Home Office

Animals in Science Regulation Unit
Annual Report 2017

© Crown copyright 2018

This publication is licensed under the terms of the Open Government Licence v3.0 except where otherwise stated. To view this licence, visit http://nationalarchives.gov.uk/doc/open-government-licence/version/3/ or write to the Information Policy Team, The National Archives, Kew, London TW9 4DU, or email: psi@nationalarchives.gsi.gov.uk.

Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

ISBN: 978-1-78655-757-5

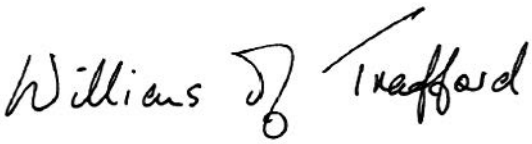
Contents

Ministerial foreword

The use of animals in scientific research helps us to ensure that medicines are safe to use and to find treatments for cancer and other diseases, among a range of other benefits. This work must continue to be authorised within a rigorous regulatory system. This ensures that animal research and testing is carried out only where no practicable alternative exists and under controls that keep suffering to an absolute minimum. Central to this UK commitment is our continuing full application of the 3Rs (the replacement, reduction and refinement of the use of animals in science).

The UK's life science strategy is based on a vision of how the UK may exploit its current strengths to support strong economic growth in this sector. As a regulator, the Home Office has an important role in balancing the need to enable innovation and research in the life sciences whilst maintaining public trust through a strong framework that has the necessary checks and balances. The Animals (Scientific Procedures) Act 1986 provides this underpin of assurance, thus promoting high standards of animal welfare and also opportunities to deliver high quality science of international standing.

As we plan a future of the UK outside of the European Union we mark the start of a new beginning. The transposition of European Directive 2010/63/EU has given us a strong platform for the delivery of the use of animals in science in the UK. In the near term we seek to provide seamless continuation of the rigorous regulatory framework. We look forward to working together with the EU to deliver the best outcomes for science and animal welfare as we build a new comprehensive partnership that sees us stay the closest of friends and allies.



Baroness Williams of Trafford

Foreword

The Animals in Science Regulation Unit (ASRU) has continued to focus efforts on high quality, effective and efficient regulation. This is framed in our three overarching aims of becoming a 'modern, consistent and responsive regulator'.

At the heart of regulation is our e-licensing system (ASPeL). At the beginning of 2014 we first rolled out an e-licensing system that placed our paper-based licences into an electronic format. This has been particularly effective in delivering more rapid personal licence authorisations. Now, in 2017, we have embarked upon the next phase of the e-licensing project that will improve functionality for users and be located on the Government website. The project is being delivered through a process that places the system user – establishments, inspectors and licensing officers – at the centre of the design. Our plans are for extensive consultation during the build; a process of agile delivery. Through agile delivery we will pilot the system with users as we build it. The new system will deliver:

- increased efficiencies for the processing of licences;
- a robust assessment process and application of the 3Rs (replacement, reduction and refinement of the use of animals in science); and
- the protection of confidential information.

The system will undergo an iterative roll-out for full delivery in 2019.

Whilst the new ASPeL system is being developed we have listened to licence applicants for whom the process has been frustrating. Although we have met legislative targets (99.9% and 99.8% on personal and project licences respectively) this does not reflect the lead-in period for project licences. After listening to applicants' concerns we responded and developed an annotated licence form. The annotated form sets out our expectations for a 'complete and correct' application and clearly presents how to implement the 3Rs and produce a non-technical summary that supports openness and transparency.

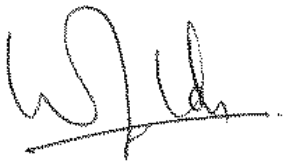
Developing and maintaining a culture of compliance is a key part of the effective delivery of the Animals (Scientific Procedures) Act 1986 (ASPA). During 2016 we undertook a review of our compliance operations and policy. Our aims were to have a new policy that:

- embedded the principles of good regulation;
- continued to improve the efficiency and effectiveness of enforcement processes; and
- worked with the research community to improve the openness and transparency of ASRU's operations and decision making.

We used the lessons learned from complex cases and focus groups of licence holders to support the production of a new compliance policy. In 2017 we published our new compliance policy that we believe will better achieve our aims through positive support and effective enforcement.

During 2017 there were significant changes to the Government estate as departmental buildings in central London were closed in a drive for better value for money. In late 2017 ASRU relocated part of its operation to government offices in Croydon, along with many other parts of the Home Office family. At the end of 2017, the Operations Team (Licensing, IT and Finance) and the Compliance Team were entirely based in Croydon. The Policy Team has remained in 2 Marsham Street. The inspectors are mainly home working so as to be located near establishments for inspection. We also maintain one-hub site and a few desks within touch-down offices around the UK. The fact that many of our stakeholders were unaware that a move had even taken place is testament to the hard work of the ASRU team that made it so smooth.

Our planning for a seamless exit from the European Union continues apace. The aim is to maintain substantially similar regulations with the EU, thus preserving a level of parity that will support the UK to retain competitiveness in global markets. ASPA already enjoys that parity through the relatively recent transposition that we undertook in 2012. Through 2016 and 2017 we have continued with our legislative plans that uphold the integrity of the Act from March 2019 onwards and assure licensees of the continuation of the framework currently in place. Thus, we will not make any substantive changes to ASPA, other than those required to move from working under an EU Directive to working under UK law only.



Will Reynolds
Head of the Animals in Science Regulation Unit

Section 1: What the Animals in Science Regulation Unit does

"We regulate the use of animals in scientific research for the benefit of people, animals and the environment through the provision of impartial licensing procedures and evidence-based advice, and by encouraging the development and use of the 3Rs (replacement, reduction and refinement)."

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

The Unit is led by the ASRU Leadership Team (ALT), comprising the Head of Unit, Chief Inspector, Head of Policy, Head of Operations and Strategy and three principal inspectors.

The Policy and Administration Group

The Policy and Administration Group is based at the Home Office in Westminster, Croydon and Swindon. The group comprises three teams:

- policy;
- compliance; and
- business support.

These teams fulfil the following functions.

Policy and legislation

The Policy Team provides direct support to Ministers to develop and deliver policy objectives. The team is responsible for the development of new policies and guidance supporting the delivery of ASPA. In 2017 the team's work included:

- responding to the EU Commission's requests regarding the transposition of the EU Directive 2010/63/EU;
- advising on matters related to the UK's exit from the EU;
- supporting the requirements of the Judicial Review process;
- the development of central government and operational policy;
- the production of various Advice Notes; and
- the publication of statistics.

The Policy Team also responds to Parliamentary Questions, Freedom of Information requests and all correspondence (Ministerial and official).

At the end of 2017 the Policy Team comprised three policy advisers who report to the Head of Policy.

Compliance

The ASRU Compliance Team consists of a Principal Inspector, an Operational Inspector, a Senior Complex Cases Manager and administrative support. The Compliance Team supports inspectors during the investigation of potential non-compliance with the aim of promoting a robust, efficient and consistent national approach to cases. The team advises on the appropriate investigation of cases and the proportionate application of sanctions.

The team reports directly to the Head of Policy.

Business support

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

- providing general support to inspectors and management;
- gathering and analysing management information;
- providing a secretariat function;
- organising internal and external recruitment;
- organising ASRU training, events and conferences, including external stakeholder events;
- conducting risk management, including health and safety;
- collecting and administering the annual Return of Procedures exercise;
- managing procurement and general finance; and
- collecting licence fees.

During 2017 the Business Support Team comprised one Senior Manager supported by one Executive Officer.

The Inspectorate

Inspectors act as professional advisers to the Secretary of State. They play a key role in the implementation of the controls of scientific procedures on animals covered by ASPA. Their work is split broadly into thirds between their commitments to:

- inspection;
- licence assessment; and
- providing operational and strategic advice.

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

At the end of 2017 the Inspectorate comprised 22 individuals (17.6 full-time equivalents [FTE]), which is no significant change from 2016. Following the retirement of the previous Head of Unit in 2016, the role of the Chief Inspector was combined with the Head of Unit role and is not included in these figures.

The Licensing Team

The purpose of the Licensing Team is to act on behalf of the Secretary of State in operating the licensing system. Its core functions within this remit are:

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

At the end of 2017 the team comprised the Head of Licensing (reporting to the Head of Operations), two licensing managers and four licensing officers.

Section 2: The regulatory framework

The UK regulatory framework is underpinned by the Animals (Scientific Procedures) Act 1986 (ASPA), which was amended by transposition of Directive 2010/63/EU in January 2013. The standards associated with the Act and guidance on its administration and enforcement are provided in the *Code of Practice for the housing and care of animals bred and supplied or used for scientific purposes* (the Code of Practice)[1] and the *Guidance on the Operation of the Animals (Scientific Procedures) Act 1986* (the Guidance)[2] respectively. Both documents are publicly available and support establishments in both understanding ASPA and being compliant.

When the transposed Directive was embedded into ASPA the Animals in Science Regulation Unit (ASRU) made a commitment to publish further Advice Notes as required. The Advice Notes complement the Guidance and provide further explanation where required. To ensure that they meet this aim the Advice Notes have been drafted with 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.

Judicial Reviews

In 2016 Cruelty Free International (CFI) brought a case for Judicial Review against the Home Secretary, in relation to the licensing of safety testing for prescription-only medicinal products containing botulinum toxin (BT), commonly known as 'botox'.

CFI's principal allegations included the following.

- An allegation that the Home Office is not compliant with various duties to ensure that licensed establishments were not testing BT for 'cosmetic' (as opposed to medicinal) use.
- A repeated demand that the Home Office should seek an additional declaration from licence holders, recognising that the licence 'does not permit testing where the end use of the toxin is vanity'.
- An allegation that where ASRU licenses testing on animals, and it is 'known' that some of the product will be used for what CFI call 'purely cosmetic purposes', there is a significant breach of the cosmetics testing ban.

The case was heard in 2017 and the judge dismissed all of the claims made by CFI. In summing up the judge said:

"I have been unable to discern any Public Law error in the way the Secretary of State and her specialist team of Inspectors and Civil Servants were delivering and carrying out their regulatory duties."

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

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

The court's ruling endorses the Home Office's long-standing approach to licensing the safety testing of medicines containing BT. Such testing is undertaken to ensure that patients with debilitating conditions have continued access to the medicines that they need, in line with the regulatory requirements of medicines' regulators. Those requirements are that safety testing is conducted to ensure that the toxicity levels of each batch of medicine are safe enough to give it to patients.

ASRU does not license animal testing for cosmetics, and the court concluded that the Secretary of State takes reasonable steps to ensure that batches of BT tested on animals are only used for medicinal purposes. ASRU only issues licences after carrying out a full harm/benefit analysis and seeks to ensure that animal suffering is kept to a minimum.

Publications

1. Compliance policy

A new document on ASRU's compliance policy was published on ASRU's website.[3] This document explains how ASRU:

- identifies and investigates potential incidents of non-compliance; and
- decides on appropriate and proportionate measures and sanctions aimed to minimise the risk of recurrence.

This document is primarily aimed at those who work within the life science research community under ASPA, but will also be of interest to those wishing to know more about how ASRU regulates.

2. Updated annotated project licence application form

ASRU has committed to providing advice to improve the standards of project licence applications. In the short term ASRU has a 'one high quality' draft initiative, which has culminated in the publication of the annotated project licence application form. In the medium term ASRU is making plans to re-design the project licence form:

- to make the process more efficient; and
- to gather information as effectively as possible for project evaluation, with the same levels of scrutiny and rigour.

Last year ASRU published the annotated project licence application form to assist all those applying for a licence. Following feedback from several groups of stakeholders this has been revised and the updated version is available on ASRU's website.[4] The revised form explains what is required in each box of the form. Failure to adhere to this guidance could significantly increase the time taken to grant a licence and could result in a rejection of the application.

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 2017 senior representatives from ASRU, as the UK competent authority, attended a number of meetings in Brussels.

There were two National Contact Point meetings in 2017, both of which ASRU attended as UK representatives. Updates were provided by EU Member States on their transposition of the Directive.

1. EU Exit

The UK voted to leave the EU in June 2016. Subsequently, the Government began a process of compiling an evidence base to plan for the future in the best way. The Department for Exiting the European Union quickly ramped up engagement with government departments in preparation for the EU exit, including the Home Office and ASRU.

3 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/670174/ASRU_Compliance_Policy_December_Final.pdf

4 https://www.gov.uk/government/publications/animal-testing-and-research-improve-your-project-licence-application

Unlike many government regulators ASRU does not operate for the express purpose of achieving a product to be delivered. ASRU's 'product' is to provide the legal and ethical framework, under ASPA, to make decisions as to whether to allow tests that other regulators, such as the Medicines and Healthcare products Regulatory Agency (MHRA), require.

Therefore, the regulation of animals in science impacts on a number of other regulatory systems. For example:

- medicines cannot be brought to market without testing on animals;
- new chemicals need to be tested on animals to provide assurances on public safety; and
- a great deal of medical and biological research relies on the use of animals.

ASRU is therefore continuing to engage with other relevant government departments and agencies to contribute full support in gathering evidence and information to plan for EU exit.

The EU Directive 2010/63/EU, on the protection of animals used for scientific purposes, was transposed in detail into UK law through an amendment to ASPA in 2012. This means that the legislation required for UK animals in science regulation to operate following EU exit is already in place. Other than minor changes to references to the Directive that are embedded in ASPA, no further legislative action is needed for animals in science regulation around EU exit. There will be no change to the high standards of animal welfare required or to the required standards of housing and care as set out in the Code of Practice.

Working with the Animals in Science Committee

The Animals in Science Committee (ASC) is an independent, non-executive, non-departmental public body convened under 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 ASPA. 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 provides advice on specific categories of project licences, including those seeking authority for:

- the use of wild-caught non-human primates;
- the use of cats, dogs, equidae or non-human primates in severe procedures;
- the use of endangered species;
- projects with major animal welfare or ethical implications;
- projects of any kind raising novel or contentious issues, or giving rise to serious societal concerns;
- projects involving the use of admixed embryos as advised in the *Guidance on the use of Human Material in Animals*;[5] and
- projects that may invoke any of the 'safeguard clauses' in the Directive 2010/63/EU with respect to the purpose of primate use, proposals for the use of a great ape, or proposals to cause long-lasting pain, suffering or distress that cannot be ameliorated.

During 2017 the ASC reviewed four applications for which it provided the Home Office with advice.

5 https://www.gov.uk/government/publications/guidance-on-the-use-of-human-material-in-animals

ASPA requires that the ASC engages in the promotion of good practice, through knowledge sharing, between Animal Welfare and Ethical Review Boards (AWERBs). This is a challenging remit due to the geographical spread of establishments, breadth of scientific interest of establishments and different ways of operating. To help address this, the ASC has set up a network of AWERB hubs to facilitate knowledge transfer. ASRU welcomed this initiative as a means of improving communication of good practice.

Under the terms of ASPA the ASC provides independent scrutiny and advice to the Home Office on matters concerned with the regulation of animals in science, which includes ASRU's Advice Notes.

Section 3: Licensing

The framework

The UK's three-tier licensing system provides a framework for authorising research using animals. It ensures that animal research and testing is only undertaken:

- where no practicable alternatives exist; and
- under rigorous controls where suffering must be kept to a minimum.

The Animals in Science Regulation Unit (ASRU) administers the licensing function under the Animals (Scientific Procedures) Act 1986 (ASPA). The licensing framework comprises the following requirements:

- 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.

In 2017 ASRU licensed and regulated 160 establishments. These are predominantly in the pharmaceutical, biotechnology and contract research industries, and in academia (universities and research institutes). At the end of 2017 there were 2,585 active project licences and 16,109 personal licensees.

Performance

Establishment licences: During 2017, one new establishment application was received and three new establishment licences were granted (one from a 2016 application).

Project licences: During 2017 a total of 568 licences were granted. Of these 567 complete and correct applications were granted within the 40 days target (99.8%). The remaining licence was granted during the statutory 15-day extension to 55 days. This is a 8% increase in project licences granted compared with 2016; and an improvement in processing where previously 99.1% were granted in 40 days.

Personal licences: During 2017, 2,985 personal licences were granted. This is a 5.8% decrease on 2016. The team successfully processed 99.9% of licences within the internal 20-day target.

Licensing Team stakeholder engagement

The engagement of licence holders with ASRU's Licensing Team continues to play an important role. Establishments have welcomed visits from members of staff from the Licensing Team through their single point of contact (SPoC) roles and this has assisted in forging stronger bonds and greater understanding of the work undertaken on both sides. The SPoCs have continued to visit their associated establishments and have a target of three visits a year.

The Home Office Liaison and Training Information Forum (HOLTIF) has been an effective platform for establishments and licensing staff to meet on a quarterly basis to discuss mutually relevant topics to enhance an improved relationship. Since the introduction of the SPoC scheme, both sides are striving to deliver effective outcomes for licence applicants.

Animals Scientific Procedures e-Licensing

Animals Scientific Procedures e-Licensing (ASPeL) continued to handle the processing of all licence types and has almost entirely replaced the previous paper-based system. ASPeL improved ASRU's internal efficiency and this facilitated the continuity of business during the team's relocation to Croydon.

ASPeL users have regularly provided feedback on the usability and capability of the system, and this allowed ASRU to define the limitations of the existing ASPeL product. This has been particularly demonstrated in processing establishment licence amendments, project licence applications and generating reports for customers.

In 2017 ASRU completed a tender process for the development of a new system to replace ASPeL. The contract was awarded to Marvell Consulting and work on the replacement e-licensing product began in December. Marvell is focused on user experience and stakeholder engagement, and these will form an integral part of the product's development.

Section 4: Promoting the principles of replacement, reduction and refinement of animals in research

Work with the National Centre for the 3Rs

The National Centre for the Replacement, Reduction and Refinement of Animals in Research (NC3Rs) is the UK national organisation for the discovery and application of new technologies and approaches to replace, refine and reduce the use of animals for scientific purposes. The NC3Rs is an important stakeholder organisation for the Animals in Science Regulation Unit (ASRU) to engage with.

NC3Rs colleagues have continued to contribute to ASRU in-house training events to establish strong relationships with inspectors and to support the need for the 3Rs being fully considered in project licence applications. The ongoing link between NC3Rs and ASRU ensures that the Inspectorate is well placed to disseminate 3Rs knowledge to the science community.

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 Act 2000 (FOI) requests and correspondence from the general public on any issue related to the use of animals in science. PQs and correspondence are an important way in which the Government communicates current policy and thinking.

Correspondence

During 2017 ASRU handled 165 pieces of correspondence. This compromised 18 FOI requests, 23 PQs, 66 items of Ministerial correspondence and 58 other pieces of correspondence.

Correspondents were concerned with a breadth of issues. Among these the main topics were:

- transparency and openness in animal research;
- the use of dogs in research; and
- the use of non-animal alternatives in research.

Parliamentary Questions

PQs represent a means by which Ministers are held to account and provide an opportunity for scrutiny of operations. Since the answers become official Ministerial statements, it is of paramount importance to ensure their accuracy. Answers must also be provided within a very tight timeline, which is often less than 24 hours. ASRU provided advice to Ministers on 23 PQs in 2017.

Topics for PQs included what steps the Government is taking:

- to reduce the use of live animals in experiments; and
- to ensure that there is a reduction in the importation of monkeys for research.

Freedom of Information requests

ASRU received 18 FOI requests on a variety of topics during 2017. In line with the Government's policy on openness and transparency ASRU's approach is to act with a presumption to openness to assist public understanding. Nevertheless, it is essential ASRU protects all information that is legally exempt from disclosure, such as personal details and information given to the Home Office in confidence. Such protected information includes intellectual property/ commercially sensitive information and that which could identify people or places.

Meetings with stakeholders

In support of ASRU objectives, the Unit's Leadership Team held regular meetings with a wide range of stakeholders during the year. Maintaining these relationships is vital to help:

- inform ASRU policy decisions;
- understand the expectations and perspectives of ASRU's stakeholders; and
- receive valuable feedback.

The meetings covered matters related to:

- the revision of the project licence application form;
- updates on operational matters; and
- policy issues.

The meetings were with representatives from:

- industry, academia, government research institutes, medical research charities and research funders;
- animal welfare and alternatives – the replacement, reduction and refinement of the use of animals in research (the 3Rs) – groups;
- animal protection groups; and
- the Animals (Scientific Procedures) Act 1986 (ASPA) Named Persons and others performing functions under the Act.

ASRU met periodically with other government departments and agencies including:

- the Department for Business, Energy, and Industrial Strategy (BEIS);
- the Department for Environment, Food and Rural Affairs (Defra);
- the Department of Health (DH);
- the Medical Research Council (MRC);
- the Medicines and Healthcare Products Regulatory Authority (MHRA);
- the National Centre for the 3Rs;
- Public Health England (PHE); and
- the Veterinary Medicines Directorate (VMD).

ASRU also met with a range of non-governmental organisations (NGOs) and charities including:

- Animal Free Research UK;
- the Royal Society for the Prevention of Cruelty to Animals (RSPCA); and
- the Wellcome Trust.

These meetings were generally to discuss specific issues of mutual interest.

In addition, ASRU staff routinely join the Minister in meetings with stakeholder groups to provide advice as appropriate.

Stakeholder communication

ASRU publishes two regular newsletters that are sent out quarterly to all establishment licence holders and Home Office liaison contacts.

ASRU operational newsletters provide information on what is required on a day-to-day basis, for example, the requirement for the annual Return of Procedures.

Establishment licence holder newsletters contain overarching information on:

- what is happening within ASRU; and
- any information that must be brought to the attention of senior management at establishments, for example, changes to the licensing or compliance process.

- All newsletters can be found on ASRU's website: https://www.gov.uk/government/publications/animals-in-science-regulation-unit-newsletters

Licensee engagement

Engagement with those who hold a licence under ASPA is an important aspect of ASRU's work. Such engagement allows ASRU to explain its policies and plans, and to receive feedback on the quality of its work and delivery. Importantly, ASRU's ongoing engagement is conducted through regular engagement at an operational level between:

- the ASRU Licensing Team and the Home Office Liaison and Training Information Forum (HOLTIF); and
- the ASRU Senior Leadership Team and the Establishment Licence Holders Forum.

External representation

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

Some highlights of engagement with stakeholders in 2017 included:

- the Institute of Animal Technologists Congress in March;
- the Animal Welfare and Ethical Review Bodies Forum in May;
- the Establishment Licence Holders Forum in July;
- the Laboratory Animals Veterinary Association Conference in September; and
- the Laboratory Animal Science Association Conference in November.

Section 6: Inspection

The Animals in Science Regulation Unit (ASRU) inspection programme is a cornerstone 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 undertaken comply with the requirements of ASPA and the relevant conditions specified in licences.

Inspection

In 2017 ASRU undertook 966 inspections of places where scientific work on animals was conducted. Of the visits to animal units, 59% were unannounced.

The risk-based programme of inspection is based on consideration of the factors specified in Section 18 (2C) of ASPA. These are:

- the compliance history of an establishment;
- any information relating to potential non-compliance;
- the number and species of animals kept; and
- the number and type of regulated procedures carried out.

Baseline setting

Each establishment is assigned a baseline number of inspections. This number depends on a range of factors. The most significant factors are:

- a measure of the size and complexity of the establishment; and
- the type of work that is carried out there.

Baseline setting is done by drawing up the number of regulatory units that an establishment has (a regulatory unit is calculated from the number of individual licences at an establishment added to twice the number of project licences).

Other factors are then taken into consideration.

- Establishments with specially protected species are given additional inspection time.
- Establishments with access difficulties relating to their geography may be given additional inspection time. There are two types of geographical difficulties:
  - establishments might be remote and difficult to get to; or
  - establishments might be difficult to get around because of multiple sites and/or biosecurity restrictions.

The number of inspections at establishments may be altered because of their risk profile.

Contract research laboratories may be given additional inspections as they tend to have proportionately fewer project licences; this means that the regulatory unit approach understates their inspection demand.

Risk management

In 2015/16 ASRU put a more structured risk management process in place, and this was continued in 2017. This comprises a review of the national risk profile, and local establishment factors. It is undertaken quarterly by the Chief Inspector and the principal inspectors. Prior to the meeting, the principal inspectors discuss the concerns, observations and findings of each of the inspectors reporting to them. These discussions identify the main concerns each Inspector has regarding the institutions they inspect.

The quarterly review meetings gather together the inspectors' evaluation of the risk for institutions they inspect and the results of the inspections of the previous quarter. Additional consideration is given to:

- the incidence and nature of non-compliance cases;
- significant low level concerns;[6]
- new procedures;
- new species; and
- any other relevant information.

The result of the meeting is a summary of the key evidence and an action plan to resolve concerns. The action plan might include additional inspections but could include other measures, such as defined review points to assess progress and achievements. Additional inspection time is targeted to specific concerns rather than necessarily to a more general increase in the number of inspections to a particular establishment.

Where the risk factors have been addressed, or the nature of work at the establishment changes to a lower risk profile, the inspection time will move closer to the baseline.

Inspector training and continuous professional development

Two new inspectors joined ASRU and completed their three-month induction programme. As well as training provided by current inspectors, ASRU actively sought help from its stakeholders to widen the programme:

- leading universities;
- the pharmaceutical industry;
- contract research organisations;
- government and non-governmental research institutes;
- the Research Councils;
- the Wellcome Trust;
- the Home Office Parliamentary Team;
- the Royal Society for the Prevention of Cruelty to Animals (RSPCA); and
- animal protection organisations.

These all combined to bring together a training programme of the highest quality.

External recruitment for further new inspectors, to cater for anticipated future requirements, was instigated during the latter part of the year.

All inspectors (who are either veterinary or medical professionals) are required to satisfy the continuous professional development (CPD) requirements of their relevant professional regulator.

As well as individual research and self-directed learning, CPD related to the work of ASRU is delivered at regular inspector conferences.

Conferences include presentations from external expert speakers, information sharing between inspectors, and training in other professional skills.

A mix of other CPD activities are undertaken by inspectors:

- to maintain professional specialist expertise; and

6 https://www.gov.uk/guidance/animal-testing-and-research-compliance-with-aspa#patterns-of-low-level-concerns

- to increase knowledge in an area related to specific science, administrative skills, or the replacement, reduction and refinement (the 3Rs) of animals used in research.

Inspectors are active in developing and delivering presentations on topics relevant to ASRU's work areas to a diverse range of stakeholders and representative groups.

Inspection reporting

The aim of the Inspector is to make the key findings of the inspection clear to the relevant establishment contacts during, or at the end of the inspection. This is so that the relevant people at the establishment can take any action that may be necessary, and so that good practice may be identified and promoted locally.

A new electronic system of inspection reporting was implemented in 2017. The new system provides:

- improved functionality for recording, categorising and rating findings of inspection; and
- improved management data, that is closer to real time.

The inspection reporting system continues to be under review, with a view to allowing the findings from all contact with establishments, including remote contact and outcomes, to be recorded and reported centrally. A large part of the inspectors' time is spent discussing and advising establishments and licence holders outside of inspection visits. This includes time spent meeting with licence applicants as part of licence assessment work.

Where practical issues prevent local reporting (for example, on multi-site establishments) this will normally be followed up after the inspection. Any issues requiring immediate action are communicated during the inspection to the person most appropriate to deal with them. Where necessary this will also be confirmed in writing. In most cases minor issues or concerns are addressed in this way.

The inspection reporting system now allows better recording of follow up and resolution of actions that are not dealt with at the time of inspection.

The inspection record allows access to the history when establishments transfer between inspectors.

Investigating allegations made to the Animals in Science Regulation Unit

ASRU periodically receives allegations about potential breaches of ASPA, from individuals at establishments, commonly referred to as 'whistle blowing' allegations. These are taken seriously and where sufficient information is provided they are followed up by the most appropriate means, including by carrying out inspections. Some of these allegations may have relevance to legislation other than ASPA, and others may not be breaches of ASPA. Where it appears that there may have been a lack of compliance with ASPA these are investigated in accordance with ASRU's non-compliance policy.

Section 7: Compliance

The Animals in Science Regulation Unit's (ASRU's) compliance policy focuses on the delivery of a proportionate, consistent and outcome-based approach to incidents of non-compliance.

In December 2017 ASRU published a revised compliance policy document, developed in consultation with the Animals in Science Committee (ASC) and those regulated by ASRU.

The compliance policy document explains how ASRU identifies and investigates potential incidents of non-compliance and decides on appropriate and proportionate remedies aimed to minimise the risk of reoccurrence. The document can be found at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/670174/ASRU_Compliance_Policy_December_Final.pdf

Every establishment licensed under the Animals (Scientific Procedures) Act 1986 (ASPA) has a Named Person Responsible for Compliance (NPRC). This individual is responsible for ensuring compliance with the conditions placed on their establishment licence. A culture of compliance is a key part of a good culture of care at an establishment, meeting both the letter and the spirit of the law. The NPRC must maintain robust systems and frameworks that support and encourage compliance. By so doing, they can ensure that all licensees comply with their licences when working at their establishment.

Inspectors advise licensees and others working with animals in science on how to comply with and promote a culture of compliance. During inspections, inspectors determine whether establishments and licensees are complying with the provisions of ASPA and with the conditions of their licences. Inspectors report any non-compliance and make recommendations on what action may be required. This is primarily aimed at the prevention of repeated similar incidents.

In most cases of non-compliance, the assigned Inspector consults with colleagues and gathers sufficient information to determine whether there is a case that merits investigation. An initial report is then submitted to the Compliance Team. A full investigation report is typically submitted within 30 working days of discovery, together with a recommendation for action. Those directly involved in the case will normally be notified by the Inspector and, in writing, by the Senior Compliance Manager. They will be given the opportunity to provide any information that they wish to be considered before a decision is taken regarding the appropriate sanction. Complex or serious cases may take longer to resolve than the suggested timescales above. There is also the opportunity to make representations regarding 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.

Case summaries of non-compliance cases from 2017 are summarised in Annex 1 of this document.

Non-compliance

Each case is considered on an individual basis with regard to its seriousness. The most appropriate remedy is applied with the aim of deterring or preventing recurrence, and

considers both aggravating and mitigating circumstances. These factors include:

- the extent of any unnecessary suffering;
- the timeliness of any remedies applied by the establishment;
- the risk of recurrence; and
- evidence of dishonesty or attempts to evade responsibility.

As set out in the *Animals in Science Regulation Unit Compliance Policy* there are a range of sanctions available to the Secretary of State:

- Inspector advice;
- a compliance letter;
- variation of the licence;
- a Compliance Notice;
- revocation of a licence; and
- prosecution.

Inspector advice

Where there is a minor breach the Inspector will provide advice stating what provision was breached and what is expected in the future. A minor breach is one where:

- there are no or minor avoidable adverse animal welfare consequences;
- the facts are agreed;
- there was no intention to subvert the controls of ASPA; and
- the risk of a recurrence is judged to be low.

Compliance letter

Where Inspector advice is not considered appropriate, most cases of non-compliance are dealt with by a letter from ASRU, with or without a variation of the relevant licence(s). Where a breach has been committed by a licensee, a letter of reprimand is sent. Where a non-licensee has contributed significantly to the breach, a letter of censure may be sent.

Letters note the breach(es) that have occurred and summarise the evidence for those breaches. The letter is a formal record of non-compliance that will be taken into account should there be a further breach within five years. All letters are copied to the NPRC at the relevant establishment so that they can review local practices and processes.

Variation of the licence

Requirement for retraining

Retraining is required where a licensee has demonstrated that they do not have the expected level of knowledge of their legal responsibilities, of the animals they are using or of the procedures.

Requirement for reporting

Where action is required to improve weaknesses identified by the breach, including poor record keeping, a report would typically be required to monitor progress. Reports are also useful for formally monitoring improvements in scientific outcomes or the implementation of refinements.

Suspension

Where a breach has been identified, licences may be suspended as a sanction. Typically, such suspensions are applied when there is a need to protect animal welfare. Animal welfare must be safeguarded in such circumstances. This is likely to be appropriate where a requirement for retraining has been identified and there may be ongoing risks to animal welfare until retraining is completed.

Compliance Notice

A Compliance Notice is issued where ASRU requires particular action to be taken to prevent further non-compliance. Such a notice will specify:

- the licence condition(s) or ASPA provision(s) that have been breached;
- the action that must be taken to ensure that the failure does not continue or is not repeated; and
- any action that must be taken to eliminate or reduce any consequences of the breach.

The Compliance Notice will set out the consequences of failing to comply. In this

eventuality the licence holder may then be sanctioned with suspension, variation or revocation of their licence.

This type of remedy is particularly effective where weaknesses in governance have been identified, or where cultural change in attitudes towards welfare or compliance is needed. Such changes may reasonably take some time to remedy, for example: increases in staffing, refurbishment of facilities, or embedding an improved culture of care.

It provides a formal mechanism for assuring and monitoring improvements over time.

Revocation of a licence

Revocation of any type of licence issued under ASPA is only used in the most serious cases. It is appropriate where a licensee has shown a disregard for the controls of the Act and has caused avoidable suffering. It may also be appropriate where significant avoidable suffering has been caused through negligence or ignorance, or where the licensee otherwise appears to be unsuitable for the role. The Secretary of State has a duty to ensure that the welfare of animals is not adversely affected by the revocation of a licence.

Prosecution

Only extremely serious cases would be referred to the prosecuting authorities to make a judgment as to whether it would be in the public interest to prosecute. Prosecution could lead to a fine or imprisonment.

Desired outcomes following the application of sanctions/remedies

In all cases the remedy applied aims to address the underlying cause. ASRU's aim is to drive behaviour, at both individual and establishment level, to the following desired outcomes:

- to build capability to improve compliance by individuals and the establishment;
- to strengthen establishment governance systems; and
- to improve knowledge of the regulatory and licensing system.

Compliance in 2017, self-reporting and a culture of care

In 2017, 40 cases of non-compliance were reported, fully investigated and completed:

- 27 occurred at universities;
- 9 at commercial organisations; and
- 4 at government research establishments.

Of these 40 cases, 37 (93%) were self-reported. In 2016 and 2015, 40 (90%) and 43 (78%) cases respectively were self-reported.

Table 1 provides a summary of the discovery of the cases of non-compliance for 2014 to 2017.

Table 1. Discovery of cases of non-compliance, 2014 to 2017

	2014	2015	2016	2017
Cases reported by the establishment	49	43	40	37
Cases discovered by an Inspector	12	12	5	3
Cases reported by others independent of the establishment	2	0	0	0
Total cases	**63**	**55**	**45**	**40**

Self-reporting is generally indicative of an establishment that is committed to a culture of compliance. It indicates that an establishment is aware of its responsibilities under ASPA and is committed to building a good culture of care. Self-reporting is expected to be normal practice within establishments and part of good governance frameworks. It continues to be encouraging that the trend of a significant proportion of self-reported cases has continued from 2015 to 2017.

The Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (the Guidance),[7] published in 2014, increased awareness among licence holders of their responsibilities under the amended Act. It is expected that the publication of the compliance policy at the end of 2017 will also help to inform licensees about compliance. Reports about major or high-profile investigations continue to be used by licensees to improve compliance and help to develop a culture of care. Establishment licence holders are continuing to reflect on the meaning of 'culture of care' and how it can be improved.

Key compliance messages

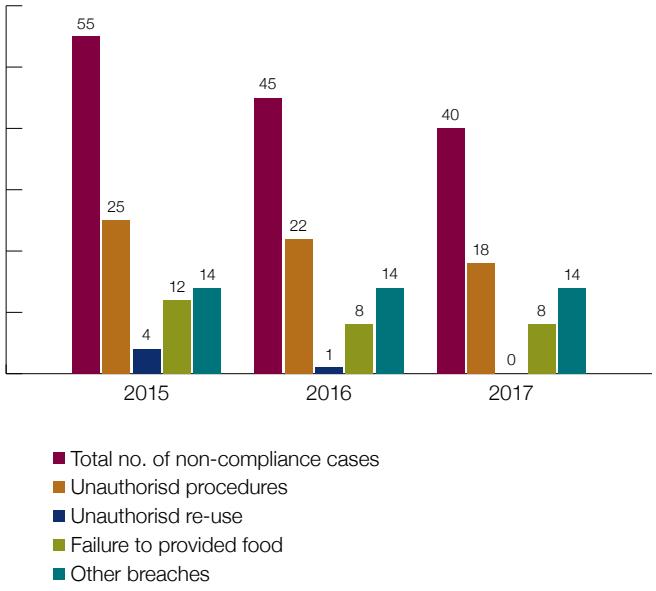
As in 2015 and 2016 a common cause of non-compliance in 2017 was again that the details of granted authorities had not been sufficiently checked. Failure to be familiar with licence authorities is not considered to be a mitigating factor and licensees must ensure that they are familiar with their authorities.

In order to compare data published in previous years, three common non-compliance types have been highlighted in this report:

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

These data should be used to gain a better understanding of how to avoid non-compliance and support establishments to build and maintain effective frameworks to deliver a good culture of care and compliance.

Figure 1. Categories of non-compliance, by type, 2015 to 2017



1. Procedures conducted without 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;
- non-licensees were asked to undertake regulated procedures, and undertook them;
- a retrospective review of activities on a licence uncovered more use of animals than was authorised.

This group included 18 (45%) of the 40 cases.

Root causes

The primary responsibility for ensuring compliance with licence authorities rests with the individual licence holder.

The causes of these non-compliances were:

- administrative lapses and error;
- inadequate record keeping; and
- communication lapses.

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

Licensees must be aware of the authorities they hold before proceeding with regulated procedures. Establishment licence holders should review record keeping processes to ensure that animal numbers are not inadvertently exceeded.

2. A failure to provide food and/or water

Failing to provide sufficient food and/or water to animals, as part of basic husbandry and care, is unacceptable. Establishments must have robust procedures in place to ensure the provision of food and water to animals kept under the terms of ASPA. Of the total 40 cases in 2017, 8 cases (20%) were under this theme. Establishment licence holders and other named role holders are regularly reminded of the need to have in place adequate procedures and systems to minimise the likelihood of such incidents occurring. Inspectors have also targeted this area in their inspections, and this has been raised as a significant area of concern with establishment licence holders.

Root causes

The primary reasons for failure to provide food and water are related to the effectiveness of routine checks of animals to spot both lack of provision and the declining condition of the 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. Root causes must be addressed proactively. Staff resource may be over-stretched during busy times and out-of-hours, such as weekends. Proper provision for training, competence assessment and supervision should be incorporated into management systems. It is also notable that checking the wellbeing 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.

3. The unauthorised re-use of animals

'Re-use' is explained in the Home Office *Guidance on the Operation of the Animals (Scientific Procedures) Act 1986* (the 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.

ASRU drafted further guidance that was published in the form of an *Advice Note (Use, Keeping Alive and Re-use)* in October 2015. There were no cases of unauthorised re-use in 2017.

4. Solutions for non-compliance themes

There are a number of safeguards against the above themes, which all establishments should provide. These include:

- good channels of communication between those working under ASPA throughout the establishment;
- effective training and supervision, including competence assessments;
- good record keeping in accordance with ASPA requirements;
- a culture of checking licence authorities before undertaking experiments; and
- sufficient time and resource allocated for daily, meaningful routine monitoring of all animals.

The Guidance (https://www.gov.uk/government/publications/operation-of-aspa), or relevant Advice Notes published on ASRU's website, should be consulted and routinely followed. In this way, establishments should be able to assure themselves that they are conducting their work in a compliant way.

There was confusion with some establishment licence holders around the legal requirements for re-homing animals and so ASRU drafted and issued guidance on this matter through an Advice Note (https://www.gov.uk/guidance/animal-research-technical-advice#re-homing-and-setting-free) to all establishment licence holders in October 2015. This Advice Note explains the criteria required for the Secretary of State to consent to the re-homing or setting free of relevant protected animals that have been bred, supplied, kept or used in regulated procedures at the end of those procedures. All licensees should always fully check their licence authorities and the Guidance before starting any new work, and any queries or concerns should be fully explored and addressed with senior role holders and, if required, with their assigned ASRU Inspector.

Transparency of major investigations

As well as investigating each non-compliance case, whether self-reported or discovered by an Inspector, ASRU may initiate 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 that appears to describe unauthorised procedures or other evidence of non-compliance; or
- concern raised by inspectors or others that a particular procedure may 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, ASRU publishes anonymised reports of such investigations on the GOV.UK website once they are completed. This is in addition to its usual reporting in its Annual Report. ASRU believes this will help to 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 an insight into this important aspect of ASRU's work.

In determining which reports to publish, ASRU applies a public interest test. All reports involving a significant compromise to animal welfare, or those in which there is clear evidence of a deliberate intent to deceive, are normally published. In cases where the establishment licence holder is found to have failed to comply, it is likely that the issues will be wide-ranging within the establishment and ASRU will normally publish those reports to offer useful lessons to others. In the interests of transparency, ASRU expects a decision not to publish a major report to be the exception.

Links to the reports and a summary to the substantial investigations can be found at: https://www.gov.uk/government/publications/compliance-investigations-by-the-animals-in-science-regulation-unit

Section 8: Financial report

2017/18 was the third financial year that the Animals in Science Regulation Unit (ASRU) has been operating on a full cost recovery basis, meaning that licence fee income should cover all expenditure incurred in delivering the service.

The summary of income and fee-funded expenditure for the last four years is shown in Table 2.

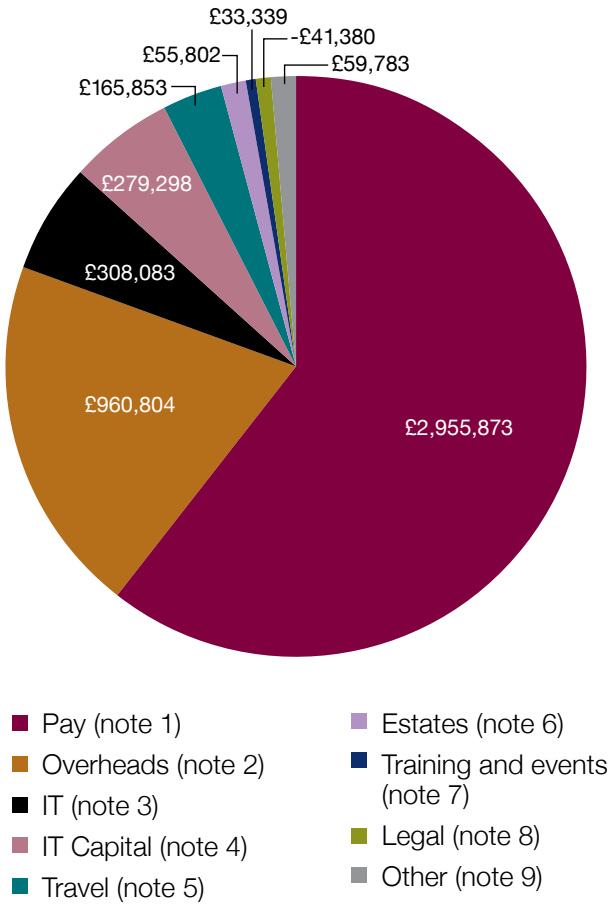
Table 2. Summary of income and fee-funded expenditure, 2014/15 to 2017/18

	Income	Expenditure	Variance
2014/15	£4,380,206	£4,378,929	£1,277
2015/16	£4,692,833	£4,207,503	£485,330
2016/17	£4,482,578	£4,467,404	£14,596
2017/18	£4,421,361	£4,777,455	-£356,094

2017/18 Expenditure

Expenditure for 2017/18 (1 April 2017 to 31 March 2018) is shown in Figure 2.

Figure 2. Expenditure, 1 April 2017 to 31 March 2018



Notes

1. Of the £2.95 million pay costs approximately £2.72 million were salary costs (including £675,747 of National Insurance/superannuation) and £218,890 was transferred to other teams in the Home Office for use of their staff on ASRU's work (for example, statistics and legal advice). A further pay cost was on contingent labour at £13,875.

2. Central overheads are calculated on a headcount basis and cover core Home Office central functions/services such as IT delivery, HR and finance. They also cover an apportionment of the accommodation and facilities costs of the London Head Office at 2 Marsham Street and the Croydon Campus at Lunar House. Overheads have increased from 2015/16 due to a new model of calculating central overheads now being used for all units that cover their cost through fees. These are projected to decrease by 7.5% a year until 2020 due to Home Office cost efficiency savings.

3. The IT costs include approximately £230,000 on hosting and support of the Animals Scientific Procedures e-Licensing system (ASPeL) during 2017/18. The remainder is for VAT and telecoms, for example, mobile phones, wifi.

4. ASRU procured for a contract to develop a new and improved version of ASPeL. The company that won the procurement was Marvell. To start the initial research into the new system £279,298 was paid to Marvell in 2017/18. The contract with Marvell will continue in 2018/19.

5. Travel and subsistence costs were mostly incurred by inspectors during their visits to establishments.

6. During 2017/18 ASRU paid other parts of the Home Office and other government departments for the use of office space in Bedford, Dundee, Glasgow and Swindon. ASRU no longer holds any commercial leases.

7. Training costs were mostly incurred by training new inspectors or existing inspectors completing their continuous professional development as required by their professions (all inspectors are either vets or doctors). This includes the costs incurred by running four annual events for all inspectors and managers.

8. Legal costs included the cost of defending Judicial Reviews and handling appeals against licensing decisions taken.

9. Other costs include publications, fees, subscriptions to professional bodies, for example, the Royal College of Veterinary Surgeons, and office costs such as couriers and supplies.

2017/18 Income

Since April 2015 the fees have been:

- personal licence £242 per licence held;
- establishment licence £631 per licence held.

Invoices are raised in arrears so income for the financial year 2017/18 has not yet been fully invoiced and received. However, it is forecast to be approximately £4.3 million and therefore ASRU expects this will be very close to actual expenditure.

As part of the conversion from paper licences to e-licences ASRU knew that establishments would take the opportunity to check that all licences were required and revoke those that were no longer needed. This has resulted in a decrease in the number of licences held and reduced income. Now that the conversion programme is complete ASRU has a much better idea of how many licences will be held each year and therefore whether the fees need to be increased or decreased.

There will be a fee increase for 2018/19. This comes into force on 6 April 2018 and is set out below. It is necessary to ensure that fee income covers all expenditure incurred in delivering the service.

- The establishment licence fee will increase from £631 to £757.

- The personal licence fee will increase from £242 to £257.

Annex 1: Non-compliance cases

This section provides summaries of all 40 cases of non-compliance that were concluded in 2017. These cases should be used to gain a better understanding of how to avoid these types of non-compliance and to support establishments in their frameworks for delivering the requirements under the Animals (Scientific Procedures) Act 1986.

Non-compliance case 1

During routine observations, two mice were found dead in a cage by an animal technician. Water was provided for the animals but no food was present. It is likely that the mice had been without food for five days. The lack of provision of food and the deteriorating health of the mice were not noticed during routine daily observations.

The establishment licence holder ensured that all technicians at the establishment underwent retraining. Procedures were put in place to ensure that responsibility for a single rack of cages/animals was assigned to a specific technician. The standard operating procedures were redrafted to minimise the possibility of such an incident recurring. The racks were also rearranged to enable the backs of the cages to be fully examined. The establishment licence holder was sent a letter of written reprimand.

Non-compliance case 2

A non-human primate (NHP) died when it became trapped between a restraint mechanism and a cage wall. Attempts by the Named Animal Care and Welfare Officer and other staff to resuscitate the animal were unsuccessful.

The incident was caused by the failure of a member of staff to lock a cage mechanism correctly when not in use, and the failure by staff to check that an animal was not in the mechanism before operating the handle. The death of the animal was due to poor working practices at the establishment.

A Compliance Notice was served on the establishment licence holder, which required them to ensure that all staff working with NHPs were aware of the correct procedure for this type of handling. They were also required to ensure that all cage fixtures and fittings were in proper working order and that any defects would be detected and repaired as quickly as possible. The establishment was required to send a report to the Animals in Science Regulation Unit providing assurances that these points had been adequately addressed within four months of the date of the Compliance Notice. Failure to do this would have resulted in the revocation of the establishment's licence.

Non-compliance case 3

A project licence holder bred approximately 13,200 more genetically altered mice than the 2,500 that were authorised on their project licence. The project licence holder misunderstood the authorities of the project licence and the limits on the numbers allowed, and there was inadequate project licence management. The animals were bred because they were needed for legitimate experiments that were authorised under the project licence. There was no attempt to circumvent the regulations. There was no additional compromise to animal welfare as a result of the incident and the licence holder accepted full responsibility for the error. A detailed local investigation was undertaken and arrangements were put in place to prevent any recurrence. The project licence holder was sent a letter of written reprimand.

Non-compliance case 4

A personal licence holder instructed a non-licence holder to flush and remove cannulae from the limbs of 40 non-human primates under supervision. The personal licence holder mistakenly believed this was a task that could be legitimately delegated to a non-licence holder. The incident arose due to a misunderstanding by the personal licence holder as to which tasks could be delegated. The non-licensee subsequently supervised two other non-licensees to undertake the procedure. The procedures were carried out competently with no apparent avoidable adverse welfare consequences. The personal licence holder who delegated the tasks was sent a letter of written reprimand. The non-licence holders who undertook the tasks were each sent a letter of censure.

Non-compliance case 5

A personal licence holder relocated to a second establishment to continue their studies. Their licence was subsequently revoked by the first establishment without the licensee's knowledge. As a result of failings by both the second establishment and the licensee, the non-licensee performed regulated procedures at the second establishment. The procedures were performed competently with no animal welfare consequences. The non-licensee performed the procedures in the belief that they still held a personal licence.

When the second establishment recognised that there was no personal licence authority they sought to remedy the position. The personal licence holder should have ensured that authority was in place when they moved to the second establishment before commencing work. The personal licence holder was sent a letter of written reprimand and was required to undertake training in module L within six months. The establishment licence holder at the second establishment had failed to take reasonable steps to prevent the performance of procedures by non-licensees at their establishment and was sent a letter of written reprimand.

Non-compliance case 6

A wild-caught animal failed to eat after being brought into captivity, despite appropriate food being freely available. After four days it became ill and was euthanased. The failure of the animal to eat did not prompt interventions before it became ill. Communications between the animal care technician, the licensees who planned to use the animal, and the Named Persons responsible for it were poor. There was also evidence of a poor relationship between some Named Persons and the management. The establishment licence holder failed to provide adequate and effective liaison with and between:

- those entrusted with responsibilities under the Animals (Scientific Procedures) Act 1986; and
- others who had responsibility for the welfare of protected animals kept at the establishment.

The establishment licence holder was sent a letter of written reprimand. They were also required to submit a report within four months detailing the measures they would put in place to ensure that there would be:

- regular and effective liaison with and between Named Persons and animal care staff at the establishment; and
- effective cover whenever the Named Veterinary Surgeon or Named Animal Care and Welfare Officer was absent or unavailable.

Non-compliance case 7

An establishment identified that more guinea pigs (9,820) had been used on a project licence protocol than was authorised (6,000). The incident was identified as a mistake and there was no intent to circumvent the regulations. The project licence holder immediately self-reported the incident to the Home Office once they were aware. The project licence holder was sent a letter of written reprimand.

Non-compliance case 8

A project licence holder allowed the use of more mice than were permitted on two experimental protocols on their project licence; using 23 mice when only 10 were permitted,

and 35 when only 30 were permitted. The error was detected when the establishment installed new systems, demonstrating that the new systems were effective in both detecting and preventing further use of excess numbers.

The licensee reported the matter as soon as they discovered that the numbers were higher than the estimates in the project licence. The licensee also took steps to apply to increase the numbers authorised on a number of protocols to accommodate future planned work, which was granted. The work on the additional animals was otherwise competently performed and the project licence holder took full responsibility for the error and underwent refresher training. The new systems will be effective in matching numbers licensed to numbers for use. The project licence holder was sent a letter of written reprimand.

Non-compliance case 9

A personal licence holder took blood samples from 25 mice while they were still conscious at the end of an experiment. The method of sampling used was not authorised on the project licence. Samples were collected incompetently from the tail vein of the animals resulting in trauma to the tails of three mice, which were later humanely killed.

Given the seriousness of the allegations and the potential for the personal licensee to conduct further regulated procedures on other protected animals with the consequent risk of adverse animal welfare issues, the Secretary of State immediately suspended the personal licence for an initial period of three months under powers contained in Section 13(1) of the Animals (Scientific Procedures) Act 1986 (ASPA). Independently of this action, the establishment licence holder also suspended access to the animal unit at the establishment for this individual. In order to safeguard the welfare of protected animals, the Secretary of State revoked the personal licence under powers contained in Section 11(5) of ASPA.

The individual was informed that if they were ever to reapply for a personal licence they would require retraining. This retraining would be required to refresh their understanding of their personal, legal and ethical responsibilities when working as a personal licensee and to also improve their technical and practical knowledge. Any necessary local training would also have to be successfully undertaken. Any application submitted would have to be supported by a letter of endorsement from the establishment licence holder, indicating their full knowledge of the incident. The assigned Animals in Science Regulation Unit Inspector would also advise if it would now be appropriate to grant a new personal licence to this individual.

Non-compliance case 10

Following the removal of a mouse colony, one cage was inadvertently left behind in an isolator. Two mice were found dead and a third was found in distress and was euthanased in order to prevent further suffering. The cause of death of the two mice was a lack of food and water. The establishment indicated this was part due to staff resource issues. The establishment licence holder immediately took a number of steps to reduce the risks of a recurrence, including changes to both equipment and practices, and a review of staff resource. The establishment licence holder was sent a letter of written reprimand.

Non-compliance case 11

When being assessed for competence by an animal technician, a personal licence holder gavaged a mouse with water. The dosing was not undertaken as part of an authorised programme of work and the incident occurred due to an error of judgement, with no intent to circumvent the regulations. The animal was not harmed. The personal licensee was sent a letter of written reprimand.

Non-compliance case 12

While preparing the 2016 end of year Return of Procedures form to the Home Office a project licence holder discovered that they had used approximately 9,970 zebra fish when only 5,000 were authorised. Further investigation revealed that the number had also been exceeded in 2015.

The project licence holder agreed to work with the Named Animal Care and Welfare Officer to improve the oversight of the breeding and maintenance of the fish. The project licensee also undertook to prepare a realistic estimate of the numbers of animals required in the remaining term, submitting an amendment request justifying the use of the increased numbers. The project licensee was sent a letter of written reprimand. They were also required to submit, within one month, a report detailing the provisions that they would put in place to ensure appropriate breeding and colony management throughout the remaining duration of the project licence.

Non-compliance case 13

A project licence holder discovered that a PhD student had used 134 chickens for studies under authority of a project licence when the use of only 40 chickens were authorised. Further, two chickens being subjected to heat stress as part of a series of regulated procedures had died unexpectedly some years previously. The project licence holder did not notify the Home Office that the severity limitations had been exceeded. The project licence holder had recently attended internal project licence holder refresher training at their establishment to reinforce their personal licence holder responsibilities. As they had undertaken this training so recently, the project licence holder was sent a letter of written reprimand.

Non-compliance case 14

A former personal licence holder undertook regulated procedures on 95 mice involving the induction of anaesthesia and intranasal instillation of substances without the personal licence authority to do so. The individual had previously held a personal licence that authorised these procedures, but this licence had been revoked with their acknowledgement. They failed to reapply for a new personal licence before carrying out the regulated procedures, as they had assumed that their licence had been reactivated. The procedures were competently performed and there were no avoidable animal welfare issues. They were sent a letter of censure. They were also informed that if at some future date they wished to apply for a personal licence, they would be required to retrain before applying. In addition, any application they might make would need to be supported by a letter of endorsement from the establishment licence holder at the primary establishment, indicating that they were aware of the circumstances of the non-compliance.

Non-compliance case 15

During a local routine retrospective review, a project licence holder discovered that the numbers of genetically altered mice permitted to be bred under authority of their project licence had been exceeded. The licence authorised the breeding of 2,000 mice. However, approximately 9,000 mice were bred. The incident occurred unintentionally and there was no intent to circumvent the regulations. The project licence holder undertook a number of steps to ensure no repetition of the incident, including the appointment of a new colony manager to strengthen the oversight of breeding colonies used by groups on the project holder's behalf. The project licence holder was sent a letter of written reprimand.

Non-compliance case 16

A personal licence holder's licence was revoked at the request of an establishment. A notification email was sent to the licensee to indicate their licence had been revoked. The licensee did not access the e-licensing system as they should have done, and so they believed that they still held a personal licence. The former licence holder subsequently continued to conduct regulated procedures until the error was identified by the establishment. There was no intent to circumvent the regulations and the procedures undertaken were otherwise well performed with no welfare issues for the animals involved. As a result, and following local internal investigations, appropriate measures were put in place to avoid a recurrence. The former personal licence holder was sent a letter of censure.

Non-compliance case 17

Following an Inspector's review of a standard condition 18 report, which had been submitted by a project licence holder following the deaths of three mice, it was discovered that the licence holder allowed animals to be transferred between protocols. This was not authorised in the programme of work in the licence. Arrangements were put in place by the project licence holder and the establishment to prevent any recurrence and the licence holder sought an amendment to their licence. Had the project licence holder applied for an amendment on the first occasion, the Inspector would have recommended that it be granted. The project licence holder was sent a letter of written reprimand.

Non-compliance case 18

A project licence holder who also held a personal licence continued to breed genetically altered (GA) mice after the expiry of their project licence for a period of eight days until they realised there was no longer project licence authority to do so. There was also no evidence that local establishment control systems were in place to flag the need to apply for continuing authority to breed and maintain the GA mice. The incident occurred as a result of human error and the performance of the unauthorised regulated procedures was not deliberately carried out. Improvements were made to the local management control systems to guide against the recurrence of such incidents. The establishment licence holder and the project licence holder were each sent a letter of written reprimand.

Non-compliance case 19

The holder of a personal licence failed to monitor mice properly despite being aware that the tumours they had implanted in the mice were growing rapidly. The licensee left the tumours to grow in excess of the limit authorised in the protocol. The licensee also failed to use required analgesia, after surgery, to remove a tumour. The licence holder failed to fulfil their primary responsibility for the welfare of the animals on which they had performed regulated procedures and also demonstrated a lack of knowledge of their responsibilities. The licence holder therefore subjected animals in their care to unnecessary pain, suffering and distress.

The Secretary of State suspended the personal licence for a period initially not exceeding three months. The licensee was also required to successfully complete retraining. This was:

- to refresh knowledge of their personal, legal and ethical responsibilities as a personal license holder; and
- to improve their knowledge of the principles of surgery, anaesthesia and analgesia.

The Home Office required that evidence of the successful retraining was to be submitted within four months of the date of suspension. Once the retraining was successfully completed the assigned Inspector would assess if it would be appropriate to reinstate the personal licence. The licensee was also informed that if the suspension was lifted they would then be required to be supervised in any subsequent surgical procedures until they were deemed to be competent. Further, their personal training and competence records were required to be completed by the establishment Named Training and Competency Officer.

The licence holder undertook and passed all the training that was required from them and was then interviewed by the Inspectorate. The licence holder took full responsibility for their actions that led to the suspension. Following the interview, the Inspectorate was able to advise that it would be appropriate to reinstate the licence and it was accordingly reinstated three months after the date of suspension. The establishment licence holder arranged to provide ongoing supervision of the licence holder.

Non-compliance case 20

The holder of a personal licence undertook regulated procedures on 48 mice and then took a period of annual leave during their recovery period. They did not make adequate arrangements for the provision of care and welfare for the animals during their absence, which was over a period of 17 days. During their absence a number of mice died or required

humane killing. The incident occurred due to poor planning and the licensee overlooking the need to provide adequate monitoring and cover for animals during a period of absence. There was no intention to circumvent the regulations. The licence holder accepted full responsibility and regret for their actions. They also confirmed that that they had since completed refresher training. Had they not undergone the retraining immediately after the incident the Secretary of State would have required that they do so. The personal licence holder was sent a letter of written reprimand.

Non-compliance case 21

Over a period of 7 months a former personal licence holder performed regulated procedures on 41 protected animals without the necessary personal licence authority in place to do so. They erroneously believed that they still held a personal licence at the time of applying the procedures when in fact they had requested the revocation of their licence approximately seven months earlier. Upon discovery they immediately ceased all regulated procedures and reported the incident to the Home Office.

The incident occurred due to a misunderstanding of the processes involved in licence revocation. The systems in place at the establishment to prevent the conduct of unauthorised regulated procedures were not adequate to prevent them from being carried out. There was no intent to circumvent the regulations and when the incident was discovered, the establishment licence holder introduced robust local controls to reduce the risk of any recurrence of this type of incident. The establishment licence holder was sent a letter of written reprimand, and was required to provide a report, within four months, on the outcomes of the improvements to local controls they had implemented, or intended to implement, in order to prevent recurrence and provide reassurances that local controls had been adequately strengthened. The former licence holder was sent a letter of censure.

Non-compliance case 22

During routine morning checks an animal technician found two mice, out of a group of ten, dead in a cage without provision of water. The remaining mice had signs of dehydration. Following the supply of hydration gel and the replacement of the water bottle the eight mice made a full recovery. Examination of the records revealed that the water bottle was checked twice daily but these checks did not identify that there was insufficient water in the bottle. The establishment licence holder was sent a letter of written reprimand and was required to carry out a detailed review of the establishment's training programme and how daily checks are undertaken to identify and remedy any weaknesses in staff competencies. They were also required to submit to the Secretary of State, within one month, the outcome of the review and the actions that were taken, or would be taken, in response to those outcomes.

Non-compliance case 23

At the conclusion of a series of regulated procedures, a personal licensee attempted to kill a rat humanely using a rising concentration of carbon dioxide (CO_2). On removal from the CO_2 chamber, the personal licensee tested the animal's withdrawal reflex. The licensee incorrectly relied on the lack of reflex response to indicate that the animal was dead and then used cervical dislocation to complete the humane killing process. The rat was then placed in the freezer designated for the holding of cadavers. Approximately 40 minutes later the rat was found to be alive in the cadaver freezer by an animal technician who was undertaking routine checks. Upon discovery, the rat was immediately killed humanely using a Schedule 1 method. The rat is likely to have experienced pain from neck injuries for up to 40 minutes and distress due to both being held in the cold for that time and the previous exposure to CO_2. The personal licensee was retrained by the establishment in Schedule 1 methods of killing and their competency was re-assessed. Had they not undergone the retraining immediately after the incident the Secretary of State would have required the licensee to do so. The personal licence holder was sent a letter of written reprimand.

Non-compliance case 24

Two research groups had decapitated approximately 200 mouse pups over a period of approximately 2 years without the appropriate licence authority to do so. Those involved in the euthanasia included five personal licence holders and two members of staff who did not hold a personal licence, but were being trained and assessed by the establishment Named Animal Care and Welfare Officer on the handling and Schedule 1 killing of mice. The incidents came to light following that training session. Once recognised, the matter was immediately reported to the Home Office. There was no suggestion that any of the procedures were performed incompetently and there were no avoidable welfare issues to the animals involved. All seven mistakenly believed that decapitation was a Schedule 1 method of killing. Internal disciplinary action was taken and the research groups were informed not to use that method of killing mouse pups again without licence authority. The five personal licence holders were each sent a letter of written reprimand. The two non-licence holders were each sent a letter of censure. The establishment licence holder was sent a letter of written reprimand acknowledging a recent appointment to strengthen internal controls and to improve the culture of care.

Non-compliance case 25

Over a period of 25 hours during a weekend, 27 animals were not provided with their daily food ration. Upon discovery it was found that there was no record in the day book that the animals had been fed. The animals were inspected; all appeared in good health and were immediately provided with food and water. The incident arose due to inadequate management systems for the individual allocation of tasks, exacerbated by poorly organised weekend rota duties.

The establishment licence holder was sent a letter of written reprimand. The Home Office was concerned that the staffing levels at weekends were inadequate to provide acceptable levels of care. Therefore the establishment licence holder was required to carry out a detailed review of how appropriate staffing levels in the units at weekends/bank holidays were calculated, and how husbandry tasks would be allocated at weekends/bank holidays. They were to submit, within one month, details of the conclusions and recommendations of this review. They were also required to submit, within two months, a further report detailing the actions that were being taken in response to the conclusions and recommendations of the review. The requirements were to provide assurance of adequate staffing levels and clear personal responsibility for undertaking husbandry tasks.

Non-compliance case 26

A personal licence holder performed regulated procedures on 16 mice and placed them in a warmed incubator to recover. They noticed that the temperature of the incubator was set higher than usual but were unable to adjust the temperature. They failed to identify anyone to help with the adjustment. Three mice were found dead the following day when a technician checked the animals; the cause of death was considered to be hyperthermia. It was also necessary to cull one animal because it appeared to be unwell. The personal licensee was instructed by the establishment of the correct procedures to follow when using the incubator in future. The assigned Inspector discussed personal licence holder responsibilities with the individual. The Animals in Science Regulation Unit accepted that this lapse in judgement was uncharacteristic of an otherwise competent personal licence holder. The personal licence holder was sent a letter of written reprimand.

Non-compliance case 27

A personal licensee gave two more intraperitoneal injections of a substance than were authorised by the project licence. The dose rate given to a total of 14 mice was higher than the dose used by other members of the research group. Some days later, five mice (including one in the control group) were found dead and a further three mice were culled due to ill health.

The cause of death was believed to be toxicity of the substance that had been injected. The occurrence was a failure by the personal licence holder to adhere to the limits on the numbers of injections permissible in the project licence. The licensee also failed to consult colleagues regarding the most appropriate dose of the substance to use in the particular mouse strain. The personal licence holder was sent a letter of written reprimand.

Non-compliance case 28

Following direction from a study protocol, three personal licence holders injected eight mice subcutaneously on an initial pilot study for a new compound for a total of eight days. The injections were stopped when adverse skin reactions were noted and all the mice were humanely killed on the advice of the Named Animal Care and Welfare Officer and the Named Veterinary Surgeon. The severity of the protocol was not exceeded, but when reviewing the pilot study the project licence holder noted that subcutaneous injections were not authorised by the relevant project licence protocol.

The establishment has automated compliance checks using an electronic database. When the personal licence holders were unable to enter the details of the subcutaneous injection onto the database, an animal technician with read-write permissions added 'subcutaneous injection' to the authorised list of procedures permitted by the project licence. On further enquiry the subcutaneous route of administration was not an appropriate route, resulting in the avoidable adverse effects. Each personal licence holder was sent a letter of reprimand and was required to undertake accredited training within four months to improve their knowledge of their legal and ethical responsibilities as a personal licensee.

The project licence holder, although unaware of the unauthorised procedures undertaken by the personal licensees, was strongly advised to review their systems to ensure future work was carried out in accordance with the project licence authority.

Non-compliance case 29

Five mice were placed in an isolator by an animal technician on a Friday and were left, in error, over a weekend. The animals were discovered during routine checks by another technician on the following Monday morning. Two of the mice were found dead and the remaining three animals were immediately humanely killed to prevent further suffering. The five mice were not provided with food and water, or checked over a period of more than 48 hours, which caused avoidable suffering and distress. The incident occurred due to a lack of robust processes and proper oversight by key personnel, and deficiencies in the control systems in place at the establishment. The establishment licence holder was sent a letter of written reprimand. They were also required to submit a detailed report within one month detailing how they would:

- ensure that daily checks would be effective in identifying and remedying deficiencies;
- ensure that there would be effective communication between technical team members; and
- reinforce knowledge of the personal responsibility for care and welfare of animals to all care staff, and particularly to senior members of the team.

Non-compliance case 30

Over a period of nearly one year, an experienced, trained and competent researcher performed regulated procedures on animals at an establishment after their personal licence had been revoked at the request of the previous establishment where they had been working. On three occasions, implants involving 12 mice were performed under general anaesthesia. When the researcher moved to their new establishment they did not re-apply for a personal licence as they mistakenly believed that their licence was still in place. The researcher claimed that they did not receive the automated email confirming revocation. The procedures were undertaken competently and there were no avoidable welfare concerns with regard to the animals. The personal licence holder was sent a letter of censure.

The establishment licence holder failed to have systems in place to prevent the performance of unauthorised procedures so was sent a letter of written reprimand. They were also required to provide a report, within one month, providing details of the improvements to local controls implemented, or that they intended to implement, that would prevent such a situation from arising in the future.

Non-compliance case 31

A personal licence holder carried out regulated procedures on ferrets on six occasions over a period of nine months without the personal licence authority to conduct such work. The licensee had successfully completed the mandatory training course on the species prior to this incident but failed to apply to amend their personal licence to authorise the use of the species. The incident came to light during an internal audit exercise when it was discovered that the licensee did not have authority to perform regulated procedures on that species of animal. All the procedures were carried out under supervision. However, on each occasion the establishment systems in place to prevent the conduct of unauthorised procedures failed as the licensee indicated they had authority on internal paperwork, but without checking their personal licence.

The procedures were performed competently with no avoidable welfare issues and resulted in robust scientific data. The controls in place to prevent such an incident were considered reasonable although they were strengthened as a result of this incident to prevent any recurrence. The personal licence holder was sent a letter of written reprimand.

Non-compliance case 32

An engineer isolated the water supply to a bank of poultry cages containing 60 stock birds to resolve problems with the water supply. After the repair, the engineer did not restore the water supply. As a result of the failure of staff to perform competent welfare checks over the ensuing weekend, the birds became severely dehydrated and when the incident was discovered, three days later, ten birds needed to be humanely killed. The surviving birds were able to drink unaided and rehydrate themselves. Daily animal husbandry and welfare checks failed to detect the engineer's omission. The establishment licence holder implemented a raft of measures to improve the physical plant and the training and competence of staff. Had they not done so the Home Office would have required a report from them setting out how they would prevent a recurrence. The establishment licence holder was sent a letter of written reprimand.

Non-compliance case 33

An inexperienced animal technician placed cages one on top of the other when weaning mice. The mice had room to move, however, 26 mice in the bottom cages died of asphyxia due to inadequate ventilation. The poor practice was a result of lack of training and inadequate supervision. The establishment licence holder took responsibility for the failings and instituted immediate remedial measures to prevent a repetition of the incident. As the measures appeared appropriate, the establishment licence holder was sent a letter of reprimand and required to provide a report within one month on how knowledge of personal responsibilities for animal care and welfare would be reinforced, including amongst senior technical staff.

Non-compliance case 34

While an animal technician was performing daily checks on a cage of three genetically altered mice they discovered that two of the mice had severe injuries. Due to the severity of the injuries, the mice were promptly humanely killed by the Named Animal Care and Welfare Officer. The Named Veterinary Surgeon confirmed that the wounds were not fresh and had been sustained over a period of four to five days. The injuries included numerous bites and scabs. Investigation revealed that over the previous four to five days, three animal technicians carried out the daily cage and husbandry checks, but failed to notice or report the condition of the mice. The unit records confirmed that daily checks in the room for those days had been fully completed and were noted as satisfactory. Although there was a standard operating procedure

in place for daily cage checks and the animal technicians were able to describe clearly the procedures to follow to the Inspectorate during the investigation of this incident, the daily checks did not detect the fighting or severe fight wounds. The severe injuries caused avoidable pain, suffering, distress and lasting harm, which was not eliminated as quickly as possible.

The establishment licence holder took the incident very seriously and lessons were learned to avoid recurring recurrence. These included:

- appraisal and retraining of the animal care staff involved to ensure that appropriate and thorough daily checks were completed;
- rotation of animal care staff through all the animal rooms on a daily basis; and
- minimum core working hours for weekends and bank holidays across animal units.

The establishment licence holder was sent a letter of written reprimand. They were also required to provide a written report within one month on the action they would take following the incident:

- to address issues of staff resources, competence and the effectiveness of daily checks; and
- to assure the Animals in Science Regulation Unit that provision of care was adequate in this unit.

The three animal technicians were each sent a letter of censure.

Non-compliance case 35

An establishment licence holder, who also held a project licence and a personal licence, together with three other personal licence holders, conducted regulated procedures on large animals outside the controls and limits of the project licence, resulting in avoidable adverse welfare consequences to the animals. The Home Office suspended the project licence initially for a period of up to one month because of immediate welfare concerns. The project licence holder's personal licence was also suspended for a period of three months. The Inspectorate provided a report that provided assurance that those immediate concerns had been addressed. The suspension of the project licence was removed but the personal licence remained suspended. Further investigation showed that:

- regulated procedures had been conducted without project licence authority;
- regulated procedures had been performed on animals in an unsuitable condition;
- there was a failure of provision of veterinary care and oversight;
- there was inadequate record keeping; and
- relevant protected animals were kept at a place not specified on the establishment licence, and in accommodation that was not compliant with the Code of Practice.

The evidence presented failures in management and governance over animal use in the establishment, which had led to avoidable adverse animal welfare, including inadequate nutrition, coupled with multiple breaches of the Animals (Scientific Procedures) Act 1986 (ASPA) and of the standard conditions of the establishment, project and personal licences. The incidents of non-compliance raised serious concerns relating to:

- compliance with the establishment and project licence authorities;
- inadequate training and supervision of personal licence holders;
- ineffective communication between role holders; and
- inadequate attention to animal welfare.

The establishment licence holder agreed to a transfer of responsibility to new named role holders and establishment and project licence holders in order to provide a more robust framework to ensure compliance. The establishment licence holder was sent a letter of written reprimand. Furthermore, in view of the seriousness of the breaches of ASPA, the Home Office revoked the establishment holder's personal licence and they were informed that should they wish to apply for a licence under ASPA again the Home Office would require

them to undertake all mandatory training for those roles and to provide other specific reassurances.

Three other personal licence holders sampled animals more frequently than authorised and applied procedures to animals that did not meet the authorised health and welfare criteria. All three personal licence holders left the establishment where the non-compliance occurred. They were each sent a letter of written reprimand. They were also informed that should they wish to reapply for a personal licence their application would not be considered until they had provided evidence of:

- having successfully completed accredited training modules in order to refresh their knowledge of their personal, legal and ethical responsibilities; and
- improving their specific species care and welfare knowledge.

Non-compliance case 36

A personal licensee undertook surgery on the thyroid of 42 mice under the authority of a project licence. At an unannounced inspection the Inspector discovered that post-surgical analgesia had not been provided to the mice. On further investigation it was discovered that when changing from using an injectable anaesthetic/analgesia combination to inhalation anaesthesia approximately 18 months previously the licensee failed to consider the requirement for administering analgesia separately. They estimated that they did not provide analgesia to approximately 350 mice following surgery. The personal licence holder admitted liability and regret for their oversight and for the unnecessary suffering they had caused the mice. The surgical procedure was swift and skilfully performed by the licensee, although the animals did suffer some post-operative swelling and pain. By failing to provide analgesia, the personal licensee breached a number of personal licence standard conditions.

The establishment licence holder stopped the personal licensee from conducting surgery, pending the outcome of an internal investigation. Had this internal control not been put in place the Home Office would have considered suspension of the personal licence in order to safeguard the welfare of protected animals. The personal licence holder was sent a letter of written reprimand. They were also required to undertake further accredited training to improve their knowledge of their legal and ethical responsibilities as a personal licensee, to ensure that they:

- fully understand their responsibilities under the Animals (Scientific Procedures) Act 1986 (ASPA);
- fully understand the need for analgesia; and
- improve their knowledge about surgical anaesthesia and analgesia.

They were also required to work under supervision until they were signed off by an assessor as being fully competent in the provision of anaesthesia and analgesia.

The project licence holder was sent a letter of written reprimand. They were also required to undergo accredited retraining to ensure that they fully understand:

- their responsibilities under ASPA;
- the need to ensure that people working under the authority of their project licence are familiar with the protocols; and
- that the 3Rs (the replacement, reduction, refinement of the use of animals in science) are fully applied by all those working under the authority of the project licence.

Non-compliance case 37

Two mice were moved to a new cage at weaning and three days later one of the mice was found dead and the other unwell, such that it had to be humanely killed the following day. The death of the first mouse and poor condition of the second mouse were a direct result of:

- the failure by those with responsibility for the care and welfare of the animals to provide them with food; and
- subsequently failing to identify this deficiency at succeeding checks over the following three days.

Following the incident the establishment licence holder took immediate and appropriate action to prevent any recurrence. The establishment also ceased all work with animals falling under the remit of the Animals (Scientific Procedures) Act 1986. The establishment licence holder left their post for purposes unconnected with the incident and for this reason they were sent a letter of written censure.

Non-compliance case 38

An establishment employee was driving a van that was transporting boxes of mice from one part of the establishment to another. As the van turned a corner the side door slid open and two boxes of mice, containing 15 non-genetically altered stock animals, fell out of the van onto a public highway. The boxes were damaged, resulting in the escape of the mice. Twelve mice were collected although one subsequently died at the scene of the accident. Three of the mice escaped and their fate is unknown. Upon recapture, the remaining mice were later humanely killed as they had been exposed to the outside environment. The employee was very experienced in transporting animals and admitted to the Inspector that, although they checked the van's sliding side door before the journey, the door was not closed properly. Furthermore, on this occasion the animal boxes were unsecured and against the side door that opened.

The establishment licence holder put into place a number of measures to minimise the risks of such an incident recurring. As the establishment licence holder identified and implemented sufficient measures to prevent recurrence, they were sent a letter of written reprimand.

Non-compliance case 39

A cage of five mice was split into two cages; one of three mice and one of two. One week later an animal technician undertook a full cage change of the individually ventilated cages in the holding room and discovered that the mice housed as a group of three were dead. No food was in the cage. The technician had been responsible for the husbandry and welfare of the mice during this period and had undertaken the daily checks. The technician could not give an explanation as to why the lack of food had not been identified. The conclusion was that it was likely that no or insufficient food was provided when the mice were initially moved.

There was no doubt that the daily checks failed to identify the lack of food and the deteriorating condition of the mice. The establishment licence holder introduced a range of measures to minimise the possibility of recurrence as a result of this incident. The assigned Inspector was able to confirm that senior staff had taken robust action to improve the quality of the daily checks, including retraining and supervision of the technician. The establishment licence holder was sent a letter of written reprimand. The Home Office would have required the technician to be retrained and assessed for competence in carrying out their daily checks had this not already been undertaken by the establishment.

Non-compliance case 40

Following routine administrative action on a project licence, the licence holder realised that many more genetically altered mice (approximately 8,800) had been bred than was authorised by the licence (5,000). The over-breeding occurred for a period of approximately one year. Upon discovery, the project licence holder self-reported the over-breeding to their assigned Inspector and took full responsibility for the error. The use of this number of animals was scientifically justifiable; the project licence holder subsequently sought an amendment increasing the numbers bred on their licence and it was granted.

There was no intent to circumvent the regulations and a detailed local investigation was undertaken with a new system put in place to prevent any recurrence. The project licence holder was sent a letter of written reprimand.

Annex 2: Tables and figures

Table A1. Licence applications and amendments, 2016 and 2017

	Total			Per inspector FTE		
	2017	2016	Change	2017	2016	Change
PILs granted	2,985	3,166	-6%	169.9	215.4	-21%
PILs amended	521	551	-5%	29.7	37.5	-21%
PILs in force at year end	16,109	16,178	-0.4%	916.8	1,100.5	-17%
PELs granted	3	3	0%			
PELs amended	160	159	1%	9.1	10.8	-16%
PELs in force at year end	160	167	-4%	9.1	11.4	-20%
PPLs granted	568	533	7%	32.3	36.3	-11%
PPLs amended	1,129	1,012	12%	64.3	68.8	-7%
PPLs in force at year end	2,585	2,631	-2%	147.1	179	-18%
Inspectors FTE	**17.6**	**14.7**	**20%**			

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

Figure A1: Inspectorate staff, 2010 to 2017

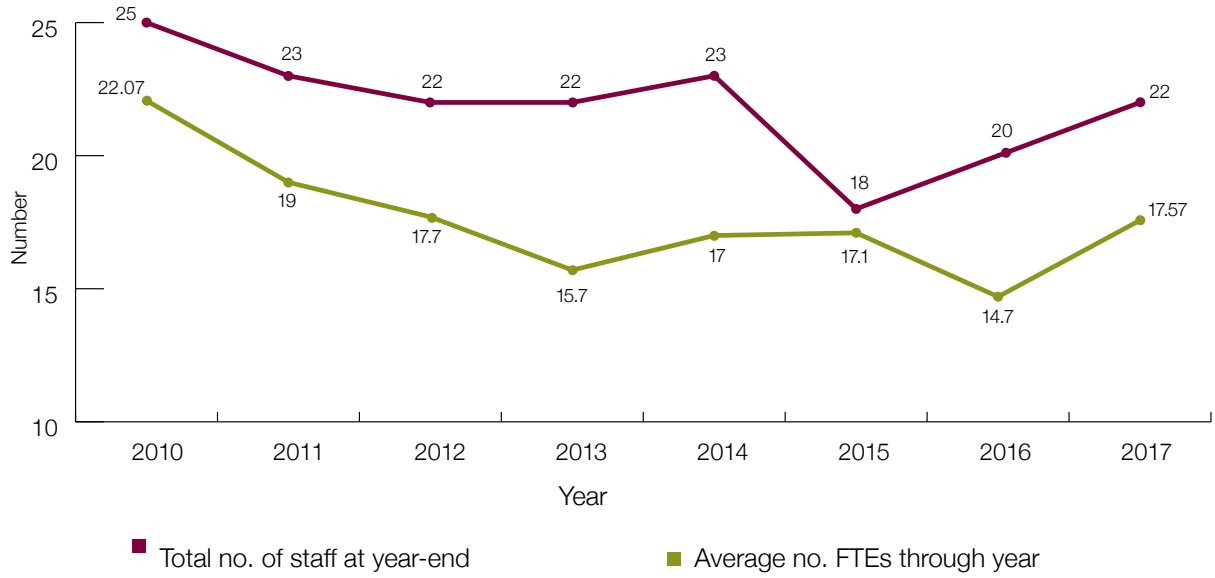


Figure A2: Project licences granted, 2010 to 2017

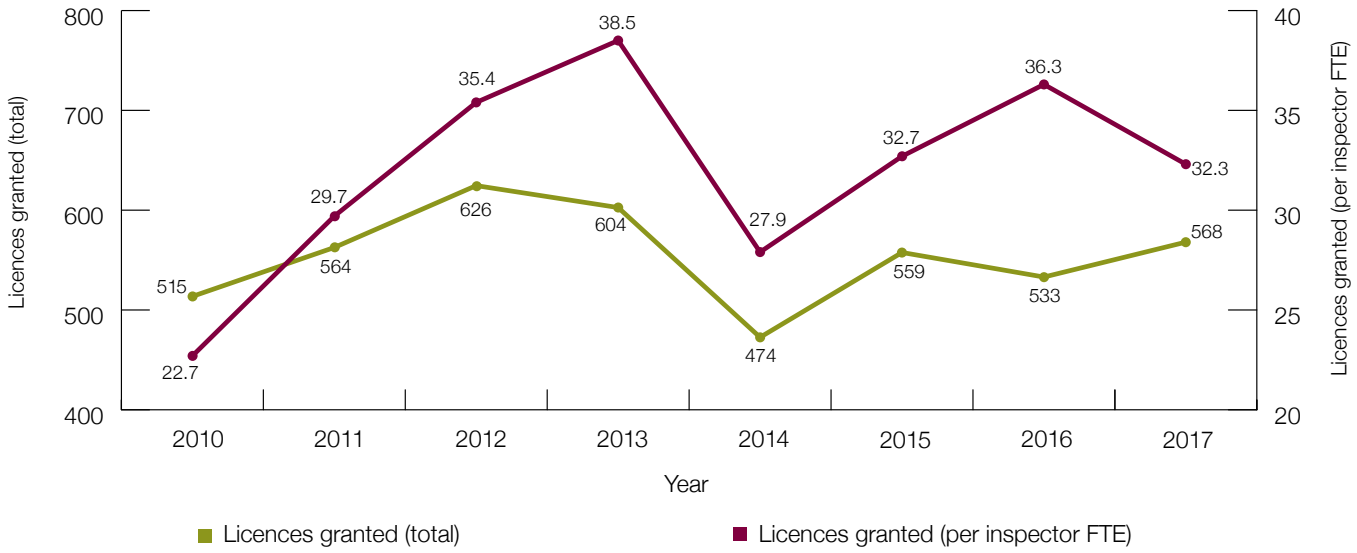


Figure A3: Project licence application processing, 2010 to 2017

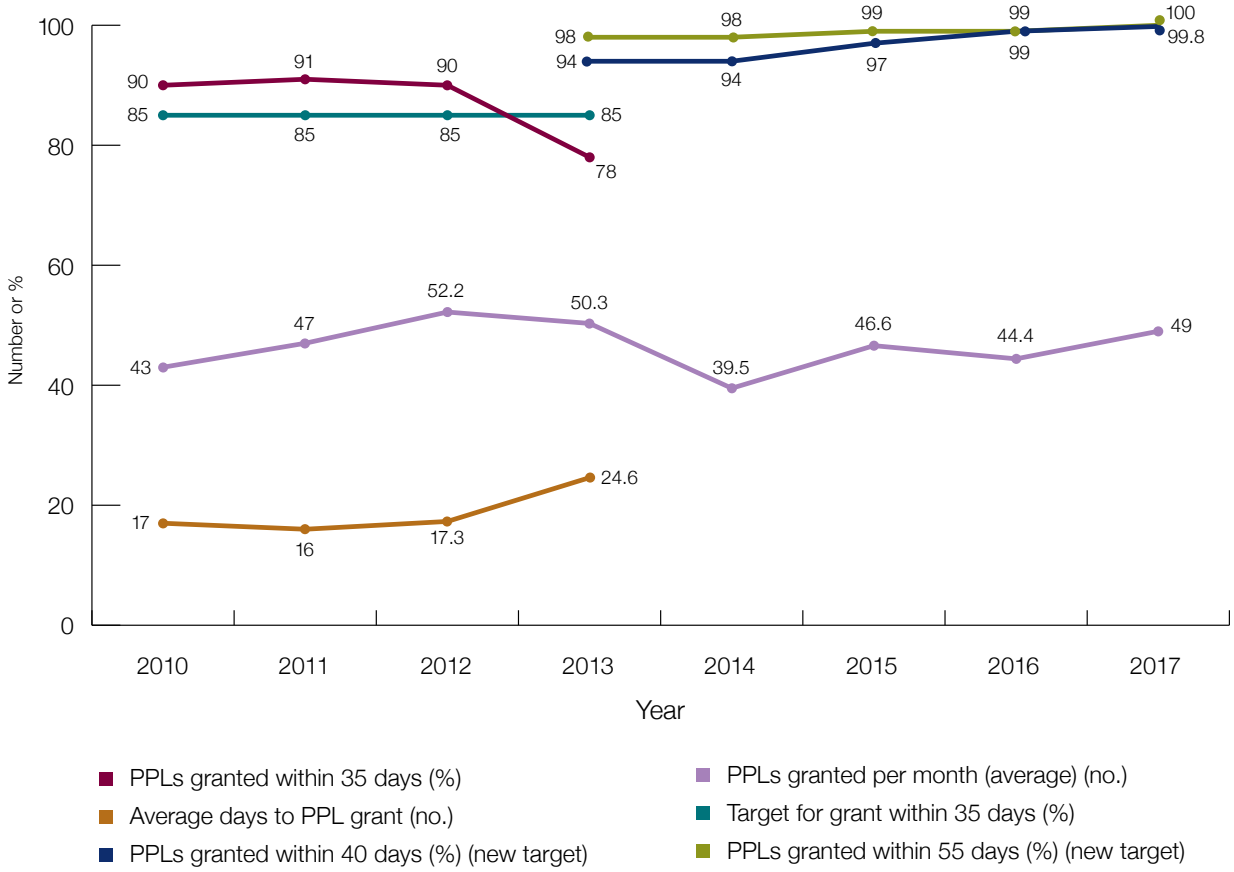


Figure A4: Inspections, 2010 to 2017 (total)

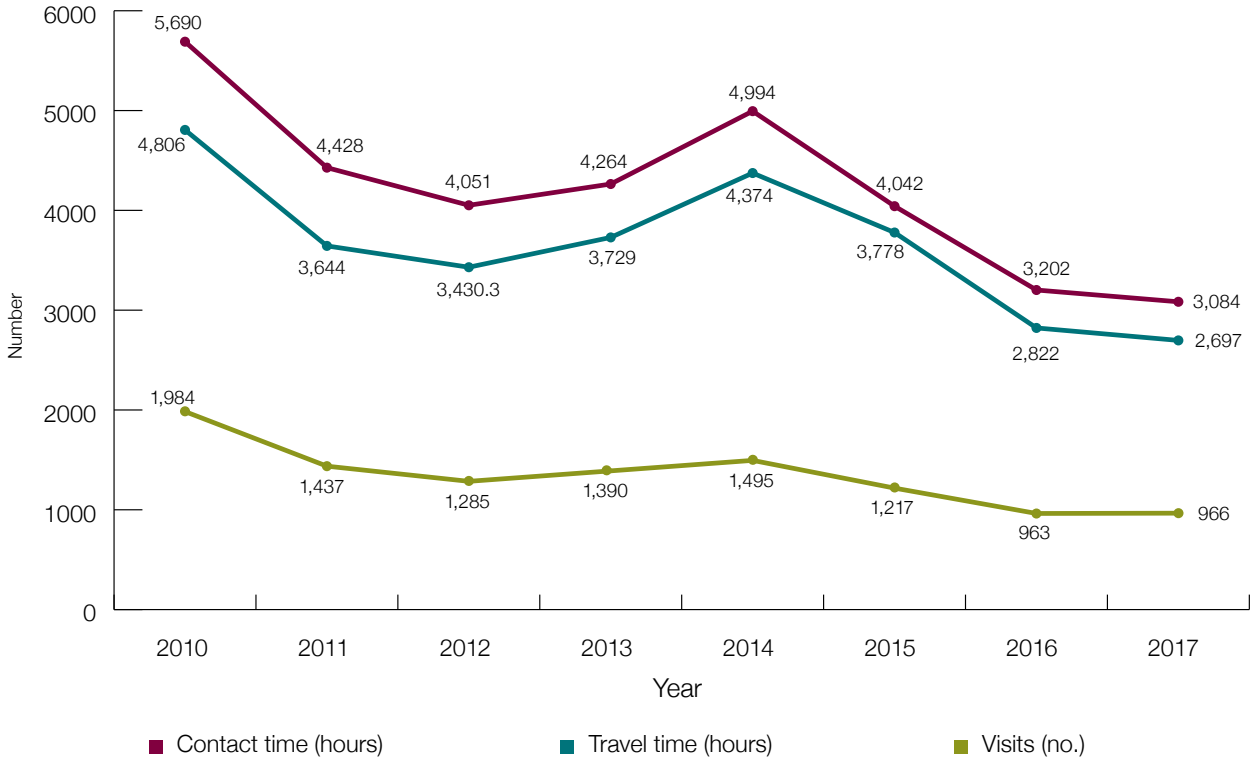
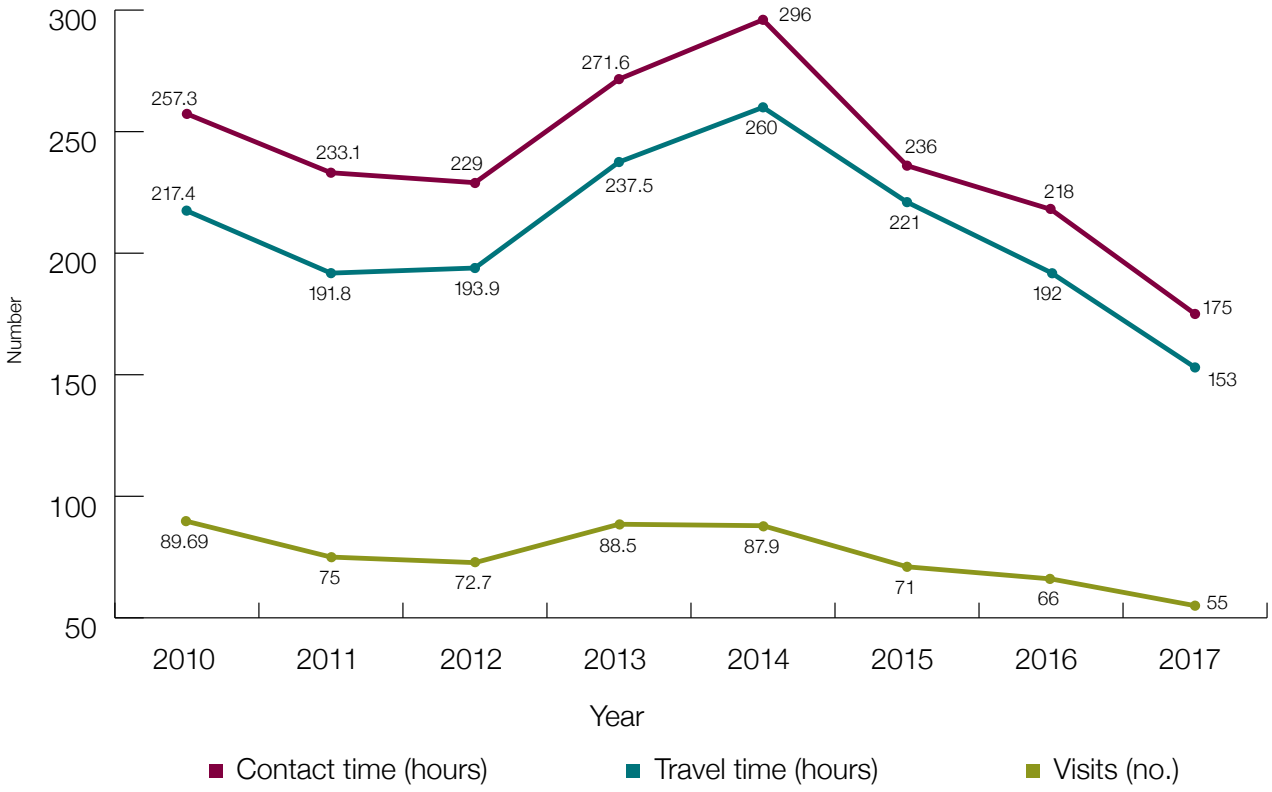


Figure A5: Inspections, 2010 to 2017 (per FTE)



Annex 3: Household products ban update

The testing of finished household products on animals and the testing of ingredients has been banned since 1 November 2015. Exemption is only provided if the testing is required by current regulations (requiring retrospective notification), or in exceptional circumstances, which requires prospective authorisation.

As science has advanced over recent years, so also has the validation of alternative approaches to assessing product safety without resorting to animal testing. In particular, the need to test finished household products in animals is now generally accepted to be no longer necessary, and the testing of ingredients is expected to be more limited.

Between 1 January 2017 and 31 December 2017, 451 animals were used for household product ingredients testing. Of these 348 were rats, 99 were mice and 4 were rabbits. The majority (77%) of these animals experienced mild actual severity, 21% experienced moderate severity and 2% experienced severe severity.

The *Annual Statistics of Scientific Procedures on Living Animals Great Britain 2017* provides annual figures for the number of procedures on animals for the purposes of household product testing in Great Britain. Each animal was only used once, therefore the numbers of animals used is the same as the number of procedures undertaken for household product testing.[8]

8 There is a difference of one between the total numbers of animals used and the total number of procedures reported in the Annual Statistics. This due to the rounding convention used in the Annual Statistics.