding system prior to regulated procedures. Fish deaths started to escalate over the Christmas period resulting in the death of 101 fish. The animal technician responsible for the fish opened the outlet valve to discharge water from the system, thereby exposing the water pump and compromising the fish, which led to more deaths. The animal technician had not received induction training on the new aquarium, and neither the NACWO nor the NVS had followed the agreed establishment procedure regarding actions to be taken on fish deaths. The establishment licence holder was sent a written reprimand, which was also recorded on their file, and required to submit detailed information on the processes to be put in place to ensure future compliance with establishment licence conditions.

11. During an unannounced inspection at an establishment, several cages were discovered to be inadequately labelled. The protocol and project licence numbers were missing from the cage labels. In addition, the anaesthetic regime being used during a partial nephrectomy procedure by a project licence holder was considered not to be the most refined method available and was likely to affect the quality of the science, nor was there an anaesthetic machine available. The defects on the labels were immediately rectified and, notwithstanding the other issues, there were no adverse animal welfare issues. The project licence holder and personal licence holder were each sent a written reprimand which were also recorded on their files.

12. Two tumour-bearing nude mice were found dead a day after ten of the animals had been injected by a personal licensee with a test drug dissolved in neat ethanol. The volume of ethanol used exceeded a lethal dose for intra-

peritoneal injection into mice. No pilot study had been undertaken prior to embarking on the full experimental trial. Upon discovery, immediate action was taken to humanely kill seven of the eight remaining mice while the remaining mouse was placed on a heated pad, given extra bedding and made a full recovery. Both the personal licence holder and the project licence holder were each sent written reprimands which were also recorded on their files.

13. In a room housing rabbits at an establishment, there was a crack in the concrete ceiling of the room that extended approximately three-quarters of the width of the room. A water leak occurred through the ceiling so that water accumulated onto the top of, and underneath, six of the rabbit cages. The establishment licence holder was issued with a Compliance Notice which required the removal of the rabbits from the room and for the facility to be brought up to the standards required by the Code of Practice within three months. The establishment licence holder was also required to repair and refurbish the whole animal facility, and was notified that failure to complete these works could lead to revocation of the establishment licence.

14. Two birds died when a total of 36 birds were being blood sampled. The birds were removed from their floor pen and placed in plastic crates where it was thought they died from overheating and/or suffocation. The establishment instigated a detailed investigation to optimise local practices and prevent similar incidents from occurring. The establishment licence holder also mandated retraining for the personal licence holder involved. Written reprimands were sent to the personal licence holder and the project licence holder which were also recorded on their files. The establishment licence holder was issued with a Compliance Notice requiring that suitable animal holding equipment should be provided, standard operating practices should be put in place whenever birds were to be handled and transported, and better standardised training for staff should be introduced. All this was to be put in place within three months of issue of the compliance notice.

15. The Home Office received allegations from an animal protection organisation that work carried out at an establishment and published in 2007 had resulted in unacceptable suffering of mice. The allegations were investigated and found to be proved. A former project licence holder had exceeded the humane endpoints authorised in the project licence and had failed to report this to the Home Office in accordance with standard condition 18 of the project licence. The former project licence holder claimed to be unaware of the requirement to notify the Home Office of the breach of her licence conditions and committed to changing future practice to avoid any such recurrence. The former project licence holder was sent a written reprimand which was also recorded on their file in case for consideration in the event of a future application for a licence.

16. A group of five mice died suddenly after being placed in water that was too hot (40ºC) whilst undergoing a procedure by a personal licensee. The animals were quickly removed; however, all but one died. The sole surviving mouse was promptly humanely killed by Schedule 1 method after examination by the NACWO. The personal licensee responsible for placing the animals in the water was undergoing training in the technique and was being supervised by a second personal licensee at the time. Consequently the supervising licensee was considered to be the licensee responsible for the animals. The supervising personal licensee had previously raised concerns with the project licence holder about the difficulties in supervising inexperienced licensees whilst having to perform the procedure themselves. Several management initiatives to prevent reoccurrence were subsequently introduced by the project licence holder and establishment. A written reprimand was sent to the personal licence holder and the project licence holder.

17. A group of 40 rats were dosed by 3 personal licence holders with an anti-cancer drug over 5 days. This was contrary to the protocol authorised which permitted only a single dose. Adverse and unexpected clinical signs developed earlier than expected in 10

of the rats which were humanely killed. Post-mortem findings showed that the animals had experienced a greater inflammatory response and pulmonary atrophy than would normally be expected. Changes to procedures were put in place by the establishment within a week of reporting the incident. Written reprimands were sent to the three personal licence holders, the project licence holder and the establishment licence holder and each was also recorded on the individual files.

18. Following a procedure at an establishment, mice were placed by the personal licence holder in an enclosed heated box to recover. The box was new equipment and the thermostat had not been checked. The mice were left in the box for about 30 minutes. One mouse was later found dead in its cage. The personal licence holder failed to report the overheating of the mice, and the death of one mouse, to the project licence holder in a timely manner. Subsequently, the establishment submitted the personal licence holder's licence to the Home Office to be revoked. A written reprimand was sent to the former licence holder which was also recorded on their file. Had the licence not been revoked, the personal licence holder would have been required to undergo module one retraining.

19. Regulated procedures on a group of mice resulted in severe suffering in one mouse which had to be humanely killed on the advice of the NVS. Skin lesions also appeared in several other mice and there was a failure to ensure that the mice were provided with post-operative analgesia. Two weeks post surgery the surgical wounds were still visible on the mice and the skin lesions over the wounds appeared scabby on a number of animals. One mouse had a severe skin infection overlying the area of the wound which was being treated. The establishment licence holder submitted the licence of the personal licence holder involved in the incident to the Home Office for revocation. Accordingly a written reprimand was sent to the former licence holder which was also recorded on their file. Had the licence not been returned for revocation, the individual would have been required to undergo module four retraining.

Appendix 2: Inspectorate review: Stakeholder survey results

A total of 675 people filled in the stakeholder survey of the inspectorate Review. The detailed breakdown of the people who answered the survey is given below.

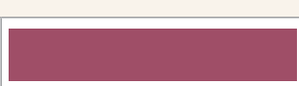
What role do you have around animals in science? (more than one box may be ticked).

		Response Per cent	Response Total
1	PEL holder	3.90%	26
2	PPL holder	37.18%	248
3	PIL holder	68.22%	455
4	HO Liaison	10.94%	73
5	NVS Named Veterinary Surgeon	5.10%	34
6	NACWO Named Animal Care and Welfare Officer	17.99%	120
7	NTCO Named Training and Competency Officer	10.19%	68
8	NIO Named Information Officer	9.45%	63
9	NPRC Named Person Responsible for Compliance	0.60%	4
10	Member of the Animal Protection Stakeholder Group	0.45%	3
11	Member of the Animal Welfare Stakeholder Group	0.90%	6
12	Member of the Biosciences Group	1.80%	12
13	Member of HOLALG	1.35%	9
14	Member of local AWERB committee	23.99%	160
15	Member of ASC	0.60%	4
16	Other (please specify):	5.10%	34
		answered	667
		skipped	8

2. Purpose of inspections

The inspections are an essential component in ensuring the effective implementation of the Animals (Scientific Procedures) Act.			Response Per cent	Response Total
1	Strongly Agree		65.97%	440
2	Tend to Agree		26.54%	177
3	Neither Agree nor Disagree		4.50%	30
4	Tend to Disagree		2.10%	14
5	Strongly Disagree		0.90%	6
6	Don't Know		0.00%	0
			answered	667
			skipped	8

3. Purpose of inspections (2)

The inspections are effective in providing public reassurance in the regulatory system around animal experimentation.			Response Per cent	Response Total
1	Strongly Agree		38.46%	255
2	Tend to Agree		39.82%	264
3	Neither Agree nor Disagree		12.67%	84
4	Tend to Disagree		5.43%	36
5	Strongly Disagree		1.51%	10
6	Don't Know		2.11%	14
			answered	663
			skipped	12

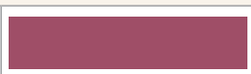
4. Purpose of inspections (3)

The inspection regime helps to prevent unnecessary suffering of animals used in science.			Response Per cent	Response Total
1	Strongly Agree		27.26%	181
2	Tend to Agree		38.25%	254
3	Neither Agree nor Disagree		17.77%	118
4	Tend to Disagree		12.05%	80
5	Strongly Disagree		4.37%	29
6	Don't Know		0.30%	2
			answered	664
			skipped	11

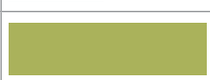
5. Effectiveness of inspections

Unannounced inspections are an important part of the inspection regime.			Response Per cent	Response Total
1	Strongly Agree		49.62%	330
2	Tend to Agree		32.48%	216
3	Neither Agree nor Disagree		12.18%	81
4	Tend to Disagree		4.66%	31
5	Strongly Disagree		0.90%	6
6	Don't Know		0.15%	1
			answered	665
			skipped	10

6. Effectiveness of inspections (2)

The inspectors are sufficiently competent to carry out their roles.			Response Per cent	Response Total
1	Strongly Agree		31.78%	211
2	Tend to Agree		38.25%	254
3	Neither Agree nor Disagree		12.05%	80
4	Tend to Disagree		5.42%	36
5	Strongly Disagree		2.86%	19
6	Don't Know		9.64%	64
			answered	664
			skipped	11

7. Effectiveness of inspections (3)

The standards applied by inspectors are consistent across different institutions.			Response Per cent	Response Total
1	Strongly Agree		4.20%	28
2	Tend to Agree		15.62%	104
3	Neither Agree nor Disagree		12.61%	84
4	Tend to Disagree		26.43%	176
5	Strongly Disagree		15.62%	104
6	Don't Know		25.53%	170
			answered	666
			skipped	9

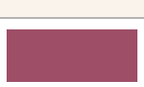
8. Effectiveness of inspections (4)

The inspectors have sufficient breadth of experience of welfare issues across different species to carry out their roles.

			Response Per cent	Response Total
1	Strongly Agree		18.14%	121
2	Tend to Agree		36.73%	245
3	Neither Agree nor Disagree		16.19%	108
4	Tend to Disagree		8.70%	58
5	Strongly Disagree		2.25%	15
6	Don't Know		17.99%	120
			answered	667
			skipped	8

9. Effectiveness of inspections (5)

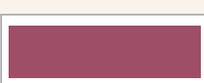
The inspectors have sufficient breadth of experience of the background science and research methods to assess project licence applications.

			Response Per cent	Response Total
1	Strongly Agree		17.44%	116
2	Tend to Agree		37.74%	251
3	Neither Agree or Disagree		13.98%	93
4	Tend to Disagree		10.38%	69
5	Strongly Disagree		6.02%	40
6	Don't Know		14.44%	96
			answered	665
			skipped	10

10. Effectiveness of inspections (6)

3Rs – The inspectors promote best practice with regard to replacement (promotion of alternatives).			Response Per cent	Response Total
1	Strongly Agree		21.62%	144
2	Tend to Agree		41.14%	274
3	Neither Agree nor Disagree		20.42%	136
4	Tend to Disagree		7.36%	49
5	Strongly Disagree		1.95%	13
6	Don't Know		7.51%	50
			answered	666
			skipped	9

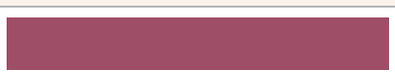
11. Effectiveness of inspections (7)

3Rs – The inspectors promote best practice with regard to reduction and refinement.			Response Per cent	Response Total
1	Strongly Agree		25.64%	171
2	Tend to Agree		46.33%	309
3	Neither Agree nor Disagree		15.59%	104
4	Tend to Disagree		4.35%	29
5	Strongly Disagree		1.65%	11
6	Don't Know		6.45%	43
			answered	667
			skipped	8

12. Relationships and reporting of inspections

The relationship between inspectors and the establishments they inspect is independent enough to allow objective and impartial regulation.			Response Per cent	Response Total
1	Strongly Agree		41.72%	277
2	Tend to Agree		37.95%	252
3	Neither Agree nor Disagree		7.68%	51
4	Tend to Disagree		3.46%	23
5	Strongly Disagree		0.75%	5
6	Don't Know		8.43%	56
			answered	664
			skipped	11

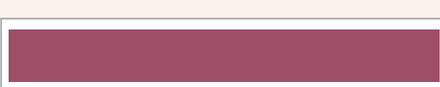
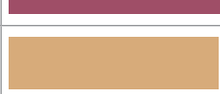
13. Relationships and reporting of inspections (2)

Advice provided by an inspector to the institution is a vital part of an effective regulation regime.			Response Per cent	Response Total
1	Strongly Agree		50.97%	340
2	Tend to Agree		34.63%	231
3	Neither Agree nor Disagree		8.10%	54
4	Tend to Disagree		3.15%	21
5	Strongly Disagree		1.20%	8
6	Don't Know		1.95%	13
			answered	667
			skipped	8

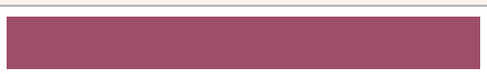
14. Relationships and reporting of inspections (3)

A report on an inspection should be provided to the inspected institution after inspections.			Response Per cent	Response Total
1	Strongly Agree		69.17%	460
2	Tend to Agree		20.90%	139
3	Neither Agree nor Disagree		6.62%	44
4	Tend to Disagree		2.56%	17
5	Strongly Disagree		0.60%	4
6	Don't Know		0.15%	1
			answered	665
			skipped	10

15. Relationships and reporting of inspections (4)

The report should include a statement of compliance with the Act (that the inspector found/did not find any non compliance).			Response Per cent	Response Total
1	Strongly Agree		57.51%	383
2	Tend to Agree		27.93%	186
3	Neither Agree nor Disagree		10.21%	68
4	Tend to Disagree		2.70%	18
5	Strongly Disagree		0.75%	5
6	Don't Know		0.90%	6
			answered	666
			skipped	9

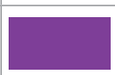
16. Relationships and reporting of inspections (5)

The report should include recommendations and agreed actions.				
			Response Percent	Response Total
1	Strongly Agree		63.21%	421
2	Tend to Agree		28.98%	193
3	Neither Agree nor Disagree		5.26%	35
4	Tend to Disagree		1.80%	12
5	Strongly Disagree		0.15%	1
6	Don't Know		0.60%	4
			answered	666
			skipped	9

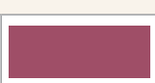
17. Organisation and administration of inspections

The administrative burden of hosting inspections is onerous.				
			Response Per cent	Response Total
1	Strongly Agree		8.58%	57
2	Tend to Agree		16.87%	112
3	Neither Agree nor Disagree		24.70%	164
4	Tend to Disagree		19.13%	127
5	Strongly Disagree		8.73%	58
6	Don't Know		21.99%	146
			answered	664
			skipped	11

18. Organisation and administration of inspections (2)

The value of the advice given by inspectors outweighs the administrative burden of hosting the inspections.			Response Per cent	Response Total
1	Strongly Agree		23.76%	158
2	Tend to Agree		32.78%	218
3	Neither Agree nor Disagree		20.90%	139
4	Tend to Disagree		6.62%	44
5	Strongly Disagree		2.41%	16
6	Don't Know		13.53%	90
			answered	665
			skipped	10

19. Organisation and administration of inspections (3)

The frequency of the inspections is proportionate to perceived risk.			Response Per cent	Response Total
1	Strongly Agree		18.80%	125
2	Tend to Agree		34.59%	230
3	Neither Agree nor Disagree		20.60%	137
4	Tend to Disagree		4.21%	28
5	Strongly Disagree		2.26%	15
6	Don't Know		19.55%	130
			answered	665
			skipped	10

Appendix 3: Tables and figures

Table A1: Licence applications and amendments 2012–2014

	Total				Per inspector FTE			
	2012	2013	2014	Change	2012	2013	2014	Change
PILs granted	2,639	2,770	2,949	6%	149.2	176.4	173.5	-2%
PILs amended	2,858	2,025	814	-60%	161.6	129.0	47.9	-63%
PILs in force at year-end	14,875	16,112	*		841.0	1,026.2	*	
PELs granted	3	3	6	100%	-	-	-	-
PELs amended	247	247	243	-2%	14.0	15.7	14.3	-9%
PELs in force at year-end	176	174	178	2%	10.0	11.1	10.5	-6%
PPLs granted	626	604	474	-22%	35.4	38.5	27.9	-28%
PPLs amended	1,156	1,157	964	-17%	65.4	73.7	56.7	-23%
PPLs in force at year-end	2,698	2,672	2,693	1%	152.5	170.2	158.4	-7%
Inspectors FTE	17.7	15.7	17.0	8%				

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

* Data not available for this year.

Figure A1: Inspectorate staff, 2006-2014

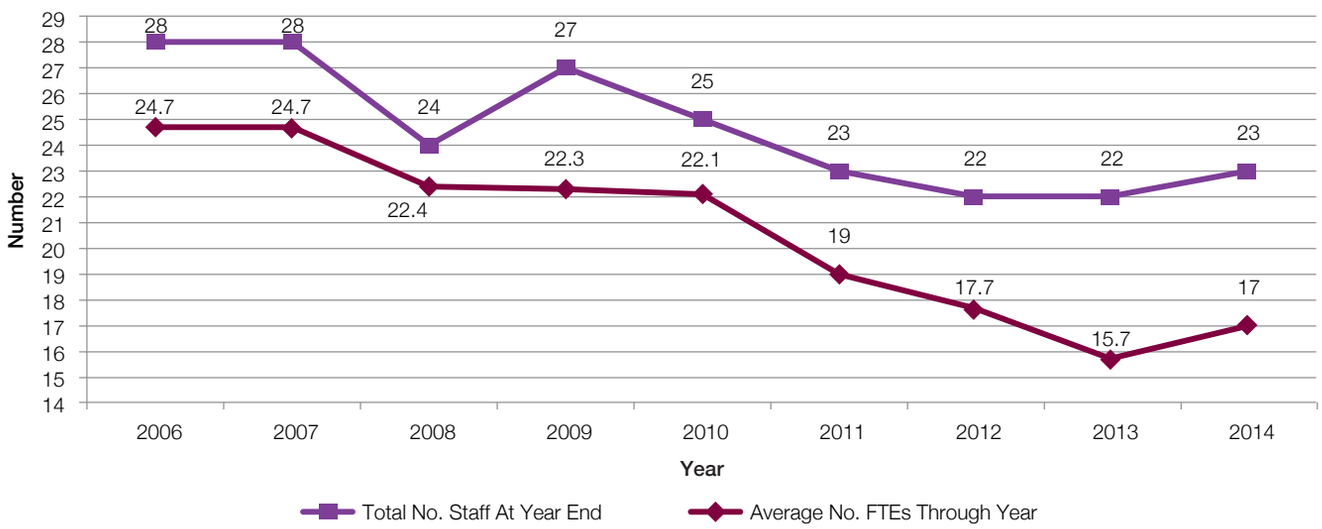


Figure A2: Project licences granted, 2006-2014

Figure A3: Project licence application processing, 2006-2014

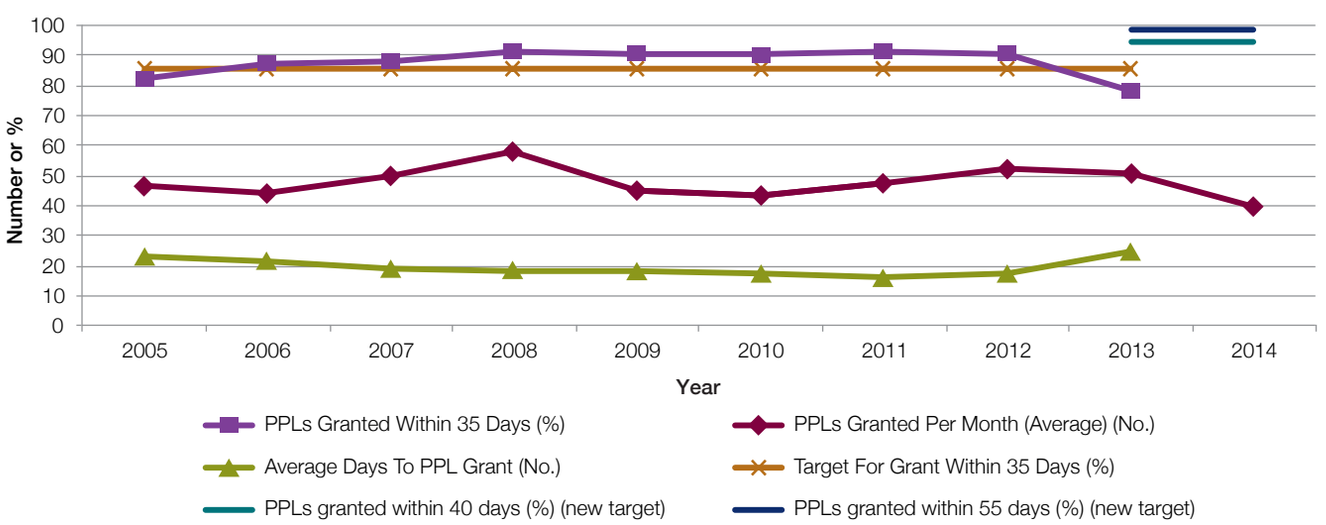


Figure A4: Total inspections, 2006-2014

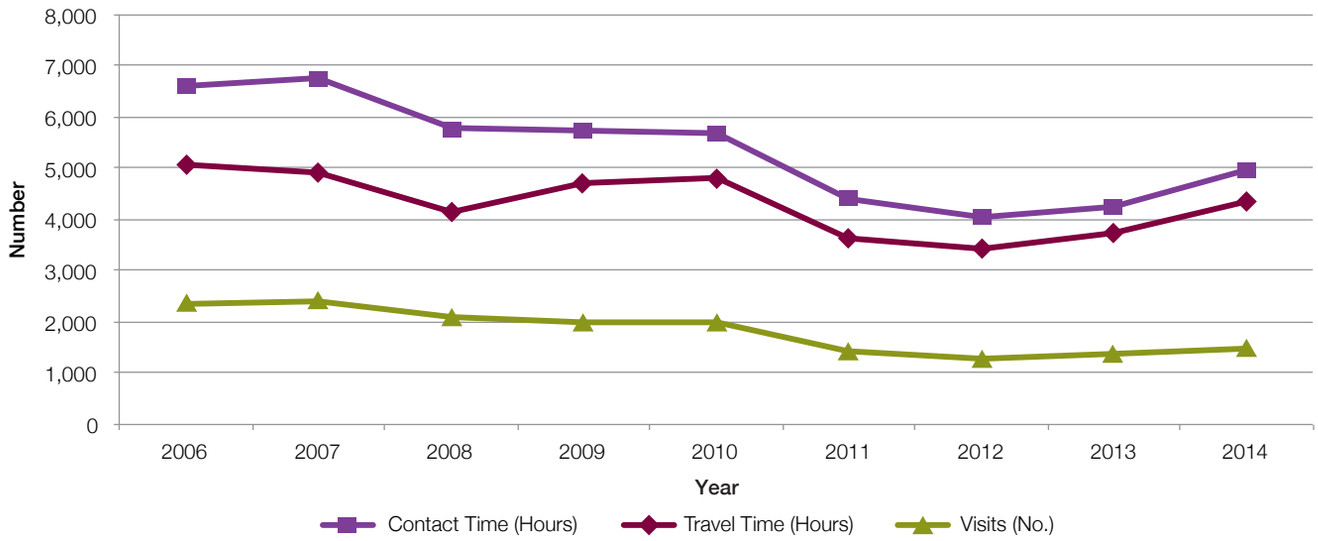
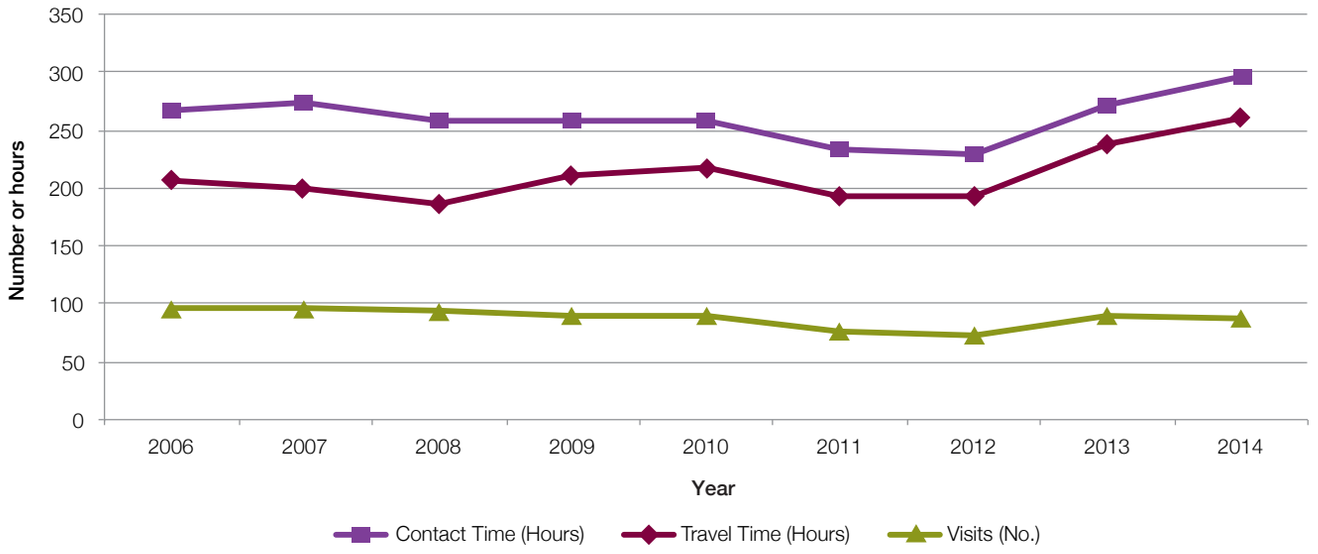


Figure A5: Inspections per FTE, 2006-2014



FTE = full-time equivalent

OGL

ISBN: 978-1-78246-858-5
Published by the Animals in Science Regulation Unit,
Home Office