Home Office

Animals in Science Regulation Unit

Annual reports 2019 to 2021

Summary of corrections

This ASRU Annual Report 2019-2021 was originally published in October 2022.

In March 2024, this report was revised to correct errors in the data. The corrections are summarised below. The reasons for the errors and the subsequent actions taken by ASRU, are set out in a separate explanatory note, which can be found here: **https://www.gov.uk/government/publications/animals-in-science-regulation-unit-annual-reports-2019-to-2021**

Non-compliance data corrections

A total of 17 cases of non-compliance were omitted in the original report. To correct this, 14 omitted cases have been published in the 2019 record and 3 omitted cases have been published in the 2020 record. There were no omitted cases in the 2021 record. A total of 24 cases published in the original report were the result of administrative errors and have been removed. Therefore, this revised report shows 7 fewer non-compliance cases overall.

In addition, some cases were found to have discrepancies in case details which have been corrected. The number of cases affected were: 63 cases in 2019, 50 cases in 2020 and 30 cases in 2021.

The non-compliance summary tables (Annexes 1, 2 and 3) have been corrected to include the omitted cases and amend the case details.

Section 9 has been updated to reflect these changes.

Project licence data corrections

A total of 53 project licences were omitted from the figures in the original report. To correct this, the number of reported project licences has increased by 42 in 2019, 7 in 2020, and 4 in 2021.

Section 5 has been updated to reflect these changes.

This publication is available at **https://www.gov.uk/government/collections/animals-in-science-regulation-unit-annual-reports**

Any enquiries regarding this publication should be sent to us at **asruoperationalrelationshipmanagement@homeoffice.gov.uk**

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Foreword

High quality UK life science research brings economic and educational benefits as well as a direct benefit from research outcomes. Some of this research still necessitates the use of animals. It is vital that we afford appropriate protections to the animals that are used, and retain public confidence that animals are only used in scientific research when there is a justified requirement. The protections start from ensuring that: animals are only used in research where there are no alternatives; they are only used to the extent needed to meet the objectives of the research; and harms are minimised. The Animals in Science Regulation Unit (ASRU; the Regulator) is committed to assuring that full compliance is maintained with the '3Rs' (replacement, reduction and refinement of the use of animals), keeping it at the heart of our regulatory delivery. Thereby we will continue to assure protections to animals in science through maintaining compliance with the Animals (Scientific Procedures) Act 1986.

Science, including regulatory and animal welfare science, is constantly changing. It is vital that we continue to seek opportunities for regulatory reform to ensure that we are following best practice in regulatory delivery. In 2020 we began a review process with the aim of ensuring that ASRU, and the regulated community, have strong systems to ensure compliance. Our review aimed to continuously improve how we assess the standards and processes used by licence applicants to ensure the benefit from their research is maximised while minimising the harms to animals.

The years 2019, 2020 and 2021 were defined by the significant events of the UK's exit from the EU and the COVID-19 pandemic. While there were significant perturbations in the external environment, we maintained high standards of regulatory delivery and our focus on the protections to animals in science through maintaining compliance with the Animals (Scientific Procedures) Act 1986.

The pandemic changed the landscape both for those we regulate and ourselves as the regulatory authority. In 2020 the requirements of the national measures meant that our operating model of on-site inspection had to change. From a total of 470 on-site inspections in 2019 we moved to 712 remote inspections in 2020. Between 16 March and 7 September 2020, compliance was evaluated using a number of methods for assurances of compliance with the legislation. From January to July 2021, remote inspection activity was continued, with the addition of on-site inspections when national lockdowns were lifted in May 2021. An interim operating model, 'Bridging Ways of Working', was launched in July 2021 which was underpinned by modern regulatory practice.

Audit systems were developed throughout 2021, and a pilot of full systems audits was initiated at the end of 2021. Although all regulatory staff moved to a home-based working model during the pandemic, we maintained the expected levels of delivery of our licensing service to establishments.

The success of being able to transition smoothly from an on-site and office-based model to a remote and home-based one was largely due to our e-licensing system (ASPeL (Animals in Scientific Procedures e-Licensing)). Since the initial launch of ASPeL in 2014 and the move away from a paper-based system, we have iterated for continuous improvement and reinforced our commitment to better regulation. Both 2019 and 2020 saw major investment into the system with the aims of improving the ability for establishments to be compliant and reducing the overall administrative burden. ASPeL ensures that licence and duty holders can easily access the information they need to do their work, helping to reduce instances of accidental non-compliance. Nevertheless, we recognise the ongoing needs for improvement. In 2021 to 2022 we will continue the development of project licence functionality to ensure the production of legally sound licences alongside the minimum administration required.

In 2013 the UK legislation that delivers protections for animals used in science was harmonised with EU legislation. The harmonisation provided opportunities to improve protections through new legislation and strengthened regulatory delivery. The aim of the UK's exit from the EU in this policy space was to only remove the mandatory requirements that tied us to the EU. The preparation for exit and the legislative process we conducted achieved a smooth process of legal and regulatory trat successfully met our aims, thus retaining all of the standards, scrutiny and rigour of the current framework.

In 2020, ASRU benchmarked its regulatory performance against the 'Regulators' Code' and the National Audit Office's 'Good practice guidance: Principles of effective regulation'. This exercise identified areas for improvement. Insights were also gained from internal review, external commentary and the independent advisory body – the Animals in Science Committee.

A programme of transformational regulatory change was then initiated to improve the performance of ASRU. Specifically, 10 strategic shifts were identified that underpinned the regulatory reform programme – these are provided at Annex 5. By delivering on these strategic shifts, the regulatory reform programme will provide greater protections for animals used in science and overall improved assurances to the public.

Kate Chandler,
Head of the Animals in Science Regulation Unit, April 2022 to present

Section 1: The Animals in Science Regulation Unit

Introduction

The purpose of animals in science regulation is to:

- contribute to meeting desired government and public outcomes
- facilitate the delivery of the benefits of the use of animals in science

while maximising protection for those animals in line with the law.

The purpose of the Animals in Science Regulation Unit (ASRU) is to protect animals in science by maintaining compliance with the Animals (Scientific Procedures) Act (ASPA). This is done by focusing on governance of ourselves and the Regulated community.

ASRU is a part of the Home Office Science Directorate and is responsible for the regulatory delivery of ASPA in England, Scotland and Wales. In Northern Ireland, this responsibility is devolved to Northern Ireland's Department of Health, which reports its activities separately.

The use of animals in science is regulated through a 3-tier system of licensing which licenses each establishment, project, and individual involved in undertaking regulated procedures on animals. All establishments are required to have dedicated individuals, including veterinary surgeons, with legal responsibilities for the care and welfare of animals, and an ethical review body, which reviews any proposals for the use of animals and promotes the 3Rs (replacement, reduction and refinement) of animal use in science. ASRU assesses the compliance of all licence holders through compliance assurance activities that include on-site inspections. ASRU has published and enforces standards for the care and accommodation of all animals bred, supplied or used for scientific purposes.

ASRU delivers through the following functions:

Policy and legislation functions

In 2019 and 2020, ASRU had a dedicated Policy Team responsible for and providing direct support to ministers to advance and deliver the government's policy objectives. The team's work included:

- contributions to the UK's approach and negotiating positions regarding the regulation of the use of animals in science, as the UK exited from the EU and during the transition period
- supporting the delivery of secondary legislation, such as statutory instruments relating to fee increases
- developing operational policy to deliver ASPA and protect animals in science
- publication of statistics and project licence non-technical summaries
- delivery of judicial reviews and tribunal processes relating to animals in science
- co-ordinating engagement and communications with stakeholders, including the Animals in Science Committee

The Policy Team responds to Parliamentary questions, Freedom of Information requests and all correspondence.

In 2019, 2020 and 2021 the team comprised 2 policy advisers who reported to the Head of Policy.

Business support and IT functions

ASRU's Business Support Team provides business support to all ASRU colleagues, including managers and leaders.

In 2019, 2020 and 2021, the Business Support Team comprised the following specific functions:

- risk management activities, including health and safety
- organising internal and external recruitment
- organising ASRU training, events and conferences, including external stakeholder events
- providing a secretariat function and publication of newsletters
- administering and collecting the return of procedures for publication of the annual statistics
- managing procurement and finance
- collecting licence fees
- maintaining our e-licensing system (ASPeL (Animals in Scientific Procedures e-Licensing)) and IT resources within ASRU

In 2019, 2020 and 2021 the team comprised one senior manager supported by one higher executive officer and one executive officer. In addition, IT activities were overseen by one higher executive officer and one executive officer. The teams reported to the Head of Operations in 2019 and 2020, and to the Head of Business Support in 2021.

Licensing function

The UK's 3-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
- under rigorous controls where suffering must be kept to a minimum

In 2019, 2020 and 2021, the Licensing Team's work included:

- issuing establishment, personal and project licences, and amending these
- handling appeals against decisions taken
- taking action in cases of non-compliance
- leading on the technology for e-licensing

At the end of both 2019 and 2020, the team comprised the Head of Licensing (reporting to the Head of Operations), 4 licensing managers and 2 licensing officers. In 2021 the licensing operating model was updated – this is described in more detail later in this report.

ASRU inspectors evaluate licence applications against the requirements of ASPA and use a harm-benefit analysis process to determine whether a licence should be authorised.

Compliance

In 2019 to 2021, non-compliance cases were dealt with by a dedicated Compliance Team with the aim of promoting a robust, proportionate and consistent national approach to cases. The team advised on the appropriate investigation of cases and the proportionate application of sanctions, as described in the published compliance policy. In 2021, the compliance assurance function was created, incorporating enforcement (previously known as non-compliance), inspection audit. The function reviews reports submitted to ASRU, including Standard Condition 18 and other reports required under ASPA.

Section 2: Regulatory Reform Programme

In 2020, the Animals in Science Regulation Unit (ASRU) benchmarked its regulatory performance against the 'Regulators' Code' and the National Audit Office's 'Good practice guidance: Principles of effective regulation' and identified areas for improvement. This evidence was complemented by various insights gained from internal review, external commentary and the independent advisory body – the Animals in Science Committee.

A programme of transformational regulatory change was initiated to improve the performance of ASRU. Specifically, benchmarking identified 10 strategic shifts that underpinned the Change Programme and are provided at Annex 5. By delivering on these strategic shifts, the Change Programme would deliver alignment of the Regulator with the following expectations:

- improved ability for licensed establishments to be compliant with the Animals (Scientific Procedures) Act 1986
- greater protections for animals used in science
- improved assurances to the public
- greater openness and transparency of the Home Office in how it meets its regulatory obligations
- improved value for money

The extent of the reforms required supported the initiation of transformational change. Three broad pillars of change were identified:

- the requirement for a policy function to which the Regulator would be structurally aligned
- delivery of a new regulatory operating model that is aligned to leading practice
- organisational redesign of the Regulator, mapped to the operating model

Creation of a policy function

This government identified that the integrated co-ordination of policy for the use of animals in science could be optimised and that greater clarity and direction given to the Regulator. Therefore, a function will be created by Quarter 2 of 2022 to provide high-quality cross-government policy leadership on the use of animals in science. This will support the delivery of an effective regulatory framework with clarity of accountabilities.

The new policy function will have the following broad responsibilities (to be finalised) that will be transferred from ASRU:

- ownership of the legislation for the use of animals in science
- development of policy relating to use of animals in science by advising ministers through:
    - engaging with the regulated sector and other life science and animal welfare stakeholders
    - working with other government departments with relevant policy crossover
    - commissioning and interpreting advice from the independent advisory body – the Animals in Science Committee
- sponsorship of the GB regulator (ASRU) by setting policy direction, ensuring operational independence, and holding it to account for delivery
- working in Partnership with Northern Ireland's policy function on policy development

Delivery of a new regulatory operating model that is aligned to leading practice

In 2021, we identified that fundamental changes to ASRU's operating model were required to align with leading regulatory practice and in accordance with strategic shifts. A new operating model, **'Bridging Ways of Working'**, was launched in July 2021, which was more aligned with modern regulatory requirements (Section 3). In the new model: inspectors are no longer assigned to establishments; compliance assurance and licensing functions are separated; and regulatory queries are handled centrally.

Organisational redesign of the regulator – mapped to the operating model

The process of organisational design is scheduled for starting late 2022 to 2023, once the operating model has been finalised and embedded.

Section 3: Regulatory operating model – 'Bridging Ways of Working'

On 5 July 2021, the Animals in Science Regulation Unit (ASRU) made changes to the regulatory operating model to align ways of working with leading regulatory practice and modern regulatory systems. The new operating model separates compliance assurance and licensing functions, and inspectors are no longer assigned to specific establishments.

In the new model, ASRU provides regulatory delivery through 2 teams; one covering licensing activities and the other, compliance assurance activities.

Licensing

Under 'Bridging Ways of Working', the principles, processes and standards used in licence assessment, in accordance with the requirements of the Animals (Scientific Procedures) Act 1986 (ASPA), remain unchanged.

Licences are no longer assessed by an inspector assigned to a specific establishment. The licensing service is delivered through a 'taxi rank' system" with applications being assessed by an inspector in the order they are submitted through our electronic licensing system (ASPeL (Animals in Scientific Procedures e-Licensing)). Licence applications are prioritised using typical timelines that are aligned within the statutory timelines defined in ASPA. Typical timelines can vary, based on the complexity of the application and level of incoming applications to the Regulator.

Compliance assurance

Compliance activities are dealt with separately to licensing. All compliance assurance functions have been brought together in a co-ordinated compliance function. Compliance assurance comprises the following activities which provide oversight and assurance of licence holder compliance with ASPA and their licence conditions:

- provision of facility, systems and thematic audits
- enforcement activities through investigation and management of potential cases of non-compliance
- reviewing reports submitted which are part of compliance assurance (such as Standard Condition 18 reports, retrospective assessments, other reports required by a specific licence)

Requests to keep animals alive

The compliance assurance function deals with requests to keep animals alive when the severity limits in a project licence and/or observance of any other controls appear to have been, or are likely to be, breached.

Standard Condition 18 reports

Notification to ASRU under PPL Standard Condition 18 relates to breaches or likely breaches of either severity limits or any other controls set in the licence. Notification provides an important opportunity for the licence holder, the establishment and ASRU to review whether any changes need to be made to licence

authorities and is an important source of data for ASRU compliance assurance. Notification under PPL Standard Condition 18 is not the same as reporting a non-compliance.

The requirement for reporting under PPL Standard Condition 18 is described in more detail in an **ASRU advice note**. This will be superseded by updated advice to be published in 2022.

Enforcement

Cases of non-compliance are managed in line with existing processes within the compliance assurance function. Management of non-compliance is described in more detail in this report. Cases from 2019 to 2021 are summarised in Annexes 1, 2 and 3.

Audit

Under 'Bridging Ways of Working', an audit programme was initiated, which is aligned with ASRU's strategic focus on establishment governance.

An audit is a process which verifies conformance to standards through review of objective evidence. The purpose of ASRU's audit process is to assess compliance against ASPA and associated licence conditions, and to objectively measure the risk of non-compliance within the establishment by assessing the robustness of governance systems.

Audits are conducted primarily in 3 ways:

- facility audit: based on the facility itself to ensure it meets the 'Code of Practice for the Housing and Care of Animals Bred, Supplied or Used for Scientific Purposes'
- systems audit: evaluating governance systems within an establishment or a project to understand how robust they are at maintaining compliance
- thematic audit: evaluating one particular area of compliance across the regulated community to assess the overall approach to maintaining compliance in this area

Culture and tone of audit

The purpose of audit is primarily supportive and aims to recognise areas where systems are strong to maintain compliance as well as identifying areas where improvements could be made. Although non-compliance may be detected during an audit, it is not primarily an enforcement activity but a monitoring and educational activity.

ASRU's full systems audit process is published in full here: **Full System Audit Process – ASRU (publishing.service.gov.uk)**

Regulatory advice

Under 'Bridging Ways of Working', answers to regulatory queries are provided centrally through the compliance assurance and licensing functions, depending on the nature of the query. Central provision of advice ensures that queries are dealt with in a timely consistent manner. Common types of queries can be identified, and this will inform future published advice with the aim of making it easier to comply.

Relationship management

Under 'Bridging Ways of Working', the operational management function was created with the purpose of engaging with the regulated community in a more co-ordinated and centralised way. In 2021, ASRU commenced quarterly meetings between Home Office liaison contacts at establishments and ASRU's operational management lead. Complaints from the regulated community about regulatory delivery are also managed through the relationship management function. A new ASRU complaints process will be published in 2022.

For more information on 'Bridging Ways of Working', refer to our published **Bridging Ways of Working advice note**.

Section 4: Regulatory framework

The standards associated with the Animals (Scientific Procedures) Act 1986 (ASPA) and the guidance on its administration and enforcement are provided in the 'Code of Practice for the Housing and Care of Animals Bred, Supplied or Used for Scientific Purposes' (the Code of Practice)[1] and the 'Guidance on the Operation of the Animals (Scientific Procedures) Act 1986' (the Guidance)[2] respectively. Both documents are publicly available and support establishments in both understanding ASPA and being compliant with the requirements.

Publications

Advice notes complement the published guidance and provide further explanation where required (**Animal testing and research – GOV.UK (www.gov.uk)**).

In 2020, the Animals in Science Regulation Unit (ASRU) published a guidance document highlighting the need for establishment licence holders to have prepared in advance robust internal governance (systems and processes) and be able to activate these in the event of a significant disruption to business activities over a prolonged period of time. The requirement remains on the establishment licence holder to demonstrate how they will fulfil their legal responsibilities in compliance with ASPA and their licence authorities, including the licence standard conditions. However, all licensees and other duty holders under ASPA should review the robustness of the processes and systems governing their work with protected animals, particularly those areas in the standard conditions of their ASPA licences.

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 2019, senior representatives from ASRU, as the UK competent authority, attended 2 meetings in Brussels. At these meetings, updates were provided by each EU member state on their transposition of the Directive. Following the UK's exit from the EU on 31 January 2020, ASRU has not attended these meetings.

EU exit

EU Directive 2010/63/EU on the protection of animals used for scientific purposes was transposed into UK law through an amendment to ASPA in 2012. This means that the UK has harmonised legislation for animals in science regulation with all EU member states. In 2018, arrangements were made for EU exit by preparing secondary legislation to amend ASPA and deliver EU exit. The legislation was enacted on 31 January 2020, the day of EU exit. The legislation had the result of removing mandatory requirements to work with the EU Commission and other member states (**Directive 2010/63/EU**).

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 delivery of the animals in science regulatory framework has continued with the same standards of oversight, rigour and scrutiny following the UK's exit from the EU. There have been no changes made to the UK regulatory framework, including the standards of animal welfare or housing and care as set out in the Code of Practice.

Working with the Animals in Science Committee

The Animals in Science Committee (ASC) is an independent, non-departmental public body convened under sections 19 and 20 of ASPA. The ASC is responsible for providing independent, balanced and objective advice to the Secretary of State on issues relating to the regulation of animals in science. At all times, the ASC must consider both the legitimate requirements of science and industry and the protection of animals from avoidable suffering and unnecessary use in scientific procedures.

The **ASC has a website** detailing its activities.

The ASC also provides advice on specific categories of project licences, including those seeking authority for:

- the use of wild-caught non-human primates
- the use of cats, dogs, equidae or non-human primates in severe procedures
- the use of endangered species
- projects with major animal welfare or ethical implications
- projects of any kind raising novel or contentious issues, or giving rise to serious societal concerns
- projects involving the use of admixed embryos as advised in the 'Guidance on the use of Human Material in Animals'[3]
- projects that may invoke any of the 'safeguard clauses' in Directive 2010/63/EU with respect to the purpose of primate use, proposals for the use of a great ape, or proposals to cause long-lasting pain, suffering or distress that cannot be ameliorated

ASPA requires that the ASC engages in the promotion of good practice through knowledge sharing between the animal welfare and ethical review bodies (AWERBs). The ASC has set up a regional network of AWERB hubs to facilitate knowledge transfer and introduced a secure information-sharing platform open only to AWERB members. The ASC hosts an annual workshop to enable the ASC AWERB subgroup to meet with the Chairs of AWERB hubs to discuss key aspects of the role and operation of AWERBs. Reports of the 2019, 2020 and 2021 ASC annual AWERB Hub Chair workshops can be found on the ASC website. ASRU welcomes these initiatives as a means of improving communication of good practice.

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

Section 5: Licensing

The framework

The UK's 3-tier licensing system provides a framework for authorising research using animals.

The licensing system ensures that animal research and testing is only undertaken:

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

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

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

In 2019, ASRU licensed and regulated 152 establishments. These establishments included universities, pharmaceutical companies and contract research laboratories. At the end of 2019 there were 2,537 active PPLs, with 3,044 PPLs active at some point in 2019. At the end of 2019 there were 16,009 active PILs.

In 2020 ASRU licensed and regulated 144 establishments. These establishments include universities, pharmaceutical companies and contract research laboratories. At the end of 2020 there were 2,429 active PPLs, with 3,088 PPLs active at some point in 2020. At the end of 2020 there were 14,796 active PILs.

In 2021 ASRU licensed and regulated 137 establishments. These establishments include universities, pharmaceutical companies and contract research laboratories. At the end of 2021 there were 2,423 active PPLs, with 2920 PPLs active at some point in 2021. At the end of 2021 there were 14,402 active PILs.

Licensing activities

Establishment licences

During 2019, 2 PELs were granted and a total of 2,297 amendments were made to PELs. This was a large increase compared with 2018, predominantly due to administrative changes such as the change in layout of 'approved areas' within the establishment licence in the new e-licence format.

During 2020, 3 PELs were granted and a total of 27 amendments were made to PELs.

During 2021, no PELs were granted and a total of 20 amendments were made to PELs.

Project licences

During 2019, a total of 523 new PPLs were granted. There was a 3% decrease in the number of PPLs granted in 2019 compared with 2018.

During 2020, a total of 478 new PPLs were granted.

During 2021, a total of 497 new PPLs were granted.

Personal licences

During 2019, 2,792 new PILs and 564 PIL amendments were granted. This was a 19% decrease on new PILs compared with 2018.

During 2020, 1,732 new PILs and 679 PIL amendments were granted. This was a 38% decrease on new PILs compared with 2019 and was likely due to the impact of the COVID-19 pandemic.

During 2021, 2,327 new PILs and 789 PIL amendments were granted.

Licensing Team

In 2019, 2020 and 2021 each establishment was assigned a single point of contact from within the Licensing Team to assist with any queries that may arise and to process all licensing recommendations made by the assigned inspector.

Animals in Scientific Procedures e-Licensing

In 2019, ASRU rolled out a refreshed digital e-licensing system ASPeL (Animals in Scientific Procedures e-Licensing) to improve:

- consistency of approach
- the ability for establishments to be compliant

This system replaced the earlier version of ASPeL, which was decommissioned in August 2019.

The new ASPeL website is built on the government's principle of user-centred design. Over 500 research sessions have been conducted with users of ASPeL to ensure that its design meets user needs and completes tasks without the need for further guidance. The new ASPeL system ensures that licence and duty holders can easily access the information they need to do their work, helping to reduce instances of accidental non-compliance. Previously, approximately 40% of licences remained on paper files with limited access.

The new ASPeL system is more transparent and auditable. It allows applicants to easily track the progress of their applications and see when mandatory actions are required, such as when a PIL is due for review. The enhanced auditability also enables ASRU to continually review and improve the service.

The system has a robust, secure architecture. It provides a single-source of truth, giving establishments and ASRU the confidence that the information being viewed is correct and up to date.

Changes to the licence application and amendment processes have been designed to assist applicants and reduce the administrative burden. More PPL applications are now complete and correct upon first submission and the average number of iterations per application has reduced. Previously, the mean number of iterations required for a PPL application was 4.6; the revised application form has reduced this mean to 2.6 iterations. ASRU recognises that the new project application form can continue to be improved. Further improvements to the form and the performance of ASPeL continued in 2021.

PELs are now easier to view and amend. This facilitates all authorised users to review the list of approved areas to view their contemporaneous authorisations. Similarly, all PILs are visible quickly and easily to all administrators and named people, enabling all duty holders to ensure that the appropriate authorisations are held. The time taken to authorise a PIL application or amendment has been reduced from up to 20 days to the next working day, with many applications processed on the same day.

Further features have been added to ASPeL during 2019, 2020 and 2021. Establishments are automatically alerted when the mandatory 5-year PIL reviews are required and provides an improved workflow to enable reporting of the completed reviews. The ability to submit and add a retrospective assessment to an expired or revoked PPL is now embedded for those licences that are required to supply them.

The introduction of financial and invoicing information for PELs and PILs, which began in January, has provided establishments greater transparency over their financial data.

The new ASPeL has passed all the Government Digital Service standard assessments required by the Cabinet Office and is seen as an exemplar of good service design. It has been built in such a way that it can be continually improved and upgraded as technology moves on. ASRU has committed to the ongoing development of ASPeL to ensure its continued development to meet user needs, both internally and externally.

The progress and development of the e-licensing software is made publicly available.

Section 6: 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's national organisation for the discovery and application of new technologies and approaches to replace, reduce and refine the use of animals for scientific purposes. The Animals in Science Regulation Unit (ASRU) and the NC3Rs have a shared aim of maximising 3Rs (replacement, reduction and refinement) delivery.

In 2018 ASRU signed a Memorandum of Understanding (MoU) with the NC3Rs.[4] The MoU represents a bilateral agreement for the mutual exchange of information, thus supporting ASRU in its legislative requirement to implement fully the delivery of the 3Rs.

From 2019, ASRU and the NC3Rs met regularly to work together to advance the 3Rs. ASRU has supported the use of the NC3Rs self-assessment tool in establishments and provided representation at NC3Rs events. ASRU has also promoted NC3Rs events and opportunities to establishments being regulated under the Animals (Scientific Procedures) Act 1986 (ASPA).

In 2019, themed inspection activity was undertaken in the following areas:

- how the reuse of hypodermic needles can be avoided to reduce suffering during injection procedures
- using more refined mouse-handling procedures
- how to reduce non-compliance associated with the failure to give animals food and water, and to understand why such cases still arise. Details relating to this activity can be found in Section 9 of this report – Management of non-compliance

Reuse of hypodermic needles

The practice of hypodermic needle reuse has negative implications for animal welfare and data quality in scientific studies. The point of the needle is deformed from a single use and this deformity increases with each reuse of the needle. Use of deformed needles will cause more pain and tissue damage than a new needle. Furthermore, tissue products adhere to needles so the reuse of needles is likely to result in transfer of these products between animals. Data quality may be affected due to the increased chances of spreading infection between animals and the increased pain from using a deformed needle. Consequently, reuse of needles should be avoided to ensure compliance with 3Rs expectations, in line with ASPA 2A(2)(c), establishment licence (PEL) Standard Condition 1 and personal licence (PIL) Standard Condition 1.

ASRU conducted inspections between November 2018 to March 2019 to investigate needle reuse in establishments. Using a structured questionnaire-based approach, this allowed ASRU to assess the level of needle reuse across establishments as well as identify instances where it may be justifiable, and determine barriers to adopting good practice.

4 Establishment_licence_holder_newsletter_–_August_2018.pdf (publishing.service.gov.uk)

A total of 98 questionnaires were returned from 86 establishments. These indicated that the majority (73%) of surveyed establishments were aware of needle reuse as an issue. Where needle reuse did occur, establishments were asked the reasons for this. The most frequent reasons for needle reuse were due to resource, culture within the establishment, and health and safety concerns. To gain a better quantitative understanding of the level of needle reuse awareness within establishments, the number of establishments with either formal or informal needle reuse policies was recorded. The majority of establishments had a needle reuse policy, and, within these establishments, the incidence of needle reuse was found to be less than in those establishments without a policy.

In summary, the themed inspection in needle reuse found that this practice does occur within GB establishments and a large proportion of this reuse could justifiably be reduced without impacting on scientific outcomes. One way of potentially reducing reuse could be through the application of a needle reuse policy within an establishment. ASRU continues to challenge any needle reuse observed on inspection or reported as occurring in an establishment.

To reduce the risk of non-compliance and nurture a good culture of care, licensed establishments should institute a policy on needle reuse where relevant and potential exemptions from single use should be considered on a case-by-case basis by the establishment's Animal Welfare and Ethical Review Board (AWERB). Potential example exemptions may relate to health and safety considerations, use of automated systems and species-specific considerations. AWERBs should consider the occurrence of and reasons for needle reuse within the establishment and should record the decisions and evidence considered around requests for such exemptions.

Refined mouse-handling procedures

The NC3Rs promoted the use of refined mouse-handling methods (cup and tunnel handling). There is scientific evidence that use of these techniques:

- reduce anxiety of the mice being handled
- have a positive impact on their metabolic parameters
- alter hedonistic value of reward
- decrease experimental variation

Thus, these techniques are beneficial both for animal welfare and scientific reproducibility.

The mice can still be effectively restrained, as needed for procedures, and habituate to the techniques quickly. Once skilled there is no difference in the time taken by technicians or researchers to use these techniques. Within establishments it is the high-level support that is considered a critical success factor for this type of change, such as:

- training technicians
- engagement with researchers
- implementation
- evaluation

There are resources available to support the transition to these techniques on the NC3Rs website (**https://www.nc3rs.org.uk/how-to-pick-up-a-mouse**). Despite this evidence there has been patchy uptake and implementation of these techniques. ASRU prioritised engagement with licensed establishments to improve the handling of mice in line with best practice.

Following refresher training for inspectors on mouse-handling techniques, during 2019 inspectors engaged with establishments through

a variety of mechanisms and during inspection visits to assess their current strategies for the uptake of these techniques. Inspectors used a structured questionnaire-based approach when gathering information from the establishments.

Data were collected from 110 establishments out of a total of 134 establishments that held mice, representing 82% of establishments. Overall, 68% of responding establishments were only using non-aversive methods. Of the respondents, 48% reported that they were in the process of implementing non-aversive methods and 6% had not yet started the implementation process.

The success factors for implementation were largely related to the degree to which technicians owned the initiative.

These data showed a higher take-up rate of non-aversive mouse handling techniques than was expected prior to the start of the themed inspection programme. The NC3Rs had previously reported that in their experience researchers and animal care staff were not always aware of the underpinning research studies into the benefits of using these techniques.[5] Potential reasons for this are:

- that all data were self-reported and thus the rate of progress may have been overstated
- the focus on mouse handling was shared by ASRU with establishments via multiple methods prior to the start of data collection
- the existence of the themed inspection itself may have improved or sped up implementation activities

All establishments should have a clear strategy for the implementation and monitoring of refined mouse-handling techniques. The strategy and implementation plan must be owned by those using and directly responsible for the use of the animals, including technicians and named role holders within the establishment. This strategy should be reviewed by the AWERB, which should have accountability for monitoring its implementation.

5 **Mouse-handling research papers | NC3Rs**

Section 7: Stakeholder engagement

Communications

In 2019, 2020 and 2021, The Animals in Science Regulation Unit (ASRU) responded to Freedom of Information Act 2000 (FOI) requests and correspondence from the general public on issues related to the regulation of the use of animals in science. Correspondence is an important way in which the government communicates current policy and thinking in an open and transparent way.

Correspondence

During 2019, ASRU handled 23 FOI requests, 60 items of ministerial correspondence and 39 other pieces of correspondence.

In 2020, ASRU handled 24 FOI requests, 18 items of ministerial correspondence and 58 other pieces of correspondence.

In 2021, ASRU handled 32 FOI requests, 215 items of ministerial correspondence and 67 other pieces of correspondence.

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

- the phasing out of the use of animals in research
- the use of primates in research
- the use of non-animal alternatives in research
- the use of dogs in research
- the welfare of animals during the COVID-19 pandemic

Freedom of information requests

In line with the government's policy on openness and transparency, ASRU's approach is to act with a presumption to openness to assist public understanding of the use of animals in science. Topics for requests for the release of information included:

- the licensing for the use of animals
- animal use statistics
- the rehoming of animals used for science

Nevertheless, it is essential that ASRU protects all information that is legally exempt from disclosure, such as personal details and information given to the Home Office in confidence. Such protected information includes intellectual property, commercially sensitive information and that which could identify people or places.

Meetings with stakeholders

Over the last 3 years ASRU has continued to engage with stakeholders both face to face and virtually. Meetings were held with a wide range of stakeholders. Maintaining these relationships is vital to help understand the expectations and perspectives of ASRU's stakeholders and receive valuable feedback in the performance of the unit and the effective implementation of the Animals (Scientific Procedures) Act 1986 (ASPA).

The meetings were with representatives from:

- the animal-using community, such as industry, academia, government research institutes, medical research charities and research funders
- organisations devoted to the replacement, reduction and refinement of the use of animals in research (the 3Rs)
- animal welfare and animal protection groups
- ASPA-named persons and others performing functions under ASPA
- the Animals in Science Committee and professional organisations
- other government departments

Relationship management

In 2019 and 2020, the Home Office met 3 to 4 times a year with counterparts in establishments through the Home Office Liaison and Training Information Forum (HOLTIF). The meetings are an opportunity to discuss service delivery, for ASRU to receive feedback and to solve any associated issues. The main external attendees are the Home Office Liaison Contacts (HOLCs), who undertake many of the administrative functions required under ASPA at each establishment and support licence applicants and existing licence holders.

HOLTIF is attended by up to 60 HOLCs. In 2020 and 2021 the frequency of meetings was reduced due to COVID-19 restrictions. The virtual meetings focused on service delivery and continued improvements to our ASPeL (Animals in Scientific Procedures e-Licensing) system.

In 2021, the role of operational management lead was created with the purpose of engaging with the regulated community in a co-ordinated and centralised way. We commenced quarterly meetings between HOLCs and ASRU's operational management lead with the aim of gathering feedback on ASRU's regulatory delivery.

External representation

External representation and engagement with stakeholders is an important aspect of ASRU's work. Examples of engagement with stakeholders in 2019, 2020 and 2021 included attendance and presentations at the:

- Institute of Animal Technology Congress
- Animal Welfare and Ethical Review Bodies Forum
- Establishment Licence Holders Forum
- Laboratory Animals Veterinary Association Conference
- Laboratory Animal Science Association Conference
- Royal Society of Biology Annual Science meeting

Section 8: Inspection and audit

The Animals in Science Regulation Unit (ASRU) inspects and audits establishments licensed to breed or supply animals, or to undertake regulated procedures on animals under the Animals (Scientific Procedures) Act 1986 (ASPA) in England, Scotland and Wales. The purpose of inspection and audit is to provide assurance to ministers and the public that there are systems in place to ensure care of animals and that the experiments undertaken comply with the requirements of ASPA and the relevant conditions specified in licences. ASRU provides advice to duty holders on how to comply with the requirements of ASPA and will apply enforcement where non-compliance is detected.

Inspection is undertaken for the following purposes:

- determine whether licence holders are compliant or to advise how to be compliant with the legal requirements of ASPA
- inspect areas included on establishment where animals may be kept or used under ASPA to ensure that they comply with the standards laid down in the 'Code of Practice for the Housing and Care of Animals Bred, Supplied or Used for Scientific Purposes'
- determine whether animals are being or have been used in procedures, or being used for breeding or supply, in areas not included on establishment licences
- determine whether the breeding, supply and/or use of animals in procedures is compliant with licence authorities and conditions on licences
- determine whether people named in the establishment licence understand and are fulfilling their required duties, and to advise on these roles

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

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

On-site and remote inspection during the COVID-19 pandemic

In 2019, ASRU undertook 470 inspections to places holding establishment licences, or places other than licensed establishments (POLEs) where scientific work on animals was conducted. Of the inspections to animal units, 169 were unannounced.

In 2020, following the implementation of national lockdown measures, assessment of compliance was undertaken remotely in most cases between 16 March and 7 September, using remote inspection activities rather than on-site inspection visits. Inspectors evaluated compliance remotely using telephone interviews, assessment of records and information, online meetings, and video inspection of areas. On-site inspection activity resumed between 7 September 2020 and 4 January 2021 and was again paused between 5 January and 4 May 2021, in response to national lockdowns. Throughout 2020 and 2021, remote inspection activity was used to evaluate compliance where the inspection objectives could be achieved without on-site visits.

Throughout the COVID-19 pandemic, on-site inspection visits were undertaken to evaluate serious non-compliance cases or serious animal welfare concerns that could not be evaluated remotely.

In 2020, ASRU undertook 790 inspections of licensed establishments where scientific work on animals was conducted; 712 were undertaken remotely and 78 were undertaken on-site.

In 2021, ASRU launched the 'Bridging Ways of Working' operating model and introduced a more rigorous full systems audit process as part of compliance assurance activity, which consisted of longer and more rigorous on-site audit visits. These involved teams of ASRU officials assessing selected establishments in depth. The numbers of inspection visits undertaken are therefore not comparable between 2018, 2019, 2020 and 2021.

In 2021, ASRU undertook 211 inspection visits and audits to licensed establishments; 41 were undertaken on-site and 170 were undertaken remotely. On-site inspections were not routinely undertaken between 5 January and 3 May due to national lockdowns. Overall, fewer number of on-site visits were undertaken in 2021 compared to 2019 and 2020. This was due to 2 main factors:

- national lockdowns between 5 January and 3 May 2021 during which compliance assurance and inspection activity was undertaken remotely. On-site visits were still conducted for serious non-compliance cases or serious animal welfare concerns that could not be evaluated remotely

- launch of the 'Bridging Ways of Working' from 5 July 2021 which consolidated and expanded compliance assurance activity. The new operating model introduced full systems audits which are extended, structured compliance visits requiring teams of ASRU officials evaluating selected establishments in depth. ASRU also updated the Standard Condition 18 system leading to increased compliance oversight of all GB establishments through collection and analysis of Standard Condition 18 reports. Standard Condition is applied to all project licences to ensure that the licence holder adheres to the specific severity limits (the scientific and humane endpoints that set limits on pain) in each licence

Changes to Inspection and audit programme throughout the COVID-19 pandemic

2020	1 January 2020 to 15 March 2020	16 March to 6 September 2020	7 September 2020 to 31 December 2020
External events	n/a	National lockdowns	Reduced lockdown restrictions
ASRU ways of working	Risk-based inspection programme	Remote inspection	On-site and remote inspection
Inspection and audit priorities	Risk-based inspection programme	On-site visits for serious non-compliance cases or serious animal welfare concerns that could not be evaluated remotely	On-site visits for serious non-compliance cases or serious animal welfare concerns that could not be evaluated remotely

2021	5 January 2021 to 3 May 2021	4 May 2021 to 4 July 2021	5 July to 31 December 2021
External events	National lockdowns	Reduced lockdown restrictions	Reduced lockdown restrictions
ASRU ways of working	Remote inspection	On-site and remote inspection	Launch of **'Bridging Ways of Working'**
Inspection and audit priorities	On-site visits for serious non-compliance cases or serious animal welfare concerns that could not be evaluated remotely	On-site visits where desired outcomes could not be met by remote inspection	Full systems audit pilots Establishments were selected for audit on a risk-basis taking into account their non-compliance data

Risk management

ASRU's establishment risk management process comprises a review of the national risk profile and local establishment factors. ASRU undertakes reviews periodically throughout the year.

Evaluation of risk includes:

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

Inspections and audit programmes are planned taking these factors into account.

Themed inspections

Themed inspections are targeted activities intended to focus efforts on issues that have implications across many establishments. For example, where particular issues require closer examination or evidence gathering to assist with the development of policy, or the provision of advice on the implementation of the replacement, reduction and refinement of the use of animals in science (the 3Rs).

A review of non-compliance cases reported in our 2018 Annual Report identified common themes and associated risk factors. The most common theme was a failure to provide adequate food and water. Failure to provide food and water accounted for between 15% and 22% of non-compliance cases between 2015 and 2018. Examples of causes of the failure of the provision of food and water include recent changes in housing or failure to effectively communicate the change-over of responsibility for care of the animals, such as when undertaking procedures, or at weekends.

In 2019, a themed inspection programme was undertaken to review the arrangements in establishments for the provision of food and water.

As in 2015 to 2018, the risks inspectors identified as most likely to be associated with inadequate provision of food and water were:

- recent changes in housing
- the care of animals whilst undergoing regulated procedures
- failure to provide at weekends

Changes in housing typically occur following transportation or delivery of animals, weaning or separating animals into different cages. Risks associated with procedures typically reflect failures of communication and responsibility, for example between duty holders and technicians. Similarly, changes in staff numbers and routines at weekends increases the risk of failures in the adequate provision of food and water.

To identify effective strategies for the uninterrupted provision of food and water, ASRU attended meetings with stakeholders and engaged with establishments during inspection activities. Strategies were disseminated to and between stakeholders, including licensed establishments and the Institute of Animal Technology, through presentations and publication[6] to encourage their adoption across establishments. Inspectors were also provided with the outcomes to inform their inspection activities regarding the provision of food and water.

6 Stevens, C., Hawkins, P., Lovell-Badge, R., Hubrecht, R., Golledge. H,, Slaviero, A., Ellis, C., Minhinnett, D., Terry, R., Hohlnaum, K., Wells, D., Snoeks, T. and Marshall, J. (2019) 'Report of the 2018 RSCPA/UFAW Rodent and Rabbit Welfare Group meeting', Animal Technology and Welfare, 18 (2), pp 81–91.

Successful animal care strategies included:

- twice daily (morning and afternoon) checks (ideally by different staff members)
- physically touching the food or water bottle
- adequate labelling to alert staff to at-risk cages, for example, post-weaning or transport

No thematic inspections were conducted in 2020 and 2021 due to changes in ways of working during the pandemic. An updated thematic audit system will be developed as part of the regulatory reform programme.

Investigating allegations made to ASRU

ASRU periodically receives allegations about potential breaches of ASPA, commonly referred to as 'whistle-blowing' allegations. These are taken seriously, and where sufficient information is provided, they are followed up by the most appropriate means, including inspection or audit if appropriate. Where it appears that there may have been a lack of compliance with ASPA, these are investigated in accordance with ASRU's non-compliance policy.

Section 9: Management of non-compliance

ASRU's compliance policy

The Animals in Science Regulation Unit's (ASRU's) compliance policy[7] focuses on the delivery of a proportionate, consistent, and outcome-based approach to incidents of non-compliance.

Every establishment licensed under the Animals (Scientific Procedures) Act 1986 (ASPA) has a named person responsible for compliance (NPRC). This individual ensures compliance with the conditions placed on their establishment licence. A good culture of compliance at an establishment reflects evidence of effective governance over the use of animals in science. The NPRC must maintain robust systems and frameworks that support and assist all licensees to comply with their licence conditions.

Inspectors determine whether establishments and licensees are complying with the provisions of ASPA and the conditions of their licences through various inspection activities. Inspectors gather sufficient information to determine whether there is a case that merits investigation and reports initial findings of any potential non-compliance to the ASRU Compliance Team within five working days of discovery. In the report, the inspector provides details of the case and recommendations to support the delivery of appropriate sanctions and necessary actions aimed at preventing the repeat of similar incidents.

The Compliance Team notifies licensees and the establishment in writing when a non-compliance investigation is being conducted and gives them an opportunity to provide any information they wish to be considered before ASRU decides the appropriate sanction(s). Complex or serious cases may take longer to resolve than the suggested timescales above. In rare cases, ASRU may take a view that the offence is sufficiently serious to merit referral for prosecution.

ASRU's potential remedies for non-compliance

ASRU considers cases individually and applies the most appropriate remedy based on the severity of the non-compliance and any aggravating and mitigating circumstances. It takes the resulting measures and sanctions to deter or prevent recurrence.

Factors considered when determining a suitable remedy include:

- the extent of any unnecessary animal suffering
- evidence and extent of governance and systems failures
- the timeliness of any remedies applied by the establishment
- the risk of recurrence
- evidence of dishonesty or attempts to evade responsibility

The range of remedies available, as set out in the published compliance policy, benchmark

7 ASRU's compliance policy can be found at: **https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/670174/ASRU_Compliance_Policy_December_Final.pdf**

and help to determine the outcome associated with each breach. We briefly outline them below.

Inspector advice

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

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

Inspector advice has been recorded centrally since 2019.

Compliance letters

Where provision of inspector advice is not considered sufficient, ASRU deals with most cases of non-compliance by sending a letter, with or without a variation of the relevant licence(s). Where a licensee has committed a breach, ASRU sends a letter of reprimand. Where a non-licensee has contributed significantly to the breach, a letter of censure may be sent.

Letters note the breach(es) that have occurred and summarise the evidence for those breaches. These letters are formal records of non-compliance and may be used as evidence should there be a further breach within five years. All letters are copied to the NPRC so that it can review local practices and processes, as appropriate.

Variation of licence

Requirement for retraining

Retraining is required where a licensee has demonstrated they do not have the expected level of knowledge of their legal responsibilities or to undertake procedures.

Requirement for reporting

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

Suspension

Where ASRU has identified a breach or urgent animal welfare concerns, it may suspend licences as a sanction. Suspensions are appropriate where there is a risk to animal welfare and significantly urgent action is required to protect it. When a suspension is required, ASRU must ensure that the suspension itself does not result in an adverse impact on animal welfare.

Compliance Notices

ASRU will issue a Compliance Notice where it requires action to be taken to prevent further non-compliance. Such a notice will specify:

- the licence condition(s) or ASPA provision(s) that have been breached
- the action that must be taken to ensure that the failure does not continue or is not repeated
- any action the licensee must take to eliminate or reduce any consequential risk of harms caused by the breach

The Compliance Notice will set out the consequences of failing to comply. In this eventuality, ASRU may then sanction the licence holder with suspension, variation or revocation of their licence.

This type of remedy is particularly effective where weaknesses in governance have been identified or where cultural change in attitudes towards welfare or compliance is needed. Over time, it provides a formal mechanism for assuring and monitoring improvements. Such changes may take some time to remedy; for example, increases in staffing, facility refurbishment or embedding an improved culture of care.

Revocation of a licence

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

Prosecution

Extremely serious cases of non-compliance are referred to the prosecuting authorities to judge whether it would be in the public interest to prosecute. Prosecution could lead to a fine or imprisonment.

Summary of non-compliance cases in 2019, 2020 and 2021

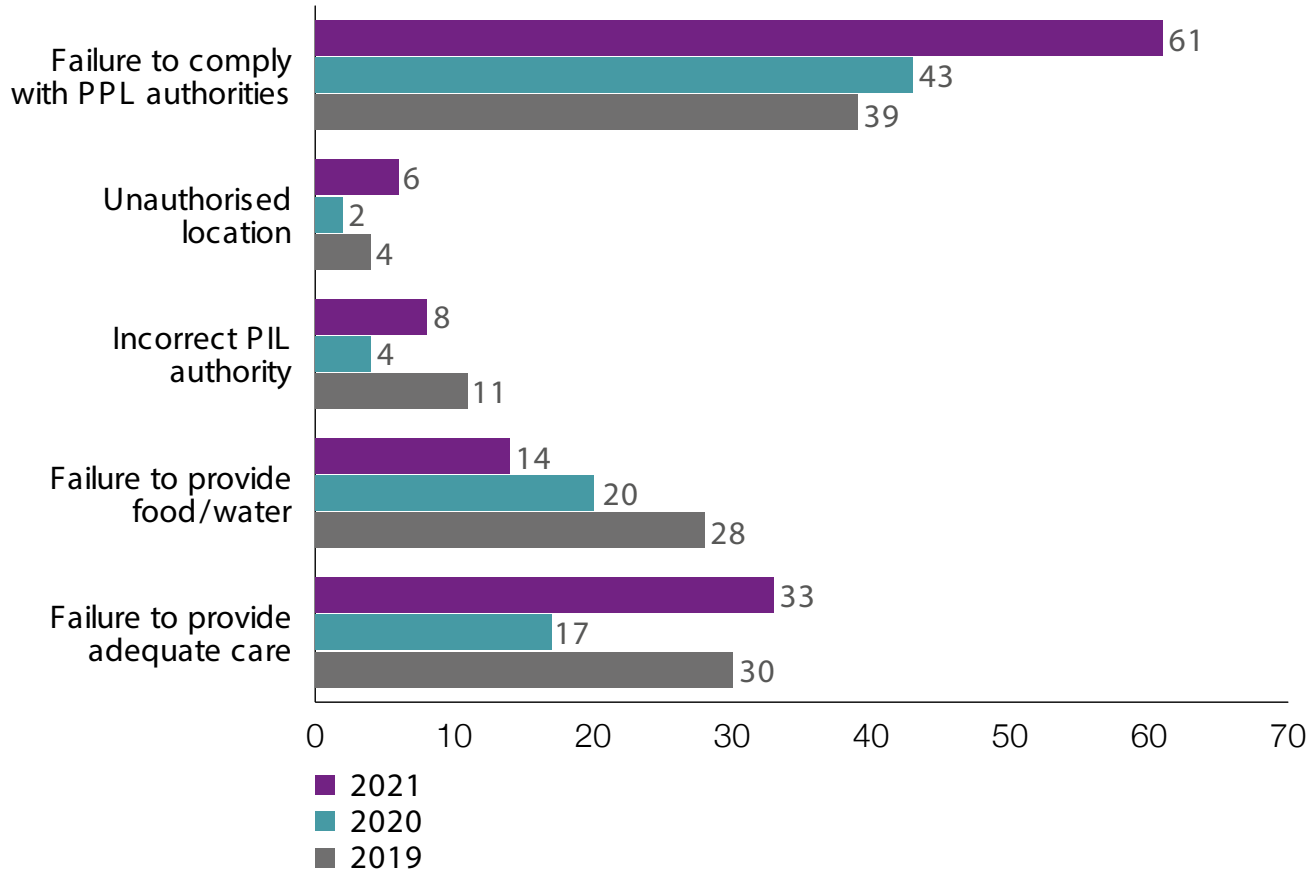
In 2019, 112 cases of non-compliance were finalised. These included 57 cases where the sole remedy was inspector advice; the remainder included other remedies. These 112 cases occurred in 44 different establishments. Of the total cases, 54 (48%) related to failing to have or adhere to licence authorities, while the other 58 (52%) related to failing to provide appropriate care (including food, water and suitable facilities).

In 2020, 86 cases of non-compliance were finalised. These included 45 cases where the sole remedy was inspector advice; the remainder included other remedies. Of the total cases, 49 (57%) related to failing to have or adhere to licence authorities, while the other 37 (43%) related to failing to provide appropriate care (including food, water and suitable facilities).

In 2021, 122 cases of non-compliance were finalised. These included 61 cases where the sole remedy was inspector advice; the remainder included other remedies. Of the total cases, 75 (61%) related to failing to have or adhere to licence authorities, while the other 47 (39%) related to failing to provide appropriate care (including food, water and suitable facilities).

A further breakdown of the types of non-compliance is shown in Figure 9.1.

Figure 9.1: Types of non-compliance between 2019 and 2021



Notes: PPL = project licence; PIL = personal licence

Number and type of animals

In 2019, of the 112 cases of non-compliance, 106 involved 25,589 animals, comprising 16,176 fish, 8,740 mice, 213 rabbits, 402 rats, 14 birds (13 unhatched), 28 dogs and 4 non-human primates. There were an additional 12 animals of the same species where the species type is not disclosed as it may reveal the establishment at which the non-compliance occurred.

These numbers are significantly impacted by three cases where there was over-breeding of large numbers of genetically altered animals. In all these cases, had requests been made to authorise the additional numbers of animals bred, this would have been granted. Of the total animals reported, 22,624 (88%) were from cases involving over-breeding beyond the licence authorities.

In 6 out of 112 cases, the total number of animals involved were not reported. Of these, in one case, regulated procedures were undertaken competently by an individual who did not have the correct category of personal licence (PIL) and, in two cases, regulated procedures were undertaken competently in an area of the establishment that was not designated for this purpose on the establishment licence (PEL). The other cases were:

- one case where terminally anaesthetised fish were used to teach additional procedures that were not authorised.
- one case where zebrafish larvae were inadvertently left to develop beyond the age at which they can be kept without the provision of food.

- one case where there were multiple incidences of a lack of adequate provision of food/water to animals of more than one species/type

In 2020, of the 86 cases of non-compliance, animal numbers were reported in 71. These 71 cases involved 3,354 animals comprising 2,091 fish, 893 mice, 346 rats, 10 non-human primates, four birds, eight ferrets, one cattle and one rabbit.

These numbers were not as influenced, as has been the case in previous years, by including a large number of animals bred without authority.

In 15 cases, the number of animals involved was either not relevant or not known. The reasons for this are:

- one case that involved failure of establishment governance systems
- one case that involved failing to keep adequate records
- one case of failing to use most refined killing methods
- two cases where blood was not taken by the most refined method
- one case where more animals were bred than were authorised
- one case where animals were kept alive after experiencing unauthorised adverse effects
- two cases where rooms were not included on the establishment schedule of premises
- one case where a room was not checked on one day
- one case where environmental measurements were not taken as required
- one case where an unauthorised substance was administered
- one case with a late submission of required reports
- one case where a PPL was not revoked when the holder left the establishment
- one case where procedures were conducted without the correct PIL

In 2021, of the 122 cases, animal numbers were reported in 114. These 114 cases involved 4,606 animals comprising 2,218 fish, 2,244 mice, 107 rats, two non-human primates, two dogs, 24 sheep, six horses, two guinea pigs and one cattle.

These numbers were not as influenced, as had been the case in 2019, by including a large number of animals bred without authority.

In eight cases, the number of animals involved was either not relevant or not known. The reasons for this are:

- one case of late submission of required reports
- one case where procedures were conducted without the correct PIL authority
- one case where the environment was not maintained as required
- one case where a room was not checked over a weekend
- four cases where rooms were either not included on the establishment schedule of premises or were used for a purpose not permitted by the designated holding code

The number of animals involved in non-compliance cases by type from 2019 to 2021 are shown in Tables 9.1 and 9.2.

Table 9.1: Number[1] of animals involved in non-compliance cases, 2019 to 2021

Animal type	2019	2020	2021
Bird (including eggs)	14	4	0
Cattle	0	1	1
Dog	28	0	2
Ferret	0	8	0
Fish	16,176	2,091	2,218
Guinea pig	0	0	2
Horse	0	0	6
Mouse	8,740	893	2,244
NHP	4	10	2
Rabbit	213	1	0
Rat	402	346	107
Sheep	0	0	24
Not stated due to potential to identify establishment	12	0	0
Total	**25,589**	**3,354**	**4,606**

Notes:

1 Totals are taken from cases where the numbers of animals involved were reported.

It is of concern that in 2019, 2020 and 2021, although few, there are cases of non-compliance involving species specially protected under ASPA (that is, dogs, non-human primates and horses) including some with adverse welfare outcomes. Also, that the number of cases involving non-human primates increased from 2019 to 2020 and all with adverse welfare outcomes. The two cases where numbers were known (one animal in each case) involving non-human primates in 2021 did not result in adverse welfare outcomes. A third case in 2021 involved non-human primates and related to late submission of required reports. The number of animals involved in this case was not known; however, there were no adverse welfare outcomes.

Adverse welfare outcomes

An animal was assessed as having an adverse welfare outcome as the result of a non-compliance if they experienced more than minor and transient pain, distress, suffering or lasting harm than was authorised. Animals that were over-bred in excess of the authorised numbers, but that were required to achieve the scientific objectives, were not considered to have experienced an adverse welfare outcome.

In 2019, 615 animals experienced adverse welfare outcomes because of non-compliance; in 2020, 1,082 animals; and in 2021, 2,234 animals, as shown in Table 9.2. A large proportion of the increase in adverse welfare outcomes in 2021 is attributable to two cases in which 300 and 430 fish died due to draining of tanks, and a third case where a chlorine tablet was added into the incorrect tank during system cleaning, resulting in the death of 1,300 fish.

Table 9.2: Number of animals[1] with adverse welfare outcomes, 2019 to 2021

Animal type	2019	2020	2021
Bird (including eggs)	0	4	0
Cattle	0	0	0
Dog	4	0	0
Ferret	0	0	0
Fish	382	830	2037
Guinea pig	0	0	0
Horse	0	0	0
Mouse	101	119	140
NHP	0	8	0
Rabbit	0	0	0
Rat	128	121	56
Sheep	0	0	1
Not stated due to potential to identify establishment	0	0	0
Total	**615**	**1,082**	**2,234**

Notes:

1 Totals are taken from cases where the numbers of animals involved were known.

Reporting of non-compliance cases

In 2019, 112 cases of non-compliance were finalised. These included 57 cases where the sole remedy was inspector advice; the remainder included other remedies. These 112 cases occurred in 44 different establishments. Of the total cases, 54 (48%) were related to the failure to have or adhere to licence authorities, while the other 58 (52%) were related to the failure to provide appropriate care (including food, water and suitable facilities).

In 2020, 86 cases of non-compliance were finalised. These included 45 cases where the sole remedy was inspector advice; the remainder included other remedies. Of the total cases, 49 (57%) were related to the failure to have or adhere to licence authorities, while the other 37 (43%) were related to the failure to provide appropriate care (including food, water and suitable facilities).

In 2021, 122 cases of non-compliance were finalised. These included 61 cases where the sole remedy was inspector advice; the remainder included other remedies. Of the total cases, 75 (61%) were related to the failure to have or adhere to licence authorities, while the other 47 (39%) were related to the failure to provide appropriate care (including food, water and suitable facilities).

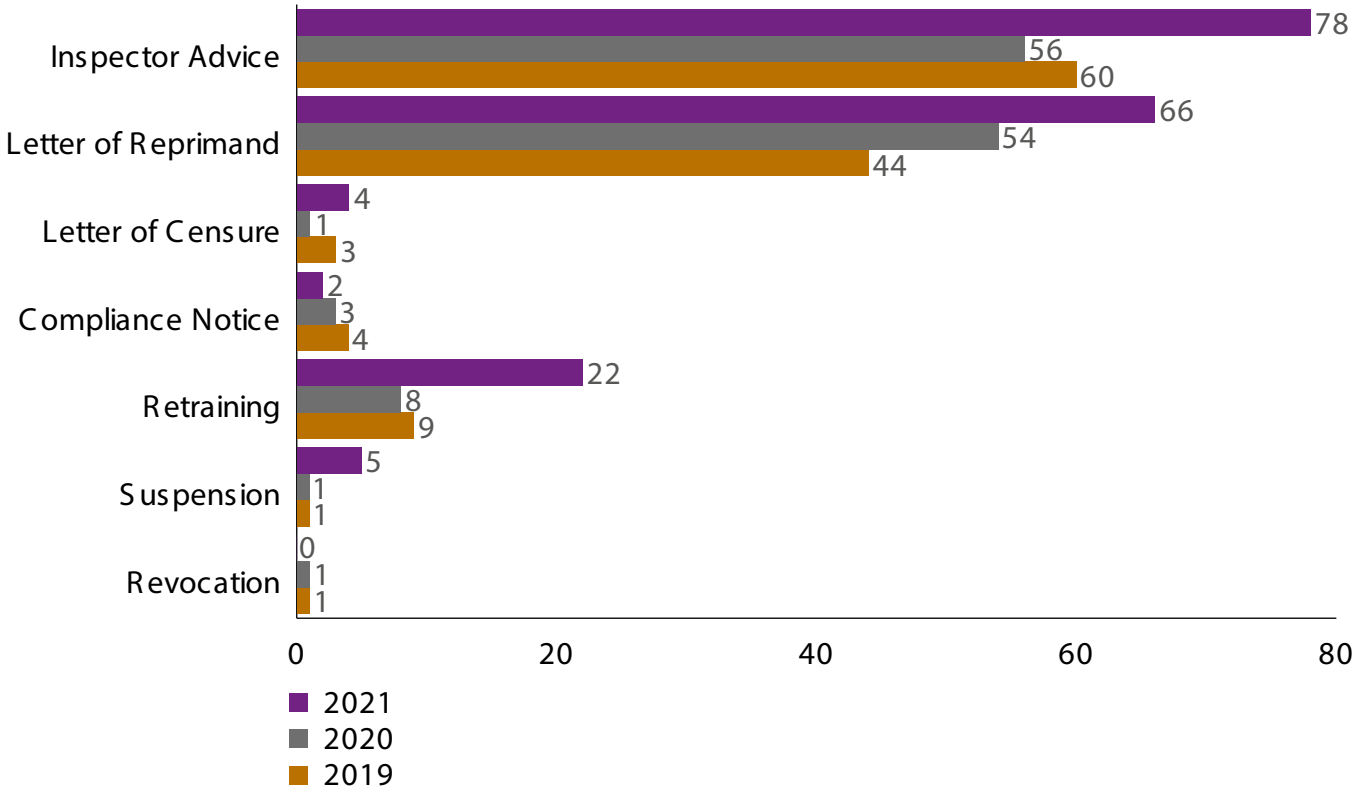
Remedies

It should be noted that in a single case of non-compliance, there can be several different remedies applied to a variety of individuals. Therefore, the number of remedies is not the same as the number of cases. The number of remedies issued in 2019, 2020 and 2021 is shown in Figure 9.2.

Summaries of all 112 non-compliance cases completed in 2019 are in Annex 1, all 86 non-compliance cases completed in 2020 are in Annex 2 and all 122 non-compliance cases completed in 2021 are in Annex 3. Please note the exact number of cases and animals does not fully align between the appendices and this summary text due to:

- consolidation of case reports
- cases involving multiple species
- cases where exact species are not disclosed as it would potentially identify the establishment

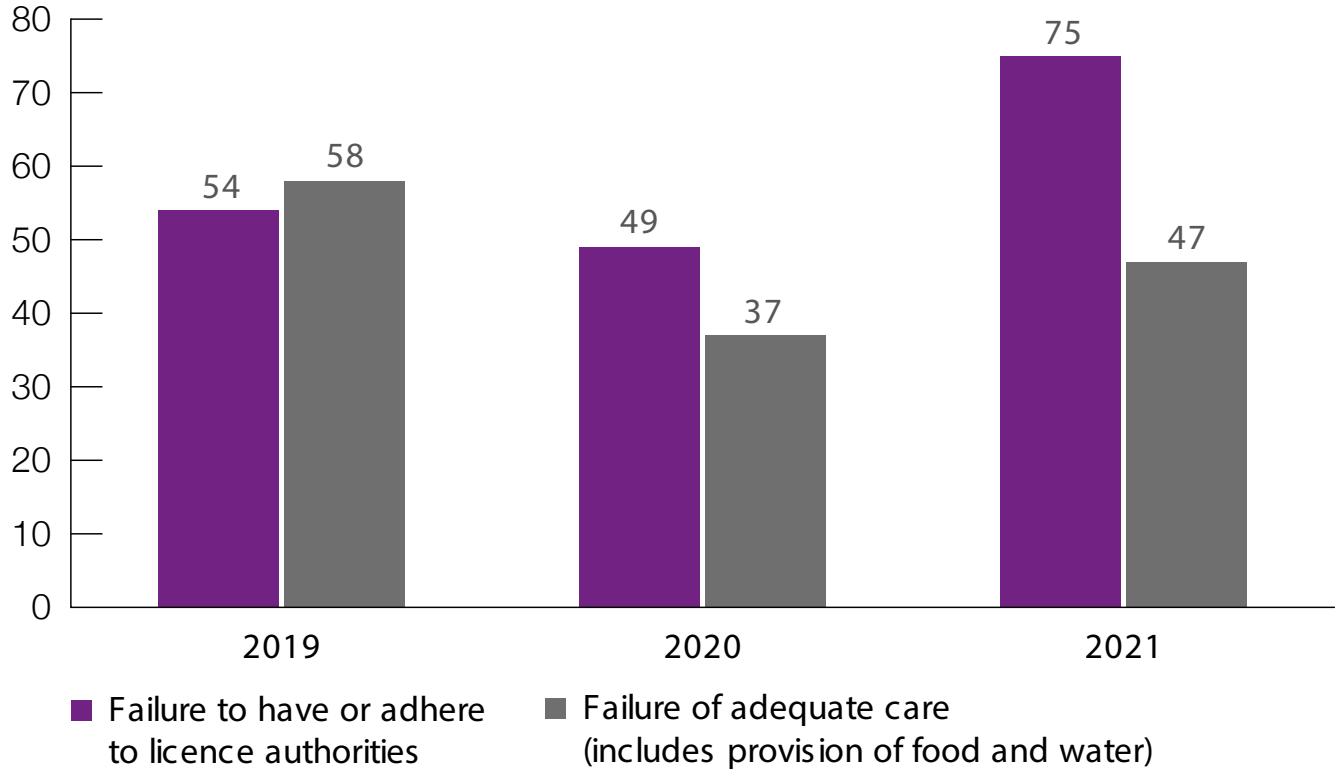
Figure 9.2: Remedies, 2019, 2020 and 2021



Trends in non-compliance cases over time

The number of non-compliance cases by a principal breach of licence by year from 2019 to 2021 is shown in Figure 9.3.

Figure 9.3: Non-compliance, by principal breach of licence, by year, 2019[1] to 2021



Note:

1 In 2019, inspector advice started to be formally collected and reported, and is included in the totals in Figure 9.3; this distorts a direct comparison with previous years. Therefore, it is not possible to use these figures as a direct longitudinal comparison, but they will provide a baseline for comparison in future years.

Key learnings from 2019, 2020 and 2021 non-compliance cases

Failure to comply with project licence authorities

This was the most frequent cause of non-compliance in 2019, 2020 and 2021 – 39 (35%) of the 112 cases in 2019; 43 (50%) of the 86 cases in 2020; and 61 (50%) of the 122 cases in 2021.

The main root causes of these types of non-compliances were:

- PPL and PIL holders failing to understand the authorities granted on the relevant PPL
- PPL and PIL holders failing to stay within the limits for procedures stipulated within the PPL (for example, the number of procedures permitted or route of administration permitted)
- inadequate monitoring of animals in line with measures stipulated on the PPL
- PPL holders failing to be aware of and/or comply with the Standard Conditions on their PPL
- PEL holders failing to have adequate systems in place to prevent unauthorised procedures being undertaken.

The following recommendations are made to reduce cases of failing to comply with PPL authorities:

- PPL holders must ensure that all individuals working under their PPL authority are fully aware of the exact authorities granted.
- PPL holders should have processes in place to review planned experiments to ensure compliance with PPL authorities.
- PEL holders must ensure that robust processes are in place to prevent unauthorised procedures from being conducted

Failure to provide food and/or water

Failing to provide sufficient food and/or water to animals, as part of basic husbandry and care, is unacceptable. Establishments must always have robust procedures in place to ensure the adequate provision of food and water to animals kept under ASPA provisions.

In 2019, of the 112 cases of non-compliance, 28 (25%) were due to failing to provide adequate food and/or water and resulted in adverse welfare outcomes. In 2020, there were 20 cases (23%), which is a marked decrease. This decrease continued in 2021, where there were 14 cases (11%).

In 2019, increased awareness due to a focus by ASRU on educating establishments about the importance of checking food and water may have led to the increased reporting of these cases.

Cases in which there was a welfare impact always involved the failure of establishment processes to ensure that the necessary daily checks were performed adequately, since if these were performed competently, the absence of food and water would be detected prior to adverse welfare outcomes occurring. All the cases in which inspector advice was given involved the establishment's daily checks to spot an absence of food and water prior to adverse welfare outcomes occurring, which are recorded as 'near misses' from a welfare perspective.

The following recommendations are made to reduce the number of cases where there was a failure to provide food and water:

- PEL holders must ensure adequate staffing levels to perform daily checks competently, especially at weekends.
- PEL holders should implement processes

to ensure that the system of daily checks is robust.

- PEL holders should identify high-risk situations that may cause failure to provide adequate food and water, and implement specific actions to mitigate these.

- PIL holders and other staff performing duties under ASPA must be explicitly trained and reminded to ensure that they check for the presence of food and water after any activities involving animals

Failure to provide adequate care

In 2019, there were 30 cases of inadequate care, which involved the greatest number of animals experiencing an adverse welfare outcome. These numbers were heavily impacted by three cases that involved 669 fish, as follows:

- one case where miscommunication between PIL holders led to 200 zebrafish larvae inadvertently being allowed to develop beyond the age when the conditions of care did not support their needs.

- one case where failing to close a tank valve after flushing led to the death of 120 fish.

- one case where water drained from an apparatus resulted in the death of 49 fish

Another significant incident involved the inadvertent movement of boxes containing 112 live rats to the compactor where they were crushed. This case resulted from a failure to follow the establishment's standard operating procedures on one occasion when an item of equipment failed. This might have been avoided had a mechanism been followed that quickly identified when animals were missing.

There were also 11 cases where animals were not checked or monitored adequately, and two other cases where rodents were trapped in food hoppers or lids.

In 2020, there were 17 cases of inadequate care, including:

- one case where a non-human primate died due to being trapped behind a device for restraint and the animal was not noticed to be missing from the main enclosure

- three cases in which animals were killed optimally

- two cases involved animals whose tails became trapped in cage lids

- one case where a head restraint was applied too forcefully while taking blood, causing injury to the animal

- one case where an isolator fan and alarm were accidentally switched off, resulting in the death of 16 animals

In 2021, there were 33 cases of inadequate care, including:

- three cases where water either drained from tanks or a toxic substance was added to a tank, resulting in the death of 2,030 fish across the three cases
- two cases where inadequate analgesia was provided to rats after surgery
- one case involving an animal whose tail became trapped in a cage lid
- two cases where the most refined method of regulated procedure was not used
- two cases where animals exceeded weight loss humane endpoints
- two cases where animals exhibited adverse effects not authorised by the PPL and action was not taken

Recommendations to reduce the number of cases where there was a failure to provide adequate care are:

- PEL holders must ensure that fish facility equipment and tanks are properly maintained, and that the risks associated with manipulation of tanks are identified and provision made to mitigate these
- PEL holders must implement processes to ensure that animals are present in the cage and not trapped after any intervention inside the cage

Failure to have appropriate personal licence authority

Section 3(a) of ASPA requires that no person shall apply a regulated procedure as part of an authorised project to an animal unless they hold a relevant PIL

In 2019, 2020 and 2021, 11 (10%), 4 (5%) and 8 (7%) cases respectively were recorded where the principal breach was either failing to hold a PIL or have the relevant authorities on their PIL to conduct the regulated procedures. The most common underlying cause for this breach was a degree of confusion by potential PIL holders about the difference between receiving the certificate for completion of their modular training and holding a PIL. The relevant training body provides the certificate of completion of the modular training, which is required before an individual can apply for a PIL. Thus, the reduction from 2019 to 2020 may be linked to a reduction in new PIL applications occurring during the first national lockdown as a result of COVID-19. In line with this, the number of reported cases of this type of non-compliance has increased from 2020 to 2021.

Recommendations to prevent this type of non-compliance:

- Providers of modular training should reinforce that, following the successful completion of the module training, a PIL must be applied for and held before they undertake regulated procedures.
- Establishments must ensure that processes are in place to ensure that those undertaking regulated procedures hold appropriate PIL authorities. This includes appropriate checks of the PIL authorities of individuals visiting an establishment to perform regulated procedures.

Section 10: Financial report

Since the financial year 2014 to 2015, the Animals in Science Regulation Unit (ASRU) has been operating on a full cost recovery basis, meaning that the licence fee income should cover all expenditure incurred in delivering the service. As a full cost recovery unit, ASRU receives all its income from the licence fees it charges. It is only permitted to spend this income on its regulatory duties and associated business costs.

Finance is reported and discussed with key stakeholders throughout the year to maintain the openness and transparency within ASRU's accounts. These reports are presented in meetings with key duty holders. Updates on predicted licence fees are shared with stakeholders throughout the year to assist with future financial planning within establishments.

The summary of income and fee-funded expenditure for the last 7 years is shown in Table 10.1.

Table 10.1: Summary of income and fee-funded expenditure, by budgeting year, including capital spend, 2014 to 2015 through to 2021 to 2022

		Expenditure		
Year	Income	Running budget	Capital[2]	Variance
2014 to 2015	£4,380,206	£4,378,929	–	£1,277
2015 to 2016	£4,692,833	£4,207,503	–	£485,330
2016 to 2017	£4,482,578	£4,467,404	–	£15,174[1]
2017 to 2018	£4,421,361	£4,777,455	–	£356,094
2018 to 2019	£4,752,912	£4,579,303	£1,625,492[3]	£173,609
2019 to 2020	£4,943,224	£4,947,844	£1,800,230[4]	(£4,620)
2020 to 2021	£5,012,744	£5,408,987	–	£396,243
2021 to 2022	£5,067,060	£5,163,588	(£100,992)[5]	(£96,528)

Notes:

1 This figure has previously been reported as £14,596.

2 In addition to the annual running budget of ASRU, there was additional capital expenditure which occurred for the replacement of our e-licensing system (ASPeL).

3 In 2018 to 2019, £1,625,492 of agreed capital expenditure occurred for the replacement of the ASPeL system.

4 In 2019 to 2020, £1,800,230 of agreed capital expenditure occurred for the replacement of the ASPeL system.

5 In 2021 to 2022, ASRU received a credit of £100,992 for the replacement of the ASPeL system due to a previous administrative error.

ASRU income and expenditure for the years 2019 to 2020, 2020 to 2021 and 2021 to 2022

Income

In 2019 to 2020, ASRU had a delegated budget from the Home Office in anticipation of the fee income of £4.94 million; by the close of the year ASRU remained within 0.01% of the assigned budget.

In 2020 to 2021, ASRU had a delegated budget from the Home Office in anticipation of the fee income of £5.49 million. However, ASRU had to reduce the expected fee income to £5.01 million due to fewer licence applications being made as a result of the impact of the COVID-19 pandemic on the activities within the establishments.

In 2021 to 2022, ASPU had a delegated budget from the Home Office in anticipation of the fee income of £5.06 million; by the close of the year ASRU remained within 1.90% of the assigned budget.

Fee income

Increases in licence fees are necessary to ensure that fee income continues to cover all expenditure incurred in delivering the ASRU service.

Invoices are raised in arrears, so the income for the financial year 2020 to 2021 will be collected in the 2021 to 2022 financial year.

The 2021 to 2022 fees have remained the same as 2020 to 2021.

Table 10.2: Annual licence fees, 2014 to 2015 through to 2021 to 2022

Annual fee[1]	2015 to 2018	2018 to 2019	2019 to 2020	2020 to 2021	2021 to 2022
Personal licence	£242	£257	£275	£299	£299
Establishment licence	£631	£757	£826	£915	£915

Note:

1 From 2018 fees are charged from the 6 April each year, which is the common commencement date and is in line with practices in other government departments. Prior to 2018, fees were charged from 1 April.

Expenditure

Details of the expenditure for the years 2019 to 2020, 2020 to 2021 and 2021 to 2022 are shown in Table 10.3.

Table 10.3: Summary of expenditure, by budgeting year, 2019 to 2020 through to 2021 to 2022

Category	2019 to 2020	2020 to 2021	2021 to 2022
Pay[1]	£3,338,623	£3,397,001	£3,187,412
Overheads[2]	£901,311	£700,000	£516,556
IT and telecommunication[3]	£437,556	£1,231,632	£775,639
IT capital[4]	£1,800,230	£0	(£100,992)
Travel[5]	£143,858	£7,742	£29,933
Estates[6]	£56,667	£56,903	£1,771
Training and events[7]	£17,509	(£5,171)	£13,667
Legal[8]	£15,496	£12,143	£24,453
Other[9]	£36,824	£8,738	£14,158
Depreciation[10]	**-**	**-**	**£600,000**
Expenditure TOTAL	**£4,947,844**	**£5,408,987**	**£5,163,588**
Income TOTAL	**£4,943,224**	**£5,012,744**	**£5,067,060**
Variance	**(£4,620)**	**£396,243**	**(£96,528)**

Notes:

1 In 2019 to 2020, approximately £3.34 million of the total pay costs were salary costs, of which £160,995 was transferred to other teams in the Home Office for the use of their staff on ASRU's work, for example for the provision of statistical and legal advice.

In 2020 to 2021, approximately £3.40 million of the total pay costs were salary costs, of which £164,500 was transferred to other teams in the Home Office for the use of their staff on ASRU's work, for example for the provision of statistical and legal advice.

In 2021 to 2022, approximately £3.19 million of the total pay costs were salary costs, of which £202,695 was transferred to other teams in the Home Office for the use of their staff on ASRU's work, for example for the provision of statistical and legal advice.

2 Central overheads are calculated on a headcount basis and cover core Home Office central functions and services such as central IT infrastructure, human resources and finance. They also cover an apportionment of the accommodation and facilities costs of the London Head Office at 2 Marsham Street and the Croydon Campus at Lunar House.

3 The majority of IT and telecommunication costs for 2019 to 2020, 2020 to 2021 and 2021 to 2022 include the hosting and support of the legacy e-licensing system (ASPeL). Legacy ASPeL closed in late summer 2019 with additional cost associated with the permanent destruction of the servers and data. It was replaced by the new e-licensing system, which went live in August 2019. The remainder of the IT costs for all 3 years is for VAT and telecoms, for example secure mobile phones.

4 ASRU only had an IT capital budget for 2019 to 2020. ASRU continued its contract with Marvell Consulting Ltd to develop the new version of ASPeL. Research and development spend in 2019 totalled £1.8 million. The new system moved into public beta in August 2019.

5 Travel and subsistence costs were mostly incurred by inspectors during their visits to establishments. All travel occurred within Home Office policy guidance, which aims to balance speed and efficiency of travel against minimal cost. For 2020 to 2021, ASRU's travel costs were greatly reduced following the implementation of national lockdown measures to control COVID-19, following which most inspection was undertaken remotely.

For 2021 to 2022, travel costs increased due to the easements of COVID-19 restrictions.

6 During 2019 to 2020 and 2020 to 2021, ASRU paid other parts of the Home Office and other government departments for the use of office space in Glasgow, Dundee and Swindon.

From 2021 to 2022, ASRU no longer holds any direct commercial leases.

7 Training costs in 2019 to 2020 were mostly incurred by training new inspectors or by existing inspectors completing their continuous professional development, as required by their professional bodies. This includes the costs incurred in running 4 annual training events for all staff. The 2020 to 2021 figure represents refunds for events that were cancelled because of the COVID-19 pandemic; these events had been booked and paid for in 2019 to 2020.

In 2021 to 2022 training was aligned with the requirements of the change programme.

8 Legal costs for 2019 to 2020, 2020 to 2021 and 2021 to 2022 included the costs of handling appeals against licensing decisions taken. In 2019 to 2020 there were additional costs relating to an appeal, which led to a tribunal.

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

10 Financial year 2021 to 2022 Is the first year that ASRU paid for depreciation for the ASPeL asset; this will be £600,000 for the next 3 years.

Annex 1: Non-compliance cases 2019

Glossary of terms	
ASPA	Animals (Scientific Procedures) Act 1986
NVS	Named veterinary surgeon
PEL	Establishment licence
PIL	Personal licence
PPL	Project licence
SC	Standard Condition
Breach	Section of ASPA or licence condition that was breached

Failure to provide food and/or water

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached[8]		Regulator action taken
			Primary breach	Other breach(es)	
Water bottle turned wrong way during cage clean, no access to water for more than 36 hours. Establishment check failed to detect this	Rat	2	PEL SC4(3)		Compliance Notice and Letter of Reprimand
Failure to replace water bottles at daily check, water withheld overnight.	Rat	6	PEL SC4(3)		Letter of Reprimand

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

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached[8]		Regulator action taken
			Primary breach	Other breach(es)	
Food removed from home cages and failed to be replaced. Daily checks failed to notice absence of food	Mouse	8	PIL SC 2	PEL SC 4(3) PEL SC 4(5)	Letters of Reprimand
Food hopper not placed in cage and not noticed at daily checks for 2 days	Mouse	1	PEL SC4(3)		Letter of Reprimand
Water bottle not replaced after cage change and no water overnight.	Rat	3	PEL SC4(3)		Letter of Reprimand
Rats left overnight in transport cage without food and water	Rat	3	PEL SC4(3)		Letter of Reprimand
Failure to kill zebra fish larvae before week-end, left without food over weekend.	Fish	Not Known	PIL SC2		Letter of Reprimand
Failure to provide water for a period of 43 hours	Mouse	1	PIL SC 2		Letter of Reprimand
2 animals left in heat box overnight without food and water	Mouse	2	PIL SC 2		Letter of Reprimand
2 NHP failed to have food and water replaced after a period of authorised withdrawal.	Non-human primate	2	PEL SC 4(5)		Letter of Reprimand
Water bottles not place on cages at cage change. Found next day and all animals were reported to be in good health.	Mouse	17	PEL SC 4(3)	PEL SC 5	Letter of Reprimand
Animal not provided water after period of approved water restriction. Establishment check failed to detect this for >24 hours.	Non-human primate	1	PIL SC 2		Inspector Advice
Animals left without food for approximately 21 hours. Establishment check failed to detect this.	Mouse	2	PEL SC 4(3)		Letter of Reprimand
Mice left without water overnight. Establishment check failed to detect this.	Mouse	17	PEL SC 4(3)	PEL SC 4(1) PEL SC 4(5)	Letter of Reprimand
Food and water withheld from animals and picked up at next scheduled check	Mouse	2	PIL SC 2		Inspector Advice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached[8]		Regulator action taken
			Primary breach	Other breach(es)	
Water withheld from rats in error and detected at next scheduled check	Rat	2	PIL SC 2		Inspector Advice
Food withheld from animal in error for approximately 18 hours	Mouse	1	PIL SC 2		Inspector Advice
Water withheld from animals in error and detected by establishments checking system	Mouse	28	PIL SC 2		Inspector Advice
Animals inadvertently left without food but detected at next scheduled check	Mouse	2	PIL SC 2		Inspector Advice
PIL holder did not provide food and water to animals after conducting procedures. Establishment checks picked this up and corrected it at next scheduled check	Mouse	2	PIL SC 2		Inspector Advice
Water failed to be replaced by PIL following conduct of task	Mouse	8	PIL SC 2		Inspector Advice
Mouse left in transport box without food and water. Noted and addressed at next scheduled check	Mouse	1	PIL SC 2		Inspector Advice
Fish found dead after a tap controlling water flow to the tank in which they were housed had been accidentally turned off	Fish	13	PEL SC 4(5)		Inspector Advice
Mouse left without access to water. Noted and addressed at next scheduled check	Mouse	1	PEL SC 4(3)		Inspector Advice
Animals not provided food but noticed and remedied by scheduled check	Rats	72	PEL SC 4(3)		Inspector Advice
Animals not provided with food and lost weight	Mouse	3	PEL SC 4(3)	PIL SC 2	Inspector Advice
Animals left in behavioural testing chambers overnight with no food or water	Rats	7	PIL SC14		Inspector Advice
Numerous incidents in 2018 and 2019 of animals not provided with food and/or water.	Multiple species	Not known	PEL 4(3)	PEL 5	Compliance Notice

Failure to provide adequate care

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
Boxes containing rats mistakenly moved to compactor where animals were crushed	Rat	112	PEL SC 4(1)		Letter of Reprimand
Failure of daily checks on 4 separate occasions. Failure to maintain killing register accurately	Mouse	21	PEL SC 4(3)	PEL SC 4(5) PEL SC 2(1)	Compliance Notice and Letter of Reprimand
Seven mice not weighed on one day as required by PPL; two mice were not given analgesia for abdominal discomfort as advised by NVS; PPL holder not advised of animal exceeding severity limit	Mouse	7	PIL SC12	PIL SC 2 PIL SC13	Letter of Reprimand
Lack of communication between 2 personal licence holders resulting in failure to kill fish larvae prior to them reaching protected status as defined in law	Fish	200	PIL SC 14	PPL SC1	Letters of Reprimand
Mice left in dark chamber for longer than authorised on project licence	Mouse	10	PIL SC2		Letter of Reprimand
Human error led to failure to close tank valve after flush	Fish	120	PEL SC4(1)		Letter of Reprimand
Failure to calculate weight loss of mice with subsequent loss of weight exceeding authorised limits	Mouse	17	PIL SC 2	PIL SC 13	Letter of Reprimand
Cage of mice not closed properly so mice escaped	Mouse	6	PEL SC 5		Letter of Reprimand
Animal left out of cage following health check	Rat	1	PIL SC2		Letter of Reprimand
PIL holder dropped mouse from trolley onto floor	Mouse	1	PIL SC 2		Letter of Reprimand
Water drained from apparatus resulting in death of fish. Equipment was known to have risk associated with its use that were not adequately mitigated	Fish	49	PEL SC 4(4)		Letter of Reprimand
PIL holder failed to weigh or assess mice in immediate post operative period	Mouse	4	PIL SC 14		Letter of Reprimand
Mice left in quarantine room not checked	Mouse	34	PEL SC 4(5)		Inspector Advice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
Female mouse instead of male mouse removed from cage of neonatal pups	Mouse	8	PIL SC 2		Inspector Advice
Animals not weighed and monitored adequately	Mouse	4	PIL SC 14		Letter of Reprimand
Mouse found trapped between hopper and cage	Mouse	1	PEL SC4(1)	PEL SC 4(5) PIL SC2	Inspector Advice
Failure to adequately monitor eggs	Un-hatched birds	13	PIL SC 2	PPL SC 1	Inspector Advice
Animals left in hot box longer than authorised	Rat	5	PIL SC 2	PIL SC19	Inspector Advice
Mice were not monitored appropriately	Mouse	6	PIL SC 2	PIL SC 14	Inspector Advice
Failure to monitor animals appropriately	Mouse	1	PIL SC 2		Inspector Advice
Mice not killed as planned and transported alive to screening laboratory	Mouse	3	PEL SC 4(6)		Inspector Advice
PIL holder did not seek appropriate veterinary Advice for animals experiencing adverse events	Mouse	1	PIL SC 15		Inspector Advice
Mice moved into new room and did not receive daily checks	Mouse	26	PEL SC 4(5)		Inspector Advice
Conducted experiments in environmental conditions which were not appropriate	Mouse	6	PIL SC 2	PPL SC 1	Inspector Advice
Animal held in necropsy area in transport cages for up to 3 hours	Rabbit	1	PEL SC 4(1)	PEL SC 4(2) PEL SC 4(7)	Inspector Advice
Failed to monitor animals appropriately but no adverse welfare outcome	Rat	42	PIL SC 2	PIL SC 12 PIL SC 1	Inspector Advice
Mouse escaped from cage	Mouse	1	PIL SC 2		Inspector Advice
Numerous incidents of inadequate daily checks	Mouse	13	PEL 4(5)		Compliance Notice
Three incidents where mouse pups were found in the cagewash area	Mouse	3	PEL 5		Inspector Advice
Animal found dead in food hopper – daily checks failed to detect	Mouse	1	PEL 4(5)		Inspector Advice

Failure to comply with authorisations and/or conditions on project licence

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
PIL holder completed procedures without sufficient training and supervision and failed to use the most refined methods. PIL holder did not hold correct category licence for procedures undertaken. Further investigation revealed other breaches within the conduct of the project licence including failure to ensure adequate training and competence, conduct of unauthorised procedures, failure to stay within controls of the licence and conduct of procedures not authorised in terms of purpose of the licence. Failings at the establishment included failure to have a robust system for ensuring adequate training and competence and inadequate system for preventing unauthorised procedures	Mouse	24	ASPA 3(a) ASPA 3(b)	PIL SC13 PIL SC 14 PIL SC 15 PIL SC 16 PIL SC 17 PIL SC 19 PIL SC 20 PPL SC 18 PPL SC 6 PPL SC 1 PPL SC 19 PEL SC 20 PEL SC 21	Revocation of PIL. Suspension of PIL, Suspension of Project Licence, Compliance notices to PPL holder and PEL holder, Letters of Reprimand Retraining
Animals transferred from one project to another without appropriate authority. Inadequate knowledge of ASPA demonstrated	Mouse	4	ASPA 14	PIL SC19 PPL SC 11 PPL SC 1 ASPA 22(2)	Suspension of PIL, Letter of Reprimand with retraining
Failure to kill animals when reached humane end point	Mouse	9	PIL SC 5	PPL SC 8	Letters of Reprimand
Mice fed high fat diet for 2 weeks without authorisation. No adverse effects noted	Mouse	20	ASPA 3(b)	PIL SC19	Letter of Reprimand
Over the first three years of a project licence, greater than three-fold more zebrafish were bred and used than were authorised on the project licence. Inadequate control demonstrated over conduct of licence	Fish	15,790	ASPA 3(b)		Letter of Reprimand

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
Animals exceeded humane endpoints with no Regulator action taken	Mouse	2	PIL SC 5	PIL SC1 PIL SC 15 PIL SC 19	Letter of Reprimand with retraining
PIL holder performed anaesthesia to remove wound clips and sham surgery neither of which were authorised on the project licence	Mouse	69	ASPA 3(b)	PIL SC 19 PPL SC 23(a) PPL SC 1 PEL SC 15 PEL SC 20	Letters of Reprimand with retraining
Failure to implement known refinements to study and failure to provide adequate supervision to personal licence holders	Mouse	20	PPL SC 6	PIL SC 16	Letters of Reprimand
5 cranial implants performed when authority only given for 4	Non-human primate	1	ASPA 3(b)	PPL SC 1 PIL SC19	Letter of Reprimand
A small pilot study using minimum dose of agent was not used as required in PPL. Animals were administered substance doses higher than required for scientific outcome	Rat	24	PPL SC1		Letter of Reprimand
Unauthorised repeat injections of substance	Mouse	6	ASPA 14	PIL SC 19	Inspector Advice
Mouse anaesthetised for purpose not authorised in PPL	Mouse	1	ASPA 3(b)	PIL SC19	Letter of Reprimand
Mice received substance not authorised on PPL; unauthorised re-use	Mouse	7	ASPA 14	ASPA 3(b)	Letter of Reprimand
Tail tip performed without PPL authorisation	Mouse	11	ASPA 3(b)	PIL SC19	Letters of Reprimand
Animals not weighed in line with licence authority	Mouse	53	PIL SC 19		Letter of Reprimand
Animal had blood sample taken, which was accidental and unauthorised re-use	Dog	1	PIL SC 19		Inspector Advice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
Substance administered to dogs which was not authorised for testing	Dog	4	PPL SC1		Letter of Reprimand
Unauthorised substance administered to mice	Mouse	8	ASPA 3(b)	PIL SC19	Letter of Reprimand
PPLh exceeded number of animals permitted to be used on the PPL. Evidence of lack of adequate control over licence conduct	Mouse	3834	PPL SC 1		Letter of Reprimand
Animal anaesthetised for purpose not authorised in project licence	Mouse	1	ASPA 3(b)		Inspector Advice
Mice were blood sampled from tail which was not authorised on project licence	Mouse	25	ASPA 3(b)		Inspector Advice
Mouse kept alive after surgery longer than authorised	Mouse	1	PIL SC 19		Inspector Advice
Most refined methods not applied to radiotherapy procedure	Mouse	4	PPL SC 6	PPL SC 1 PIL SC 4	Inspector Advice
Substance administered by an unauthorised route	Mouse	17	ASPA 3(b)	PIL SC 19	Inspector Advice
Animals not monitored and exceeded authorised controls and humane end-points	Mouse	4	PPL SC 1		Inspector Advice
Administered substance via route not authorised in project licence	Mouse	2	ASPA 3(b)		Inspector Advice
Number of rabbits used exceeded those permitted on PPL	Rabbit	212	PPL SC 1	PPL SC 20	Inspector Advice
Substance administered via route which is not authorised on PPL	Mouse	3	PIL SC 19	PPL SC 23(a)	Inspector Advice
Exceeded authorised numbers of animals on one protocol	Mouse	3000	PPL SC 1		Inspector Advice
Used more mice than were authorised on project licence	Mouse	804	PPL SC 1		Inspector Advice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
Terminally anaesthetised fish were used to teach blood sampling to others at the establishment. PPL does not authorise blood sampling for the purpose of training	Fish	Not Known	ASPA 3(b)		Inspector Advice
More mice used than were authorised on project licence	Mouse	350	PPL SC 1		Inspector Advice
Used more mice than were authorised on project licence	Mouse	91	ASPA 3(b)		Inspector Advice
Animals kept alive beyond the age authorised	Mouse	30	ASPA 3(b)	PPL SC1	Letters of Reprimand
Topical eye treatment given unnecessarily	Rat	87	PIL SC19	PEL SC20	Inspector Advice
Unauthorised procedures performed, due to administration error	Mouse	22	PPL SC6	PIL SC19	Inspector Advice
Topical eye treatment given unnecessarily	Rat	24	PIL SC19	ASPA 3(b)	Inspector Advice
Animals supplied to another establishment without project licence authority	Fish	4	PPL SC 1		Inspector Advice
Extra injection given, which was not authorised on project licence	Rat	12	ASPA 3(b)		Inspector Advice

Failure to have correct personal licence

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
Conduct of regulated procedures without personal licence	Dog	23	ASPA 3		Letter of censure
Procedure undertaken by individual without PIL	Mouse	6	ASPA 3(a)	PPL SC6	Letter of censure and Inspector Advice
PIL holder carried out surgery on mice without category C PIL	Mouse	6	ASPA 3(a)	PIL SC 19	Letter of Reprimand
Procedure undertaken without personal licence. PPL holder aware of lack of personal licence	Mouse	2	PPL SC1		Letter of Reprimand with retraining
Procedure undertaken without personal licence.	Mouse	10	ASPA 3(a)		Letter of censure
PIL holder carried out surgery on mice without correct category of PIL authority	Mouse	10	ASPA 3(a)		Letter of Reprimand
PIL holder carried out surgery on mice without correct category of PIL authority	Mouse	Not known	ASPA 3(a)	PIL SC 19	Letter of Reprimand
Individual undertook regulated procedures without having a PIL	Not stated due to potential to identify establish-ment	12	PIL SC 19		Inspector Advice
PIL performed one regulated procedure when moved establishments before new PIL granted	Mouse	1	ASPA 3(a)	PEL SC 20	Inspector Advice
PIL holder performed anaesthesia of greater duration than permitted by the authorised PIL category	Mouse	3	ASPA 3(a)		Inspector Advice
Regulated procedure performed without PIL authority	Bird	1	ASPA 3(a)		Inspector Advice

* Detail of species withheld to prevent disclosure of establishment or persons.

Performing procedures or keeping animals in area not correctly specified on PEL

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
Procedure performed competently but in area not licensed for regulated work	Fish	Not known	ASPA 2B(1)	PIL SC19	Letter of Reprimand
Several rooms were used for regulated procedures or animal holding, which were not approved for such use on the establishment licence	Various	Not known	ASPA 2B(1)		Letter of Reprimand
Regulated procedure carried out in room not on establishment licence	Mouse	1	ASPA 2B(1)		Inspector Advice
Animals undergoing regulated procedures in areas not licensed for this purpose	Mouse	9	ASPA 2B(1)		Inspector Advice

Annex 2: Non-compliance cases 2020

Glossary of terms	
ASPA	Animals (Scientific Procedures) Act 1986
NACWO	Named animal care and welfare officer
PEL	Establishment licence
PIL	Personal licence
PPL	Project licence
SC	Standard Condition
Breach	Section of ASPA or licence condition that was breached

Failure to provide food and/or water

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
Systemic deficiencies in establishment systems including failure to monitor environmental conditions, failure to maintain killing register accurately, failure of systems to prevent unauthorised procedures, deficiencies in named persons skills and knowledge and failing to oversee training and competency	Not applicable	Not applicable for full range of breaches identified	PEL SC 4(3)	PEL SC 2 PEL SC 4(5) PEL SC 5 PEL SC 8 PEL SC 15 PEL SC 17 PEL SC 20 PEL SC 21	Compliance Notice followed by Suspension of Establishment Licence

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
Water bottle found missing from pair of breeding animals. Signs of dehydration present and animals were humanely killed. Weekend check found to not be adequate	Mouse	2	PEL SC 4(3)		Letter of Reprimand
Food missing from cage and two animals found dead. Food not replaced after PIL holder intervention and not picked up by establishment checks	Mouse	5	PIL SC 2	PEL SC 4(3) PEL SC 5 PIL SC 19	Letters of Reprimand
Mismatch between size of food particles and size of openings in aperture so food was not accessible by animals. Failure of daily checks to detect this leading to death of two animals	Mouse	2	PEL SC 4(3)	PIL SC 2 PEL SC 4(1) PEL SC 4(2)	Letters of Reprimand
PIL holder failed to replace food in cages after conducting procedures. Absence of food not detected by establishment checks leading to death of animals	Mouse	15	PIL SC 2	PEL SC 4(3)	Letters of Reprimand
PIL holder failed to replace food in cage after conducting procedures. Absence of food not detected by establishment checks	Mouse	12	PIL SC 2	PEL SC 4(3)	Letters of Reprimand
Cage of animals not provided with food after weaning. Establishment checks failed to detect absence of food leading to death of animals	Mouse	4	PEL SC 4(3)	PEL SC 4(5) PEL SC 5	Letter of Reprimand
Animal found without food and water in heat box in area outside core animal unit following surgery the previous day	Mouse	1	PIL SC 2	PPL SC 6	Letters of Reprimand
Failure of watering system leading to death of animals	Bird	4	PEL SC 15		Inspector Advice
Cage of animals not provided with food or water after weaning. Establishment checks failed to detect absence of food or water leading to death of animals	Mouse	6	PEL SC 4(3)	PEL SC 5	Letter of Reprimand
Animal placed in metabolism cage without water. Establishment checks failed to detect the absence for over 40 hours and animal was humanely killed	Mouse	1	PIL SC 2	PEL SC 4(3) PEL SC 4(5)	Letters of Reprimand

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
Hydropac bag (designed to deliver water to the animals). not working properly resulting in absence of water provision. Not picked up by establishment checks. Animals were humanely killed	Mouse	5	PEL SC 4(3)	PEL SC 4(5)	Letter of Reprimand
Cage sent for washing with animal still inside in error. Animal left without water and subsequently humanely killed	Mouse	1	PEL SC 4(3)		Letter of Reprimand
PIL holder placed pair of animals in hopper but omitted food. Not picked up by routine establishment checks over weekend	Mouse	2	PIL SC 2	PEL SC 4(3) PEL SC 4(5) PIL SC 14	Letters of Reprimand
Water valve failure resulted in failure of water supply. Not detected by establishment checks	Mouse	2	PEL SC 4(1)	PEL SC 4(4)	Letter of Reprimand
Animals failed to be fed. Detected at next scheduled establishment check	Ferret	8	PEL SC 4(3)	PEL SC 4(5)	Inspector Advice
Animals were water restricted for a period of 6 hours on a number of occasions during two studies	Rat	120	PEL SC 4(3)	PEL SC 20 PPL SC 1	Inspector Advice
Food was withheld from an animal in order to take a fasting blood sample as required for scientific purposes. The blood sample was not taken and food was not reintroduced. Detected by establishment at next scheduled check	Mouse	Not known	PIL SC2	PIL SC 19	Inspector Advice
Mouse left overnight without water but detected at next scheduled establishment check	Mouse	1	PEL SC 4(3)		Inspector Advice
Water bottle not placed correctly so animals could not access water. Detected at next establishment check by different technician	Mouse	3	PEL SC 4(3)	PEL SC 4(5)	Inspector Advice

Failure to provide adequate care

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
Animal was able to crawl behind crush back in enclosure and become trapped and died. Absence of animal not noticed by establishment checks for several days. Root causes included lack of adequate maintenance and use of an enclosure in which it was difficult to count animals accurately	Non-human primate	1	PEL SC 4(5)	PEL SC 4(4)	Compliance notice
Failure to confirm death following attempt to humanely kill animals resulting in animals being alive after initial killing step. Animals killed and dissected in presence of live animals	Mouse	30	ASPA 15A		Revocation of licence and Letter of Reprimand with retraining
Failure to confirm death after initial humane killing method resulting in animal escaping after initial overdose of anaesthetic	Rat	1	ASPA 15A(1)		Inspector Advice
Failure to kill animals by most humane method through use of dry ice (solid carbon dioxide intended to cause death through freezing)	Mouse	Unknown	ASPA 3(a)	ASPA 3(b) PPL SC 1	Letter of Reprimand with retraining
Alarm and fan switched off for isolator in error resulting in death of 16 animals through lack of oxygen causing suffocation	Rat	32	PEL SC 4(5)	PEL SC 4(4)	Letter of Reprimand
Failure of caging security system resulting in animals reaching others and fighting causing wounds which required repair under general anaesthesia	Non-human primate	4	PEL SC 4(1)		Letter of Reprimand
Animal died due to head restrainer being applied too hard whilst a blood sample was taken	Rat	1	PIL SC 2	PEL SC 5	Letter of Reprimand and Inspector Advice
Failure of water pumping system resulting in turbid water	Fish	6	PEL SC 4(1)	PIL SC 2	Letters of Reprimand
Mice sent to cage wash area by mistake on three separate occasions	Mouse	4	PEL SC 4(1)		Inspector Advice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
Thermal injury to animals during surgery due to contact with heat mat	Rat	2	PIL SC 2		Inspector Advice
Inadequate supervision of animal whilst under general anaesthesia	Rat	1	PIL SC 2	PIL SC 14	Inspector Advice
Mice trapped tail in cage lid discovered by routine checks	Mouse	2	PEL SC 5		Inspector Advice
Mice trapped tail in cage lid discovered by routine checks	Mouse	2	PEL SC 5		Inspector Advice
Room not checked on one day but no adverse welfare outcomes to animals	Mouse	Not known	PEL SC 4(5)		Inspector Advice
Failure to monitor environmental conditions on several days in different rooms	Various	Not known	PEL SC 4(5)		Inspector Advice
Mouse sent to cage wash area by mistake	Mouse	1	PPL SC 11		Inspector Advice
Animal not checked for 24 hours	Mouse	1	PEL SC 4		Inspector Advice

Failure to comply with authorisations and/or conditions on project licence

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
Personal licence holder unable to demonstrate understanding of their responsibilities under ASPA. PIL failed to keep adequate contemporaneous records of regulated procedures	Various	Not known	PIL SC 19	PIL SC 20 PPL SC 6 PEL SC 15	Letters of Reprimand, one with retraining; Inspector Advice
Flask containing fish larvae due to be humanely killed left on bench area outside of licensed animal holding areas	Fish	824	PPL SC 1	PEL SC 4(1) PEL SC 4(3)	Letter of Reprimand with retraining; Compliance Notice
Substances administered in a combination which was not authorised	Mouse	22	ASPA 3(b)	PPL SC 23 PIL SC 19 PEL SC 20 PPL SC 4	Letters of Reprimand with retraining
Animals not humanely killed at end of experiment as required by PPL authorities	Mouse	6	ASPA 15	PIL SC 8 PIL SC 19 PPL SC 11 PPL SC 23	Letters of Reprimand with retraining; Inspector Advice
Animals died due to overdose of substance administered. Error made by project licence holder in calculation of dose	Rat	60	PPL SC 6	PPL SC 17 PEL SC 5	Letters of Reprimand
Animal received accidental traumatic brain injury during surgery and was kept alive and underwent further regulated procedures whilst exhibiting adverse events that were not authorised in the project licence	Non-human primate	1	PPL SC 18	PEL SC 15	Letters of Reprimand
Animal experienced adverse events(prolonged noisy breathing following extubation) which were not authorised	Non-human primate	1	PPL SC 18	PEL SC 15	Letter of Reprimand and inspector Advice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
Substance administered to incorrect animal	Non-human primate	1	ASPA 3(b)	PEL SC 20	Letters of Reprimand
Animals breached severity limit in project licence and were kept alive	Mouse	25	PIL SC 13	PPL SC 1 PIL SC 15 PIL SC 19	Letters of Reprimand with retraining; Inspector Advice
Animals using for breeding after undergoing regulated procedures without required project licence authority	Mouse	6	ASPA 14(1)	PPL SC 11	Letter of Reprimand and Inspector Advice
Animal exceeded humane endpoint on licence(exceeded permitted percentage weight loss)	Mouse	1	PIL SC 2		Letter of Reprimand
Animals exceeded authorised reduction in weight	Mouse	5	PIL SC 2	PEL SC 5	Letters of Reprimand
More mice bred than were authorised in project licence	Mouse	105	ASPA 3(b)	PPL SC 1	Letter of Reprimand
Animals exceeded age limit authorised on licence	Mouse	31	ASPA 3(b)	PPL SC 1 PEL SC 20	Letters of Reprimand
Failure to kill animals which had reached their humane endpoint following direction by NACWO	Mouse	2	PIL SC 2	PIL SC 13 PPL SC 18	Letters of Reprimand
Administered substances to animals in error	Mouse	5	ASPA 3(b)	PIL SC 19	Letter of Reprimand
Topical administration of substances to animals in error	Rat	58	ASPA 3(b)	PIL SC 19 PEL SC 20	Letters of Reprimand
Administration of incorrect dose of substance to animals	Rat	26	PPL SC 18	PEL SC 15	Letters of Reprimand
Substance administered via unauthorised route	Mouse	1	ASPA 3(b)	PIL SC19	Letter of Reprimand
Substance administered which was not authorised	Mouse	Not known	PIL SC 19	PPL SC 6	Inspector Advice
More fish bred than were authorised	Fish	1218	ASPA 3(b)		Inspector Advice
More mice bred than were authorised in project licence	Mouse	520	ASPA 3(b)		Inspector Advice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
Cage labelling not correct	Mouse	2	PIL SC 16		Inspector Advice
Calculation and recording of weight loss not performed correctly	Mouse	2	PPL SC 18	PPL SC 1	Inspector Advice
Weight loss not monitored correctly	Mouse	1	PIL SC 2		Inspector Advice
Delay in reporting unexpected death of mouse	Mouse	1	PPL SC 18		Inspector Advice
Restraint outside authorised frequency	Non-human primate	2	PIL SC 19		Inspector Advice
Procedures conducted on terminally anaesthetised mice which were not authorised	Mouse	12	PIL SC 19		Inspector Advice
Live animals exported from United Kingdom without required authorisation	Rat	36	PPL SC 1		Inspector Advice
Reports required under PPL Standard Condition 18 not submitted in required timeframe	Various	Not Known	PPL SC 18		Inspector Advice
Failed to comply with reporting condition on project licence and more animals used than authorised	Mouse	36	PPL SC 19	PPL SC 1	Inspector Advice
Animal kept alive and rehomed after regulated procedure without required veterinary assessment	Cattle	1	ASPA 15	ASPA 17A	Inspector Advice
Number of animals bred higher than authorised and incorrect reporting of numbers of animals used	Mouse	Not known	PPL SC 1	PPL SC 20	Inspector Advice
Inadvertent reuse of an animal in a terminal procedure	Mouse	1	ASPA 14		Inspector Advice
Additional day of dosing performed than was required	Rat	6	PEL SC 20		Inspector Advice
Permission to keep animals alive with unauthorised adverse events not requested in timely way	Mouse	Not known	PPL SC 18		Inspector Advice
Genotyping carried out by unauthorised method	Rat	1	PIL SC 19	PPL SC 1	Inspector Advice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
PPL not revoked at time of PPL holder departure	Not applicable	Not applicable	PEL SC 22	PEL SC 20	Inspector Advice
Failure to use aseptic technique during surgical procedure	Rat	1	PIL SC 1	PIL SC 19	Inspector Advice
Failure to monitor animal in accordance with project licence requirements	Mouse	3	PIL SC 2		Inspector Advice
Animals kept beyond age limit on project licence	Mouse	4	ASPA 3(b)	PPL SC 18 PIL SC 19	Inspector Advice
Blood sampling performed by method which was not most refined	Mouse	Not known	PPL SC 4		Inspector Advice
Regulated procedure delayed due to problem with substance to be administered but animal had already been administered premedication	Rabbit	1	PEL SC 20		Inspector Advice

Failure to have correct personal licence

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
Conduct of regulated procedures without personal licence. Procedure performed competently	Fish	1	ASPA 3(a)		Inspector Advice
PIL holder took blood sample from terminally anaesthetised animal with incorrect category PIL. Procedure performed competently	Rat	1	ASPA 3(a)	PIL SC 19	Inspector Advice
Performed regulated procedures after completing species specific modular training, but before receiving personal licence authorisation for that species	Pig	Not known	ASPA 3(a)		Inspector Advice
Procedure carried out without personal licence authority	Fish	42	ASPA 3(a)	PPL SC 19 PEL SC 20	Letters of Reprimand and Letter of Censure

Performing procedures or keeping animals in area not correctly specified on PEL

Description	Animal type involved	Animal numbers involved	Section of ASPA or SCn breached		Regulator action taken
			Primary breach	Other breach(es)	
Killing animals in area not included in schedule of premises	Various	Not known	ASPA 15A(1)		Inspector Advice
Rooms used for animal holding not included on schedule of premises due to administrative error. Rooms have been kept compliant with Code of Practice	Various	Not known	ASPA 2B(1)		Inspector Advice

Annex 3: Non-compliance cases 2021

Glossary of terms	
ASPA	Animals (Scientific Procedures) Act 1986
NVS	Named veterinary surgeon
PEL	Establishment licence
PIL	Personal licence
PPL	Project licence
SC	Standard Condition
Breach	Section of ASPA or licence condition that was breached

Failure to provide food and/or water

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
A cage of mice was left without water for 24 hours	Mouse	4	PEL SC 4(3)		Inspector Advice
A cage of mice was left without food for 5 days	Mouse	5	PEL SC 4(3)	PEL SC 5	Letters of Reprimand
A cage of neonatal mice was left without food and water for 2 days	Mouse	2	PIL SC 2		Letters of Reprimand
A mouse did not have access to water overnight	Mouse	1	PEL SC 4(3)		Inspector Advice
A mouse was left without food or water for approximately 48 hours	Mouse	1	PEL SC 4(3)	PEL SC 4(5)	Inspector Advice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator action taken
			Primary breach	Other breach(es)	
Four mice were left without water for 4 days after the watering system in the cage failed to function properly	Mouse	4	PEL SC 4(3)	PEL SC 4(5)	Letter of Reprimand
A mouse was left without water for 24 hours	Mouse	1	PEL SC 4(3)		Inspector Advice
Three sheep were left without food and water for approximately 24 hours	Sheep	3	PEL SC 4(3)		Inspector Advice
Three mice were left without water for 3 days after the automatic watering system in the cage failed to function properly	Mouse	3	PEL SC 4(3)	PEL SC 4(5)	Letter of Reprimand
A transport error led to 17 mice being left in a transport box with limited food and water for 6 days	Mouse	17	PEL SC 4(3)	PEL SC 4(1) PEL SC 4(5)	Letter of Reprimand
A PIL holder did not replace an animal in its cage correctly, resulting in it being unable to access water for approximately 14 hours	Mouse	1	PIL SC 2	PEL SC 4(1) PEL SC 4(3)	Inspector Advice
A food hopper was placed in a cage in the incorrect orientation, resulting in the animals in the cage not having access to food for 3 days	Rat	3	PEL SC 4(3)	PEL SC 4(5)	Letter of Reprimand
A cage of 2 mice was set up without a food hopper. This was not identified by the establishment's checks for 3 days	Mouse	2	PEL SC 4(3)		Letter of Reprimand
A mouse was left in a cage without food and water for less than 24 hours	Mouse	1	PEL SC 4(3)	PEL SC 4(1)	Inspector Advice

Failure to provide adequate care

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator Action taken
			Primary breach	Other breach(es)	
Seven fish jumped out of gaps in the lids of 2 tanks and died	Fish	7	PEL SC 4(1)	PEL SC 4(4)	Letter of Reprimand
A licence holder did not monitor animals adequately after applying regulated procedures and did not take action to prevent avoidable suffering	Mouse	2	PIL SC 2	PIL SC 5 PIL SC 13 PIL SC 19	Suspension
A licence holder failed to provide adequate care during and after applying regulated procedures and did not prevent avoidable suffering for these animals. The licence holder was inadequately supervised by the PPL holder	Rat	12	PIL SC 2	PPL SC 6 PIL SC 1 PIL SC 5 PIL SC 14 PIL SC 15 PIL SC 19 PEL SC 15	Letters of Reprimand with retraining; suspension; Inspector Advice
A system drain tap was left open, leading to unobserved drainage of a tank overnight and the death of 300 fish	Fish	300	PEL SC 4(1)	PEL SC 4(7)	Letter of Reprimand
A drain valve in an aquarium tank was not properly closed. Consequently, the tank drained overnight, resulting in the death of fish	Fish	430	PEL SC 4(1)		Letter of Reprimand
Cage of neonatal mice were left in a cage wash area	Mouse	8	PEL SC 4(1)	PEL SC 4(4) PEL SC 13(b)	Inspector Advice
Four mice died after receiving intra-venously an injection containing fragments from a faulty pestle and mortar	Mouse	4	PIL SC 13	PPL SC 1 PPL SC 18 PIL SC 15	Letters of Reprimand
Two rats escaped from their cage during transport between buildings	Rat	2	PEL SC 4(6)	PEL SC 5	Letter of Reprimand

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator Action taken
			Primary breach	Other breach(es)	
A mouse became trapped during a cage change and was discovered dead 5 days later	Mouse	1	PEL SC 4(1)	PEL SC 4(5)	Letter of Reprimand
A mouse was kept alive having exceeded the weight loss limit that constituted a humane endpoint in the PPL	Mouse	1	PIL SC 2		Letter of Reprimand
Two mice escaped from their cages and were unaccounted for	Mouse	2	PEL SC 17		Letter of Reprimand
1,300 fish died when a chlorine tablet was accidentally added into the reservoir tank, feeding directly into the fish tanks	Fish	1300	PEL SC 4(1)	PEL SC 4(3)	Letter of Reprimand
A mouse underwent blood sampling via a method that was not the most refined than could have been applied	Mouse	1	PIL SC 1		Inspector Advice
The incorrect test substance was administered, resulting in a requirement to repeat the study (to fulfil regulatory requirements) and the use of an additional 5 animals	Rat	5	PEL SC 1		Letter of Reprimand
The incorrect dose of test substance was administered to a group of mice, resulting in a requirement to repeat the study and the use of an additional 8 animals	Mouse	8	PIL SC 1		Inspector Advice
An electrical failure at the establishment led to the lights in 3 animal holding rooms being left on for 3 nights	Not specified	Not known	PEL SC 4(5)		Inspector Advice
A PIL holder performed a hepatectomy procedure in 6 mice without having adequate training and competency records. The absence of these records was not identified by the establishment. In addition, the PPL holder's oversight of the programme of work was insufficient	Mouse	6	PEL SC 15	PPL SC1 PIL SC 20	Letters of Reprimand
A cage of neonatal mice was left in a cage wash area	Mouse	4	PEL SC 4(1)	PEL SC 13(b) PEL SC 4(4)	Inspector Advice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator Action taken
			Primary breach	Other breach(es)	
A mouse with overgrown teeth was not detected at weaning and the animal was subsequently found dead	Mouse	1	PEL SC 4(5)		Inspector Advice
A PIL holder failed to ensure that they had been assessed for competency in a regulated procedure (brain fibre implantation) prior to performing the procedure	Mouse	1	PIL SC 17	PEL SC 15	Letters of Reprimand
A nephrectomy procedure was performed on a rat without adequate analgesia being provided and without veterinary Advice being sought for the animal	Rat	1	PIL SC 15	PEL SC 1 PPL SC 1 PIL SC 11 PIL SC 12	Letters of Reprimand with retraining
A malfunctioning heat mat led to thermal injuries to the tails of 4 mice. Issues with the functioning of heat mats had previously been identified at the establishment, but no effective action had been taken	Mouse	4	PEL SC 4(4)	PEL SC 15 PEL SC 21	Letter of Reprimand
The incorrect dosage of a test substance was administered to 18 rats, resulting in the required benefits of the study not being achieved	Rat	18	PPL SC 4		Inspector Advice
A mandated daily check of mice in a temperature-controlled cabinet was missed	Mouse	33	PEL SC 4(5)		Inspector Advice
A PIL holder forgot to inform other staff that the animals on which they had performed surgery required analgesia, although requirement for analgesia was identified by the establishment's staff and administered	Rat	4	PIL SC 14		Inspector Advice
A mouse escaped from a behavioural testing box	Mouse	1	PEL SC 17		Inspector Advice
A PIL holder failed to accurately monitor weight loss in 4 mice and, as a result, they exceeded the weight loss humane endpoint specified in the PPL	Mouse	4	PIL SC 2	PPL SC 1 PIL SC 13	Letters of Reprimand with retraining

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator Action taken
			Primary breach	Other breach(es)	
Mice underwent surgery using a method that was not the most refined and some experienced unauthorised adverse effects. In addition, veterinary Advice for the animals was not sought	Mouse	27	PPL SC 4	PPL SC 1 PIL SC 1 PIL SC 15	Letters of Reprimand
A mouse experienced unauthorised adverse effects and was not culled. In addition, the PIL holder did not inform the PPL holder that the constraints of the licence had been exceeded	Mouse	1	PIL SC 13	PIL SC 1 PIL SC 19	Inspector Advice
A mouse exhibited adverse effects after stereotaxic surgery, but the PIL holder failed to seek veterinary Advice for the animal	Mouse	1	PIL SC 15		Letter of Reprimand
Stock zebrafish held at an establishment were not checked over a weekend	Fish	Not known	PEL SC 4(5)	PEL SC 4(3)	Inspector Advice
An additional blood sample was erroneously taken from 18 rats	Rat	18	PEL SC 1		Inspector Advice
Ten mice were dosed with a test substance for an insufficient number of days to ensure benefits of the study were met. Regulatory requirements meant the study was repeated with an additional 10 animals	Mouse	10	PPL SC 1	PEL SC 1	Inspector Advice

Failure to comply with authorisations and/or conditions on project licence

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator Action taken
			Primary breach	Other breach(es)	
A licence holder failed to provide 3 annual reports required under a condition of their PPL	Non-human primate	Not applicable	Additional PPL condition		Inspector Advice
Unauthorised procedures were carried out in a manner not consistent with the principle of refinement and not causing the least pain, suffering, distress or lasting harm required to fulfil the benefits of the study. Failure to ensure animals used in the study were properly monitored	Mouse	15	ASPA 3(b)	PEL SC 13 PEL SC 15 PPL SC 1 PPL SC 4 PIL SC 2 PEL SC 20	Letters of Reprimand
Four mice were singly housed without PPL authority	Mouse	4	PIL SC 19		Letters of reprimand
Twelve mice experienced adverse effects not authorised in the PPL, humane endpoints were not applied in a timely fashion and no authority was sought to keep the animals alive when humane endpoints were reached	Mouse	12	PIL SC 19	PPL SC 18 PIL SC 5	Letters of Reprimand
Procedures were performed for a purpose (training) that was not authorised by the PPL	Mouse	20	ASPA 3(b)	PEL SC 5	Letters of Reprimand
A PIL holder implanted electrocardiogram devices into 2 mice in a site not authorised in the PPL	Mouse	2	ASPA 3(b)	PEL SC 20 PPL SC 1 PPL SC 23 PIL SC 19	Compliance Notice and inspector Advice
An animal was kept alive with an unauthorised adverse effect without permission from the Secretary of State and without veterinary Advice being sought	Mouse	1	PPL SC 18	PIL SC 15 PIL SC 16	Letters of Reprimand with retraining

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator Action taken
			Primary breach	Other breach(es)	
Procedures were conducted incorrectly resulting in the incorrect leg bone being operated on and the animal subsequently suffering a fracture	Sheep	1	ASPA 3(b)	PEL SC 20 PPL SC 1	Letters of Reprimand with retraining
Procedures were performed for a purpose not authorised in the PPL, which resulted in 6 mice experiencing adverse effects	Mouse	102	ASPA 3(b)	PPL SC 1 PIL SC 19	Letters of Reprimand
Thirty-five mice that had undergone stereotaxic surgery to apply head implants exceeded a time constraint specified in the PPL	Mouse	35	PPL SC 1	ASPA 3(b) PPL SC 6 PIL SC 19	Letters of Reprimand with retraining
A mouse underwent surgery for a purpose not authorised in the PPL	Mouse	1	ASPA 3(b)	ASPA 14 PIL SC 19	Letter of Reprimand with retraining
An animal experienced adverse effects that were not authorised in the PPL was kept alive for 10 days without permission from the Secretary of State	Rat	1	PPL SC 18	PPL SC 8	Letter of Reprimand
320 mice underwent a temporary withdrawal of anaesthesia during application of regulated procedures when this was not authorised by the PPL	Mouse	320	ASPA 3(b)	PPL SC 1 PIL SC 19	Letters of Reprimand
Two mice underwent wound reclosure on 2 occasions when only a single wound closure was authorised by the PPL	Mouse	2	ASPA 3(b)		Letter of Reprimand with retraining
A PIL holder anaesthetised mice to measure subcutaneous tumours with callipers. The use of anaesthesia for this purpose is not authorised by the PPL	Mouse	33	ASPA 3(b)	PIL SC 19	Letter of Reprimand
A mouse underwent 2 intraplantar injections when PPL authority permitted application of only one	Mouse	1	ASPA 3(b)		Inspector Advice
A mouse underwent wound repair more than 48 hours after surgery, when wound repair was only permitted within 48 hours by the authorities of the PPL	Mouse	1	ASPA 3(b)		Inspector Advice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator Action taken
			Primary breach	Other breach(es)	
Twenty-five mice exceeded the maximum age limit of 12 months authorised by the PPL	Mouse	25	PPL SC 1	PPL SC 18	Inspector Advice
A mouse underwent a second administration of anaesthetic after the first anaesthetic induction failed. A repeat anaesthetic induction was not authorised by the PPL	Mouse	1	ASPA 14(1)	PIL SC 10	Inspector Advice
An animal was re-used between protocols on the PPL without the re-use being authorised	Mouse	1	ASPA 14		Inspector Advice
A mouse was implanted with a microchip and then killed for training purposes. Training was not an authorised purpose under the PPL	Mouse	1	ASPA 3(b)	PIL SC 19	Inspector Advice
Animals exceeded a weight loss humane endpoint specified in the PPL and no permission was sought from the Secretary of State to keep them alive. The training of personnel in the measurement of weight loss and identification of associated humane endpoints was inadequate	Mouse	17	PEL SC 5	PPL SC 1 PPL SC 18	Inspector Advice
Procedures that were not authorised by the PPL were performed in 16 rats. In addition, a responsible PIL holder had inadequate training and competency records in the procedures	Rat	16	ASPA 3(b)	PEL SC 1 PEL SC 15 PPL SC 1 PPL SC 8 PIL SC 19 PIL SC 20	Suspension and Letters of Reprimand with retraining
Two mice underwent cranial surgery over the course of 2 procedures rather than the single surgery authorised by the PPL	Mouse	2	ASPA 3(b)	PEL SC 21 PIL SC 19	Inspector Advice
A PPL holder failed to report the deaths of 8 mice in a breeding colony to the Secretary of State as soon as possible	Mouse	9	PPL SC 18		Inspector Advice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator Action taken
			Primary breach	Other breach(es)	
A guinea pig was killed by a method not authorised by a PPL	Guinea pig	1	ASPA 15A		Inspector Advice
Eight mice exceeded the maximum age limit of 12 months authorised by the PPL	Mouse	8	ASPA 3(b)		Inspector Advice
A PPL holder failed to report the deaths of 6 genetically altered mice which died as a result of the genetic alteration to the Secretary of State as soon as possible	Mouse	6	PPL SC 18		Letter of Reprimand
A mouse was allowed to age to 21 months, exceeding the maximum age limit of 12 months authorised by the PPL	Mouse	1	ASPA 3(b)	PPL SC 18 PPL SC 1	Inspector Advice
More mice were bred than was authorised by the PPL	Mouse	1043	PPL SC 1		Inspector Advice
Sixty-one fish exceeded the maximum age limit of 18 months authorised by the PPL	Fish	61	PPL SC 1		Inspector Advice
Unauthorised procedures for an unauthorised (training) purpose were performed in 4 mice; all animals subsequently died or were culled due to adverse effects associated with the procedures	Mouse	4	ASPA 3(b)	PPL SC 1 PPL SC 6 PIL SC 19	Letters of Reprimand with retraining
Unauthorised procedures were carried out in 52 mice	Mouse	52	ASPA 3(b)	PPL SC 1	Inspector Advice
A PIL holder performed oral gavage in 2 mice for training purposes. Training was not an authorised purpose under the PPL	Mouse	2	ASPA 3(b)		Letter of Reprimand
Mice underwent vasectomy via a laparotomy approach rather than the scrotal approach authorised by the PPL	Mouse	120	ASPA 3(b)	PPL SC 1 PEL SC 20 PIL SC 19	Letters of Reprimand
A PIL holder did not cull an animal after it had reached a weight loss humane endpoint and did not notify either the PPL holder or the NVS that the endpoint had been exceeded	Rat	1	PIL SC 2	PIL SC 13 PIL SC 15	Letter of Reprimand with retraining

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator Action taken
			Primary breach	Other breach(es)	
A mouse was ear clipped for genotyping purposes without authority under the PPL	Mouse	1	ASPA 3(b)	PIL SC 19	Inspector Advice
Twelve mice received a dose of test substance via the intra-peritoneal route that exceeded the maximum permitted volume under the PPL authorities	Mouse	12	PIL SC 19		Inspector Advice
An individual took a blood sample from a dog for a scientific purpose without PIL or PPL authority at a place not specified in a PPL	Dog	1	ASPA 3		Letter of Censure
70 fish exceeded the maximum age limit of 18 months authorised by the PPL	Fish	70	ASPA 3(b)		Inspector Advice
A PIL holder decapitated 3 mice without PPL authority and did not use the most refined method for the procedure	Mouse	2	ASPA 3(b)	PIL SC 1 PIL SC 19	Suspension and Letter of Reprimand with retraining
A PIL holder performed procedures on 3 mice for a purpose not authorised in the PPL	Mouse	3	ASPA 3(b)		Letter of Reprimand with retraining
A second person was not present during surgical procedures when a neuromuscular blocking agent was being used, as required by an additional condition of the PPL	Guinea pig	1	PPL SC 1	PIL SC 19	Inspector Advice
Six mice exceeded the weight loss humane endpoint mandated by the PPL	Mouse	6	PEL SC 5	PPL SC 1 PIL SC 18	Letters of Reprimand
Fourteen mice had blood samples taken that exceeded the maximum volume permitted by the PPL	Mouse	14	PIL SC 2		Letters of Reprimand
The incorrect animal underwent a blood sample while under terminal anaesthesia	Rat	1	ASPA 3(b)		Inspector Advice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator Action taken
			Primary breach	Other breach(es)	
A PIL holder did not cull an (otherwise clinically well) mouse after it had reached a weight loss humane endpoint specified in the PPL	Mouse	1	PIL SC 2		Inspector Advice
A PPL holder knowingly allowed a mouse to exceed the maximum age permitted by the authorities of the PPL	Mouse	1	PPL SC 1		Retraining
A PIL holder exceed the maximum limit specified in the PPL for number of daily intra-peritoneal injections	Mouse	6	PIL SC 19		Inspector Advice
Mice underwent subcutaneous implantation of microchips for a scientific purpose. This was not specifically authorised by the PPL	Mouse	24	PIL SC 19	PPL SC 1	Inspector Advice
A PIL holder failed to identify that a mouse had reached a tumour size humane endpoint, as mandated by the PPL	Mouse	1	PIL SC 2		Letter of Reprimand
Three mice exceeded the maximum age limit authorised by the PPL	Mouse	3	PPL SC 1		Inspector Advice
A PIL holder removed blood from 12 mice by tail snipping while they were under terminal anaesthesia without PPL authority and without documented training and competency records	Mouse	12	ASPA 3(b)	PPL SC 1 PPL SC 6 PIL SC 17	Inspector Advice
The processes for identifying animals being used under a PPL was inadequate, resulting in one mouse exceeding a mandated humane endpoint due to misidentification	Mouse	1	PPL SC 1		Letter of Reprimand
A PPL holder failed to ensure that a cow was examined by a NVS prior to release from the controls of ASPA	Cattle	1	PPL SC 1		Inspector Advice
More mice were bred than was authorised by the PPL	Mouse	76	PPL SC 1		Inspector Advice
A mouse exceeded the maximum age limit of 12 months authorised by the PPL	Mouse	1	PPL SC 1		Inspector Advice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator Action taken
			Primary breach	Other breach(es)	
A mouse exceeded the maximum age limit of 12 months authorised by the PPL	Mouse	1	PPL SC 1		Inspector Advice
Mice were housed in cages that did not meet minimum requirements of the 'Code of Practice for the Housing and Care of Animals Bred, Supplied or Used for Scientific Purposes' for 22 hours longer than was authorised by the PPL	Mouse	20	PIL SC 19		Inspector Advice
Twenty-four mice were kept alive under a PPL authority for 6 months longer than was authorised by the PPL	Mouse	24	PPL SC 1	PPL SC 18 PIL SC 19	Inspector Advice
Procedures not authorised by the PPL were applied to rats, insufficient analgesia was provided for 7 of the animals and monitoring of the animals after procedures were applied was inadequate. The training and competency of the responsible PIL holder was inadequate	Rat	18	PPL SC 8	ASPA 3(b) PPL SC 1 PPL SC 6 PPL SC 18 PIL SC 1 PIL SC 12 PIL SC 17	Suspension

Failure to have correct personal licence

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator Action taken
			Primary breach	Other breach(es)	
Blood samples were taken from 20 lambs for a scientific purpose by an individual without PIL authority	Sheep	20	ASPA 3(a)	PEL SC 20	Compliance notice and Letter of Censure
Imaging procedures were carried out on 50 fish for a scientific purpose by an individual without PIL authority	Fish	50	ASPA 3(a)		Inspector Advice
Procedures were performed by an individual without PIL authority	Mouse	Not known	ASPA 3(a)		Letters of Reprimand
An individual performed regulated procedures (administration of pre-medication and implantation of a telemetry device) in a dog for a scientific purpose without PIL authority	Dog	1	ASPA 3(a)		Letter of censure
A PIL holder performed procedures (a subcutaneous and an intra-venous injection) on a non-human primate. The processes in place at the establishment failed to identify that the PIL holder did not have the application of procedures to non-human primates authorised by their PIL	Non-human primate	1	PEL SC 20		Letter of Reprimand
A PIL holder performed procedures (intra-peritoneal injections) on 5 rats. The processes in place at the establishment failed to identify that the PIL holder did not have the application of procedures to rats authorised by their PIL	Rat	5	PEL SC 20	ASPA 3(a) PIL SC 19	Letters of Reprimand
An individual performed procedures (intra-muscular injection) on a non-human primate without PIL authority	Non-human primate	1	ASPA 3(a)		Letter of censure
A PIL holder performed regulated procedures (intra-peritoneal injections) in 32 mice without having the correct PIL authority	Mouse	32	PEL SC 20	ASPA 3(a) PPL SC 6 PIL SC 19	Inspector Advice

Performing procedures or keeping animals in area not correctly specified on PEL

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached		Regulator Action taken
			Primary breach	Other breach(es)	
Six horses were housed in an area not specified on the PEL Schedule of premises	Horse	6	PEL SC 3(g)	PEL SC 13(b)	Inspector Advice
Animals were used under ASPA in a room (albeit fit for purpose) that was not authorised for use under the PEL	Not specified	N/A	ASPA 2B(1)		Inspector Advice
Two rats were kept overnight in a room designated as 'no overnight holding' by the PEL	Rat	2	PEL SC 13(b)	PEL SC 3(g)	Inspector Advice
Zebrafish were used in procedures in 3 rooms that were not listed on the schedule of premises at the establishment	Fish	Not known	PEL SC 13(b)	PEL SC 3(g)	Inspector Advice
Two rooms were used for a purpose not authorised by the designated holding code for the areas on the PEL	Not specified	Not known	PEL SC 3(g)		Inspector Advice
Animals were used under ASPA in a room (albeit fit for purpose) that was not authorised for use under the PEL	Not specified	Not known	PEL SC 13(b)		Inspector Advice

Annex 4: Tables and figures

Glossary of terms	
ASPA	Animals (Scientific Procedures) Act 1986
FTE	Full-time equivalent
PEL	Establishment licence
PIL	Personal licence
PPL	Project licence
SC	Standard Condition

Table 4.1: Licence applications and amendments, 2019, 2020 and 2021

	Total			Per inspector (FTE)		
	2021	**2020**	**2019**	**2021**	**2020**	**2019**
PILs[2] granted	2,327	1,732	2,792	102.6	74.6	125.7
PILs amended	789	679	564	34.8	29.2	25.3
PILs in force at year-end	14,402	14,796	16,009	634.7	637.4	720.8
PELs[3] granted	0	3	2	0	0	0
PELs amended	20	27	1,146	0.9	1.1	51.5[4]
PELs in force at year-end	137	144	152	6.0	4.9	6.8
PPLs[5] granted	497	478	523	21.9	20.5	21.6
PPLs amended	1,109	1,053	685	48.9	45.3	30.8
PPLs in force at year-end	2,423	2,429	2,537	106.8	104.6	112.3
Inspectors (FTE)	22.69	23.21	22.21	–	–	–

Notes:

1 FTE = full-time equivalent averaged across the year.

2 PIL = personal licence.

3 PEL = establishment licence.

4 Due to the change in licensing software there were a large number of administrative changes undertaken on PELs to better align the data of approved areas into the new licence format.

5 PPL = project licence.

Figure A4.1: Inspectorate resource, 2011 to 2021

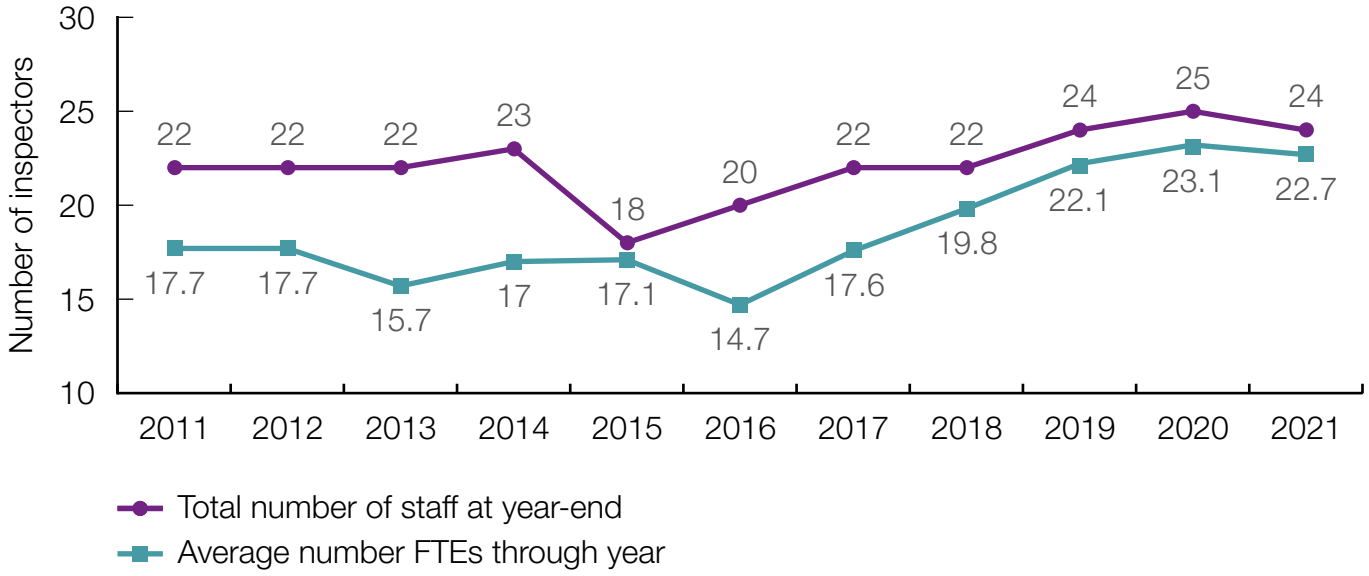


Figure A4.2: Project licences granted, 2011 to 2021

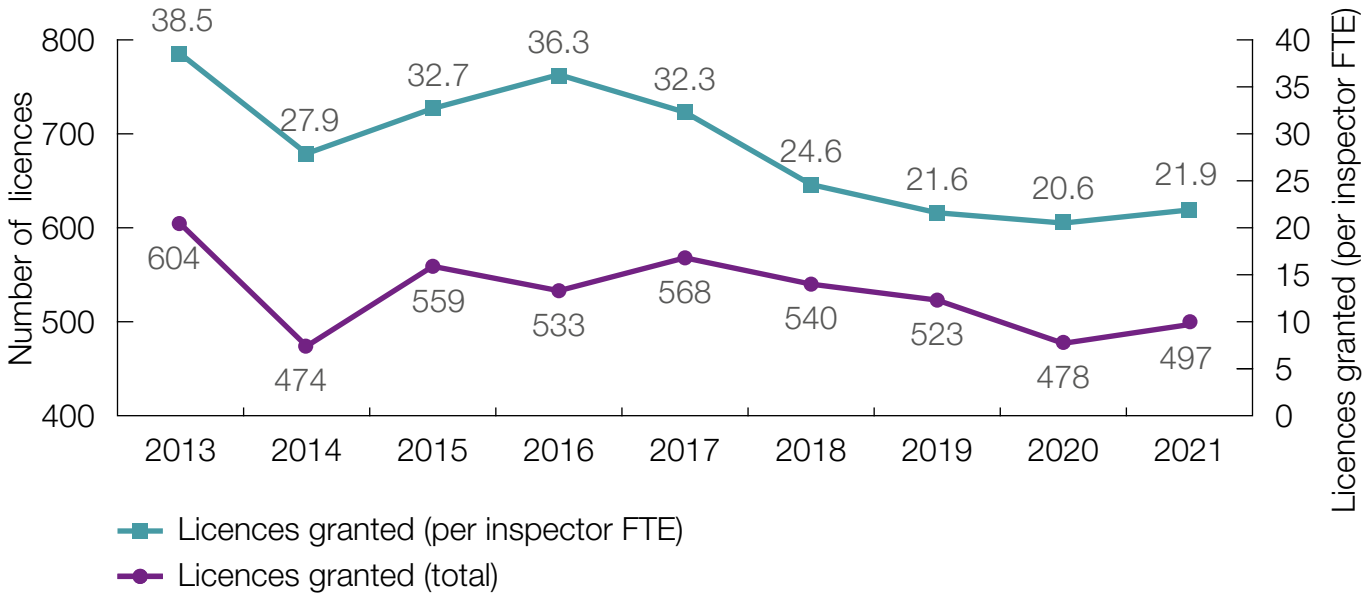


Figure A4.3: Project licence application processing, 2011 and 2018

Due to the development of the new e-licensing system (ASPeL), not all reporting functions have been developed and therefore, some statistics are unavailable and will not be produced going forwards. The graph for the period up to 2018 is included in our 2018 Annual Report.

Figure A4.4: Inspections and audits, 2019 to 2021

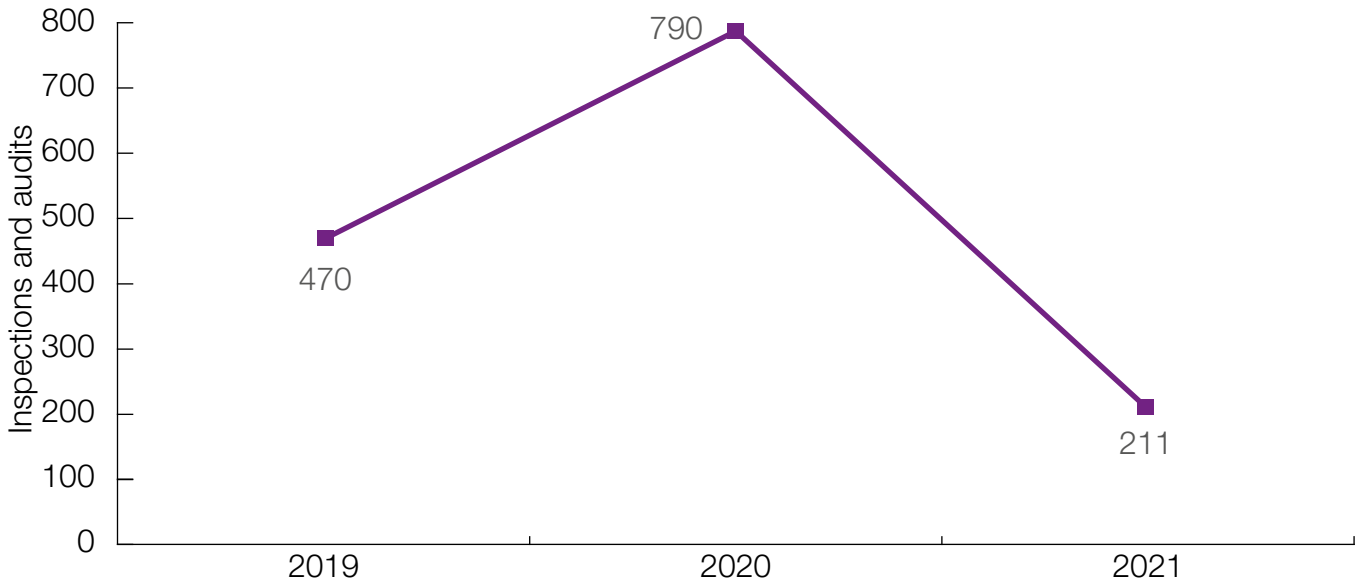


Figure A4.4: Inspections and audits, 2019 to 2021

Overall, fewer number of on-site visits were undertaken in 2021 compared to 2019 and 2020. This was due to 2 main factors:

- national lockdowns between 5 January and 3 May 2021 during which compliance assurance and inspection activity was undertaken remotely. On-site visits were still conducted for serious non-compliance cases or serious animal welfare concerns that could not be evaluated remotely

- Launch of 'Bridging Ways of Working' operating model from 5 July 2021 which consolidated and expanded compliance assurance activity. The new operating model introduced full systems audits which are extended, structured compliance visits requiring teams of officials from the Animals in Science Regulation Unit (ASRU) evaluating selected establishments in depth. ASRU also updated the Standard Condition 18 system (described further in Section 3 of the operating model) leading to increased compliance oversight of all GB establishments through collection and analysis of Standard Condition 18 reports. Standard Condition 18 is applied to all project licences to ensure that the licence holder adheres to the specific severity limits (the scientific and humane endpoints that set limits on pain) in each licence.

More detail is provided in Section 8: Inspections and audits.

Annex 5: Strategic shifts

- Relationship management of regulated establishments is separated from regulatory decision making.
- Establishment of the Animals in Science Regulation Unit's (ASRU's) clear role as a regulator with associated training and ongoing career and professional development.
- Clear written regulatory guidance will be available on ASRU's website to cover all key areas.
- Additional regulatory queries will be answered through a formal centralised process.
- There will be an increased ASRU focus on the assessment of the suitability of all licence holders (establishment licences, project licences and personal licences), including standards for licence holder training.
- There will be an increased focus in ASRU's assessment of project licences on legal requirements and integration of expert assessments.
- There will be an integrated assessment of compliance by teams of inspectors with formal documented outcomes.
- There will be increased and pro-active issue of information and insights from data in near real time.
- There will be increased horizon scanning and proactive policy development.
- There will be increased focus and capability in information and systems management within ASRU.