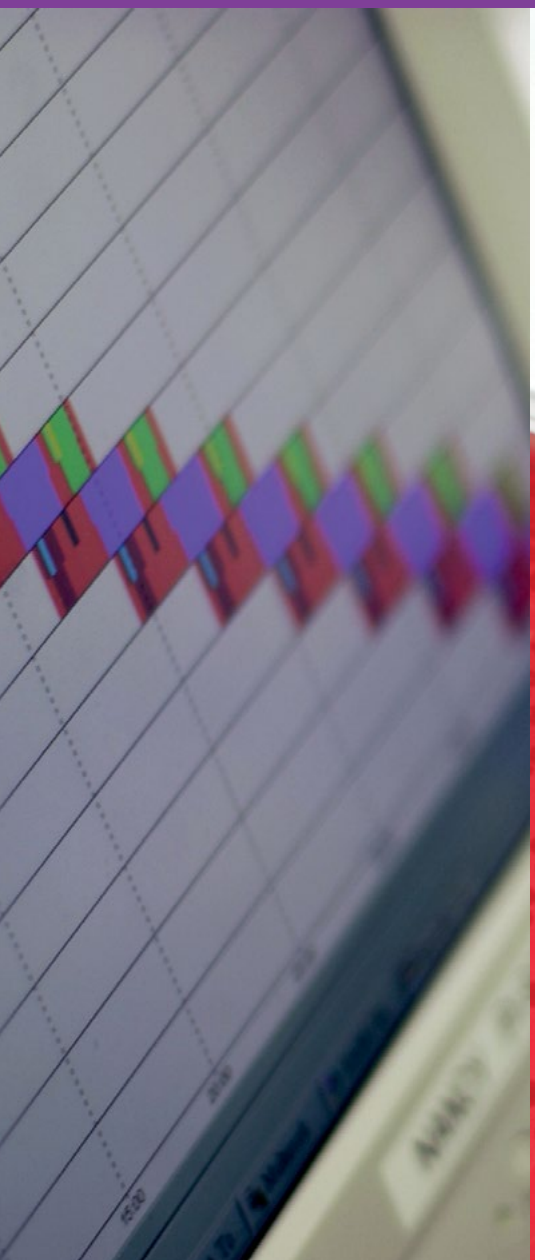
Home Office

Animals in Science Regulation Unit
Annual Report 2016



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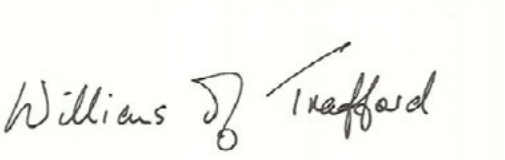
Ministerial foreword

Science and research are vital to our country's prosperity, security and wellbeing and are at the heart of our industrial strategy. The properly regulated use of animals in science has a key role in supporting the development of scientific knowledge. In so doing we must continue to maintain all the controls on only using animals where necessary and using non-animal alternatives where practicable. When animals have to be used we must continue to fully apply the principles of the 3Rs (replacement, reduction and refinement) and ensure that appropriate welfare standards are met.

The Government is committed to strengthening the UK's world-leading science and research base as we leave the EU and look to the future as Global Britain. This means ensuring the UK remains one of the best places in the world for science and innovation and the go-to place for researchers, innovators and investors in technology. We are working with colleagues across Government to ensure that the UK's interests as a leading research base are represented as we exit the EU.

We are confident that our legislation, the Animals (Scientific Procedures) Act 1986, which incorporates the transposed Directive 2010/63/EU, gives us the strongest possible starting point. We know that this legislation sets high standards for animal welfare in science, whilst ensuring continued opportunities for UK science to access world markets.

I am committed to maintaining our rigorous and robust regulation of the use of animals in science. Replacement, reduction and refinement the 3Rs must remain at the heart of the UK regulatory system, which provides assurance to the public, whilst supporting the delivery of world class science in the UK.



Baroness Williams of Trafford

Foreword

In 2016 we have focused on improving the efficiency and effectiveness of our processes, in line with our vision of being a consistent and modern regulator. A key component of this work has been the full move to an electronic licensing system and strengthening the delivery of the Animals (Scientific Procedures) Act 1986 (ASPA).

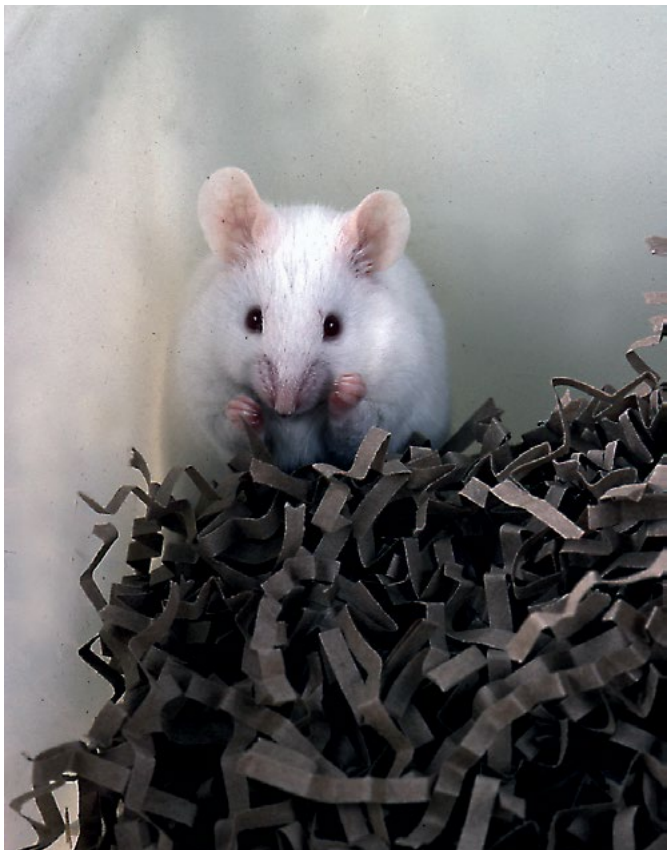
During 2016 we rolled out the pilot for the electronic project licence process, subsequently delivering to all establishments in the Autumn. Becoming fully electronic represents a major step forward in our ability to work efficiently and effectively. Nevertheless, we have longer term plans to develop the system further. This will involve taking a more fundamental look at how we construct and process licences and building in management tools and greater consistency. I look forward to consultation with establishments in 2017 as we seek the continuous improvement of our systems. Ultimately our aim is to preserve the rigour of the project evaluation process and remove unnecessary impediments for legitimate licence applications to be granted.

Advice Notes provide additional information on how ASPA is administered and enforced. They drive consistency, encourage a culture of compliance, and help to ensure openness and transparency. The Advice Notes published in 2015 continued to support both the operational Guidance and Code of Practice to deliver ASPA. Inspectors and establishments alike used the *Low-level Concerns Advice Note* as a tool for assessing their governance of animals in science issues and compliance with their regulatory obligations. In February 2016 we published an Advice Note on *Animals Containing Human Material* (ACHM). This provided guidance on how scientific research involving the use of ACHM is regulated including relevant legislation, how experiments using ACHM are classified, and the regulatory pathways relevant to the different types of research using ACHM.

The creation and breeding of genetically altered animals now accounts for around half of all scientific procedures conducted in Great Britain, the majority (73%) being mice.

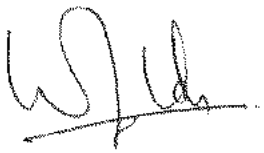
In 2015 we announced our pilot programme for a framework to support establishments to self-assess their practices so that they may identify strengths and areas in which they may improve. The framework is part of ASRU's continuing drive towards greater refinements and, where possible, reduction of numbers. During 2017 we will roll out the framework to further establishments.

At the heart of any regulatory process is the balance between the authorisation of legitimate activities and the need for a strong compliance process that acts swiftly and proportionately. We commit to openness and transparency on our compliance activities through the publication of case summaries, which can be found in Annex 1 of this report.



Our intention is that the summaries are used by establishments to gain a better understanding of how to avoid non-compliance and to support their frameworks for effectively delivering the requirements of ASPA.

The vote to leave the EU presents a new landscape for those working in the life sciences. The harmonisation of animals in science legislation across the EU through Directive 2010/63/EU has meant that we will start on a level playing field with our EU counterparts. Through the UK's transposition of the Directive in 2013 into our legislation, we can move forward with confidence that there will be no shocks to the system and we can maintain a seamless regulatory framework. During 2017 and towards exit in 2018 we will maintain our pace of planning to ensure a smooth process that preserves the UK position as a place to locate business and that maintains our standards for animal welfare.



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's role

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 2016 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;

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.

The Animals (Scientific Procedures) Act 1986 requires that inspectors are fully registered medical practitioners in the UK or Members of the Royal College of Veterinary Surgeons. They may hold additional scientific or clinical postgraduate qualifications, with experience of biomedical research in an academic, clinical or commercial environment. For example, these may include PhDs, Masters, Diplomas and other postgraduate qualifications.

At the end of 2016 the Inspectorate comprised 20 individuals (17.65 full-time equivalents [FTE]), which is an increase of 2 individuals and 1.65 FTE from 2015. 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 and regulation system. Its core functions within this remit are:

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

At the end of 2016 the team comprised the Head of Licensing (reporting to the Head of Policy and Administration), 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

Cruelty Free International (CFI) brought a case for Judicial Review against the Home Secretary, challenging the lawfulness of a decision to grant an exemption for the requirement of outside runs for dogs.

The Home Secretary decided, in a letter of July 2014 to an establishment, to agree an exemption from the transposed Directive's requirement to provide outside runs for dogs in a breeding colony. This was predicated on the basis that the animals would be used primarily for safety assessment (toxicology) for which the risk of exposure to pathogens, an inherent risk when using outdoor runs, would render the animals unsuitable.

In his summing up the Judge concluded that the claim should be dismissed – finding in favour of the Home Secretary.

The decision rested on two key elements:

- whether the Home Office had failed to pay due regard to the relevant material considerations; and
- whether the Inspector had failed to consider the local conditions with respect to the possibility of infection with pathogens.

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 judgment included the following points.

- The Directive recognises that there are disparities liable to constitute trade barriers in products and substances that require experiments on animals to be developed. At the same time the preamble commits to the need to prevent pain, suffering, distress and lasting harm, and that animals have an intrinsic value, which should be respected. In considering the provisions of the transposed Directive the Judge drew particular attention to Annex III, which requires that the physiological and ethological (welfare) needs of animals should be met and that, for dogs, there should be the provision of outside runs 'where possible'.

- He agreed that it is impossible to avoid the possibility of infection to animals, unless their run is enclosed. The Directive is clear that the application for an exemption should be made by the operator who aims to provide high quality animals to meet their clients' requirements, whilst avoiding any deterioration in the health status of their dogs and making alternate provision for the welfare needs of the animals.

- The ongoing welfare of the animals will be protected through the inspection and monitoring scheme provided by the Home Office, through its Inspectorate.

- The Judge relied extensively on the report of the then assigned Inspector as well as the internal e-mail correspondence, which demonstrated that ASRU had given due consideration to the relevant evidence in reaching the decision. The considerations of the Home Office Inspector were deemed appropriate and culminated in the decision letter granting exemption to the requirement for outside runs.

- The Home Office's decision letter was noted to set out properly what the law required, as would be expected from the licensing authority. The decision letter should be taken in the specific context of this case, and therefore any other applications of this nature must be considered on a case by case basis (i.e. this decision will not set precedent). The Judge believed that this was how a regulator (ASRU) should approach such a case.

The case was therefore dismissed.

Advice Notes

1. Animals containing human material

The Animals Containing Human Material (ACHM) Advice Note[3] was a response to a 2011 Academy of Medical Science (AMS) report proposing the need for clearer guidance on the use of these animals.

The use of ACHM can contribute to the development of medical and other scientific advances. Such use is long established in biomedical science. However, there are important moral and ethical issues associated with the use of novel developments and technologies in this area and advances (such as stem cell science) are rapidly increasing the sophistication of these approaches.

The AMS recommended that ACHM research should be classified into three categories to determine the level of regulatory scrutiny required prior to authorisation. The Guidance, published in February 2016, sets out examples of these categories and how research under each will be dealt with.

- Category 1 – the majority of ACHM experiments that do not present issues beyond those of the general use of animals in research. These experiments will be subject to the same oversight and regulation under ASPA as other animal research.

- Category 2 – includes ACHM research that may be permissible, subject to a positive harm-benefit assessment and additional specialist scrutiny by the Home Office advisory body, the Animals in Science Committee (ASC), which is the national expert body.

- Category 3 – covers a very narrow range of experiments that should not, for now, be licensed because they either lack compelling scientific justification or raise very strong ethical concerns.

The Guidance did not introduce any new regulations. It was developed in conjunction with the Department of Health to signpost the various regulations that need to be considered when carrying out work on ACHM.

2. Working with animals taken from the wild

This Advice Note provides information about the ASPA requirements that affect scientific or educational work using animals taken from the wild, including feral, stray and wild animals.[4] The considerations when working with wild animals under ASPA are complex, so this was an important addition to the Guidance.

The Advice Note provides advice on methods of capture, identification, working with animals at places that are not ASPA licensed establishments and considerations where animals are set free before the course of regulated procedures have finished. In addition to information on legal and licensing requirements under ASPA, the Advice Note provides a range of advice and signposts other considerations that may need to be taken into account by those involved in this area of work.

3 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/491496/Animals_Containing_Human_Material_Final_Guidance.pdf

4 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/535574/working-with-wild-animals-160706.pdf

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 2016 senior representatives from ASRU, as the UK competent authority, attended a number of meetings in Brussels.

There were two National Contact Point meetings in 2016. Updates were provided by EU Member States on their transposition of the Directive.

1. European Conference "Non-Animal Approaches: The Way Forward"

Two members of the senior management team attended the **"Non-Animal Approaches: The Way Forward"** conference held in Brussels on 6-7 December, organised by the EU Commission.

A report of the meeting was published at this link: http://ec.europa.eu/environment/chemicals/lab_animals/3r/pdf/scientific_conference/non_animal_approaches_conference_report.pdf

This conference was organised as one of the responses to a European Citizens' Initiative, "Stop Vivisection" (submitted to the Commission in March, 2015). A European Citizens' Initiative is an invitation to the EU Commission to propose legislation on matters where the EU has competence to legislate.

In order to be considered, a Citizens' Initiative must be backed by at least 1 million EU citizens coming from at least 7 of the 26 Member States.

There were over 320 attendees and 200 online delegates. There were a wide range of stakeholders, including representation from academia, the pharmaceutical industry, contract research laboratories, research funders and animal welfare groups.

The aim of the conference was to engage scientists and other relevant stakeholders to discuss the use of technologies to develop scientifically valid alternatives to animal testing. There was recognition that a continued focus on implementation of the 3Rs (the principles of replacement, reduction and refinement) is central to better science and the protection of human and animal health. Good quality science, including good experimental design, were recurring themes. The importance of data sharing, publication of negative data and open access publishing were also highlighted.

2. The UK referendum to leave the EU

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.

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 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.

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;
- cats, dogs, equidae or non-human primates in severe procedures;
- 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.

During 2016 the ASC reviewed 4 applications for which they provided the Home Office with advice.

ASPA requires that the ASC engages in the promotion of leading 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. 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. In 2016 the ASC provided advice on Animals Containing Human Materials Advice Note: 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). 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.

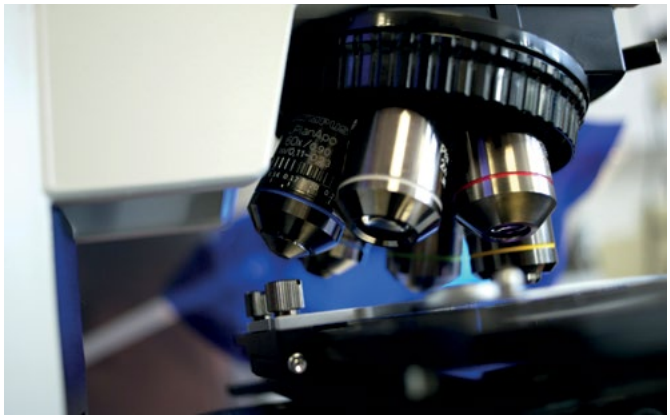
In 2016 ASRU licensed and regulated 168 establishments. These are predominantly in the pharmaceutical, biotechnology and contract research industries, and in academia (universities and research institutes). At the end of 2016 there were 2,646 active project licences and 16,178 personal licensees.

Performance

Establishment licences: During 2016 two new applications were received. Three new licences were granted and issued (including a carryover of one from 2015).

Project licences: During 2016, 528 (99.1%) licences were granted within the 40 days target and 530 (99.4%) within the 15-day extension to 55 days. This is an improvement on 2015 where 97% were granted in 40 days and up from 94% in 2014.

Personal licences: Using the Animals Scientific Procedures e-Licensing system (ASPeL), ASRU was able to achieve an overall rate of 99.9% of new personal licence applications granted within the 20-day target. ASPeL was unavailable for several weeks during the summer because of system upgrading. Contingencies ensured that temporary paper licences were issued for those with a pressing need and these were later converted to e-licences. The provision of the licensing service was not affected during the period that ASPeL was unavailable.



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 Home Office Liaison and Training Information Forum (HOLTIF) was an effective platform for establishments and licensing staff to come together 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

The aim of ASPeL is to handle the processing of all licences and replace the current paper-based system. ASPeL has already significantly improved ASRU's efficiency and is well received by users. ASRU continues to see significant benefits from its ASPeL system, especially in the processing times for personal licence applications (within the internal 20-day target). By the end of 2016 all personal licences had been converted so there are none remaining on paper.

In 2016 ASRU began rolling out the project licence functionality for obtaining an e-licence. The pilot for the project licence process was rolled out in May 2016 for new applications that had not been started. By the end of the year all new project licence applications were being processed and granted using ASPeL.

However, as many amendments to paper project licences will continue to be processed on paper ASRU will be running a parallel paper and ASPeL process until all paper project licences have expired (in up to five years time).

The next stage was converting all establishment licences to e-licences. The roll out of ASPeL for all establishments began in May 2016 and it became compulsory to use ASPeL for all new licence applications (except in exceptional circumstances) from 1 November 2016. Full guidance on using ASPeL was published at the end of the year.[5]

In addition to providing greater efficiency for the licence holders ASPeL has improved ASRU's capability to capture management and performance data in comparison to the wholly paper-based system, which had been the mainstay of the licensing and inspection processes.

5 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/629373/project_licence_process_quick_start_guide_applicants.pdf

1. Project licence pilot

In November 2015 ASRU launched the pilot for the new project licence process. Sixteen volunteer establishments piloted the e-licensing system for project licences, which facilitated the early identification of issues that needed to be addressed. In this agile framework, the invaluable feedback ASRU received from stakeholders meant that development was better directed and system improvements were identified early.

A number of workshops took place throughout the UK during 2016 to demonstrate the new functionality, answer user questions and collect feedback. This collaborative approach has been well received by users in establishments. ASRU will continue to provide a high level of support to deliver the benefits of e-licensing.

2. Annotated project licences

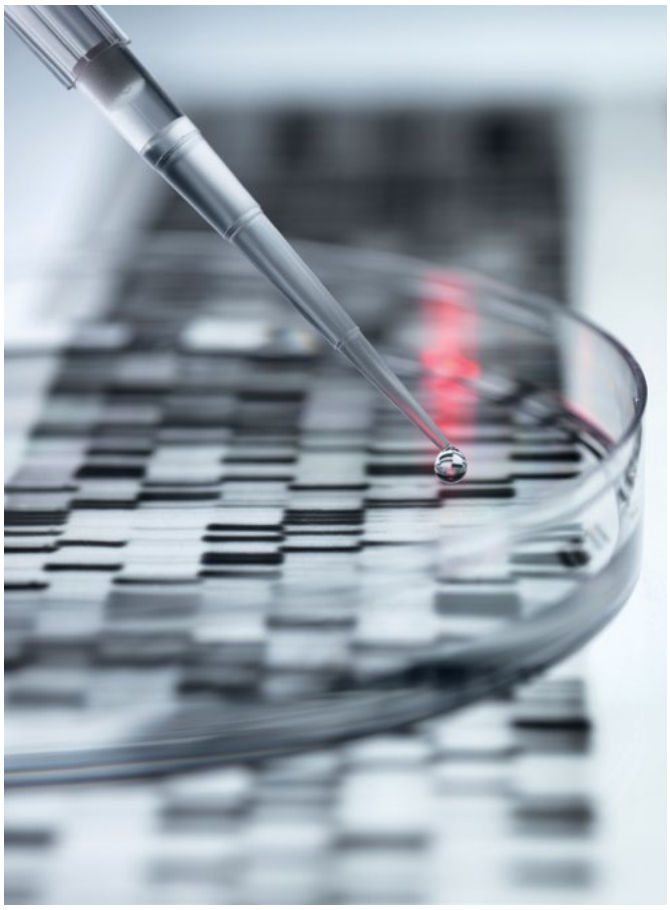
ASRU has committed to driving up standards of project licence applications. In the medium term it is making plans to re-design the project licence form to make the process more efficient and to gather information as effectively as possible for project evaluation. In the short term ASRU has a 'one high quality' draft initiative. To facilitate applicants' understanding the requirements of a licence application ASRU has published an annotated project licence at: https://www.gov.uk/government/publications/animal-testing-and-research-improve-your-project-licence-application

The annotated form clarifies, with examples, the information required in a project licence application. The benefits of the initiative are twofold:

- it reduces the time that applicants have to spend preparing their draft application and helps them to provide the correct information required in the first draft submitted, thus reducing ASRU's regulatory burden on establishments; and
- it aims to reduce the time inspectors spend reading lower quality draft applications.

The publication of the annotated project licence has been welcomed by establishments. Further work is now needed to embed its use fully. Work with the National Centre for the 3Rs

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 2016 ASRU handled 125 pieces of correspondence. This compromised 8 FOI requests, 22 PQs, 21 items of Ministerial correspondence and 71 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;
- the study of hypoxia in sheep; and
- the use of non-human primates in neuroscience research.

Parliamentary Questions

PQs represent a means by which Ministers can be held to account and provide an opportunity for scrutiny of operations. Since the answers become official Ministerial statements, it is of paramount importance to ensure their accuracy. Answers must also be provided within a very tight timeline, which is often less than 24 hours. ASRU responded to 22 PQs in 2016.

Topics for PQs included the use of non-human primates in neuroscience, the breeding of genetically altered animals and the steps taken to reduce the use of cats and dogs in research.

Freedom of Information requests

ASRU received eight FOI requests on a variety of topics during 2016. In line with the Government's policy on openness and transparency ASRU's approach is to release as much detail as the legislation permits. In responding, ASRU seeks to provide greater transparency to assist public understanding whilst also balancing this against protecting personal details and information given to the Home Office in confidence, including proprietary rights and intellectual property.

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:

- progress with the implementation of the revised regulations;
- 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 other professionals performing functions under the Act.

ASRU met periodically with other government departments and agencies including:

- the Department for Business, Innovation and Skills (BIS);
- the Department for Environment, Food and Rural Affairs (Defra);
- the Ministry of Justice (MoJ);
- the Medicines and Healthcare Products Regulatory Authority (MHRA);
- the Food Standards Agency (FSA);
- the Health and Safety Executive (HSE);
- the Human Fertilisation and Embryology Authority (HFEA);
- the Human Tissue Authority (HTA);
- the Medical Research Council (MRC); and
- the Veterinary Medicines Directorate (VMD).

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

- the National Centre for the 3Rs;
- the Wellcome Trust;
- the Royal Society for the Prevention of Cruelty to Animals (RSPCA);
- the Safer Medicines Trust; and
- the Dr Hadwen Trust.

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

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

Stakeholder communication

Previously ASRU aimed to send out monthly newsletters to all establishment licence holders and Home Office Liaison Contacts.

However, after feedback from establishments it was agreed during 2016 that ASRU would begin publishing two regular newsletters. These are now sent on a quarterly basis.

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 2016 include:

- the Institute of Animal Technology Congress in March;
- the Establishment Licence Holders Forum in April;
- the Animal Welfare and Ethical Review Bodies Forum in May;
- 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

ASRU undertook 963 inspections of places where scientific work on animals was conducted in 2016. Of the visits to animal units, 60% 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 animal 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). 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.
- 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 ASRU put a more structured risk management process in place and this was further developed in 2016. This comprises a review of the national risk profile. It is undertaken every quarter 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 their institutions 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;
- 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 the specific concerns rather than necessarily a more general increase in the number of inspections to a particular establishment.

Inspector training

Three 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;
- genetic, farm and military research institutes;
- the Royal Society for the Prevention of Cruelty to Animals (RSPCA);
- the Research Councils;
- the Wellcome Trust;
- the Home Office Parliamentary Team; and
- alternatives and animal welfare and protection organisations.

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

Inspection reporting

A new system of inspection reporting was developed during 2016 and will be implemented in 2017. The new system should provide improved functionality for categorising and rating findings of inspection, and provide improved management data.

Promoting the efficient breeding of genetically altered mice

In January 2016 ASRU piloted a framework to promote improved efficiency in the breeding of genetically altered (GA) mice. Since this was a technical document it was not published on the GOV.UK website but was introduced as a tool for inspectors to use with their establishments.

The framework was developed with the assistance of a large number of ASRU stakeholders, including research establishments and animal welfare and protection organisations. ASRU hopes that its use will be widely adopted by the end of 2016.

The aim of the framework is to assist establishments to self-assess their practices around breeding GA mice in order to identify strengths and areas for improvement. ASRU envisages that it will be used by Animal Welfare and Ethical Review Bodies (AWERBs) and project licence holders:

- to examine current practices;
- set up and assess outcome measures; and
- benchmark progress over time.

This will help them to meet their legal obligations to implement the 3Rs – replacement, reduction and refinement.

As well as being used for self-assessment, the framework will provide a consistent, UK-wide approach for ASRU's assessment of breeding practices. During 2016 ASRU inspectors piloted the use of the framework in a small number of establishments. Based on the results of the pilot, adaptations will be made as necessary.

ASRU is very grateful to the experts and staff in establishments and organisations, many of whom are listed in the framework, who helped with its development, are assisting with the pilot, and continue to provide very useful feedback.

Thematic inspections

Thematic inspections are commonly used by many inspection regimes. They enable regulators to understand an issue in depth and ensure that consistent best practice is applied across their areas of regulation.

Promoting the refinement of animal models of sepsis and septic shock

The ASRU Inspectorate was involved in a working group set up by the RSPCA to identify refinements in animal models of sepsis and septic shock. This area of research has the potential to cause severe levels of suffering for animals. The working group included researchers, veterinarians including ASRU inspectors, and animal technologists.

The work culminated in a report published in the journal Shock in 2015, which focused on implementation of the 3Rs in this area. In September 2015 the first themed inspection exploring sepsis was carried out by ASRU inspectors. In 2016 themed inspections continued, covering the major research groups involved in this area of work. This will enable ASRU to continue developing understanding and expertise in this area, influence best practice and advise on the implementation of the 3Rs.

Section 7: Compliance

A culture of compliance is a key part of the effective delivery of the Animals (Scientific Procedures) Act 1986 (ASPA) and the culture of care at an establishment. Significant responsibility is placed upon the establishment licence holder (ELH) or, in the case of a corporate entity, the named person responsible for compliance to deliver this role, thereby promulgating an appropriate culture of care in meeting both the letter and the spirit of the law. The ELH must have in place robust systems and frameworks that support and encourage compliance. By so doing, they can prevent unauthorised procedures from being carried out at their establishment and ensure that all licensees comply with the terms and conditions of their licences (personal and project licences).

Inspectors advise licensees and others on how to comply and generally promote a culture of compliance. One key function of inspection visits is to determine whether establishments and licensees are complying with the provisions of ASPA and with the conditions of their licences. This is a statutory requirement under Section 18 of ASPA. The Animals in Science Regulation Unit (ASRU) inspectors report any non-compliance and make appropriate and proportionate recommendations for the action required. This is primarily aimed at the prevention of repeated similar failures.

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 Senior Licensing 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. Those directly involved in the case will normally be notified by the Inspector and, in writing, by the Senior Licensing 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 for appeal against some sanctions. In rare cases an Inspector may take a view early in the investigation that an offence has been committed that is sufficiently serious to merit referral for prosecution.

Details of the process for dealing with non-compliance can be found in the *Guidance on the Operation of the Animals (Scientific Procedures) Act 1986* (the Guidance), which was published in March 2014.[6]

ASRU's compliance policy was updated during 2016 and this will be covered in next year's annual report. The updated policy was published online in 2017. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/670174/ASRU_Compliance_Policy_December_Final.pdf

Case summaries of non-compliance cases from 2016 are summarised in Annex 1 of this document.

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

Compliance advice

Compliance advice may be given verbally by an Inspector following the discovery of a minor breach of licence conditions. In such cases there should be:

- no disputed facts;
- no evidence of intent to subvert the controls of ASPA;
- no evidence to suggest that an offence has been committed; and
- no adverse animal welfare consequences.

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

In 2016 there were 57 recorded incidents of compliance advice given by inspectors (down from 60 in 2015).

Non-compliance

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

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

In determining the sanctions to be applied, deliberate non-compliances will be viewed more seriously than those due, for example, to misunderstanding or adherence to inappropriate instructions from those in authority. Repeated failures will generally be viewed more seriously than single incidents.

Any unnecessary animal suffering or attempts to conceal the facts may increase the gravity of any non-compliance sanction applied. A view will also be taken on whether or not the licensee is likely to observe their legal and administrative obligations in the future.

As set out in the Guidance the following range of sanctions is available to the Secretary of State.

- Letters of reprimand, with or without requirements for further action to correct perceived deficiencies, which might include:
  - requirements for formal training or retraining;
  - requirements for altered management practices; and
  - amendments to licence authorities including the addition of special conditions.
- Revocation, suspension or amendment of licences.
- Requirements specified in a Compliance Notice (see below).
- Referral to the prosecuting authorities.

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

Those involved in non-compliances, either as the personal licensee, or as the relevant project or establishment licensee, will be notified that the ASRU Inspectorate has made a report and will be informed of the nature of the breach. Once non-compliance has been investigated, those involved will be invited to provide any information that they may wish to be considered in mitigation before a decision is taken regarding the appropriate sanction. If this includes variation or revocation of authorities, the right to make representations under Section 12 of ASPA will be explained.

Once dealt with, non-compliances are reported to the Animals in Science Committee (ASC).

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

ASRU is aware that awaiting the decision from the Secretary of State is a stressful time for a licence holder and ASRU's processes were reviewed in 2015 and again in 2016 to help to conclude cases as swiftly as practicable and with proportionate sanctions. In 2016 the average time taken by ASRU to deal with reported cases of non-compliance was 12 weeks. This was one week longer than the average time taken in 2015. This was calculated from the date that the non-compliance was reported by a licensee/establishment or discovered by the assigned Inspector, through to the date that the final outcome letter was despatched by ASRU on behalf of the Secretary of State. In the second half of 2016, cases were concluded in an average time of eight weeks. Complex cases take longer than straightforward cases, where the facts are agreed by all.

Compliance Notices

The amended ASPA provides for the issue of a Compliance Notice in the event of a breach of a licence condition or a provision of ASPA, where ASRU requires a 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 and will also specify:

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

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

In 2016 the Secretary of State served a Compliance Notice on establishment licence holders on three occasions.

Compliance in 2016, self-reporting and a culture of care

In 2016, 45 cases of non-compliance were reported, fully investigated and completed:

- 36 (80%) occurred at universities;
- 6 (14 %) at commercial organisations; and,
- 3 (7%) at government research establishments.

Of the 45 cases dealt with in 2016, 40 (90%) were self-reported. In 2015 and 2014, 43 (78%) and 49 (78%) of cases respectively were self-reported.

Table 1 provides a summary of the discovery of the cases of non-compliance for 2013-16.

Self-reporting is generally indicative of an establishment making efforts to ensure compliance. It indicates that an establishment is aware of its responsibilities and is committed to building a good culture of care. Where appropriate, self-reporting should be a part of normal practice within establishments and embedded within good governance frameworks. It can be considered a good indication that the trend of a significant proportion of self-reported cases has continued from 2013 to 2016. In such cases, either the non-compliant licence holder or another named person within the establishment reported the non-compliance to the Home Office. This was then investigated by an Inspector.

Publication of the Guidance on ASPA in 2014 has helped to increase awareness among licence holders of their responsibilities under the amended Act. ASRU is aware that the reports it publishes about major or high-profile investigations are being used by duty holders to implement positive changes in the way that they approach compliance and establishing a culture of care. ASRU fully supports these trends and encourages duty holders to ask for advice.

ASRU continues to be encouraged that establishment licence holders (especially through the Establishment Licence Holders Forum) are reflecting on what a 'culture of care' means and how it can be monitored, championed and improved at their establishments. A good culture of care, supported by named persons and the Animal Welfare and Ethical Review Body (AWERB), is central to good compliance.

In September and October in 2016, two highly successful meetings were held between ASRU and a small group of establishment licence holders, which largely focused on non-compliance matters. The purpose of these meetings was to develop a new compliance policy, which further embedded proportionality, consistency and efficiency into ASRU's compliance processes. Going forward in 2017 and beyond, ASRU intends to repeat these types of meetings and engage further with this important group of stakeholders, building on relationships and broadening the range of

Table 1. Discovery of cases of non-compliance, 2013-16

	2013	2014	2015	2016
Cases reported by the establishment	21	49	43	40
Cases discovered by an inspector	7	12	12	5
Cases reported by others independent of the establishment	5	2	0	0
Total cases	**33**	**63**	**55**	**45**

subject matter for discussion. ASRU wants these meetings to be very much focused on issues and concerns that establishment licence holders may have and wish to raise with senior ASRU staff. In order to help to facilitate a full and frank discussion of matters, ASRU intends to keep numbers relatively small. ASRU has already invited expressions of interest from those establishment licence holders who wish to attend the first meeting to be held in 2017.

Key compliance messages

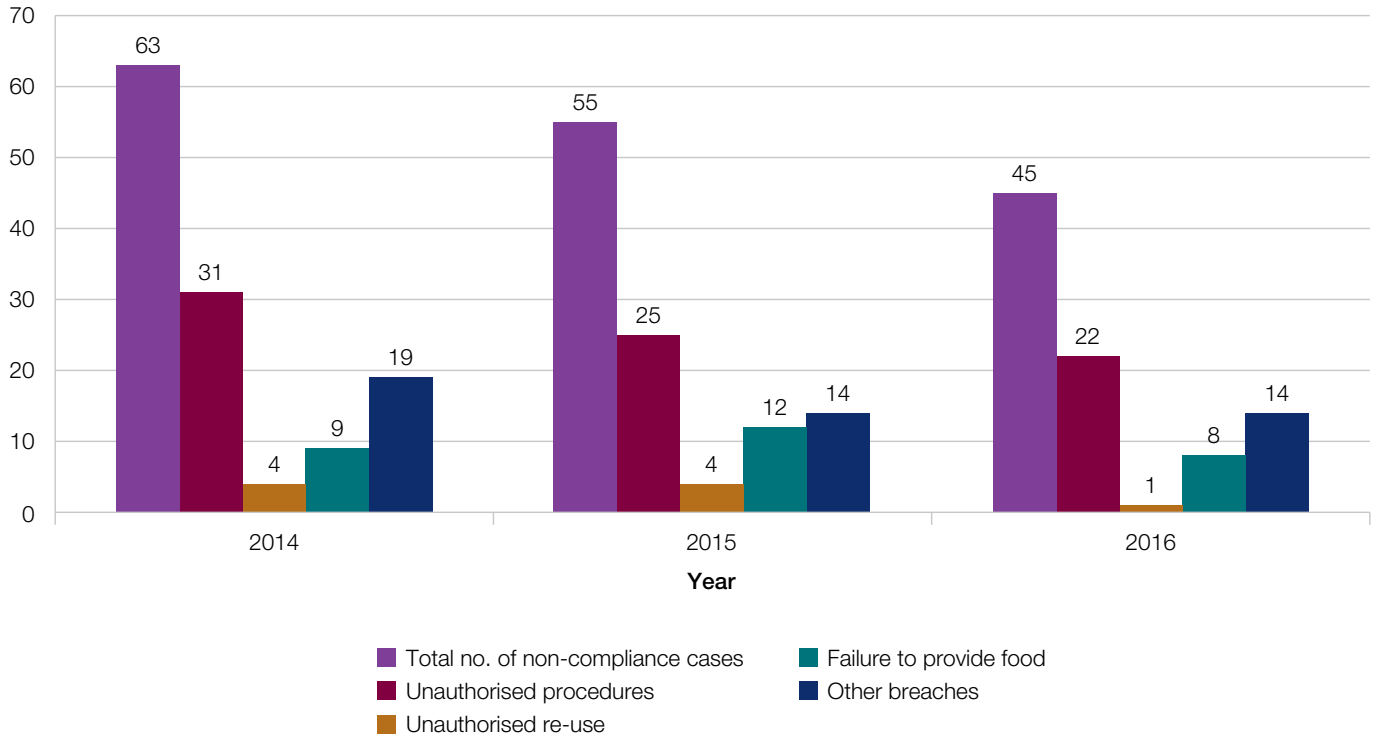
As in 2014 and 2015 a common cause of non-compliance in 2016 was that the details of the authorities granted in the personal or project licences had not been adequately checked. Failure to be familiar with authorities cannot be considered a mitigating factor. Licensees must be fully familiar with the details and authorities given in their personal licence and in the relevant project and establishment licences under which they are working.

To align with data published in previous years the following three common non-compliance themes during 2016 (Figure 1) have been set out:

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

Knowledge of these themes should be used to gain a better understanding of how to avoid non-compliance and support establishments in their frameworks for delivering requirements under ASPA. The case summaries of all non-compliances during 2016 have, where appropriate, been grouped under these themes, and are listed separately in Annex 1.

Figure 1. Categories of non-compliance, by type, 2014-16



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;
- a non-licensee was instructed, and allowed, to carry out a regulated procedure;
- a request by the holder to update a personal licence after the completion of modular training had not been submitted by the establishment to the Home Office for amendment.

This group included 22 cases (50%) of the total of 45 cases.

Root causes
The causes for these non-compliances were:

- administrative lapses and error;
- inadequate or inappropriate record keeping; and
- a lack of communication amongst key personnel.

The primary responsibility for ensuring compliance with licence authorities rests with the individual licence holder. Unfortunately, this type of non-compliance again featured significantly amongst the total cases of non-compliance that were recorded. Licensees should be aware of their authorities before carrying out regulated procedures on animals.

2. A failure to provide food and/or water

Failure to provide food and/or water to animals as part of normal husbandry and care is unacceptable. It is therefore of utmost importance that establishments have robust procedures in place to ensure the provision of food and water to animals kept under the terms of ASPA. Of the total 45 cases, 8 cases (18%) fell 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.

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. 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

The 'use' of the animal involves one or more regulated procedures applied for a particular purpose and lasts from the time of the first regulated procedure on that animal until the completion of observations or collection of data or products for a particular purpose. At the end of each 'use', a decision must be taken as to whether the animal can be kept alive. Any animal that, in the opinion of the personal licensee or the veterinary surgeon, is suffering or is likely to suffer as a result of the regulated procedures at the end of its 'use' must be killed. 'Re-use' is explained in the Home Office *Guidance on the Operation of the Animals (Scientific Procedures) Act 1986*[7] (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.

In relation to re-use under the new regulations, ASRU recognised that there was some confusion with a number of stakeholders and licensees. ASRU therefore drafted further guidance that was published in the form of an Advice Note (*Use, Keeping Alive and Re-use*) in October 2015. Since the publication of this Advice Note, and of the total 45 cases in 2016, only 1 case (2%) fell under this theme. This is a significant reduction on the 4 cases that were reported in 2015.

Root causes

The causes of this category of non-compliance are typically:

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

4. Solutions for non-compliance themes

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

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

In the first instance, the Guidance should be used as a resource and routinely followed. In this way, establishments should be able to assure themselves that they are conducting their work in a compliant way.

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

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 (Re-homing and Setting Free of Animals) 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 also initiates a number of more substantial investigations each year. These may be triggered by a number of factors including:

- an infiltration resulting in allegations in the public domain of poor practice;
- a cluster of non-compliances or 'near-misses' identified by inspectors;
- a non-compliance apparently involving significant animal harm;
- a publication that appears to describe unjustified pain, suffering or distress; 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 deliberate intent to deceive, are normally published. In cases where the ELH is found to have failed to comply, it is likely that the issues will be wide-ranging within the establishment and 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 of the lessons learnt can be found here: https://www.gov.uk/government/publications/compliance-investigations-by-the-animals-in-science-regulation-unit

Section 8: Financial report

2016/17 was the second 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 three years is shown in Table 2.

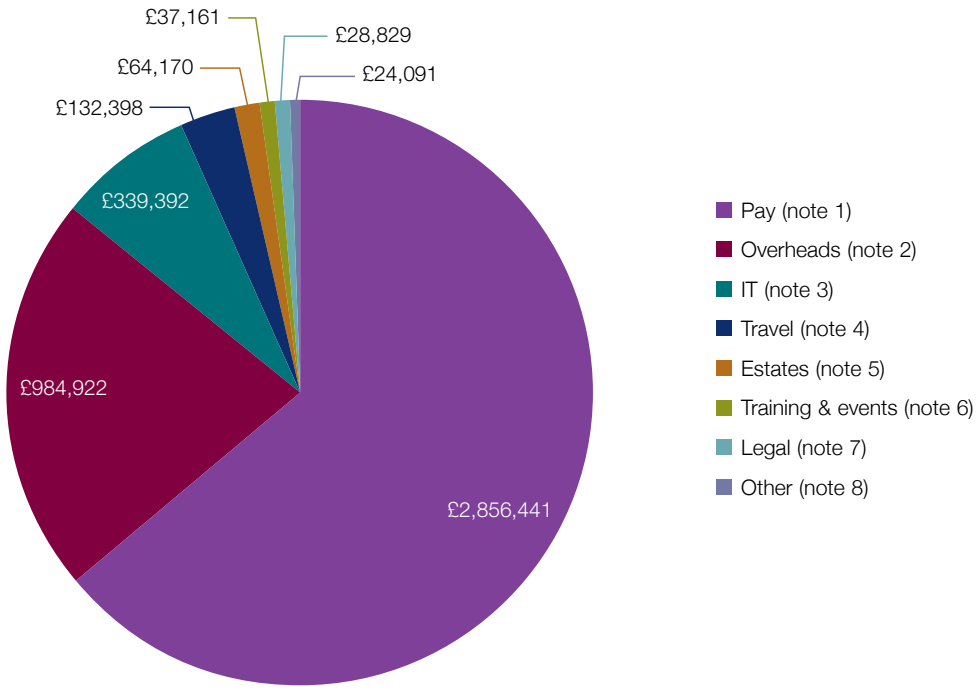
Table 2. Summary of income and fee-funded expenditure, 2014/15 to 2016/17

	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

2016/17 Expenditure

Expenditure for 2016/17 (1 April 2016 - 31 March 2017) is shown in Figure 2.

Figure 2. Expenditure, 1 April 2016 - 31 March 2017



Notes:

1. Of the £2.86 million pay costs approximately £1.97 million was salary costs, £651,000 was National Insurance/superannuation and £235,000 was transferred to other teams in the Home Office for use of their staff on ASRU's work.

2. Central overheads are calculated on a headcount basis and cover core Home Office central functions/services such as IT delivery, HR and finance. It also covers an apportionment of the accommodation and facilities costs of the London Head Office at 2 Marsham Street. 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 2016/17. Only £65,000 was spent on further development of ASPeL. The remainder is for VAT and telecoms, for example, mobile phones, wifi.

4. Travel and subsistence costs are mostly incurred by inspectors during their visits to establishments.

5. During 2016/17 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.

6. Training costs are 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.

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

8. 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.

In addition to the fee-funded costs shown above, £250,000 was paid from central Home Office funds to the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) in 2016/17. The funding supported the delivery of requirements set in the Animals (Scientific Procedures) Act 1986 and the Government's drive to support the continuing development of alternatives.

2016/17 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 2016/17 has not yet been fully invoiced and received. However, it is forecast to be approximately £4.48 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 is no fee increase for 2017/18 but an increase may be necessary for 2018/19.

Annex 1: Non-compliance cases

This section provides summaries of all 45 cases of non-compliance that were concluded in 2016. These cases should be used to understand better 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 (ASPA).

Non-compliance case 1

Under the Animals in Science Regulation Unit's (ASRU's) openness and transparency policy, this non-compliance was published on its website in October 2017. A link to the report can be found here: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/654177/asru_investigation_into_compliance_oct_2017.pdf

Non-compliance case 2

Regulated procedures causing the induction of diabetes in mice were undertaken by two personal licence holders. Two mice died unexpectedly. Appropriate action was not taken when three other mice showed adverse effects, which exceeded the severity controls specified in the project licence. A drug was also administered to eight mice without the appropriate project licence authority. The same licence holders performed unauthorised surgery on nine mice. Both licensees failed to undertake the required blood glucose tests and health monitoring requirements of the animals as specified in the project licence protocol in order to create early humane end-points thereby minimising suffering. They did not keep any contemporaneous records of the regulated procedures performed and failed to label correctly the cages in which the animals were kept.

The project licence holder, who also held a personal licence, failed to ensure that the two personal licensees were fully aware of the details of the authorised programme of work or of any of the control points that were stipulated in the project licence. They also failed to ensure that the project licence was available and its content made known to those personal licensees working under its authority. The project licence holder also agreed with them that they did not need to monitor the animals at the weekend.

Upon discovery of the incident the establishment licence holder instigated a detailed and thorough investigation and also immediately suspended access of all three licensees to the animal facilities pending the outcome of the internal investigation. As the project licence holder encouraged departure from the authorised procedures, experimental design and controls on severity authorised in their project licence, the project licence was revoked together with their personal licence. The personal licences of the other two individuals involved were also revoked. Since the establishment licence holder failed to take all reasonable steps to prevent the performance of unauthorised procedures, they were sent a letter of written reprimand.

Non-compliance case 3

A personal licence holder undertook a regulated procedure without the necessary project licence authority. Poor understanding of the nature of the authorities contained in the project licence by both the project licence holder and the personal licensee led to the project licence holder permitting the personal licence holder to perform unauthorised procedures. The project licence holder and

personal licence holder were each sent a letter of written reprimand, which was recorded on their record. They were also both required to undergo retraining in module one.

Non-compliance case 4

Genetically altered (GA) animals were bred and maintained under the erroneous assumption that project licence authority existed to do so. The project licence holder believed that the GA mice were held on a service licence at the establishment and that the animals could be transferred as required to their own project licence. Regulated procedures involving pairing and ear notching of GA animals were performed by three personal licensees without the project licence authorities in place to do so. They were each sent a letter of written reprimand, which was recorded on their record. All three were also required to retrain in module one. The project licence holder was sent a letter of written reprimand, which was recorded on their record.

The establishment licence holder was issued with a Compliance Notice that required them, within 12 months, to provide an action plan that would:

- ensure that all named persons and animal care staff would have adequate education and knowledge of the responsibilities of their role to ensure compliance;
- provide plans to strengthen the systems for preventing the performance of unauthorised procedures; and
- detail the changes necessary to the current governance processes in order to ensure adequate and effective liaison between scientific groups and technical staff.

Non-compliance case 5

Three rats that had undergone a series of regulated procedures were not killed by the personal licensee, as required by the project licence protocol, but were instead kept alive without the determination of the named veterinary surgeon (NVS) that they were in a condition to do so. The project licence stated that all rats should be killed within six months from the commencement of regulated procedures. The rats were still alive approximately ten months after the commencement of regulated procedures, i.e. approximately four months after the completion of regulated procedures.

The project licence holder was issued with a letter of written reprimand, which was recorded on their record. The project licence holder voluntarily undertook retraining in modules 1 and 5, though had they not done so the Secretary of State would have required this from them.

Non-compliance case 6

A mouse was injected with a tumour fragment, which did not develop into a tumour. The mouse was subsequently inadvertently inoculated with tumour cells by a personal licence holder, thereby being re-used without project licence authority. Re-use of a protected animal that has been subject to one or more regulated procedures without the consent of the Secretary of State constitutes a breach of Section 14 of ASPA. The regulated procedures applied to the animals appeared otherwise to have been performed competently though there was additional avoidable suffering for the mouse concerned. The personal licence holder was sent a letter of written reprimand, which was recorded on their record.

Non-compliance case 7

A personal licensee undertook regulated procedures without project licence authority. The licensee had undertaken surgery on two anaesthetised mice before killing them. The personal licensee did not check if there was project licence authority to undertake the surgery. The project licence holder instructed the personal licensee to undertake this practice.

There was no additional suffering as the mice were anaesthetised. Both licensees were issued with a letter of written reprimand, which was recorded on their records. In order to ensure that they were fully aware of the legislative requirements, they were both also required to undertake retraining in modules L and E1.

Non-compliance case 8

A personal licensee failed to keep full and proper records of all the animals on which they had conducted authorised regulated procedures. Such records of experimental data of the animals used for regulated procedures that did exist were not easily available or forthcoming when requested and were of questionable accuracy. The licensee claimed that the data had been lost due to a faulty hard drive but when this was investigated the hard drive was shown not to have contained any data. Planned regulated procedures were not completed until the intervention of the project licence holder, but data on around 40 rats could not be found.

Upon discovery, the establishment licence holder immediately stopped the personal licensee from accessing the animal unit and also requested revocation of their personal licence. Had they not done so the Secretary of State would have revoked the personal licence. The personal licence holder was issued with a letter of written reprimand, which was recorded on their record. They were also informed that should they apply for a personal licence at some future date, the Secretary of State would take the circumstances of the incident into account in arriving at a decision whether to grant or refuse any such application. They would also be required to retrain in all mandatory modules.

Non-compliance case 9

Two personal licensees were performing regulated procedures that involved the placement of intracerebral cannulae and intravenous jugular catheters into ten rats. Three rats were administered with injectable anaesthetic reversal agent. The following morning, two of those rats had exceeded the project licence endpoints and so were immediately culled. The surgeries on the three rats had commenced late in the day, and as a consequence, the conclusion of the procedures fell outside of the normal working hours of the establishment. Monitoring of the animals also took place without the assistance of an animal technician. Furthermore, due to the lateness of the surgeries and the necessity to reduce the recovery time and return the animals to their home cage, they were given an injectable reversal agent. As a consequence, these factors affected the animals' post-operative recovery. It was subsequently discovered that one of the rats had been subject to two surgeries on two consecutive days rather than one combined surgery, which would have been considered a more refined approach. Further investigation revealed that this was due to the use of an inappropriate anaesthetic regime. Scrutiny of the monitoring sheets and records of those animals on which regulated procedures had been carried out revealed a number of inconsistencies and inaccurate information.

Failure by the project licence holder to ensure that an appropriate level of supervision was provided to the two personal licensees, and the failure to maintain a contemporaneous record of procedures is a breach of standard conditions 6 and 19 of the project licence. The suffering and deaths of the animals could have been avoided had veterinary advice on appropriate anaesthesia and analgesia regimes been sought and acted upon, and if better attention to record keeping and appropriate supervision of the two personal licensees had been provided. The project licence holder was sent a letter of written reprimand, which was recorded on their record. The project licence holder was also advised to consider how they would provide appropriate levels of supervision of work conducted under the authority of their project licence to ensure competence and adherence to best practice and the principles of replacement, reduction and refinement (the

3Rs). The two personal licensees together with the establishment licence holder were each sent a letter of written reprimand, which was also recorded on their records.

Non-compliance case 10

On unpacking a delivery of mice into three cages, an animal technologist failed to provide water. This defect was not identified by the same technologist's checks the next morning but was identified by the named animal care and welfare officer (NACWO) performing room checks later that morning. The mice were immediately given water and all recovered. The incident was reported to the Home Office. The establishment licence holder reprimanded the animal technologist and introduced management measures to provide support, training and supervision until competence was assured. The establishment licence holder was sent a letter of written reprimand, which was also recorded on their record.

Non-compliance case 11

Early in the course of surgery on a mouse, a personal licensee noticed that the oxygen in the anaesthetic machine was running out. They sutured the incision and allowed the animal to recover. The procedure was not authorised in the project licence. Applying procedures that are not part of a programme of work specified in a project licence is a breach of ASPA. The anaesthetic machine was subsequently found to be defective. The personal licensee was sent a letter of written reprimand, which was recorded on their record, and also required to undergo retraining in module 1.

The establishment licence holder was issued with a Compliance Notice requiring them to provide a detailed proposal of how they would ensure that all shared equipment used by researchers, including anaesthetic equipment, would be adequately and appropriately maintained.

They were also required to confirm that all shared equipment, including anaesthetic equipment, had been serviced and or had been checked to ensure that it was in a serviceable condition. The establishment licence holder was required to provide this information within six months from the date of issue of the Compliance Notice.

Non-compliance case 12

While training and assessing the competence of a non-licensee in schedule 1 methods, a project licence holder, who also held a personal licence, blood sampled one of three stock birds that were to be used for the training without the necessary project licence authority in place to do so. The project licence holder also suggested and allowed the non-licensee to blood sample two of the birds so that they could assess their competency in blood sampling at the same time as the schedule 1 assessment. After taking the blood samples, the birds were immediately humanely killed.

The project licence holder did not follow the procedures in place at the establishment to prevent non-compliance and they procured the non-licensee to undertake regulated procedures otherwise than as part of the specified programme of work and without personal licence authority. This was a breach of ASPA.

The incident occurred due to the project licence holder's lack of understanding regarding controls on regulated procedures performed under ASPA and there was no intent to circumvent the regulations. The project licence holder was sent a letter of written reprimand, which was recorded on their record, and required to undertake retraining in module 1 within six months. The non-licensee was sent a letter of censure, which was recorded on their record, and was also required to undertake retraining in module 1 within six months.

Non-compliance case 13

During a six-month period, a study was associated with an unexpectedly high rate of morbidity and mortality in rats. In this study 17 rats were culled post-operatively. Although help was sought by the personal and project licence holders from the named people, notifications to the Home Office of unexpected and unauthorised severity were not made in a timely manner. In addition, contemporaneous record keeping was incomplete, contributing to difficulty in investigating the root causes of the morbidity and mortality. Under the same project licence, over a 2-month period, 13 rats on a single study developed skin lesions associated with the surgical site; 2 of the animals required euthanasia and the other 11 were treated and subsequently the wounds healed. These adverse effects were not specified in the project licence protocol and they caused suffering in excess of that authorised. Again, post-surgical issues that breached the authorised severity in the project licence were not reported in a timely fashion.

The personal licensees were sent a letter of written reprimand noting a failure to adequately monitor and care for animals and inadequate record keeping relating to the first incident and this was recorded on their files. The project licence holder was sent a letter of written reprimand, which was recorded on their record, noting the failure to report unexpected severity suffered by animals in a timely manner and failings in record keeping. In order to ensure that they understood their legal and ethical responsibilities, they were also required to undertake retraining in these areas.

Non-compliance case 14

In a study one rat developed a lesion associated with a surgical wound approximately ten days post-operatively. The personal licence holder discussed the case with the NVS and decided that a surgical repair of the lesion was the best option. The surgical repair was technically straightforward and clinically appropriate. However, it was not authorised by the licence. The animal went on to make an unremarkable recovery and yield valid scientific results. The personal licensee was sent a letter of written reprimand, which was also recorded on their record, and they voluntarily requested that their personal licence was revoked. Should they wish to hold a licence under ASPA again, they will be required to undertake retraining.

Non-compliance case 15

A personal licensee carried out imaging of a non-human primate under general anaesthesia. The animal was placed in a recovery incubator but the personal licensee forgot to return to monitor the animal's recovery. It was left without access to food and water overnight. When the animal was discovered the next morning by a member of staff the animal appeared unharmed and was immediately returned to its home cage. The personal licensee was contrite and acknowledged their failings. They voluntarily requested revocation of their personal licence. Had they not done so their licence would have been varied to require direct supervision until such time as the Home Office could be reassured.

The establishment licence holder was sent a letter of written reprimand, which was also recorded on their record. They reviewed and strengthened their systems for recording animals leaving the main facility and for monitoring their return. They also instituted end of day checks on rooms outside the main facility where animals may have been used.

Non-compliance case 16

A project licence holder allowed the breeding of genetically altered (GA) mice to continue under the breeding and maintenance protocol of their licence after they became aware that the authorised numbers had been exceeded. The project licence authorised a total of 5,000 mice to be used in the full 5-year life of the

licence but in 2 years, 11,000 mice had been used. The project licence holder was notified of the incident when it was discovered by a personal licensee while preparing the Return of Procedures data for 2014. Nevertheless, the project licence holder allowed the breeding of the animals to continue for over a year and took no action to notify the establishment's administrator or the Home Office.

Carrying out regulated procedures not authorised by the programme of work described in the project licence (by continuing breeding GA mice when it was known that the authorised numbers had been exceeded), and knowingly permitting a personal licensee to continue breeding GA mice after the project licence holder became aware that the authorised numbers of animals had been exceeded is a breach of ASPA. There were no animal welfare issues as the regulated procedures appeared to have been performed competently. Had authorisation been sought to use more animals it is likely that this would have been granted. The project licence holder and the personal licence holder were each sent a letter of written reprimand, which was recorded on their records. They were also both required to undertake retraining.

Non-compliance case 17

In June 2015 a group of five mice were surgically prepared with cranial windows and then exported to a collaborator in Germany. The Home Office did not give permission for that export; this is a breach of ASPA. Verbal advice had been sought from the Inspector that such requests are dealt with on a case by case basis but that advice had been misinterpreted by the NACWO. The issue came to light when the NACWO asked the Inspector for advice regarding the export of a further batch of surgically prepared mice. The Home Office accepted that this was a genuine misunderstanding with no intent to circumvent the regulations. Transport had occurred without incident and the mice had been used for legitimate scientific purposes. As the relevant parties at the establishment are now aware of the legal requirements, the establishment licence holder was sent a letter of written reprimand, which was also recorded on their record.

Non-compliance case 18

A personal licensee conducted regulated procedures on 12 mice, knowing that there was no project licence authority to permit them to conduct the study. Due to the seriousness of the non-compliance, the establishment licence holder initiated official internal disciplinary procedures to investigate possible research misconduct. The personal licensee was also suspended from the establishment. Due to the serious nature of this incident, and the need to safeguard the welfare of protected animals, the Home Office revoked the personal licence under ASPA.

Non-compliance case 19

The holder of a personal licence gave a group of 18 chickens an intramuscular injection, and 7 days later took blood samples from 9 of the birds. The procedures were authorised under a project licence and the personal licensee was supervised for both sets of procedures and performed them competently with no adverse effects on the birds. The personal licence holder had, in error, informed the NACWO that they had personal licence authority to use chickens and so was permitted to carry out the regulated procedures, but they did not in fact have such licence authority. Applying regulated procedures to chickens without holding a personal licence qualifying them to do so is a breach of ASPA. Had they applied for an amendment to their personal licence to allow the use of chickens, this would have been granted. The establishment requested revocation of the personal licence and so the individual involved was sent a letter of written censure, which was recorded on their record.

Non-compliance case 20

Two mice suffocated when a cage was not correctly repositioned in a bio-containment rack after the daily check. A second check later in the day failed to identify the error. The animal technologists involved received personal guidance in performing the necessary checks. The incident was reported to the Home Office. This was an isolated incident. The establishment licence holder was sent a letter of written reprimand, which was also recorded on their record.

Non-compliance case 21

A personal licensee inadvertently failed to provide food to a cage of three mice. The lack of food in the cage was not identified at two successive daily checks. On discovery, the mice were thin but recovered after being provided with food. The incident was reported to the Home Office. The establishment licence holder took action to reprimand the animal technologist involved and has provided additional support and supervision until they are considered to be fully competent in undertaking daily checks. The personal licensee accepted responsibility for the omission and has been monitored to ensure that there is no similar lapse in concentration. Both establishment licence holder and personal licensee were sent letters of written reprimand, which were recorded on their records.

Non-compliance case 22

There was a failure to provide food to two mice that had undergone regulated procedures. This failure was not detected and remedied at daily checks on three days; neither was the deteriorating condition of the mice noticed. One mouse was found dead and the other culled to prevent further suffering. This constitutes a breach of Establishment Licence standard condition 4. The establishment licence holder was sent a letter of reprimand, which was recorded on their record. Weaknesses in the processes for daily checks were identified. The establishment licence holder was also required to provide a report detailing the actions they would take to ensure compliance with their establishment licence standard conditions in the future. The effectiveness of these actions was followed up by an inspection.

Non-compliance case 23

Two stock mice died due to a lack of water provision over a weekend. The lack of water and the deterioration in health of the mice was not picked up by the daily checks. Evidence suggests that the animal technician spent an appropriate time on the checks, so the conclusion is that this was due to human error.

The establishment licence holder took action against the relevant staff member and they were also retrained. The establishment licence holder was sent a letter of written reprimand, which was also recorded on their record.

Non-compliance case 24

Four mice suffered skin lesions following the application of a depilatory cream to their backs, probably due to a failure to wash the cream off adequately. The lesions were noted by animal care staff but appropriate action was not taken immediately, resulting in the mice suffering longer than necessary. On investigation, the personal and project licence records relating to these mice were inadequate. Following this incident, local procedures were reviewed and improved, including improved systems for veterinary involvement and improved record keeping. Letters of reprimand were sent to the establishment licence holder, the project licence holder and the personal licensee, which were also recorded on their records.

Non-compliance case 25

A personal licensee failed to replace a mouse cage correctly in a bio-containment rack.

The air vents did not adequately engage and the mice were found dead the next morning, presumably having asphyxiated. The personal licensee had only recently been trained in using the containment racks and it is likely that their inexperience was the major factor in this error. The personal licence holder was sent a letter of written reprimand, which was recorded on their record, and underwent further training in the correct use of containment caging.

Non-compliance case 26

A personal licence holder failed to ensure that 21 mice, on which they had performed regulated procedures, were adequately monitored and cared for. When they were later absent from work for the rest of the week they made no formal arrangements for the care and welfare of the animals by another personal licence holder. As a result, 13 of the mice had to be culled due to signs of systemic illness, which may have been caused by inadequate ventilation. This was a breach of standard conditions of their licence. The harms that arose were unintended and there was no intention to breach the regulations. The personal licence holder was sent a letter of written reprimand, which was recorded on their record.

Non-compliance case 27

In two separate incidents two mice died as a result of starvation. This was due to a failure by the animal technologist responsible for taking care of the animals to detect and remedy overgrown incisor teeth. The failure to provide the two mice with adequate care, and the failure to keep restrictions on the extent to which the mice could satisfy their physiological needs to a minimum is a breach of standard conditions of the establishment licence. A detailed local investigation was carried out and meetings were held with key staff involved in order to review local practices to prevent similar incidents from occurring. The establishment licence holder was sent a letter of written reprimand, which was recorded on their record.

Non-compliance case 28

A personal licensee undertook regulated procedures, administration of substances into the brain under general anaesthesia, without personal licence authority of the appropriate category. The licensee had overseas experience of such procedures and there were no avoidable welfare consequences. The cause was an inadequate understanding of the licence authorities and the licensing system. The personal licensee was sent a letter of written reprimand, which was recorded on their record, and was required to undertake retraining in the legislation before being allowed to amend their personal licence to include authority for surgical procedures. The establishment identified weaknesses in their systems to prevent the conduct of unauthorised procedures. The establishment licence holder was sent a letter of written reprimand, which was recorded on their record. They immediately reviewed and strengthened their local controls.

Non-compliance case 29

Two personal licensees were responsible for the welfare of a group of mice, which were under experimental procedures. The mice were not appropriately fed over a number of hours. The mice were subsequently culled as a precautionary measure because their scientific use may have been compromised. The omission was noted when one of the animals was found to be subdued, cold and immobile. Each personal licence holder was sent a letter of written compliance advice, which was also recorded on their record.

Non-compliance case 30

A project licence holder used 12 (30%) more non-human primates than they were authorised by their project licence. This was a breach of ASPA. The project licence holder had genuinely misunderstood how the estimated numbers of animals to be used that is specified in

a protocol should be calculated, and was unaware of how the Home Office policy on authorised numbers of animals as laid out in the Guidance on the Operation of the Animals (Scientific Procedures) Act, paragraph 5.26, related to their programme of work. The licence holder subsequently submitted an application for amendment to their licence in order to continue with their programme of work and this was granted. On this occasion, no formal action was taken.

Non-compliance case 31

A personal licence holder carried out regulated procedures on a number of mice without the project licence authority necessary to do so. Three of the mice were found dead the next day suspected to be due to toxicity associated with the procedure. Carrying out regulated procedures that were not authorised by the project licence is a breach of ASPA. The incident appeared to have occurred due to an apparent genuine misunderstanding by the personal licence holder of the authorities held by the project licence holder and it is not considered that there was any intent to deliberately circumvent the regulations. The personal licence holder was sent a letter of written reprimand, which was recorded on their record.

Non-compliance case 32

A group of five mice in a study of metastatic bone cancer were imaged under general anaesthesia prior to humane killing by a schedule 1 method. The anaesthetic machine was not checked properly and the mice woke up in the equipment. Four mice were humanely culled but one was left behind and not discovered until the next day. This animal was left inside the imaging box and had no access to food or water overnight. It was at the scientific endpoint of a metastatic bone cancer study and was not immediately killed at the end of the study. This animal likely suffered unnecessary pain, suffering or distress both as a result of having no access to food and water and as a result of not being promptly killed at the end of procedures. The establishment licence holder ensured that local retraining was provided to the two personal licensees, working practices were revised and additional recording systems were put in place. The two personal licensees involved were sent a letter of written reprimand, which was also recorded on their records.

Non-compliance case 33

Experiments on approximately 24 mice were carried out without adequate planning and preparation, resulting in poor conduct of the regulated procedures and poor experimental design. This caused some animals to be maintained for five days after an unsuccessful injection when they could have been euthanased, although the level of additional suffering was mild. There was no project licence authority for the use of animals where the injection was unsuccessful. The project licence holder was sent a letter of written reprimand, which was recorded on their record, and required to undertake retraining within four months to acquire improved knowledge of:

- their responsibilities as a project licence holder;
- the application of the 3Rs; and
- the principles of experimental design.

Non-compliance case 34

A personal licence holder applied authorised regulated procedures to the knee joint of a rat. On the second day, the animal was transferred between animal units and provided with analgesia in the evening but the licence holder did not return to monitor the animal for three days. The licensee did not communicate with animal care staff caring for the rat or provide any specific instruction to monitor and care for the animal over the weekend, which led to unnecessary suffering. Analgesia was not provided over this time and the animal was not monitored closely as would be expected after such surgery. Furthermore, the personal

licence holder incorrectly completed monitoring records for the period they were absent, which suggested that they had inspected the rat over that period and provided analgesia when they had not. The licensee did not follow the project licence terms on how the animal should be managed following the procedure, but rather they made assumptions about the animal's pain and distress and how it was to be cared for over the weekend that resulted in a period of unnecessary suffering. As a personal licence holder, failing to act in a manner that is consistent with the 3Rs and to properly monitor and care for the animal on which they have performed regulated procedures is a breach of standard conditions 1 and 2 of the personal licence. In addition, failing to use analgesia to ensure that the pain, suffering and distress suffered by the animal was kept to a minimum was also a breach of standard conditions 11, 12 and 14 of the licence. The personal licence holder was sent a letter of written reprimand, which was recorded on their record and was also required to retrain in module 1.

Non-compliance case 35

The numbers of mice to be used during the course of a project was estimated at 127,600 but this number was significantly exceeded by 179,546. Further investigation revealed that the number of mice used was first exceeded during 2014. The error was discovered in January 2016 while processing the annual Return of Procedures of animals used to the Home Office. Although there were multiple personal licensees carrying out regulated procedures on two project licences, the systems for routine record keeping provided to project licence holders was inadequate, or not sufficiently robust, to prevent multiple personal licensees from conducting large numbers of unauthorised procedures. It was reported that the numbers of animals used appeared to have been recorded on different databases / computer systems, and that this made the reconciliation of numbers difficult. Due to the significant overuse of protected animals, which led to the performance of unauthorised procedures the establishment licence holder was sent a letter of written reprimand, which was also recorded on their record.

Non-compliance case 36

The number of mice used exceeded the authorised number of 200,000 by 25,940. This was not discovered until collating the annual Return of Procedures of animals for the Home Office in January 2016. The number was first exceeded during the year 2015 but this went unnoticed by the establishment until January 2016. At this point the number of animals that had been used was 225,940. Although there were multiple personal licensees carrying out regulated procedures on two project licences, the systems for routine record keeping provided to project licence holders was inadequate, or not sufficiently robust, to prevent multiple personal licensees from conducting large numbers of unauthorised procedures. It was reported that the numbers of animals used appeared to have been recorded on different databases / computer systems, and that this made the reconciliation of numbers difficult. Due to the significant overuse of protected animals, which led to the performance of unauthorised procedures the establishment licence holder was sent a letter of written reprimand, which was also recorded on their record.

Non-compliance case 37

Following delivery on 13 May 2016, 74 chicks died or required euthanasia over the following days due to failure to provide adequate humidity for a period of approximately 65 hours. This incident appears to have occurred due to a miscommunication between the engineer and the Biological Services Unit Manager. The process for ensuring that the environmental controls were appropriate was not robust or fail-safe, and there was an overreliance on both the automatic alarms and the individual engineer to ensure that they were set correctly. Local controls were reviewed and revised by the establishment licence holder to

prevent recurrence. The establishment licence holder was sent a letter of written reprimand, which was also recorded on their record.

Non-compliance case 38

A project licence holder exceeded the number of rat pups used in two protocols under the authority of their project licence. A total of 2,179 and 231 animals were used on the two protocols, compared to 2000 and 200 authorised on the license. This exceeded Home Office policy on estimated numbers, and together the numbers of animals used represented a significant change to the programme of work. The failure to have a system in place to keep a running tally of the number of animals being used and to share contemporaneous records with staff and scientists resulted in the project licence holder knowingly permitting a personal licence holder, who was working under the project licence authority, to carry out regulated procedures otherwise than as part of the programme of work specified in the project licence. This was a breach of ASPA. The project licence holder subsequently created and put in place a real-time mechanism to collect relevant information on the numbers of animals used. The project licence holder was sent a letter of written reprimand, which was also recorded on their record.

Non-compliance case 39

A PhD student used embryonated chicken eggs in regulated procedures without a personal licence. The student had completed all the required module training, but mistakenly believed that their module certificate was a personal licence, and did not apply to the Home Office for a licence. The project licence holder and Named Training and. Competency Officers had independently asked the student whether they held a licence but had not asked for a personal licence number or for sight of the licence. Because the student mistakenly thought they were in possession of a personal licence, they assured them that all the required authorities were in place. The regulated procedures were carried out competently and there was no adverse impact on animal welfare. The student was sent a letter of written censure, which was recorded on their record and was also required to retrain in module 1.

Non-compliance case 40

The holder of a personal licence performed regulated procedures on chickens. They had completed their chicken module training but had not amended their personal licence to include authority to work with chickens as they mistakenly believed that their module certificate provided the required authority. The procedures were performed under supervision, but the trainer did not check whether the personal licensee had personal licence authority. There was no compromise to animal welfare and the experiment was successful. They were sent a letter of written reprimand, which was also recorded on their record, and were also required to retrain in module 1.

Non-compliance case 41

In the course of inspection at an establishment, concerns were revealed over the effectiveness of communication between named persons and other personnel, and the framework for reporting potential severity breaches to the Home Office. It appeared that the establishment licence holder was likely to be in breach of standard condition 21 of their licence.

The holder was served with a Compliance Notice requiring them to instigate a short-term response and a long-term improvement in line with the following three requirements.

I. Demonstrate that there was effective communication between all staff with responsibilities under ASPA. This was to be particularly aimed at empowering named persons to perform their roles.

II. Demonstrate that there were systems in place to:

- report likely or potential breaches of severity to the Home Office;
- prevent the application of unauthorised procedures to regulated animals; and
- ensure that those responsible for regulated procedures were fully aware of their responsibilities under the Act.

III. Review the effectiveness with which they were utilising the framework provided under the Act and through the standard conditions of their establishment licence, to implement the 3Rs and appropriate animal care. This was to include:

- the performance of the establishment's Animal Welfare and Ethical Review Body (AWERB);
- the performance of named persons; and
- the effectiveness of the training of the establishment licence holder as set out in the Guidance.

In addition to these actions, the establishment licence holder was also required to deliver two reports:

- a short-term response addressing each of the three required actions within three months; and
- a second report demonstrating how sustained improvements would be embedded into the establishment's culture in relation to the 3 required actions within 15 months.

The licence holder complied fully with the requirements of the Compliance Notice and no further action was required at its conclusion.

Non-compliance case 42

An animal technician failed to provide feed to a cage of two breeding mice. Subsequent routine welfare checks carried out in the morning and evening over two days by three different technicians also failed to discover the absence of feed in the cage or the condition of the animals. The incident was later discovered during a routine morning check by a personal licensee. One mouse was found dead and the second mouse had lost weight due to lack of feed and was immediately euthanased. The establishment's local systems intended to ensure that food and adequate daily checks appropriate for the health and wellbeing of protected animals failed to identify the omission.

The failure of the technicians to provide food for the animals, together with their failure to undertake adequate daily checks on the animals was a breach by the establishment licence holder of standard condition 4(3) and 4(5) of their establishment licence. Local controls were subsequently reviewed and refresher training by the establishment was provided to all four technicians involved. The establishment licence holder was sent a letter of written reprimand, which was recorded on their record.

Non-compliance case 43

Animal technicians failed to carry out an hourly check as required by a project licence authority on approximately 110 mice. At a subsequent scheduled check, one mouse was found dead, and two more had to be euthanased as they had reached the humane endpoint. The cause of the failure to monitor the mice was a lack of clarity about the processes to be followed at the handover of responsibility for checking animals undergoing regulated procedures.

The project licence holder's failure to ensure that the programme of work specified in their licence was carried out in compliance with its conditions was a breach of standard condition 1 of the project licence. Upon discovery of this incident the project licensee took effective, corrective actions to rectify the situation, immediately instigated a full investigation and informed their Inspector. Systems were subsequently improved to make it clear at shift changeovers who was to be responsible for

checking animals at the next time point. The project licence holder was sent a letter of written reprimand, which was recorded on their record.

Non-compliance case 44

While supervising a PhD student, a non-licensee instructed the student to undertake regulated procedures on a number of mice under the project licence authority of a colleague. However, the project licence did not authorise the undertaking of the proposed regulated procedure. Because the student was not deemed trained or competent to conduct the procedures, they asked two personal licensees to undertake the procedures, which they did without first checking to confirm that there was licence authority.

The establishment licence holder did not have a robust system of checks in place to prevent the conduct of unauthorised procedures and was therefore in breach of standard condition 20 of their establishment licence. The procedures were otherwise competently performed and when subsequent adverse effects were observed, the affected mice were humanely killed to limit further suffering. Immediately after the incident, the establishment licence holder submitted a detailed action plan requiring all staff involved in ASPA-related work to undergo appropriate training in order to improve their understanding of their responsibilities under ASPA 1986.

The non-licensee supervisor and the non-licensee student were each sent a letter censure, which was recorded on their records. The two personal licensees were each sent a letter of written reprimand, which was recorded on their records. Because of the major changes instituted by the establishment licence holder following the incident, which included the requirement for all staff involved in ASPA work to undergo retraining, the establishment licence holder was sent a letter of written reprimand, which was recorded on their record.

Non-compliance case 45

The holder of a project licence did not ensure that work under authority of the licence ceased on the date of expiry in mid-September and many regulated procedures on rodents involving dosing and sampling and intracranial surgery, continued to be carried out by nine personal licensees until early-October. The underlying cause of the breach was an administrative error by staff at the establishment, who erroneously recorded an expiry date on their internal systems that was three months later than the actual expiry date. The incident occurred due to a genuine mistake by the establishment and there was no intent to circumvent the regulations. The unauthorised continuing work was competently undertaken, with no indication of avoidable animal welfare consequences, and produced useful scientific data.

The project licence holder had breached standard condition 1 of their project licence and the personal licensees had breached Section 3(b) of ASPA. Local controls were subsequently thoroughly reviewed and revised to avoid any similar incident from occurring. The project licence holder was sent a letter of written reprimand, which was recorded on their record. The nine personal licensees were given formal compliance advice, which was recorded on their records.

Annex 2: Tables and figures

Table A1: Licence applications and amendments 2016 and 2015

	Total			Per inspector FTE		
	2016	2015	Change	2016	2015	Change
PILs granted	3,166	3,264	-3%	215.4	190.9	13%
PILs amended	551	630	-13%	37.5	36.8	2%
PILs in force at year-end	16,178			1,100.5		
PELs granted	3	5	-40%			
PELs amended	159	205	-22%	10.8	12.0	-10%
PELs in force at year-end	167	173	-3%	11.4	10.1	12%
PPLs granted	533	559	-5%	36.3	32.7	11%
PPLs amended	1,012	820	23%	68.8	48.0	44%
PPLs in force at year-end	2,631	2,656	-1%	179.0	155.3	15%
Inspectors FTE	14.7	17.1	-14%			

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

Figure A1: Inspectorate staff 2008-2015

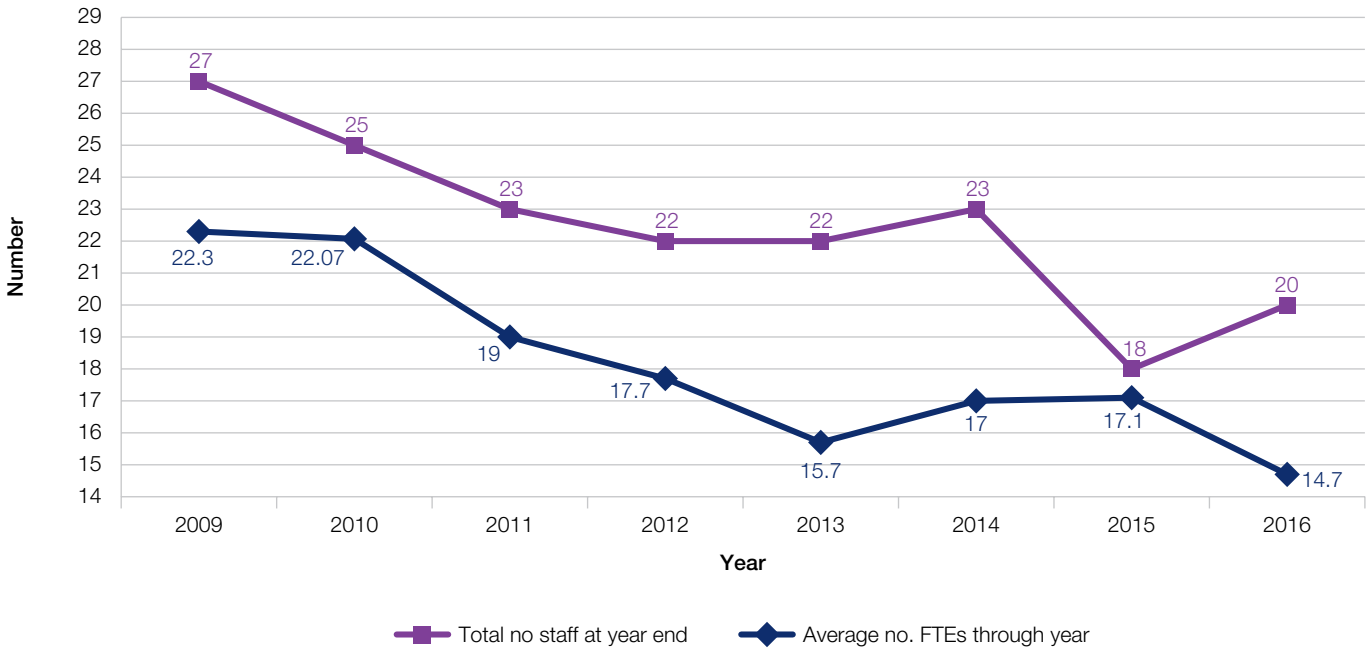


Figure A2: Project licences granted 2008-2015

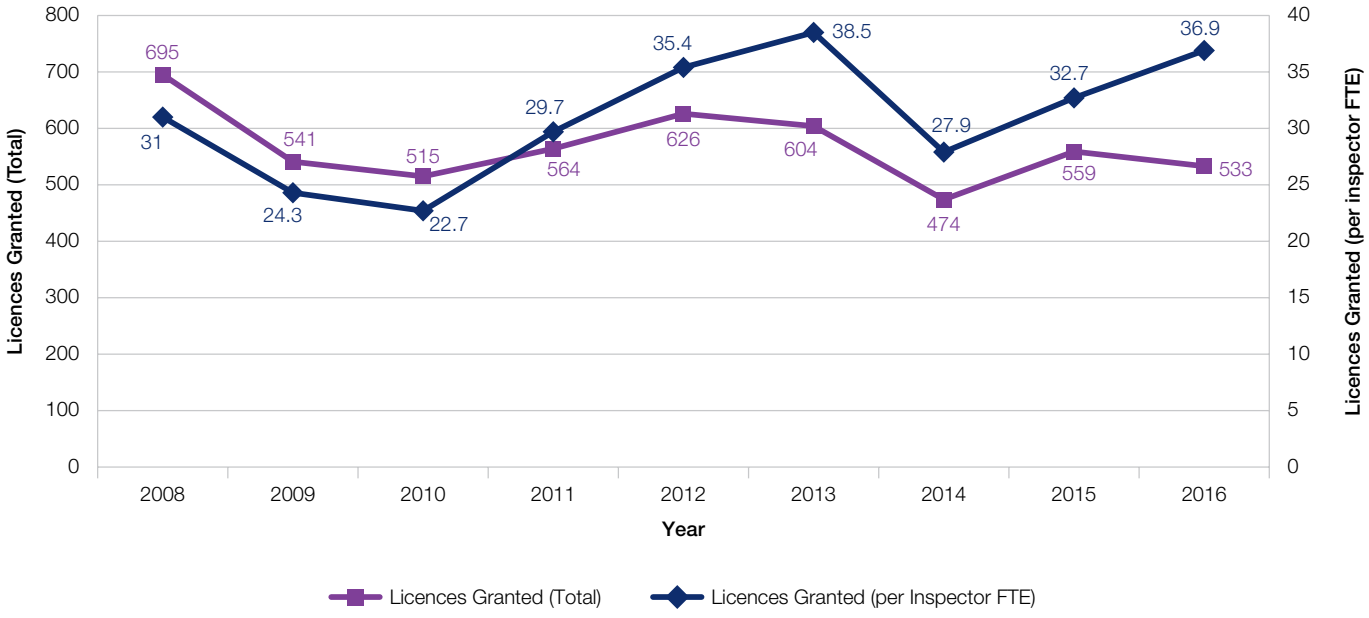


Figure A3: Project licence application processing 2008-2015

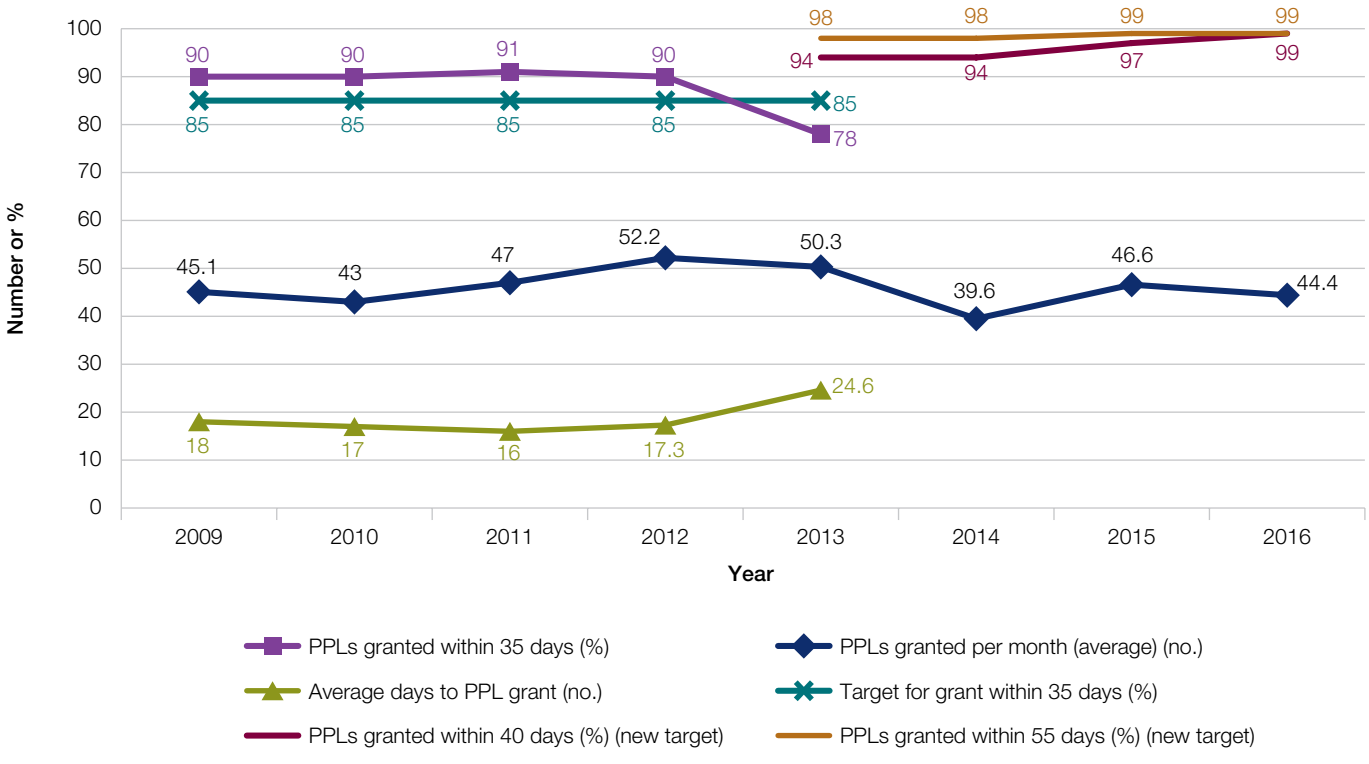


Figure A4: Inspections 2008-2015 (total)

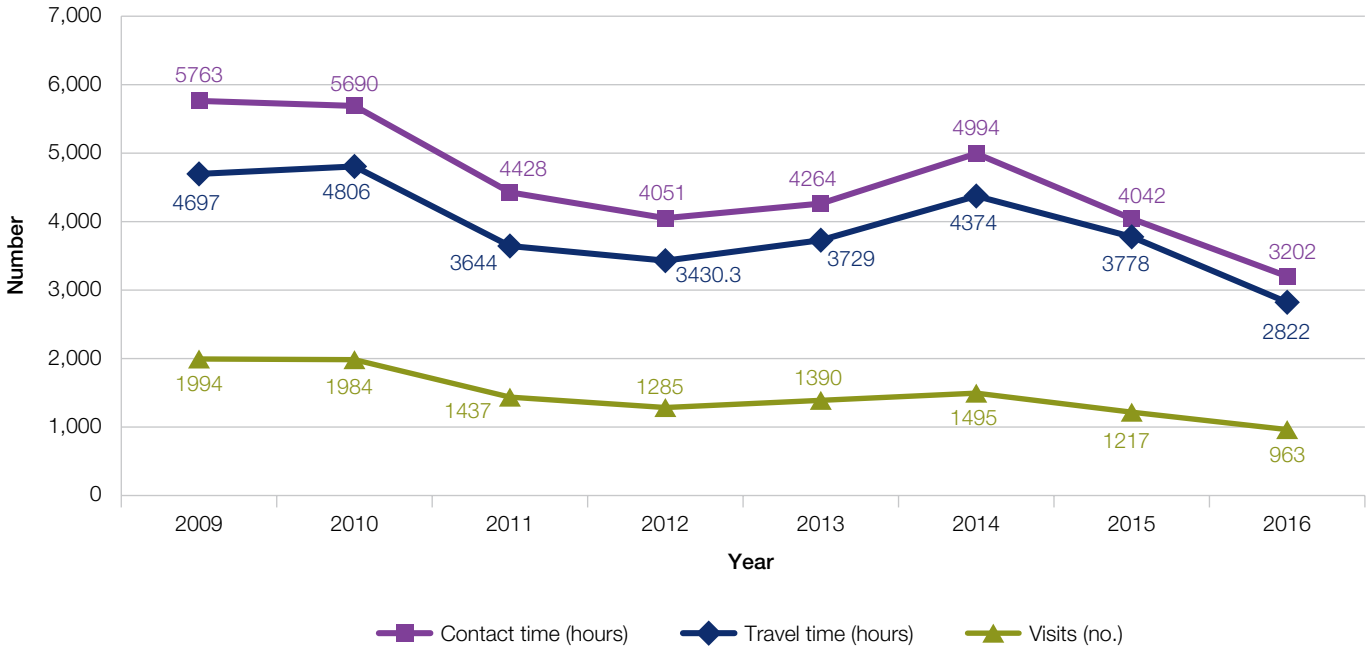
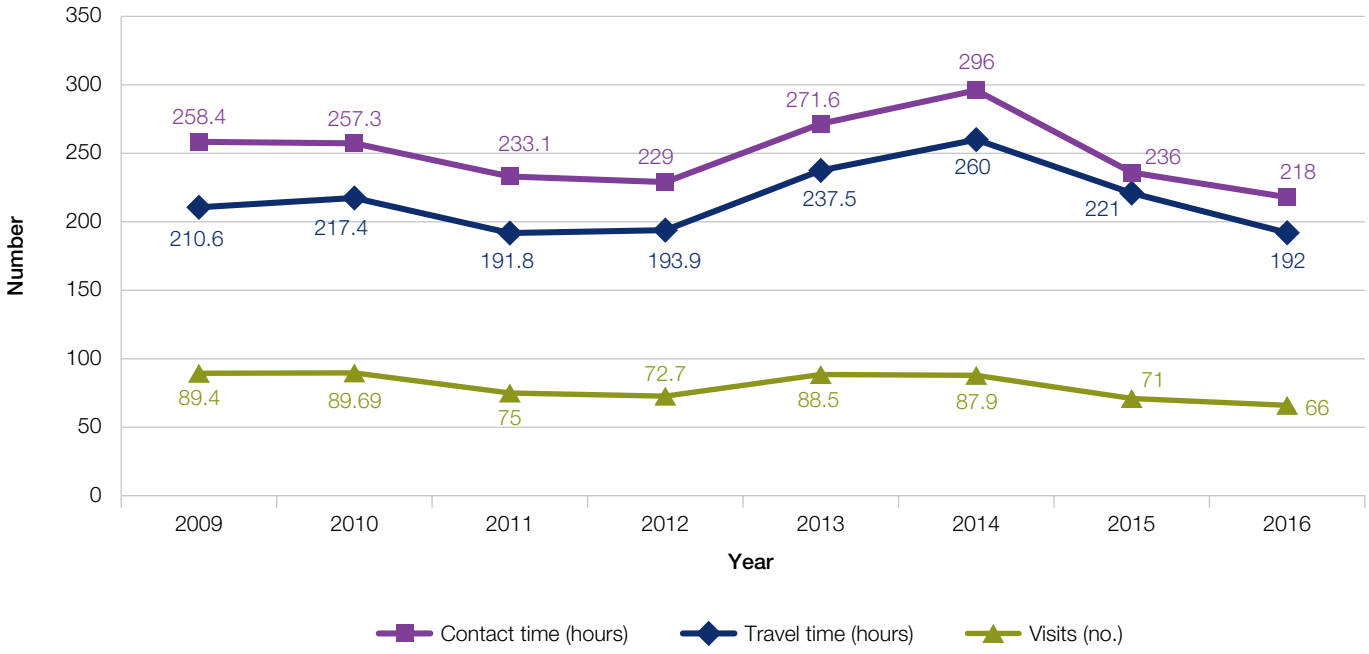


Figure A5: Inspections 2008-2015 (per FTE)



Annex 3: Household Products Ban Update

On 1 November 2015 a new policy was introduced that banned the testing of finished household products on animals and the testing of ingredients. Exemption would only be provided if the testing was required by current regulations (requiring retrospective notification) or in exceptional circumstances, which would require prospective authorisation[8].

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. Therefore, this resulted in the ban being put into place.

Between 1 November 2015 and 31 December 2016 there have been a total of 692 animals used for household product testing. Of these 478 were rats, 212 were mice and 2 were rabbits. 30% of these animals were used in severe procedures, 40% were moderate and 30% were mild.

The Annual statistics relating to scientific procedures performed on living animals provides annual figures for the number of procedures on animals for the purposes of household product testing in Great Britain[9]. The figures in the statistics publication differ from the numbers listed in this report due to:

1. This Annual Report lists the number of animals used whilst the Annual Statistics lists the number of procedures conducted. Where there are instances of re-use or repeat dosing the numbers of procedures will be greater than the number of animals used.

2. The Annual Report covers the period November 2015 – December 2016 whereas the Annual Statistics cover the January 2016 – December 2016.

3. The returns for this collection are made at the start of a programme of work whereas Annual Statistics is collected at the end of a procedure.

8 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/470007/Advice_Note_on_Household_Products_Ban.pdf

9 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/627284/annual-statistics-scientific-procedures-living-animals-2016.pdf

What were the animals used for?

The majority of animals were used to meet Registration, Evaluation, Authorisation & restriction of CHemicals (REACH) requirements. There were a small number of animals used for the registration of chemicals in other countries in conjunction with registration under REACH.

All tests were carried out according to The Organisation for Economic Co-operation and Development (OECD) practice and included: 429 (skin sensitivity), 422 (Combined repeat dose toxicity) and 407 (Repeated Dose 28-day Oral Toxicity Study).

According to the Annual Statistics there has been an increase in the number of animals used in the testing of household products in 2016. This arises because of the requirements of the REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) legislation, which require that all relevant compounds need to have tested and confirmed compliant by 2018. In particular, where compounds produced in quantities of over 10 tonnes per year are tested, reproductive studies are necessary. These result in a large number of offspring being included in the figures

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