Home Office

Animals in Science Regulation Unit
Annual Report 2018

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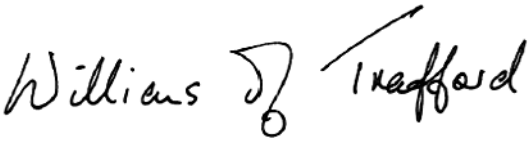
Ministerial foreword

The use of animals in scientific research remains a vital tool in improving our understanding of how biological systems work both in health and disease. Such use is crucial for the development of new medicines and cutting-edge technologies for both humans and animals, and for the protection of our environment. The UK continues to maintain a leading position in ground breaking scientific research, alongside our commitment to the highest standards in animal welfare. This would not be possible without a rigorous, animals in science regulatory system underpinned by a robust inspection process.

As we move to a future outside the European Union, we will continue to uphold our commitment to animal welfare, high-quality science, and the principles of the 3Rs - the Replacement, Reduction and Refinement of the use of animals in research. We have prepared for a seamless transition for the regulation of animal use so we can continue to deliver our current standards of oversight and scrutiny.



Baroness Williams of Trafford

Foreword

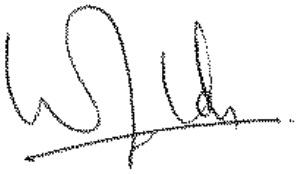
Throughout 2018 the Animals in Science Regulation Unit (ASRU) has continued to focus on modern, consistent and responsive animals in science regulation. The cornerstone of modernising our processes has been the continued development of our electronic licensing system, ASPeL.

In August 2019 a rebuilt ASPeL will be launched. The original ASPeL system was rolled out in 2014 and was a landmark in moving away from a paper-based system. The new ASPeL system will set benchmarks by delivering an improved user experience and greater efficiencies in licensing processes. Extensive user research has been undertaken to design a system that will meet the needs of service users, reduce costs and allow us to deliver better regulation. The project will provide a better electronic licensing system and will deliver a new style of project licence. The application form will be based on targeted questions that gather better quality information to inform the harm–benefit analysis process. The licence will be a shorter document that sets out the regulated work more clearly and succinctly. We are also seeking to improve the non-technical summaries to improve openness and transparency to explain the animal experience and the benefits likely to be delivered more clearly. The new process will see the application and the licence considered as two different entities. Our aim is to improve the application, assessment and enforcement processes for applicants and the Inspectorate.

Developing and maintaining a culture of compliance in licensed establishments is a key plank in the effective delivery of the Animals (Scientific Procedures) Act 1986 (ASPA) (as amended). In 2018, 29% of the total number of compliance cases reported were a failure to provide food and/or water. Our response to these cases is to apply appropriate sanctions, to understand root causes and encourage better future compliance that avoids these serious incidents. We demand that establishments have adequate procedures and systems in place that minimise the likelihood of incidents of food and water failures, and have put significant effort into targeting this area of concern.

Throughout the year we have continued to focus on the delivery of the 3Rs - the Replacement, Reduction and Refinement

of the use of animals in research - and their application throughout work conducted under ASPA. The application of the principles of the 3Rs requires gathering knowledge and evidence from many sources. In 2018 we agreed a Memorandum of Understanding (MoU) with the National Centre for the 3Rs (NC3Rs) thereby formalising our shared commitment to bridging the gap between the development and the uptake of 3Rs techniques. The MoU provides high level principles such as embedding the NC3Rs outputs into the regulatory framework; a commitment to working on topics of shared interest; and having mutual knowledge exchange for forwarding our respective work programmes.



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 Science. ASRU is responsible for the administration and enforcement of the Animals (Scientific Procedures) Act 1986 (ASPA). In Northern Ireland, this responsibility is devolved to the Northern Ireland Department of Health, which reports its activities separately.

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

The Policy and Administration Group

The Policy and Administration Group is based at the Home Office in Whitehall and Croydon. The group comprises the Policy Team in Whitehall and the business support, IT and licensing teams in Croydon.

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 2018 the team's work included:

- contributions to the implementation of the EU Directive 2010/63/EU via the European Commission;
- developing the United Kingdom's (UK's) approach to animals in science regulation as the UK exits from the European Union (EU);
- the delivery of judicial review and tribunal processes relating to animals in science;
- the development of central government and operational policy;
- the production of various Advice Notes; and
- the publication of statistics.

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

At the end of 2018 the Policy Team comprised three policy advisers who report to the Head of Policy.

Business support and IT

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 and publication of newsletters;
- 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;
- collecting licence fees; and
- maintaining the incumbent ASPeL system and the IT resources within ASRU.

During 2018 the Business Support Team comprised one Senior Manager supported by one Higher Executive Officer and one Executive Officer. The team reports to the Head of Operations.

The Inspectorate

Inspectors 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 have a breadth of expertise, including first-hand experience of biomedical research, higher scientific or clinical postgraduate qualifications.

At the end of 2018 the Inspectorate comprised 22 individuals (20.8 full-time equivalents [FTEs]), which represents no significant change from 2017. The Chief Inspector is included in these figures.

Compliance

The ASRU Compliance Team consists of a lead Inspector, a Senior Complex Cases Manager and an Executive Officer. The Compliance Team supports the assigned 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 to the ASRU Leadership Team.

The published compliance policy can be read here: https://www.gov.uk/guidance/animal-testing-and-research-compliance-with-aspa

The Licensing Team

The purpose of the Licensing Team is to undertake the administrative licensing functions of ASRU. 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 2018 the team comprised the Head of Licensing (reporting to the Head of Operations), two Licensing Managers and three 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 with its requirements.

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.

Publications

Advice Note on efficient breeding of genetically altered animals

ASRU published an Advice Note on GOV.UK[3] for establishments using animals to consider the efficiency with which they breed genetically altered animals (GAAs). The document was created in consultation with breeding experts and provides:

- background information;
- lines of enquiry
- examples of acceptable findings;
- underlying performance standards; and
- potential performance outcomes that establishments may wish to use to measure their standards.

This assessment framework is focused on rodent breeding, although the principles will apply to many species.

Advice Note on Project Licence Standard Condition 18

ASRU published an Advice Note that sets out the requirements of Project Licence Standard Condition 18 (PPL SC18).[4] This condition is one of 25 standard conditions applied to all project licences issued under ASPA.

The PPL SC18 requires project licence holders to notify ASRU if constraints on severity or observance of other controls described in

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
3 https://www.gov.uk/guidance/animal-research-technical-advice#ecient-breeding-of-genetically-altered-animals
4 https://www.gov.uk/guidance/research-and-testing-using-animals#project-licence-standard-condition-18-notification

the project licence have been, or are likely to be, breached. Breaches may have various causes; they might arise from human error, such as an unanticipated failure to observe the welfare controls specified in the project licence, or from unexpected or unforeseeable events. Notification under PPL SC18 relates to breaches or likely breaches of either severity limits or any other controls set in the licence. Notification provides an important opportunity for the licence holder, the establishment and ASRU to review whether any changes need to be made. It is important to recognise that notification under PPL SC18 is good practice and is not non-compliance.

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 2018 senior representatives from ASRU, as the UK Competent Authority, attended a number of meetings in Brussels.

During 2018 ASRU officials attended two National Contact Point meetings as UK representatives. Updates were provided by each EU Member State on their transposition of the Directive.

Matters of particular Member State interest have been discussed over the year and formal agreement reached on documents from various working groups and committees. ASRU shared its published Advice Notes with other Member States. A brief summary of key items in 2018 are:

- refining the templates for non-technical summaries to improve published information on the use of animals in science;
- preparation of a template for retrospective assessments;
- delivery of a report to the European Commission under Article 54 of the directive setting out the UK's implementation of the Directive; and
- regulation of genetically altered animal breeding without burdensome processes, whilst ensuring rigour.

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 UK has harmonised legislation for animals in science regulation with all EU Member States. In 2018 ASRU made preparation for EU exit by preparing legislation, known as a Statutory Instrument, to amend ASPA and deliver EU exit. When enacted on the day of EU exit, the legislation has the result of removing mandatory requirements to work with the EU Commission and other Member States.

The delivery of the animals in science regulatory framework will continue with the same standards of oversight, rigour and scrutiny following the UK's withdrawal from the EU. For clarity, there will be no change to the UK standards of animal welfare or housing and care as set out in the Code of Practice.

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 the use of animals and the limits to impose to minimise harms to the animals. This includes instances when other regulators, such as the Medicines and Healthcare products Regulatory Agency (MHRA), require testing to comply with legislation other than ASPA. Therefore, the regulation of animals in science impacts on several other regulatory systems where the use by testing of animals is mandated. For example:

- to allow medicines to be brought to market; and
- to provide assurances on public safety of new chemicals.

In addition, a great deal of medical and biological research relies on the use of animals.

ASRU continues to engage with other relevant government departments and agencies to make the best plan for EU exit.

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 consider both the legitimate requirements of science and industry and the protection of animals from avoidable suffering and unnecessary use in scientific procedures. The ASC has a website[5] detailing its activities.

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*;[6] 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 2018 the ASC reviewed eight separate programmes of work. Two of the programmes involved more than one application.

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 to address this, the ASC has set up a network of AWERB hubs to facilitate knowledge transfer; it also introduced a secure information-sharing platform open only to AWERB members. Additionally, during 2018, the ASC hosted two regional Roadshows for AWERBs (North England and South England), providing opportunities for members of AWERBs from across the UK to meet. ASRU welcomed these initiatives 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, including Guidance Advice Notes.

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

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), which 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 2018 ASRU licensed and regulated 160 establishments, with 156 establishments licensed at the end of 2018.These establishments include universities, pharmaceutical companies and contract research laboratories. At the end of 2018 there were 2,736 active project licences with 3,100 project licences active at some point in 2018. At the end of 2018 there were 16,278 active personal licences. Fees associated with personal licences are calculated on a financial year basis; therefore, a separate figure for the total number of personal licence holders will be reported in the financial reports for 2018/2019 financial year.

Licensing activities

Establishment licences: During 2018 two new establishment licence applications were received.

Project licences: During 2018 a total of 540 new project licences were granted. Of these 537 complete and correct applications were granted within the 40 days target (99.4%). The remaining licences were granted during the statutory 15-day extension to 55 days. There was a 4% decrease in project licences granted in 2018 compared with 2017.

Personal licences: During 2018, 3,452 new personal licences were granted, and 598 personal licence amendments were granted. This is a 1.7% decrease on new personal licences compared with 2017. The team successfully processed 96% of licences within the internal 20-day target. Reasons for longer processing times included complex requests for training and exemptions.

Licensing Team stakeholder engagement

To manage the delivery of the licensing function effectively, the Home Office meets three to four times a year with counterparts in establishments through the Home Office Liaison and Training Information Forum (HOLTIF). The meetings are an opportunity to discuss service delivery, for ASRU to receive feedback, and to solve any associated issues. The main external attendees are the Home Office Liaison Contacts (HOLCs). The HOLCs undertake many of the administrative functions required under ASPA by establishments and support licence applicants and the establishment licence holder. During 2018 the HOLTIF met with ASRU at events attended by up to 60 HOLCs. The main focus of meetings in 2018 was the delivery of the new e-licensing system (ASPeL). Additional discussions were held relating to the performance of ASRU and improvements that can be made to effective licensing, assessment, inspection and investigation of compliance matters.

Animals scientific procedures e-licensing

The new e-licensing system will enable high-quality animal science and a thriving bioscience sector by providing ongoing capability to deliver secure, end-to-end, e-licensing and associated processes for all three licence types. This £3 million IT product build was initiated by a call from users (establishments and their staff) to digitise the licensing system beyond the existing 'paper online' approach. The new system will:

- provide a replacement IT system, infrastructure and process changes to modernise the business;
- reduce costs;
- meet the needs of the users; and
- enable the Home Office to deliver better regulation, information assurance and e-business commitments.

The key strategic aims for e-licensing are to:

- maintain the rigorous and robust application of the ASPA framework;
- build a user-centred, replacement system for the 'paper online' ASPeL that meets the Government's digital service standard;
- modernise the licensing and related processes underpinning the operation of ASPA;
- reduce user compliance costs, reduce processing times, and reduce resource costs to the Home Office as the regulator;
- make proper provision for the secure exchange of protectively marked personal and other commercially sensitive information;
- comply with the EU Services Directive; and
- provide management information to inform the effective and most efficient use of ASRU resources.

Establishments have expressed a need to manage their applications more effectively and track their progress. They also need to review all licences held at their establishment on a regular basis to ensure that they are still required. The new e-licensing system will enable them to do this more easily than in the current system.

The new system will:

- reduce the burden on establishments by making the information that needs to be made publicly available easy to source; and
- enable ASRU users to be able collate and publish information.

Without digital licensing, both establishments and ASRU will have to put additional resources into providing the information that the Government will have committed to being made available to the public.

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, reduce and refine the use of animals for scientific purposes. The Animals in Science Regulation Unit (ASRU) and the NC3Rs have a shared aim of maximising 3Rs (replacement, reduction and refinement) delivery. Working effectively together on 3Rs challenges will support the delivery of high-quality science and innovation, and minimise animal suffering.

In 2018 ASRU agreed a Memorandum of Understanding (MoU) with the NC3Rs. The MoU represents a bilateral agreement for mutual information exchange, thus enhancing ASRU in its legislative requirement to implement fully the delivery of the 3Rs. A copy of the MoU can be found at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/734630/establishment-licence-holder-newsletter-august-2018.pdf.

Themed inspection programme

In 2018 ASRU inspectors undertook themed inspection activity in the following areas:

- how the re-use of hypodermic needles can be avoided to reduce suffering during injection procedures;
- using more refined rodent handling procedures; and
- how to reduce non-compliance associated with failure to give animals food and water, and to understand why such cases still arise.

Advice was taken from the NC3Rs during the development of these programmes and ASRU continues to be grateful for its advice and guidance in these areas. The themes will be concluded in 2019 and the results shared with stakeholders. ASRU will consult further with the NC3Rs, and use data and evidence as relevant, to select further areas of focus.

NC3Rs colleagues have continued to contribute to ASRU in-house training events to establish strong working relationships with inspectors and to support the requirement for the 3Rs being fully considered in project licence applications. The ongoing link between the NC3Rs and ASRU assures 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) supports 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 regulation of the use of animals in science. PQs and correspondence are an important way in which the Government communicates current policy and thinking in an open and transparent way.

Correspondence

During 2018 ASRU handled 161 pieces of correspondence. This comprised 34 FOI requests, 23 PQs, 53 items of Ministerial correspondence and 51 other pieces of correspondence.

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

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

Parliamentary Questions

Parliamentary Questions 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 be provided within a very tight timeline, which is often less than 24 hours. ASRU provided advice to Ministers on 23 PQs in 2018; the PQs and the answers to them can be found at www.parliament.uk.

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 use of primates for research.

Freedom of Information requests

ASRU received 34 FOI requests on a variety of topics during 2018. 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 that 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 to:

- inform ASRU policy decisions;
- understand the expectations and perspectives of ASRU's stakeholders; and
- receive valuable feedback in the performance of the Unit and the effective implementation of the Animals (Scientific Procedures) Act 1986 (ASPA).

The meetings covered matters related to:

- the development of the new e-licensing system, ASPeL;
- 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
- ASPA Named Persons and others performing functions under the Act.

ASRU met periodically to discuss cross-government issues 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); and
- the National Centre for the 3Rs.

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

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

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, this activity 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 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 Leadership Team and inspectors.

Some highlights of engagement with stakeholders in 2018 included attendance and presentations:

- 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 undertake 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 2018 ASRU undertook 653 inspections of places where scientific work on animals was conducted. Of the visits to animal units, 63% 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 according to 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. Although other calculation methods could be used, in practice they tend to produce similar rankings.

Other factors are then taken into consideration:

- establishments with specially protected species are given additional inspection time; and
- establishments with access difficulties relating to their geography may require 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 inspect in one visit 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 baseline inspection demand.

Themed inspections

Themed inspections are intended to focus efforts on issues that have implications across many establishments, and where a focused approach may have benefits to understanding and influencing the effective implementation of the 3Rs (the replacement, reduction and refinement of the use of animals in research).

Themed inspections may also be more targeted. For example, where particular techniques or issues require closer examination or evidence gathering to assist with the development of policy or the provision of advice on the implementation of the 3Rs.

In 2018 the scope and planning for three themed inspection programmes was developed; this will be implemented during 2019. Many licensed establishments and inspectors will be involved as the themed inspections take place. These three themed inspection programmes cover:

- the use and uptake of refined handling methods for laboratory rodents;
- the re-use of single use hypodermic needles; and
- the arrangements for provision of food and water.

These areas have been prioritised because the potential benefits are widely applicable to many animals and they have a significant implication for welfare and scientific outcomes. ASRU has taken the views of stakeholders into account in prioritising these areas.

Risk management

In 2015/2016 ASRU put in place a more structured risk management process that continued into 2018. This comprises a review of the national risk profile and local establishment factors. Review is undertaken quarterly by the Chief Inspector and the principal inspectors. Prior to meeting, the principal inspectors discussed the concerns, observations and findings of each inspector reporting to them and reviewed the key findings by establishment. These discussions identify the main concerns each inspector has regarding each institution they inspect and the current compliance picture.

These quarterly reviews gather together the inspectors' evaluation of the risk for their establishments and the results of the inspections of the previous quarter. Additional consideration is given to:

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

The principal inspectors compare and contrast the views of their inspectors and draw up a list of the major concerns and their relative significance.

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

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

External recruitment for further new inspectors, to cater for anticipated future requirements, was instigated. A campaign run during 2018 did not identify suitable candidates so a further campaign was undertaken in early 2019 to identify a pool of suitable candidates for future vacancies.

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, both face to face and remotely.

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, for example:

- to maintain professional specialist expertise; and
- to increase knowledge in an area related to specific science, administrative skills, or the 3Rs of animals used in research.

Inspectors are also 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

A new electronic system of inspection reporting was implemented in 2017 and has been used throughout 2018. The system provides:

- improved functionality for recording, categorising and rating findings of inspection; and
- improved management data.

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.

In all cases, 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 necessary action, and so that good practice may be identified and promoted locally.

Where practical issues prevent immediate feedback (for example, on multi-site establishments) key findings 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 record also allows access to the history when establishments transfer between inspectors.

The annual risk review meeting is used to discuss the general findings of the inspection and assessment programmes.

Investigating allegations made to the Animals in Science Regulation Unit

ASRU periodically receives allegations about potential breaches of ASPA, 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. Typically, allegations are found not to be breaches of ASPA, whilst others may have relevance to legislation other than ASPA. However, 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.

The ASRU compliance policy document published in December 2017 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 ASPA has a Named Person Responsible for Compliance (NPRC). This individual is responsible for ensuring compliance with the conditions placed on their establishment licence. 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. Inspectors can therefore be assured that all licensees will comply with their licences when working at their establishment.

Inspectors advise licensees and others working with animals in science on how to comply and promote a culture of compliance. During inspections, inspectors determine whether establishments and licensees are complying with the provisions of the Animals (Scientific Procedures) Act 1986 (ASPA) and with the conditions of their licences. Inspectors report any non-compliance and make recommendations on what action may be required. This is primarily aimed at the prevention of repeating similar incidents.

The assigned inspector gathers sufficient information to determine whether there is a case that merits investigation. An initial report is then submitted to the Senior Compliance Manager within five working days of discovery. A full investigation report is typically submitted within 30 working days of discovery, together with a recommendation for action.

The establishment will be notified in writing by the Senior Compliance Manager. An opportunity is given to provide any information that they wish to be considered before ASRU takes a decision regarding the appropriate sanction. Complex or serious cases may take longer to resolve than the suggested timescales above. There is also the opportunity for appeal against some sanctions. In rare cases, an inspector may take a view that an offence has been committed that is sufficiently serious to merit referral for prosecution.

Animals in Science Regulation Unit's potential remedies for non-compliance

Cases are considered on an individual basis regarding seriousness. The most appropriate remedy is applied taking into account aggravating and mitigating circumstances, with the aim of deterring or preventing recurrence. 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.

The range of sanctions available, as set out in the published compliance policy[7], benchmark and help to determine the outcome associated with each breach. They are briefly outlined below.

1. Inspector advice

Where there is a minor breach an inspector will provide advice stating what provision was breached and what is expected in future to prevent a recurrence. 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.

Inspector advice in the case of minor breaches is now being recorded centrally and will be used in the future to identify and publish trends of minor incidents and near misses. Trends and useful observations will be published in future annual reports.

2. Compliance letters

Where provision of inspector advice is not considered sufficient, 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. These letters are formal records of non-compliance and may be used as evidence should there be a further breach within five years. All letters are copied to the NPRC so that local practices and processes can be reviewed, as appropriate.

3. Variation of 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 or to undertake procedures.

Requirement for reporting

Where action is required to improve weaknesses identified by a breach, including poor record keeping, a report may be required to monitor progress. Reports are also useful to formally monitor enhanced animal welfare, the implementation of refinements or improved scientific outcomes.

Suspension

Where a breach has been identified, licences may be suspended as a sanction. Licences may also be suspended when there are urgent welfare concerns. Suspensions are appropriate where there is a risk to animal welfare and significant urgent action is required to protect it. However, when a suspension occurs, ASRU must ensure that the suspension itself does not result in an adverse impact on animal welfare.

4. Compliance Notices

A Compliance Notice is issued where ASRU requires 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 consequential risk of harms caused by 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.

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

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. Over time, it provides a formal mechanism for assuring and monitoring improvements. Such changes may take some time to remedy, for example, increases in staffing, facility refurbishment or embedding an improved culture of care.

5. 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. ASRU has a duty to ensure that the welfare of animals is not adversely affected by the revocation of a licence.

6. Prosecution

Extremely serious cases of non-compliance 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.

Summary of non-compliance cases in 2018

In 2018, 28 cases of non-compliance were completed. This was in addition to cases where inspector advice was provided.

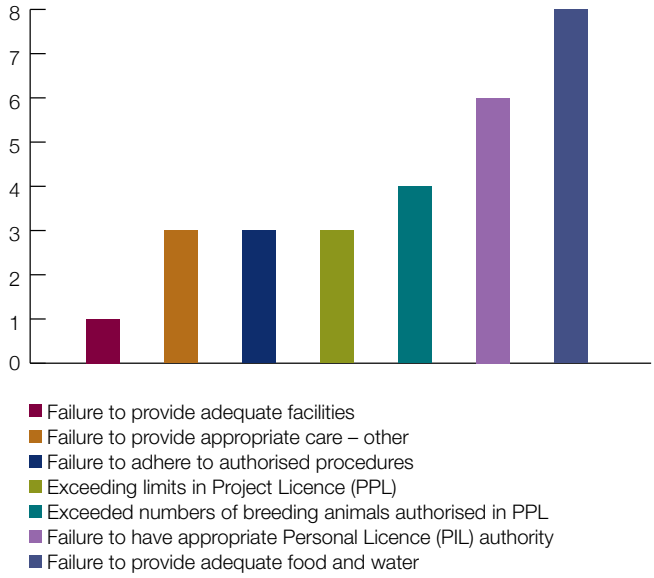
These 28 cases occurred in 20 different establishments of which 17 (85%) were universities and 3 (15%) were commercial organisations.

These 28 cases represented 33 separate incidents. In two cases, two incidents of a similar nature were reviewed together, and in another case four incidents of a similar nature were reviewed together. This occurred when separate incidents occurred close together and had the same root causes.

Of the total cases, 16 (57%) were related to the failure to have or adhere to licence authorities, whilst the other 12 (43%) were related to the failure to provide appropriate care (including food, water and suitable facilities).

A further breakdown of the types of non-compliance is shown in Figure 1 below.

Figure 1. Non-compliance cases, by type, 2018



Of these cases, 24 involved a total of 2,680 animals of which 1,631 were fish, 483 birds, 376 mice, 170 rats and 20 pigs. In 4 cases the total number of animals involved were not known. Of these four, in two cases more animals were bred than were under licensed authority, and the record keeping was inadequate to flag up or count the number of animals involved. In the third case, commercial standard facilities and transport were used for cattle regulated under ASPA. In the fourth of these, dogs were gavaged and semen collected from them by a trained and competent technician who did not have a PIL. In all these four cases, it was considered that the animals involved did not suffer adverse welfare outcomes and, had suitable licences or amendment been applied for, they would have been granted. It is a feature of the nature of these non-compliances that the numbers were not accurately known. Enhanced processes and communication will be in

place in future to minimise the uncertainties associated with the collection and collation of the number of animals involved in these types of non-compliances.

Of the total number of animals involved, the largest numbers (1,581 fish, 327 mice and 2 of the cases where numbers were not determined) reflect cases where more animals were bred than were authorised. However, in all these cases, the production and subsequent use of the increased number of animals delivered more scientific benefit. The increased number of animals and fish would have been authorised had the licence holder applied for an amendment to their project licence to allow for this.

In 16 cases (57%), there was an adverse impact on animal welfare over and above the impact of competently performed authorised procedures. These cases involved 588 animals, of which 480 were birds, 52 mice, 50 fish and 6 rats. In all these cases there was at least one animal that died or needed to be killed because of this adverse outcome. The total numbers of animals that died or needed to be humanely killed was 100, of which 50 were fish, 42 mice, 6 rats and 2 birds.

Table 1. Number of animals involved in non-compliance cases, 2018*

Animal type	Total number	Number with adverse welfare outcome	Number where adverse welfare outcome resulted in death
Fish	1,631	50	50
Birds	483	480	2
Mice	376	52	42
Rats	170	6	6
Pigs	**20**	**0**	**0**
Total	**2,680**	**588**	**100**

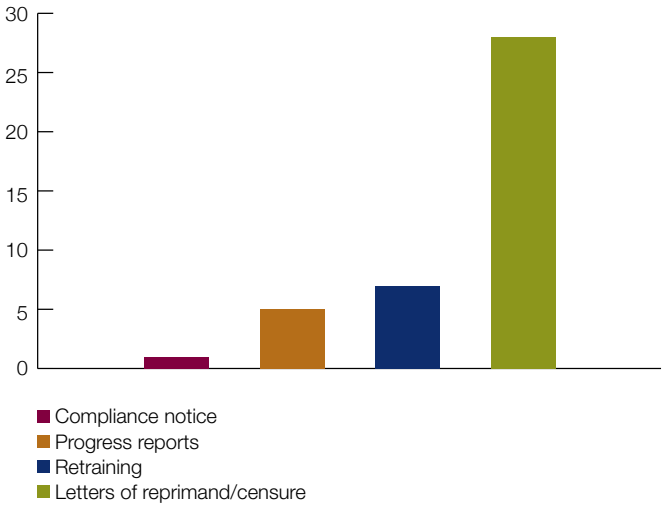
*Totals are taken from 24 of the 28 reported non-compliance cases; in 4 cases the totals were not known.

Of the 28 cases, 26 (93%) were self-reported by the establishment, 1 was identified by a whistle blower and 1 identified by the inspector during an inspection.

Self-reporting is considered to be 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 forms part of robust governance frameworks. It continues to be encouraging that a significant proportion of self-reported cases has continued since 2015.

In all reported cases of non-compliance, letters of reprimand or censure were sent. In 7 cases (25%) retraining was required. In 5 cases (18%), action plans or additional progress reports were required, and in 1 case (4%) a formal Compliance Notice was issued. The actions taken are summarised in Figure 2.

Figure 2. Action taken by ASRU in non-compliance cases, 2018*



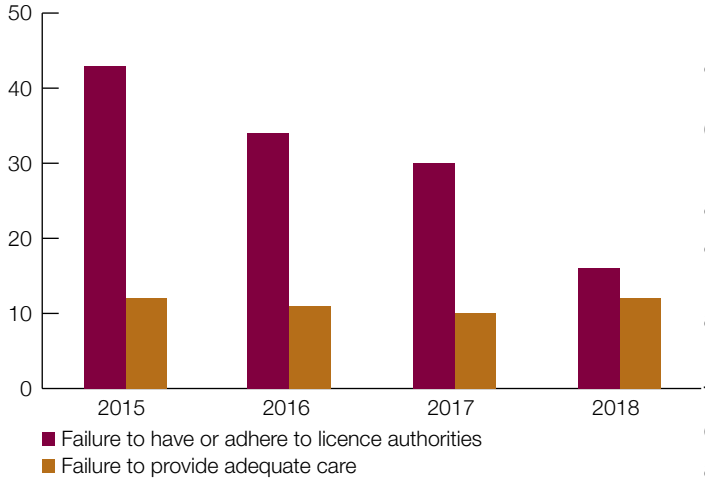
*Note that more than one action may be taken for each non-compliance case.

Summaries of all 28 non-compliance cases completed in 2018 are found in Annex 1.

Trends in non-compliance cases over time

The number of non-compliance cases, by principle breach of licence, 2015 to 2018 is shown in Figure 3.

Figure 3. The number of non-compliance cases, by principle breach by year, 2015 to 2018



The total number of non-compliance cases has decreased from 55 in 2015 to 28 in 2018. The decrease in 2018 may be partly due to the introduction of formal inspector advice during 2018; some such cases would previously have been included in the non-compliance statistics. Several non-compliance cases were detected in 2018, but investigations were not completed until 2019. From 2019 onwards, a summary of cases involving inspector advice will be included in future annual reports, but this is not possible for 2018 since the change in process and accounting for inspector advice occurred during the year.

Since 2015 the total number of cases that represent failure to provide adequate care (mostly food and water) has remained roughly constant, ranging between 10 and 12 cases a year. This is consistent with the emerging data for cases involving inspector advice since cases dealt with in this way exclude those where animal welfare is compromised.

Due to the change in the data reporting format, statistically supported conclusions cannot be drawn from a longitudinal comparison. However, it can reasonably be concluded that there has been no increase in cases of non-compliance during 2018.

Key learnings from 2018 non-compliance cases

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 adequate provision of food and water at all times to animals kept under the protection of ASPA.

Of the total of 28 cases in 2018, 8 (29%) breaches in the provision of adequate food and/or water occurred and resulted in adverse welfare outcomes. Establishment licence holders and other Named Persons 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. During 2018 a themed inspection activity to address failures to provide food and water across establishments was begun; findings and recommendations will be reported in the 2019 *Annual Report*.

Risk factors for this type of non-compliance include:

- inadequately trained, casual or inexperienced technicians;
- inadequate staffing levels;
- welfare checks performed over the weekends;
- animals moved for conduct of procedures;
- animals being delivered;
- the use of individually ventilated cages; and
- increased amount of equipment in cages.

Failure to have appropriate personal licence authority

In 2018 either no or inadequate personal licence (PIL) authority was held in 6 cases (21%). In all of these, the procedures performed by those without PILs were competently

performed and no adverse welfare outcomes were identified.

In all cases there was a degree of confusion by potential PIL holders about the difference between receiving the certificate for their modular training and receiving their personal licence. It is recommended that providers of modular training reinforce this difference and that establishments review their processes to ensure that there are adequate processes to ensure appropriate PIL authorities are in place.

Exceeded authorised number of animals on breeding protocols in project licences

In 2018 there were 4 cases (14%) where the number of animals authorised on the breeding protocols of project licences was exceeded. In all cases, these animals were legitimately needed to meet the scientific objectives of the project and, had a request for these increased numbers been submitted, it would have been approved. However, these cases represent the largest number of animals involved in non-compliance cases. In two cases, the number of animals exceeding those authorised was not recorded accurately. In the other 2 cases, a total of 1,908 animals (1,581 fish and 327 mice) were involved. In all these cases, the failure to keep adequate track of the rolling total of animals being used was identified as a systematic deficit; the excess use only came to light when the number of animals that had been used needed to be returned to the Home Office during the annual reporting of animal use.

Solutions for non-compliance themes

Focus on the highlighted themes identified a number of safeguards to minimise the risk of non-compliance. Thus, all establishments should provide:

- 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 resources allocated for daily, careful, routine monitoring of all animals.

The *Guidance on the Operation of the Animals (Scientific Procedures) Act 1986* (the Guidance), available at: 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.

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.

Section 8: Financial report

The 2018/2019 financial year was the fourth for which 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 five years is shown in Table 2.

Table 2: Summary of income and fee-funded expenditure, by budgeting year, including capital spend, 2014/2015 to 2018/2019

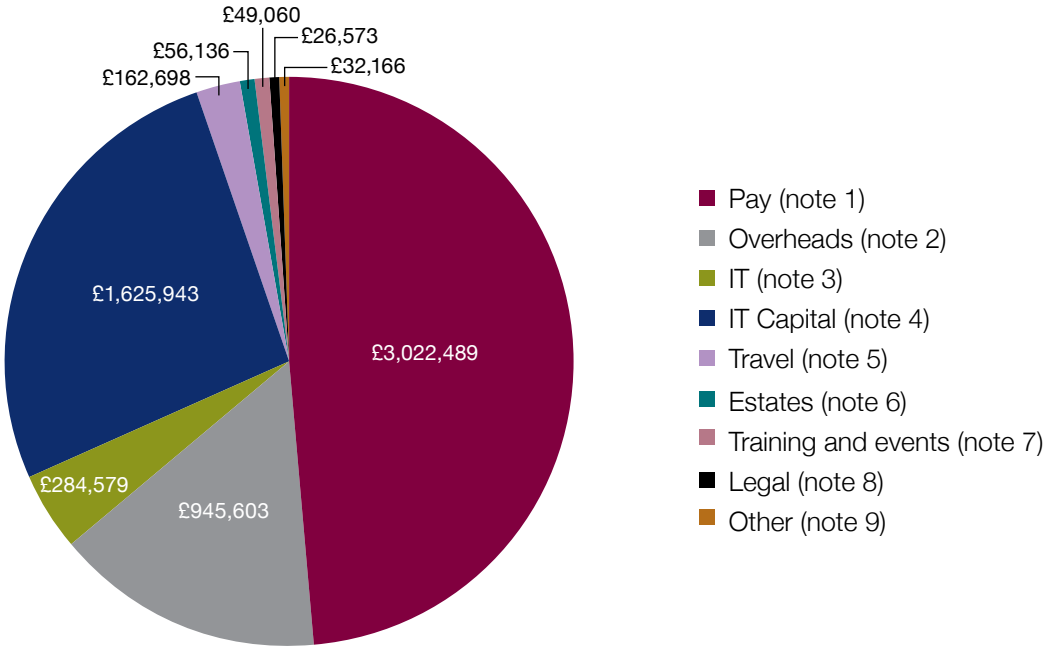
		Expenditure		
Year	Income	Running budget	Capital	Variance
2014/15	£4,380,206	£4,378,929		£1,277
2015/16	£4,692,833	£4,207,503		£485,330
2016/17	£4,482,578	£4,467,404		£14,596
2017/18	£4,421,361	£4,777,455		-£356,094
2018/19	**£4,752,912**	**£4,579,303**	[1] **£1,625,492**	**£173,609**

[1] In addition to the annual running budget of ASRU, an additional £1,625,492 of capital expenditure occurred for the replacement ASPeL system.

Expenditure for the year 2018/2019

Expenditure for 2018/2019 is shown in Figure 4.

Figure 4: Expenditure, 1 April 2018 to 31 March 2019



Notes

1. Of the £3.02 million pay costs approximately £2.82 million were salary costs and £189,083 was transferred to other teams in the Home Office for the use of their staff on ASRU's work (for example, statistics and legal advice).
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.
3. The majority of IT costs of £284,578 include the hosting and support of the Animals Scientific Procedures e-Licensing system (ASPeL) during 2018/2019. ASPeL will close in late summer 2019 and be replaced by the new e-licensing system. The remainder of the IT costs is for VAT and telecoms, for example, mobile phones and WiFi.
4. ASRU procured for a contract to develop a new and improved version of ASPeL. The company that won the procurement was Marvell. Research and development spend in 2018 totalled £1.62 million. The new system will be live in the late summer 2019.
5. Travel and subsistence costs were mostly incurred by inspectors during their visits to establishments.
6. During 2018/2019, ASRU paid other parts of the Home Office and other government departments for the use of office space in 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 professional bodies (all inspectors are either veterinarians or medically qualified doctors). This includes the costs incurred by running four annual events for all inspectors and managers.
8. Legal costs included the cost of defending a tribunal case 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.

Fee income

Between April 2015 and April 2018 the fees were:

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

Invoices are raised in arrears, so the income for the financial year 2018/2019 has only just started to be invoiced and received.

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, therefore, reduced income. Now that the conversion programme is complete, ASRU has a much more accurate estimate of how many licences will be held each year, and therefore whether the fees need to be increased or decreased.

Income for the year 2018/2019

There has been a fee increase for 2018/2019. This came into force on 6 April 2018 and is set out below.

- The establishment licence fee increased from £631 to £757.
- The personal licence fee increased from £242 to £257.

Income for the year 2019/2020

ASRU proposes a fee increase for 2019/2020. This comes into force on 6 April 2019 and is set out below. The increase is necessary to ensure that fee income covers all expenditure incurred in delivering the service.

- The establishment licence fee will increase from £757 to £826.
- The personal licence fee will increase from £257 to £275.

Annex 1: Non-compliance cases

Glossary of terms

AI Discovered by assigned inspector

ASPA Animals (Scientific Procedures) Act 1986

NTCO Named Training and Competency Officer

PEL Establishment licence

PIL Personal licence

PPL Project licence

SR Self-reported

WB Reported by whistle blower

Table A1: Failure to have or adhere to licence authority

Table A1.1a: Exceeding authorised limits in project licences

Species	Number of animals involved	Findings	Section of Act or Standard Condition[8] breached	Summary of reason for breach occurring	Mode of discovery	Outcome
Mice	5	Out of a group of 18 mice that received a nerve injection, 5 mice bit their toes causing damage to the toes and nails. One animal died, two caused damage to their toes and two had bleeding paws. All five animals needed to be humanely killed. The researchers appropriately consulted the Named Persons at the establishment and followed their advice. There is no evidence that the original injection was not conducted competently. Adverse events of autotomy (self-harm) were not authorised in the PPL.	PPL Standard Conditions 16 and 18	The establishment was uncertain as to whether these adverse events were authorised or not. There was confusion between the researchers and the Named Persons as to whether the Home Office inspector had been contacted to provide advice.	AI	Letter of reprimand to PPL holder
Mice	2	A PIL holder failed to realise that clinical signs in two mice required additional monitoring or intervention. The PIL holder failed to contact Named Persons to obtain advice. The two mice were found dead in their cage the following day.	PIL Standard Conditions 5 and 15	The PIL holder had not needed to assess unwell animals previously and was unsure of the process to follow to obtain help. There was no evidence of deficiency in training or supervision or the processes in place within the establishment.	SR	Letter of reprimand to PIL holder, retraining required
Mice	3	A PIL holder failed to notify the Named Veterinary Surgeon that three mice had exceeded 20% weight loss and subsequently failed to kill one of these mice when it lost 25% of weight. Both these limits were stipulated in the project licence. All three animals were subsequently killed.	PIL Standard Conditions 14 and 19	The PIL holder misinterpreted the humane endpoints and limits within the project licence. There was no evidence of unsatisfactory training or supervision.	SR	Letter of reprimand to PIL holder, retraining completed

8 https://www.gov.uk/government/publications/personal-licence-standard-conditions/personal-licence-standard-conditions
https://www.gov.uk/government/publications/project-establishment-licence/project-establishment-licence
https://www.gov.uk/government/publications/establishment-licence-standard-conditions/establishment-licence-standard-conditions

Table A1.1b: Failure to adhere to authorised procedures

Species	Number of animals involved	Findings	Section of Act or Standard Condition[7] breached	Summary of reason for breach occurring	Mode of discovery	Outcome
Mice	1	A PPL holder failed to identify a cage correctly and as a result inadvertently reused a single mouse. The mouse had undergone a laparotomy previously and subsequently had a large skin transplant. Both procedures were authorised on separate licences. Both procedures were conducted competently. The mouse was killed when the error was discovered.	ASPA 14(1)	This incident occurred due to carelessness by the PPL holder for which there appeared to be no obvious cause. No deficiency was identified in the establishment processes.	SR	Letter of reprimand to PPL holder, retraining required
Fish	50	Removal of the entire caudal fin of zebrafish for genotyping. Removal only of a third of the fin was authorised in the project licence. Damage was made to the deep muscle of some fish. All fish were killed when the error was detected.	PIL Standard Conditions 1, 2, 6, and 19	This incident arose from a misunderstanding of the PIL holder as to what was authorised.	SR	Letter of reprimand to PIL holder, retraining required
Birds	3	Three PIL holders performed gavage to assess a new gavage technique proposed for a future study. The procedures were not performed as part of an authorised programme of work. The gavage was competently performed.	ASPA 3(b)	Failure to understand the inability to practise techniques upon live animals.	SR	Letters of reprimand to PIL holders, retraining required

Table A1.1c: Absent or incorrect personal licence authority						
Species	Number of animals involved	Findings	Section of Act or Standard Condition[7] breached	Summary of reason for breach occurring	Mode of discovery	Outcome
Dogs	Indeterminable	An individual conducted gavage and semen collection without having authority on the PIL to perform procedures in dogs. The PIL holder had completed the required training but had not received the PIL. The procedures were competently performed.	ASPA 3(a) Standard Condition 20	Failure to understand that completing modular training and receiving the certificate of completion is not the same as amending the PIL. No management check to confirm that the appropriate PIL authorities were in place.	SR	Letters of reprimand to PIL holder and PEL holder
Pigs	20	A PIL holder who mistakenly thought that they had authorisation for work on pigs on their PIL conducted procedures on 20 pigs in accordance with PPL authorities. The PPL holder assisted with a single procedure on one of these pigs but did not hold a PIL (they had completed modular training but had not applied for a PIL). All procedures were conducted competently.	ASPA 3(a) PEL Standard Condition 20	Failure to understand that completing modular training and receiving the certificate of completion is not the same as amending the PIL. No management check to confirm that the appropriate PIL authorities were in place.	SR	Letters of censure and reprimand to PIL holder, PPL holder and PEL holder
Rats	52	A PIL holder undertook surgical procedures without updating their PIL following their PILC training to include these on their PIL. All procedures were competently completed.	ASPA 3(a) PEL Standard Condition 20	Failure to understand that completing modular training and receiving the certificate of completion is not the same as amending the PIL. Inadequate management check to confirm that the appropriate PIL authorities were in place.	SR	Letters of reprimand to PIL holder and PEL holder
Rats	92	A PIL holder undertook injections in rats but only had a PIL authorising the use of mice. All procedures were competently completed.	ASPA 3(a) PEL Standard Condition 20	Failure to understand that completing modular training and receiving the certificate of completion is not the same as amending the PIL. Inadequate management check to confirm that the appropriate PIL authorities were in place.	SR	Letters of reprimand to PIL holder and PEL holder
Rats	10	A PIL holder undertook administration of substances via inhalation to rats but only had PIL authority for dogs. All procedures were competently completed.	ASPA 3(a) PEL Standard Condition 20	Failure to understand that completing modular training and receiving the certificate of completion is not the same as amending the PIL. Inadequate management check to confirm that the appropriate PIL authorities were in place.	SR	Letters of reprimand to PIL holder and PEL holder

Table A1.1c: Absent or incorrect personal licence authority						
Mice	1	A non-licensee performed an intraperitoneal injection after the issue of an appropriate training certificate but before a licence was granted. The procedure was competently completed. A detailed investigation revealed local processes were not applied correctly to prevent unauthorised procedures.	ASPA 3(a)	Failure to understand that completing modular training and receiving the certificate of completion is not the same as obtaining a PIL. Management processes in place were appropriate but were not followed correctly by NTCO.	SR	Letter of censure and letter of admonition to NTCO.

Table A1.1d: Exceeding the number of animals authorised on project licence						
Species	Number of animals involved	Findings	Section of Act or Standard Condition[7] breached	Summary of reason for breach occurring	Mode of discovery	Outcome
Mice	Not determined	More mice were used on a breeding protocol than authorised. All procedures were competently performed, and all breeding was required to answer the approved scientific objectives. The number used would have been authorised if requested.	PPL Standard Conditions 1 and 18	Breakdown in the process to track the number of mice used on an ongoing basis.	SR	Letter of reprimand to PPL holder
Mice	Not determined	More mice were used on a breeding protocol than authorised. All procedures were competently performed, and all breeding was required to answer the approved scientific objectives. The number used would have been authorised if requested.	PPL Standard Conditions 1 and 18	More breeding than planned was needed due to the complexities of cross breeding the required genetic strains. Key staff member change contributed to the subsequent breakdown in colony management overview.	SR	Letter of reprimand to PPL holder
Mice	327	An additional 327 mice were used on a breeding protocol than were authorised. All procedures were competently performed, and all breeding was required to answer the approved scientific objectives. The number used would have been authorised if requested.	PPL Standard Conditions 1 and 18	Breakdown in the process to track the number of mice used on an ongoing basis.	SR	Letter of reprimand to PPL holder
Fish	1,581	An additional 1,581 zebrafish were used on a breeding protocol than were authorised. All procedures were competently performed, and all breeding was required to answer the approved scientific objectives. The number used would have been authorised if requested.	PPL Standard Conditions 1 and 18	Breakdown in the process to track the number of fish used on an ongoing basis.	SR	Letter of reprimand to PPL holder

Table A2: Failure to provide adequate care to animals

Table A2.2a: Failure to provide adequate food or water

Species	Number of animals involved	Findings	Section of Act or Standard Condition[7] breached	Summary of reason for breach occurring	Mode of discovery	Outcome
Rodents	8 mice and 2 rats	Involves four incidents in different units, which occurred within a two-week period. Incident one occurred when a researcher killed a dam and removed labels and water from a cage without checking for the presence of pups. Two pups were found dead in the cage after a week. Incident two occurred when a cage of five mice was left without food for four days. The animals were found in poor condition and needed to be killed. Incident three occurred when a PIL left two mice in a reverse lighting area without clearly communicating this. Thus, food and water were not provided for four days. One animal was found dead and the other needed to be killed. Incident four occurred when a hopper was not filled with adequate food and a mouse was found dead in the cage four days later.	PEL Standard Conditions 4 and 21 4(3), PIL Standard Conditions 2 and 16	Challenges in communicating lessons learnt throughout a complex organisation led to failure of communication. Illness of a PIL holder may have contributed to one incident. Remedial plan already in place to address the communication challenges and assess why the systems in place failed.	SR	Reprimand letters sent to PEL holder and two PIL holders, PIL holder retraining required. Progress plans required. Increased inspection
Mice	8	Three mice in one cage were left in an isolator without appropriate food and water for 15 days on one occasion. Two died and the third was found in poor condition and needed to be killed. On a second occasion, five mice in one cage were left in an isolator without appropriate food and water for an uncertain period. Two died and the other three were found in poor condition and needed to be killed.	PEL Standard Conditions 4 and 5	These incidences were managed together and against a background of low-level concerns. A range of contributory factors were identified including individual poor performance, process inadequacies, communication deficiencies, facility deficiencies and lack of ownership.	SR	Compliance Notice issued to PEL holder requiring action plan and regular progress reports. Increased inspection
Mice	1	One mouse escaped from a cage and this was not noted for 16 hours. When the animal was found it was dehydrated and needed to be killed.	PEL Standard Conditions 4 and 5	This incident arose from a lapse of concentration by a single technician. There was no obvious reason for this other than human error. There was no evidence of inadequate processes or lack of training or supervision.	SR	Reprimand letter sent to PEL holder

Table A2.2a: Failure to provide adequate food or water						
Mice	1	PPL holder left one mouse in a recovery heat box overnight in error. When the animal was found it was dehydrated and needed to be killed.	PPL Standard Condition 2	Confusion arose around the numbers of animals under procedure as one animal needed to be killed during procedures. PPL holder is actively engaging with Named Persons to improve processes for checking.	SR	Reprimand letter sent to PPL holder
Mice	2	A technician did not add food to a cage at the time of changing base and bedding. Cage type had no food hoppers due to the presence of large wheel. The error was not picked up by technicians at twice daily checks, including over a weekend. Two mice were found dead five days later due to starvation. The post-mortem revealed that they had been dead for some time as there was no food in their gut and the cage inspection found no faeces.	PEL Standard Condition 4(3)	Risk was associated with a specific cage type that was not mitigated. Challenging to do daily welfare checks due to the presence of equipment in the cages.	SR	Reprimand letter sent. Further progress reports required
Birds	480	Involves two incidents of a similar nature occurring close together. Incident 1 occurred when birds were left without water for an uncertain period, possibly 48 hours. A PIL holder investigated a leak and turned off the water to resolve the issue. It is possible that they forgot to turn the water back on. One bird was found dead, but all the other birds recovered once rehydrated. Incident 2 occurred when a PIL holder switched off the water supply to add a substance and failed to switch on the supply again. This was noted within 24 hours – 1 bird was culled, and the remainder fully recovered after rehydration.	PEL Standard Conditions 4(3) and 4(5), PIL Standard Condition 2	The water system is complex, and it was challenging to determine if the water supply is connected or not. Fail safe processes were not in place. Human error and distraction of the PIL holder during the performance of tasks. Establishment changed processes proactively prior to the conclusion of the investigation.	SR	Reprimand letters sent to PEL holder and one PIL holder. Action plan and progress reports required
Mice	10	A temporary technician, who was responsible for daily checks, did not correctly attach water pouches on several cages and did not provide water to one cage of mice. Two mice were found dead, all the others recovered fully after rehydration.	PEL Standard Conditions 4(3) and 5	The establishment training, competency and supervision process did not work correctly for a casual temporary worker.	SR	Reprimand letter sent to PEL holder
Mice	4	Four mice were discovered to be unwell after being accidentally left in an open laminar flow hood without access to food and water over a weekend. All needed to be killed.	PIL Standard Condition 2	The root cause was human error and no clear cause was found for this. Fail safe processes have been introduced.	SR	Reprimand letter sent to PIL holder.

Table A2.2b: Failure to provide adequate facilities						
Species	Number of animals involved	Findings	Section of Act or Standard Condition[7] breached	Summary of reason for breach occurring	Mode of discovery	Outcome
Cattle	Indeterminable	Internal stakeholders' allegations of acute animal welfare problems on commercial farms on PEL schedule of premises. No welfare concerns were identified with animals regulated under ASPA. Areas were identified on PEL schedule of premises that did not meet the Code of Practice and transport processes in place did not meet the required standards. There was inadequate oversight processes in place to ensure that PEL responsibilities can be discharged.	PEL Standard Condition 4	Challenges of running a commercial farm alongside research activities. Commercial pressures upon farm management. Changes in staff within farm management. Inadequate processes in place for PEL holder to receive adequate information to fulfil accountabilities.	WB	Reprimand letter sent. Further progress reports and PEL retraining required. Increased inspection

Table A2.2c: Failure to provide adequate care – other						
Species	Number of animals involved	Findings	Section of Act or Standard Condition[7] breached	Summary of reason for breach occurring	Mode of discovery	Outcome
Rat	1	One rat found dead in a metal clinical waste bin was still in the original transport box. Failure of the unpacking procedures occurred. The rat was likely to have died from heat exhaustion over the weekend, despite food and transport gel being present.	PEL Standard Conditions 4(1) and 4(3)	The delivery occurred later than usual. This put extra pressure upon staff unpacking the delivery. This was compounded by staff shortage caused by illness. The establishment has put in place additional checks.	SR	Reprimand letter sent to PEL holder
Rats	3	Three rats were found dead in metabolic cages (metabowls) after air pumps were turned off overnight and no alternative ventilation was provided.	PIL Standard Condition 2	The root cause was human error and no clear cause was found for this. Fail safe processes have been introduced.	SR	Reprimand letter sent to PIL holder
Mice	4	A technician was disturbed whilst changing bedding and inadvertently placed a cage containing four mice into the autoclave. The mice died within the autoclave.	PEL Standard Conditions 4(1) and 5	The staffing was low in the unit on the day and the technician involved was performing two different tasks, which meant that they were disturbed whilst completing a task.	SR	Reprimand letter sent to PEL holder

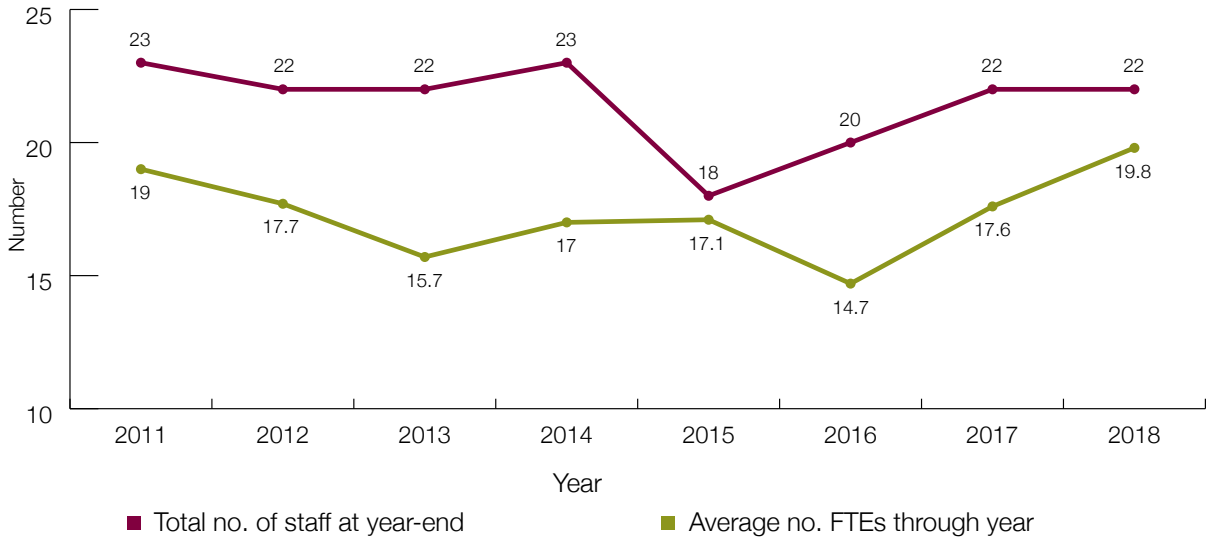
Annex 2: Tables and figures

Table A2.1: Licence applications and amendments, 2017 and 2018

	Total			Per inspector FTE		
	2018	2017	Change	2018	2017	Change
PILs granted	3,452	2,985	16%	174.2	169.9	3%
PILs amended	598	521	15%	30.1	29.7	1%
PILs in force at year end	16,278	16,109	1%	821.7	916.8	-10%
PELs granted	0	3				
PELs amended	58	160	-64%	2.9	9.1	-68%
PELs in force at year end	156	160	-3%	7.8	9.1	-14%
PPLs granted	540	568	-5%	24.6	32.3	-24%
PPLs amended	515	1,129	-54%	25.9	64.3	-60%
PPLs in force at year end	2,736	2,585	6%	138.1	147.1	-6%
Inspectors FTE	**19.81**	**17.6**	**13%**			

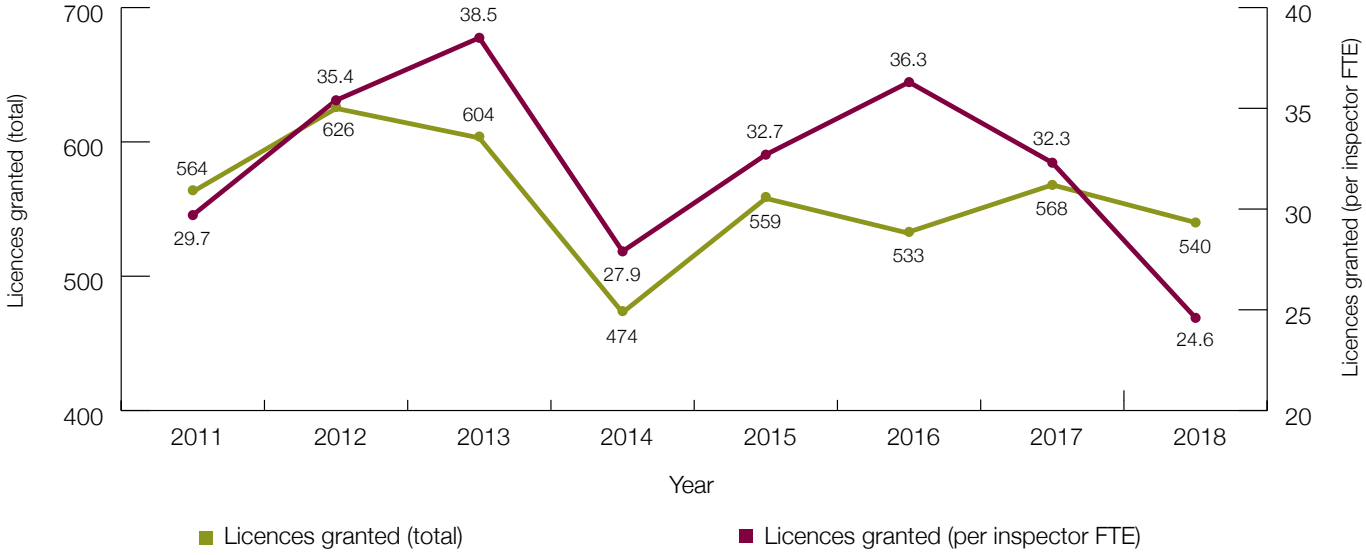
Notes: FTE = full-time equivalent; PIL = personal licence; PEL = establishment licence; PPL = project licence.

Figure A2.1: Inspectorate staff, 2011 to 2018



Note: FTE's = full-time equivalents

Figure A2.2: Project licences granted, 2011 to 2018



Note: FTE's = full-time equivalents

Figure A2.3: Project licence application processing, 2011 to 2018

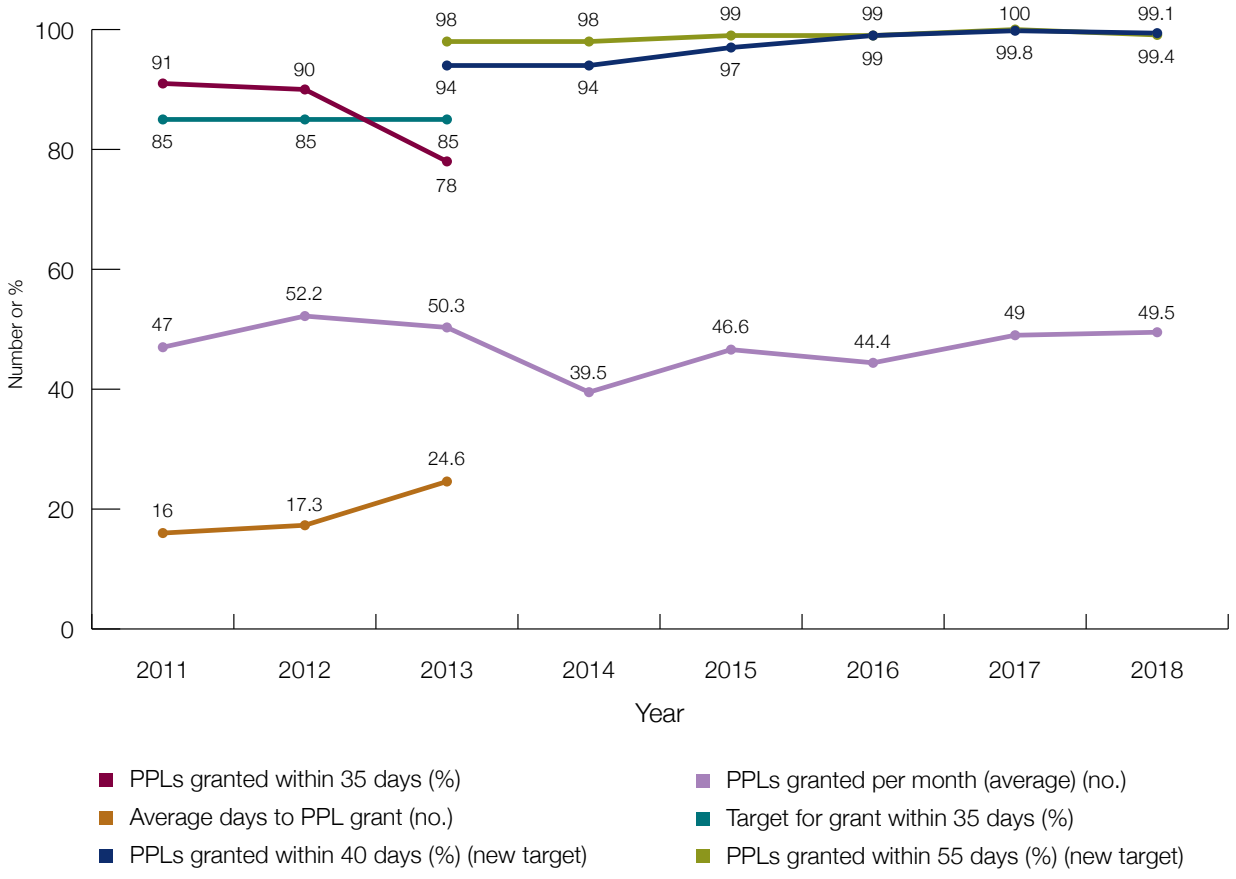
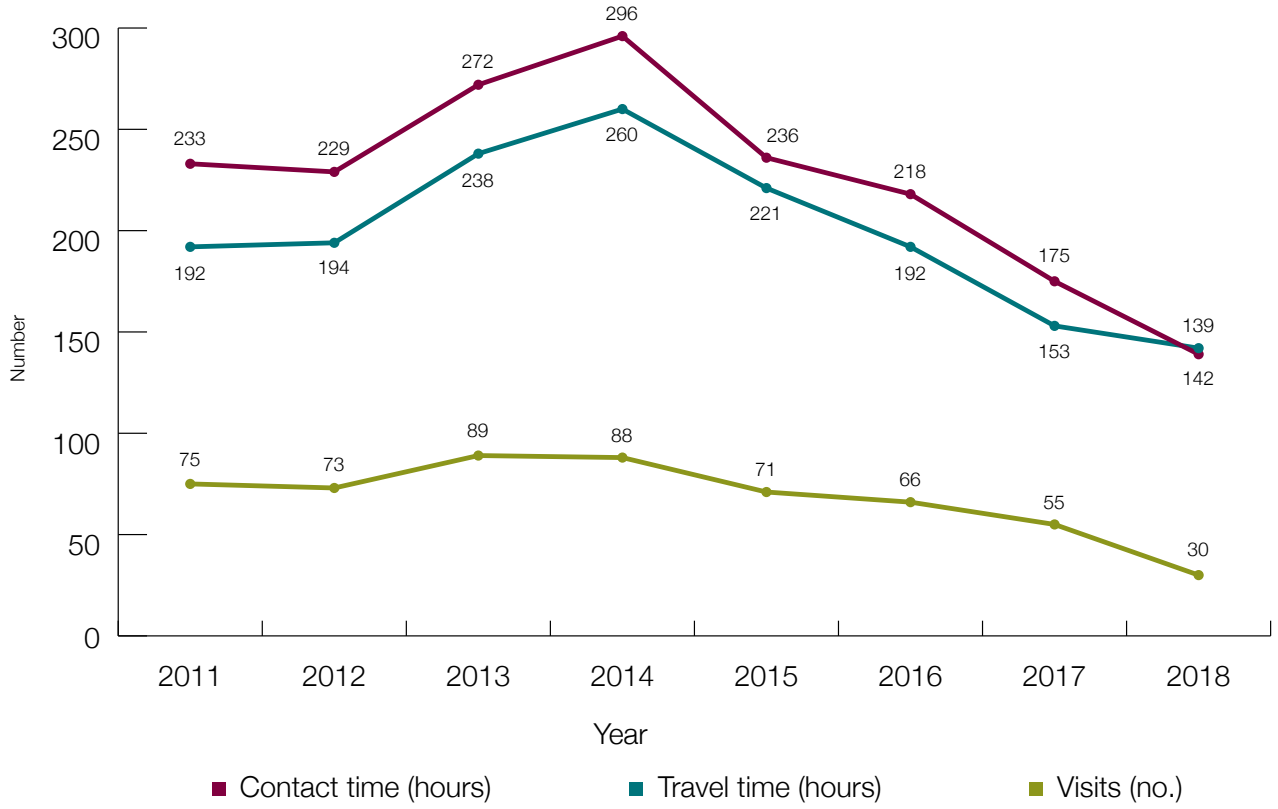


Figure A2.4: Inspections, 2011 to 2018 (total)

Figure A2.5: Inspections, 2011 to 2018 (per FTE)



Note: FTE's = full-time equivalents

Annex 3: Household products ban update

The testing of finished household products on animals and the testing of ingredients have 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, when prospective authorisation is required.

As science has advanced over recent years, so also has the validation of alternative approaches to assessing product safety without the need to resort 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.

From 2018 onwards, statistics on household product ingredients testing will be published in the *Annual Statistics of Scientific Procedures of Living Animals Great Britain*. This change will expedite the publication of this report. The 2018 *Annual Statistics* can be found here: https://www.gov.uk/government/collections/statistics-of-scientific-procedures-on-living-animals.