

## Animals in Science Regulation Unit

**Annual report 2024** 





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## **Foreword**

UK life sciences research delivers vital benefits for human and animal health, the environment and the economy. Some of this research requires the use of animals to achieve essential scientific outcomes, and it is our responsibility to ensure that those animals are afforded the highest standards of protection. Equally, it is critical to maintain public confidence that, where animals are used, their use is fully justified and there is no viable alternative.

The Animals in Science Regulation Unit (ASRU) plays a central role in safeguarding animal welfare in research and testing. We ensure animals are used only when absolutely necessary, and only to the extent required to meet research objectives. Harms must be minimised, and the principles of the 3Rs (Replacement, Reduction and Refinement) are embedded in every aspect of our regulatory approach. Our work is underpinned by the Animals (Scientific Procedures) Act 1986 (ASPA), which sets a robust legal framework for ethical and responsible science.

Regulation of animal testing in the UK is essential to protect animals from unnecessary suffering, ensure that testing occurs only when no alternatives exist, and promote the development of innovative non-animal methods. These measures uphold the ethical treatment of animals while enabling research that advances medicine and science, with the long-term goal of replacing animal use entirely.

Throughout 2024, ASRU has continued to strengthen its regulatory delivery through a transformational reform programme designed to enhance compliance and ethical standards, while supporting scientific innovation.



We have initiated an organisational restructure that will continue into 2025, ensuring our regulatory practices remain fit for purpose and responsive to future challenges.

Our reform programme will deliver stronger protections for animals, reinforce compliance with ASPA, and foster collaboration with the regulated sector to achieve meaningful improvements. We remain committed to driving forward these reforms, maintaining the highest standards of animal welfare, and supporting world-class science that benefits society.



Kate Chandler, Head of the Animals in Science Regulation Unit

# Section 1: Animals in Science Regulation Unit (ASRU)

## Introduction

The purpose of ASRU is to protect animals used in science by maintaining compliance with the Animals (Scientific Procedures) Act 1986 (ASPA).

Through its regulatory role, ASRU ensures that scientific work involving animals is conducted responsibly, legally, and with the highest regard for animals.

ASRU regulates the use of animals in science according to ASPA. This is the UK law passed by Parliament that governs how and under what circumstances animals may be used in science.

ASPA sets strict conditions on which types of animals can be used, the types of procedures permitted, and the ethical standards researchers must follow. At the heart of ASPA is the requirement to:

- only use animals in research when there are no alternatives
- use the minimum number of animals necessary to achieve scientific objectives
- ensure that any pain, suffering, distress or lasting harm to animals is minimised

ASRU is part of the Home Office and is responsible for the administration and enforcement of ASPA in England, Scotland and Wales. ASRU's activities include:

 operating the licensing system required by ASPA

- assuring the compliance of licence holders with ASPA and the terms and conditions of their licences
- advising on the requirements of ASPA

ASRU delivers these responsibilities through its Licensing and Compliance Assurance functions, supported by additional functions which deliver business support and oversee processes and standards. As of 31 December 2024, 33.8 full-time equivalent (FTE) employees worked in ASRU.

## **Licensing function**

ASRU inspectors evaluate licence applications against the requirements of ASPA and use a harm-benefit analysis process to determine whether a project licence should be authorised. ASPA has a three-tiered licensing system (a licence is required for the person, the project and the place):

- those carrying out regulated procedures must hold a 'personal licence' (PIL) that authorises them to apply those procedures to specified animals, initially under supervision until they have demonstrated competence
- the regulated procedures to be carried out must be authorised by a 'project licence' (PPL) that specifies the programme of work within which the procedures are being performed
- the place at which the work is carried out must normally be specified in an 'establishment licence' (PEL)

Those breeding and/or supplying the species of animal listed in ASPA Schedule 2 must also hold PFI.

The conduct of regulated procedures may be authorised at places other than licensed establishments (POLEs) when the nature of the work makes this necessary, and these places will be specifically identified in the relevant PPLs.

The principles of replacement, reduction and refinement (the 3Rs) as set out by the National Centre for the Replacement, Reduction and Refinement (NC3Rs).

Replacement is the principle that, wherever possible, a scientifically satisfactory method or testing strategy not entailing the use of protected animals must be used instead of a regulated procedure. Replacement accelerates the development and use of predictive and robust models and tools, based on the latest science and technologies, to replace the use of animals in addressing important research questions where they would otherwise have been used.

**Reduction** is the principle that, wherever a programme of work involving the use of protected animals is carried out, the number of protected animals used must be reduced to a minimum without compromising the objectives of the programme. On occasions, it may be necessary to use a greater number of animals than the absolute minimum scientifically justifiable if each individual animal will suffer less because of the greater number being used. The principle of reduction should apply to methods of breeding protected animals, as well as their use in procedures. Reduction results in appropriately designed and analysed animal experiments that are robust and reproducible and add to the knowledge base.

**Refinement** is the principle that, wherever a programme of work involving the use of protected animals is carried out (after rigorously applying the principles of replacement), the regulated procedures applied to those animals must be refined to eliminate or reduce to the minimum any possible pain, suffering, distress or lasting harm. Refinement and reduction must be considered in balance. Refinement applies to the methods of breeding, accommodation and care of protected animals as well as the methods used in procedures. Refinement advances laboratory animal welfare by applying the latest in vivo technologies – techniques conducted within a whole, living organism – to minimise pain, suffering and distress, and to improve understanding of how welfare impacts scientific outcomes.

#### How the 3Rs are applied

Personal licence holders' responsibilities for the 3Rs:

 the responsibilities conferred on PIL holders through standard licence conditions require that the licence holder shall act at all times in a manner that is consistent with the principles of replacement, reduction and refinement (Standard Condition 1)

Project licence holders' responsibilities for the 3Rs:

- PPL holders are required to ensure that their programme of work does not involve any regulated procedures for which there is a scientifically satisfactory alternative method or testing strategy that does not entail the use of a protected animal
  - such methods may include specific in vitro or in silico procedures as well as consideration of weight-of-evidence decision strategies
  - such decision strategies may indicate that no animal tests, or no further animal tests, are reasonably justified in order to address the question posed (Standard Condition 2)

Establishment licence holders' responsibilities for the 3Rs:

 the first standard condition of the PEL requires that the holder must put in place measures to ensure that the regulated activities carried on at the establishment are carried out in a manner that is consistent with the principles of replacement, reduction and refinement (the 3Rs) (Standard Condition 1)

In 2024, the licensing function's work included:

- issuing and amending PELs, PPLs and PILs
- providing regulatory advice to licensed establishments
- maintaining ASRU's electronic licensing system, ASPeL (Animals in Scientific Procedures e-Licensing)

As of 31 December 2024, the licensing function of ASRU comprised the following FTE personnel:

- 1 senior leader
- 8.2 inspectors
- 2 executive officers
- 3 administrative officers

Note: FTE data has been rounded to one decimal place for reporting purposes.

## **Compliance Assurance function**

The Compliance Assurance function is responsible for delivering a comprehensive suite of oversight and assurance activities to ensure that licence holders comply with ASPA and their specific licence conditions. This function plays a critical role in maintaining the integrity of the regulatory framework and upholding public confidence in the system.

In 2024, the Compliance Assurance function's key activities included:

- investigating potential cases of noncompliance and applying sanctions in a proportionate manner, aligned with the published compliance policy
- overseeing the delivery of the 2024 audit programme, as conducted by ASRU
- reviewing submitted reports to validate compliance, such as those required under Standard Condition 18 and other licencespecific reporting obligations
- responding to queries related to regulatory advice within the scope of compliance assurance

As of 31 December 2024, the Compliance Assurance function within ASRU comprised of the following personnel:

- 1 senior leader
- 4 inspectors
- 1 senior executive officer
- 1 higher executive officer
- 3 executive officers

## **Business Support function**

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

In 2024, the Business Support function's work included:

- risk management activities, including health and safety
- all assurance and governance activities, including monitoring and reporting
- workforce planning and recruitment
- administering and collecting the annual returns of procedures, for the publication of the annual statistics
- managing procurement and all financial activities
- collecting annual licence fees

As of 31 December 2024, the Business Support function of ASRU comprised 2.5 FTE personnel.

Note: FTE data has been rounded to one decimal place for reporting purposes.

## **Processes and Standards**

ASRU's Process and Standards function oversees the development, refinement and implementation of procedural documents in ASRU.

In 2024, the Process and Standards function work included:

- supporting the development and updates of Standard Operating Procedures and operational forms, including strengthened processes for identifying/filling gaps and managing approvals
- monitoring and maintaining procedural documents, including new processes to facilitate access to, and control of, documents
- monitoring published regulatory guidance and advice

As of 31 December 2024, the Processes and Standards function of ASRU comprised 2 FTE personnel.



## Section 2: Regulatory reform

## **Background**

In 2020, a programme of transformational regulatory change was initiated to improve the performance of ASRU. The change programme was targeted at delivering alignment of the Regulator with the following expectations:

- improved ability for licensed establishments to comply with ASPA 1986
- greater protection 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
- greater efficiency

## Reform changes 2021 to 2023

In July 2021, ASRU changed its regulatory operating model to align ways of working with regulatory practices and modern regulatory systems. In doing so, ASRU separated Compliance Assurance and Licensing functions, with inspectors no longer assigned to specific establishments.

In 2022, the regulatory reform programme paused to gather feedback from establishments and the wider sector, and consolidate new processes and establish the new Animals in Science Regulation Policy Unit in the Home Office. The Policy Unit is a separate entity from ASRU and advises ministers on policy relating to regulating the use of animals in science, principally under ASPA.

In 2023, the regulatory reform programme was re-initiated, and ASRU undertook a comprehensive review of its operating model and organisational design. This exercise identified opportunities for improvement to strengthen regulatory delivery. Key considerations included the robustness, proportionality and efficiency of ASRU's Licensing, Compliance Assurance and Guidance functions, as well as its culture and broader internal systems.

The new operating model and organisational design were developed to provide ASRU with the capabilities, structure and expertise required for effective operation and efficient delivery of its statutory responsibilities.

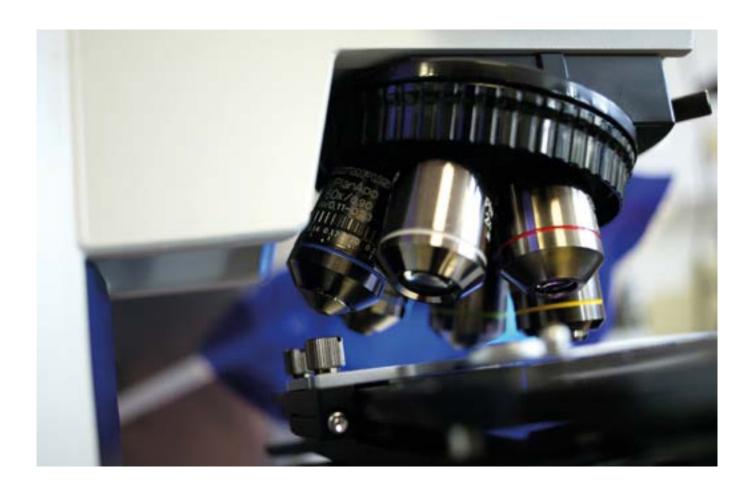
## Reform update 2024

In 2024, ASRU continued to design and implement organisational changes, aligned with its mission to strengthen animal protections and support the life sciences sector through effective and proportionate regulation. Preparations were made to launch the finalised operating model and new organisational structure in 2025.

The new operating model incorporates a strengthened strategic centre, enhanced data analysis capabilities to enable a more evidence-based approach, and increased expertise in regulatory and quality management functions. It also introduces a broader and more diverse range of skills, strengthening ASRU's capabilities across standards and guidance, quality assurance, data analysis and regulatory practice. This broader multidisciplinary input strengthens regulatory expertise, ensuring that audits and other key activities benefit from diverse perspectives.

The reform programme continued throughout 2025, with further improvements to ASRU planned and regular stakeholder engagement to support transparency and effective regulatory delivery.

Continuous improvement is at the heart of ASRU's regulatory reform programme, to ensure that changes are not only implemented, but refined over time to deliver robust, proportionate and efficient regulation.



## Section 3: Licensing

## The framework

ASRU's principles, processes and standards used in licence assessment continue to align with ASPA requirements.

The three-tier licensing system provides a framework for authorising research using animals, ensuring that animal research and testing is only undertaken:

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

ASRU administers and issues the following types of licences:

- establishment licences (PELs), for carrying out activities authorised under ASPA
- project licences (PPLs), for a programme of work and specified regulated procedures
- personal licences (PILs), which qualify the holder to apply regulated procedures to the types of animal specified in the licence

Licence applications are assessed by inspectors in the order they are submitted through ASPeL.

We prioritise licence applications using timelines aligned within the statutory timelines defined in ASPA. Timelines to grant licences can vary, as they are based on the complexity of the application and level of incoming applications to the regulator.

All days referenced are working days:

- new project application review and any returned project application review: 40 days and 55 days for complex applications
- new PPL amendment review and any returned project amendment review: 40 days

As of 31 December 2024, ASRU licensed and regulated 134 establishments.

These establishments include universities, pharmaceutical companies and contract research laboratories. As of 31 December 2024, there were 2,315 active PPLs and 13,311 active PILs.

## Licensing activities

#### **Establishment licences**

In 2024, 2 PELs were granted, 3 were revoked, and 3,440 amendments were made. These amendments included changes to areas approved for animal holding/procedures, Named Persons and administrative information.

#### **Project licences**

In 2024, 472 new PPLs were granted and 905 PPL amendments were made. This is a slight increase in the number of new PPLs granted compared to 2023 (460 PPLs granted).

#### **Personal licences**

During 2024, 2,164 new PILs were granted and 738 PIL amendments were made.

## Animals in Scientific Procedures e-Licensing (ASPeL)

In 2019, ASRU rolled out ASPeL, a refreshed digital e-licensing system, to improve consistency, efficiency and compliance.

The ASPeL system ensures that PIL holders and Named Persons can easily access the information they need to do their work, reducing the risk of inadvertent non-compliance.

Applicants can track the progress of their applications and any mandatory actions, such as when a PIL is due for review.

ASRU recognises that the new project application forms can be further improved and has committed to ongoing development of ASPeL to ensure it meets both internal and external user needs while maintaining robust animal protections. Improvements to ASPeL include:

- the 'Fate of animals' section of PPL applications
- standardised authorisation content for rehoming and setting free in PPL applications
- the PIL-E (or category E PIL) application
- added 'Forced swim test' to the Returns of Procedures for compliance reporting
- created new ASPeL user guides to support onboarding and licence transfer journeys

## Referrals to the Animals in Science Committee (ASC)

ASC is an independent, non-departmental public body convened under sections 19 and 20 of ASPA. ASC provides independent, balanced and objective advice to the Secretary of State on issues relating to the use of animals in science. At all times, ASC must consider both the legitimate requirements of science and industry and protecting animals from avoidable suffering and unnecessary use in scientific procedures.

Further information about ASC is available on its dedicated website.

ASC also advises on specific categories of PPL applications, including those applications that seek authority for:

- using wild-caught non-human primates
- using cats, dogs, equidae or non-human primates in severe procedures
- using endangered species
- projects with major animal welfare or ethical implications
- projects of any kind that raise 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'

## Section 4: Compliance

## **Compliance policy**

ASRU's compliance policy 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.

Establishments notify ASRU of any incidents where there has been a potential breach of ASPA or a licence condition (which also includes the Code of Practice for the Housing and Care of Animals Bred, Supplied or Used for Scientific Purposes (Code of Practice). Self-reporting indicates that an establishment is making efforts to ensure compliance. It demonstrates that role holders are aware of their responsibilities and are committed to building a compliant culture. ASRU expects self-reporting to be embedded within good governance frameworks and that employees are aware of the process for raising concerns within their establishment. This is set out in ASRU's published compliance policy Guidance on the operation of the Animals (Scientific Procedures) Act 1986 (ASPA) - GOV.UK

ASRU may identify potential breaches when auditing an establishment. When this occurs, the establishment is notified in the audit report that a potential non-compliance has been identified and may be investigated.

## Management of non-compliance

ASRU takes all reports of potential non-compliance seriously. An inspector will gather sufficient information to determine whether there is a case that merits further investigation. If the ASRU Enforcement Team determines that there is sufficient evidence for a breach, it will issue a suitable and proportionate remedy. The aim of this remedy is to prevent a recurrence of similar breaches.

Licensees and the establishment are notified in writing by ASRU when a non-compliance investigation is being conducted and are given an opportunity to provide any information that they wish to be considered before ASRU takes a decision regarding the appropriate remedy.

There is also the opportunity for appeal against some types of remedy, which the licence holder will be notified of at the time the remedy is issued. Complex or serious cases may take some time to resolve. In rare cases, ASRU may take a view that an offence has been committed that is sufficiently serious to merit referral for prosecution.

## Potential remedies for non-compliance

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

Factors considered when determining 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 and help to determine the outcome associated with each breach. These are briefly outlined below.

#### 1. Inspector advice

For a minor breach, an inspector will advise on what provision was breached and what is expected in the 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 by the inspector to be low

## 2. Compliance letters

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

Letters note the breach(es) that have occurred and summarise the evidence for those breaches. These letters are formal records of non-compliance and may be used as evidence should there be a further breach within 5 years. All letters are also sent to Home Office Liaison Contacts (HOLCs), so that local practices and processes can be reviewed as appropriate.

#### 3. Variations of licences

#### Requirement for re-training

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

#### Requirement for reporting

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

#### Suspension

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

## 4. 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 that must be taken to eliminate or reduce any consequential risk of harms caused by the breach

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

This type of remedy is particularly effective where specific actions are required to assure ASRU that the breach will not recur. ASRU usually specifies a timeframe for the actions to be completed; if not completed by that timeframe, it may sanction further, such as with the suspension, revocation or variation of the licence.

#### 5. Revocation of a licence

ASRU will only revoke licences issued under ASPA 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 to animals. It may also be appropriate where significant avoidable suffering has been caused through negligence or ignorance, or where the licensee otherwise appears to be unsuitable for the role. ASRU has a duty to ensure that the welfare of animals is not adversely affected by the revocation of a licence.

#### 6. Prosecution

Extremely serious cases of non-compliance 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 2024, 146 cases of non-compliance, in 45 different establishments, were confirmed and finalised. Of these, 63 (43%) were related to failing to provide adequate care (including food, water and suitable facilities) while the other 83 (57%) were related to failing to have or adhere to licence authorities. See Figure 1, below.

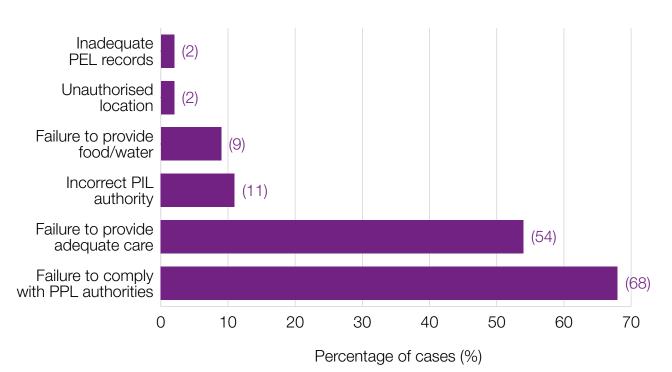


Figure 1: Breakdown of non-compliance types

Note: The graph shows the percentage of cases by category of non-compliance. The number of cases in each category is shown at the end of each bar in brackets.

In 2024, 101 (69%) of the cases closed as confirmed non-compliances were self-reported by establishments as potential non-compliances; 36 (25%) were identified by ASRU from PPL Standard Condition 18 reports, 4 (3%) during an audit, 3 (2%) by the Licensing Team and 1 case each by the Regulatory Advice Team and via the Return of Procedures process (<1% each).

## Number and type of animals

In 2024, of the 146 cases of non-compliance, animal numbers were reported in 143 cases; animal numbers were not relevant for 3 cases related to administrative errors or facility-wide issues that did not impact animals directly.

These 143 cases involved 22,204 animals.

The number of animals reported in the 143 cases, by animal type, is shown in Table 1.



Table 1: Number of animals involved in non-compliance cases, 2024

Animal type	No. of animals
Bat	5
Cat	2
Cattle	63
Dog	5
Fish	542
Frog/Xenopus	32
Guinea pig	13
Hamster	1
Mouse	19,670
Non-human primate (NHP)	4
Rabbit	1
Rat	1,829
Sheep	37
Total	22,204

There was one case that involved a larger number of animals – 13,952 mice and 1,625 rats. There was a fault with the environmental control systems at the animal facility, which led to temperature and humidity fluctuations outside the Code of Practice parameters. Five animals experienced adverse welfare as a result of this non-compliance.

## Adverse welfare outcomes

An animal is assessed as experiencing an adverse welfare outcome as the result of a non-compliance if they experienced greater than short-term mild pain, suffering or distress, taking into consideration:

- the nature of pain, suffering, distress or lasting harm caused by the non-compliance, and its intensity and duration
- the additional welfare burden of cumulative suffering caused by the non-complaint action(s)
- any additional prevention from expressing natural behaviour, including restrictions on the housing, husbandry and care standards caused by the non-compliance
- the species affected

Animals that were bred in excess of the authorised numbers, but were required to achieve the scientific objectives, were not considered as having experienced an adverse welfare outcome providing licence authorities and controls were adhered to.

In 2024, 189 animals experienced adverse welfare outcomes because of non-compliance (Table 2). This is a reduction from the number of animals that experienced adverse welfare outcomes in 2023, which was 553.

Table 2: Number of animals with adverse outcomes, 2024

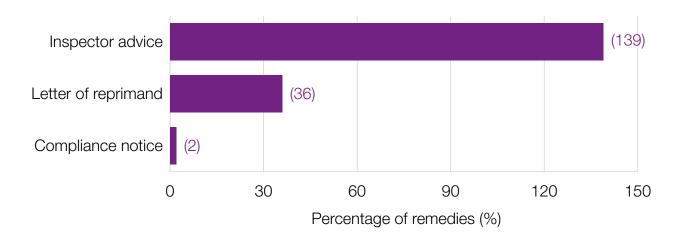
Animal type	No. of animals
Bat	0
Cat	0
Cattle	0
Dog	1
Fish	99
Frog/Xenopus	26
Guinea pig	0
Hamster	1
Mouse	58
NHP	0
Rabbit	1
Rat	3
Sheep	0
Total	189



## **Remedies**

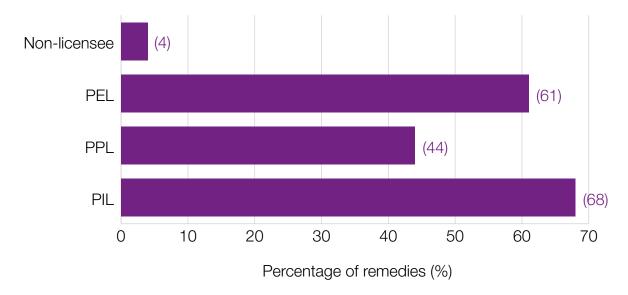
It should be noted that in a single case of non-compliance, there can be several different remedies applied to a variety of individuals. Therefore, the number of remedies is not the same as the number of cases.

Figure 2: Percentage and type of remedies issued



Note: The number of remedies issued is shown in brackets.

Figure 3: Percentage of each type of licence holder that received remedies



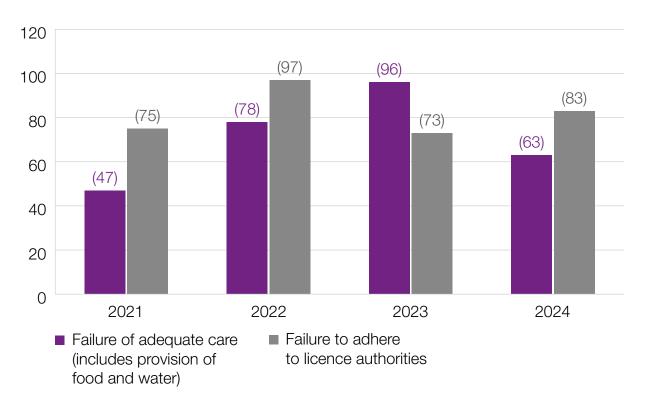
Note: The number of remedies issued is shown in brackets.

There were 110 cases (75%) for which the sole remedy was inspector advice.

Summaries of all the non-compliance cases closed in 2024 are in Annex A.

## Trends in non-compliance cases over time

Figure 4: Number of non-compliance cases by overarching category by year, 2021 to 2024



Note: The number of cases in each category is shown at the end of each bar.

## **Key learnings from 2024 non-compliance cases**

## Failure to comply with project licence authorities

In 2024, 68 (47%) of the 146 cases involved failure to comply with PPL authorities.

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 (e.g. 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 complying 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 the risk of not complying with PPI authorities:

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

## Failure to provide adequate care

In 2024, there were 54 cases (37%) of inadequate care. Recommendations to prevent this type of non-compliance 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 is 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 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 the provisions of ASPA.

In 2024, of the 146 cases of non-compliance, 9 (6%) involved failure to provide adequate food and/or water.

Cases in which there was a welfare impact occurred due to the failure of establishment processes to ensure that the necessary daily checks were performed adequately. When performed competently, the absence of food and water would be detected prior to adverse welfare outcomes occurring.

Recommendations to prevent this type of noncompliance are:

- 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 are robust
- PEL holders should identify high-risk situations that may result in failing to provide adequate food and water and implement specific actions to mitigate these
- PIL holders and staff performing husbandry duties 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 have appropriate PIL 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 2024, 11(8%) cases were recorded where the breach was either failing to hold a PIL or to have the relevant authorities on their PIL to conduct the regulated procedures undertaken.

Recommendations to prevent this type of non-compliance are:

- 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 appropriate PIL authorities are held by those undertaking regulated procedures – this includes appropriate checks of the PIL authorities of individuals visiting an establishment to perform regulated procedures

# Unauthorised location: Performing procedures or keeping animals in area not specified on PEL

In 2024, 2 (1%) cases were recorded where regulated procedures had been performed in a room not authorised on the PEL, or an animal had been kept in a room not authorised for overnight holding.

Recommendations to prevent this type of non-compliance are:

- ensure all PIL holders and staff are aware of the authorities for each room on the establishment licence
- consider labelling rooms clearly with the authorities mentioned above

# Failure to adhere to licence conditions that mandate record keeping, re-homing and security

This category was added to the 2022 annual report to accurately capture the number of non-compliance cases that cannot be placed into the five previously used categories.

In 2024 there 2 (1%) cases recorded where there were failures to adhere to licence conditions that mandate record keeping, re-homing and security.

## **Standard Condition 18**

All project licences are subject to a set of Standard Conditions. Standard Condition 18 requires that the PPL holder notifies ASRU as soon as possible if constraints on the severity limits, or observance of other controls described in the licence, have been breached or are likely to have been breached.

Licence holders are required to submit reports under Standard Condition 18 as a requirement of ASPA, ensuring that unexpected events are reported to ASRU so that advice can be provided or compliance action taken.

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 required for compliance and is not the same as reporting potential non-compliance.

In 2024, ASRU received 2,466 Standard Condition 18 reports from establishments.

## **Audit**

An audit is a process that verifies conformance to standards through a review of objective evidence. Audits 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 ASPA requirements and the relevant conditions specified in licences. ASRU advises duty holders on how to comply with ASPA requirements and will enforce noncompliances.

ASRU audits establishments licensed to breed or supply animals, or to undertake regulated procedures on animals under ASPA in England, Scotland and Wales.

The purpose of ASRU's audit activity 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.

ASRU undertakes audits for the following purposes:

- to determine whether licence holders are compliant and to advise how to comply with the legal requirements of ASPA
- to inspect areas included on the establishment licence 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
- to 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

- to determine whether the breeding, supply and/or use of animals in procedures complies with licence authorities and conditions on licences
- to determine whether people named in the establishment licence understand and are fulfilling their required duties, and to advise on these roles

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.

## **Audit approach**

The new audit approach was first rolled out in 2021 to 2022 and has continued in 2024 to replace the previous old-style inspection programme.

ASRU's audit activity is risk-based, taking into consideration the factors specified in section 18 (2C) of ASPA, which are:

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

## **Description of audit types**

## ASRU's audit activity in 2024:

- facilities audits: to record evidence of the effectiveness of the governance systems in place to maintain compliance with Standard Conditions of the establishment licence and Code of Practice for the Housing and Care of Animals Bred, Supplied or Used for Scientific Purposes, and to decide about any regulatory actions required to reduce the risk of non-compliance
- facility assessment for establishment licence amendments: to assess new facilities and/or significant changes to existing facilities that cannot be confirmed remotely

- for-cause audits: for enforcement investigations when the cause of non-compliance cannot be confirmed, and for other regulatory purposes such as investigation following a whistleblowing report received by ASRU
- dual-purpose audits: some audits had dual purpose, such as facilities audit and assessment for establishment licence amendments; the criteria used to assess establishments is published online<sup>1</sup>

## Audit activity - onsite visit duration and number of inspectors attending

Audit type	Duration	Inspectors
Facilities	1 day	1 to 3
Facility assessment for establishment licence amendment	1 day	1
For-cause audit	Min. 1 day	Min. 2
Dual-purpose audits	1 day	1 to 2



<sup>1</sup> https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_data/file/1023690/210920\_ASRU\_Full\_Systems\_Audit\_Process.pdf

#### **Number of audits**

As of 31 December 2024, ASRU had audited 68 establishments. This comprised 66 facilities audits, 2 for-cause audits and no dual-purpose audits. Of these audits, 10 were unannounced to the establishments.

Five audits included in the 66 facilities audits above were carried out by remote inspection and interview for operational reasons, such as work at POLEs that may not have physical facilities.

As part of regulatory reform the audit programme has undergone a review which will continue into 2025, with further changes anticipated through 2026 and into 2027.

#### **Audit reports**

Following an audit, an establishment receives a report detailing the findings of the audit, including timescales for confirming to ASRU that any required follow-up action has been completed. This allows any necessary action to be undertaken by the establishment and ASRU to monitor its completion in a timely manner.

#### Risk management

ASRU's establishment risk management process comprises a review of the national risk profile and local establishment factors.

Evaluation of risk includes:

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

ASRU takes these factors into account when planning audit activity.

## Investigating allegations made to ASRU

ASRU periodically receives allegations about potential breaches of ASPA. These are taken seriously and, where sufficient information is provided, they are followed up by the most appropriate means, which may include initiating a for-cause audit. Where it appears there may have been a lack of compliance with ASPA, these are investigated in accordance with ASRU's non-compliance policy.

# Section 5: Business Support (Finance Report – income and expenditure for 2024)

## **Financial Report**

Table 3: Summary of income and fee-funded expenditure, by budgeting year, including capital spend, years ending 31 March 2015 to 2025

Year ending March	Income	Running budget	Capital	Variance
2015	£4,380,206	£4,378,929	_	£1,277
2016	£4,692,833	£4,207,503	_	£485,330
2017	£4,482,578	£4,467,404	_	£15,174
2018	£4,421,361	£4,777,455	_	(£356,094)¹
2019	£4,752,912	£4,579,303	£1,625,492	£173,609
2020	£4,943,224	£4,947,844	£1,800,230	(£4,620)
2021	£5,012,744	£5,408,987	_	(£396,243)
2022	£5,067,060	£5,163,588	(£100,992)	$(£96,528)^2$
2023	£4,729,602	£4,829,571	_	(£99,969)
2024	£4,725,171	£5,391,009	_	(£665,838)
2025	£4,984,438	£4,900,000	_	£84,438

#### Notes:

- 1. This figure has been corrected, it was previously reported as a positive variance £356,094.
- 2. This figure has been corrected, it previously reported as (£86,528).

## Fee income

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

## Annual licence fees, years ending March 2015 to 2025

	Years ending March					
Annual fee <sup>1</sup>	2015-18	2018-19	2019-20	2020-24	2024-25	
Personal licence	£242	£257	£275	£299	£329	
Establishment licence	£631	£757	£826	£915	£1,007	

#### Note:

1. From 2018, fees are charged from 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.

Invoices are raised in arrears, so the income for the year ending March is collected in the following year.



## **Expenditure**

Table 5: Summary of expenditure by budgeting years ending March 2021 to 2025

Category	2020-21	2021-22	2022-23	2023-24	2024-25
Pay and recharges	£3,397,001	£3,187,412	£2,775,603	£3,355,614	£2,975,836
Consultancy	_	(£45)	_	£716,508	-
Travel	£7,742	£29,933	£27,327	£23,499	£30,642
Office supplies	£4,593	£6,888	£8,437	£12,378	£14,180
Training and recruitment	(£3,626)	£13,696	£17,018	£15,190	£5,777
Conferences	(£1,545)	(£29)	£31,755	£16,676	£43
Estates	£56,903	£1,771	£214	£10	£87
IT and comms	£1,231,632	£775,639	£793,171	£177,208	£385,599
Marketing	£719	(£719)	£5,353	-	£1,989
Legal	£12,143	£14,453	£869	£6,682	_
Special payments	_	-	_	_	_
Other	£3,427	£8,034	£113,207	£10,627	£9,307
Total direct costs	£4,708,987	£4,037,032	£3,772,954	£4,334,392	£3,423,462
Overheads	£700,000	£516,556	£456,617	£456,617	£527,554
Expenditure total	£5,408,987	£4,553,588	£4,229,571	£4,791,009	£3,951,016
Depreciation	_	£600,000	£600,000	£600,000	£600,000
Income	(£5,012,744)	(£5,067,060)	(£4,729,602)	(£4,725,171)	(£4,984,438)
Variance	(£396,243)	(£86,528)	(£99,969)	(£665,838)	(£433,422)

## Section 6: Stakeholder Engagement

Stakeholder engagement is a critical enabler of effective regulation, policy implementation and service delivery. ASRU's engagement with the regulated sector and other key stakeholders serves multiple strategic and operational purposes:

- enhancing regulatory effectiveness –
  engagement ensures that licensing decisions
  and compliance assessments are informed
  by practical insights, enabling ASRU to issue
  licences and amendments consistently,
  transparently and timely
- promoting transparency and trust regular communication with stakeholders fosters trust and accountability, providing a forum for sharing regulatory updates, clarifying expectations and addressing concerns, thereby reducing uncertainty and improving compliance
- understanding impact and improving policy – stakeholder feedback enables ASRU to understand how regulation impacts the regulated sector; these insights are essential for refining policies, identifying issues and ensuring regulatory approaches remain proportionate and evidence-based
- supporting strategic alignment and collaboration – engagement helps align regulatory goals with stakeholder needs and encourages collaboration on problem-solving

## ASRU Stakeholder engagement framework

ASRU's engagement with the regulated sector plays a critical role in delivering its regulatory responsibilities. Engagement is structured around 3 tiers of requirements:

- relational requirements including the development and maintenance of service delivery standards to support effective working relationships
- operational requirements including the provision of guidance and responses to compliance-related queries
- strategic requirements supporting the implementation of policy and contributing to long-term regulatory outcomes

Through these interactions, ASRU can:

- provide dedicated conduits and forums for addressing questions and clarifying aspects of regulation and its implementation
- provide a platform to communicate updates and key information on issues relevant to the regulated sector

#### **Stakeholder meetings**

Stakeholder meetings continue to play a vital role in ASRU's reform programme, helping to strengthen transparency, improve regulatory delivery, and support compliance with ASPA. These engagements provide valuable feedback, foster trust, and ensure the regulated sector remains informed and involved in shaping improvements.

In 2024, ASRU met with the Home Office Liaison, Training and Information Forum (HOLTIF) three times, providing a platform for the regulated sector to receive updates on key regulatory developments and contribute feedback.

ASRU also met with the Establishment Licence Holders Committee three times in 2023. These meetings included an update on the reform programme and discussions of strategic and operational matters.

#### **Publications**

In 2024, ASRU published:

- Non-technical summaries granted in 2024
- Animals in Science Regulation Unit annual report 2023
- Animals in Science Regulation Unit annual report 2022
- ASRU operational newsletter, February 2024
- ASRU operational newsletter, July 2024

#### Correspondence

ASRU supports the Animals in Science Regulation Policy Unit to respond to Freedom of Information Act 2000 (FOI) requests or correspondence from the public on issues related to regulating animals in science.

In 2024, the Policy Unit handled 71 FOI requests and 110 items of ministerial correspondence, including other related communications.

The requests and correspondence above were concerned with a breadth of issues. Among these, the main topics of interest were:

- the welfare of dogs used in animal testing
- the phasing out of animals used in testing
- the use of the forced swim test
- re-homing of animals used in testing
- correspondence requesting supplementary information following the issuing of the annual statistics and ASRU annual report 2023

## Annex A: Non-compliance cases

Glossary of terms				
Term	Definition			
ASPA	Animals (Scientific Procedures) Act 1986			
NVS	Named veterinary surgeon			
PEL	Establishment licence			
PIL	Personal licence			
PPL	Project licence			
SC	Standard Condition			

Table A1: Failure to comply with PPL authorities

Description	Animal type involved	Number of animals involved	Section of ASPA or licence condition breached	Action taken by ASRU
Appropriate action was not taken when humane endpoint specified on PPL was reached (tumour size)	Mouse	2	PPL SC1	Inspector advice
Animals experienced an unnecessary regulated procedure (anaesthesia)	Mouse	5	PIL SC1	Inspector advice
Condition on PPL breached	Mouse	40	PIL SC19	Inspector advice
Animals were administered more drug doses than authorised by PPL	Mouse	36	PPL SC1, PIL SC19	Inspector advice
Animals underwent recovery anaesthesia, not authorised by PPL	Rat	32	PPL SC1, PIL SC19	Inspector advice
Number of animals used on experimental protocol exceeded	Mouse	38	PPL SC1	Inspector advice

Description	Animal type involved	Number of animals involved	Section of ASPA or licence condition breached	Action taken by ASRU
Number of animals used exceeded number authorised by PPL	Mouse	3,817	PPL SC1	Inspector advice
Regulated procedure not authorised by PPL	Mouse	4	ASPA 3(b), PIL SC19	Inspector advice
Number of animals exceeded number authorised by PPL	Mouse	125	PPL SC1	Inspector advice
Additional regulated procedure performed on animals after humane endpoint reached	Mouse	2	PIL SC19	Inspector advice
Appropriate action was not taken when humane endpoint specified on PPL was reached	Mouse	9	PPL SC1	Inspector advice
Larger blood sample volume taken than authorised by PPL	Mouse	24	PIL SC19	Inspector advice
Unexpected weight loss in animals exceeded authorised limits on study	Mouse	2	PPL SC1, PIL SC19	Inspector advice
Drug administered to life-stage not authorised by the protocol	Mouse	9	PPL SC1, PIL SC19	Inspector advice
Animals were immunised or had blood withdrawn multiple times, but minimum interval between procedures specified in PPL was not adhered to	Sheep	32	PPL SC1	Inspector advice
Animal kept alive with unauthorised adverse effect without authorisation	Dog	1	PPL SC1	Inspector advice
Correct PPL authority not sought for regulated procedure	Mouse	14	PPL SC1	Inspector advice
Animals maintained on breeding protocol longer than was authorised	Mouse	3	PPL SC1	Inspector advice
Animals underwent procedure not authorised by PPL (re- suturing surgical wounds twice)	Mouse	3	PIL SC19	Inspector advice
Saline injected intravenously for the sole purpose of training, which was not authorised by PPL	Mouse	4	ASPA 3(b)	Inspector advice

Description	Animal type involved	Number of animals involved	Section of ASPA or licence condition breached	Action taken by ASRU
Aged animals were kept longer than authorised by PPL protocol	Mouse	5	PPL SC1	Inspector advice
Animals bred on experimental protocol without authorisation	Mouse	50	PPL SC1	Inspector advice
Regulated procedure not authorised by PPL (application of depilatory cream)	Mouse	75	PPL SC1	Inspector advice
Notification requirements not followed to report animals that had exceeded severity limits of PPL	Mouse	18	PPL SC1, 18	Inspector advice
Animals re-used without PPL authority in a second protocol	Mouse	2	ASPA 14, PIL SC19	Inspector advice
Mandatory step of PPL protocol not completed	Mouse	4	PPL SC1	Inspector advice
Animals were kept alive for 300 days beyond PPL expiry	Mouse	0	PPL SC20	Inspector advice
Animals killed by a non-Schedule 1 method, which was not authorised by the PPL	Mouse	8	ASPA 3(b)	Inspector advice
Inadequate recording resulting in duplication of microchipping	Frog/ Xenopus	6	ASPA 3(b), PPL SC19, PIL SC20	Inspector advice
Regulated procedure not performed as specified by PPL	Mouse	44	PPL SC1, PIL SC19	Inspector advice
Appropriate action was not taken when the humane endpoint specified on PPL was reached (weight loss)	Mouse	2	PIL SC 2, 13, 19	Letter of Reprimand
Analgesia not administered as specified by PPL	Mouse	23	PPL SC1, PIL SC19	Inspector advice
Animals had second tissue sample unnecessarily taken for genotyping which was not authorised	Mouse	8	ASPA 3(b)	Inspector advice
Regulated procedure not performed using an acceptably refined method	Mouse	28	PPL SC4, PIL SC1	Inspector advice

Description	Animal type involved	Number of animals involved	Section of ASPA or licence condition breached	Action taken by ASRU
Animals kept alive without authority when they developed adverse effects not authorised by PPL	Mouse	2	PPL SC1, PIL SC19	Inspector advice
Regulated procedure undertaken that was not authorised by PPL	Mouse	55	PPL SC1	Inspector advice
Larger blood sample volume taken than authorised by PPL	Sheep	1	PPL SC1	Inspector advice
Regulated procedure undertaken that was not authorised by PPL (intra-articular injection solely for training)	Sheep	4	ASPA 3(b)	Inspector advice
Animals not monitored as required by PPL controls	Mouse	1	PIL SC19	Inspector advice
Regulated procedure not performed as specified by PPL	Mouse	7	PEL SC4, PIL SC1	Inspector advice
Regulated procedure not performed as specified by PPL (more attempts at obtaining blood sample than authorised)	Rat	1	PIL SC19	Inspector advice
Animals exceeded humane endpoint, due to misunderstanding about how to calculate weight loss	Mouse	22	PPL SC1, PIL SC1	Inspector advice
Regulated procedure not authorised by PPL (re-suturing surgical wound >48 hours post-surgery)	Mouse	1	PIL SC19	Inspector advice
Animal exceeded age authorised by PPL	Mouse	1	PPL SC1	Inspector advice
Animals exceeded age authorised by PPL	Mouse	2	PPL SC1	Inspector advice
Animals not monitored as required by PPL controls	Mouse	48	PIL SC2	Inspector advice
Animals used on mild severity breeding protocol exceeded PPL authority	Mouse	37	PPL SC1	Inspector advice

Description	Animal type involved	Number of animals involved	Section of ASPA or licence condition breached	Action taken by ASRU
Regulated procedure undertaken not authorised by that protocol of PPL (repeat ear biopsy for genotyping)	Mouse	1	PIL SC19	Inspector advice
Unnecessary procedures performed due to administration errors	Rat	30	PEL SC1, PPL SC1	Inspector advice
ASRU not notified that animals experienced unexpected adverse effects in required timeframe	Mouse	3	PPL SC18	Inspector advice
Regulated procedure undertaken that was not authorised by PPL (non-surgical wound sutured)	Mouse	1	ASPA 3(b), PIL SC19	Inspector advice
Animals not monitored as required by PPL controls	Mouse	5	PIL SC19	Inspector advice
Animal exceeded age authorised by PPL	Mouse	2	PPL SC1	Inspector advice
Animals kept beyond age permitted on PPL	Mouse	7	PPL SC1	Inspector advice
Misidentification of sex led to regulated procedures performed on pregnant animals	Mouse	7	ASPA 3(b), PEL SC4(5), PIL SC2	Inspector advice
Animals on water restriction not provided with access to water for period stated in PPL	Mouse	2	PIL SC19	Inspector advice
Animals exceeded age authorised by PPL	Mouse	2	PIL SC19	Inspector advice
Regulated procedure undertaken not authorised by PPL (single housing to measure food intake)	Mouse	28	PPL SC1	Inspector advice
Animals not monitored as required by PPL controls (weighed)	Mouse	3	PIL SC2, 19	Inspector advice
Animals with unauthorised adverse effects kept on protocol	Mouse	3	PIL SC19	Inspector advice
Regulated procedure undertaken that was not authorised by PPL (ear-clip for genotyping)	Mouse	1	PPL SC1, PIL SC19	Inspector advice

Description	Animal type involved	Number of animals involved	Section of ASPA or licence condition breached	Action taken by ASRU
Regulated procedure not performed as specified by PPL (greater blood volume sampled)	Rat	33	PPL SC1	Inspector advice
Unnecessary procedures performed due to administrative errors (single housing, removal of food/water <24 hours)	Rat	10	PEL SC1, PPL SC1	Inspector advice
Animals not monitored as required by PPL controls (weighed) and not fed on one day	Mouse	10	PIL SC2	Inspector advice
Regulated procedure undertaken that was not authorised by PPL (sham surgery)	Mouse	4	PPL SC1, PIL SC19	Inspector advice
Regulated procedure not performed as specified by PPL (inadequate surgical aseptic technique)	Mouse	12	PPL SC1, PIL SC1	Inspector advice
Regulated procedure not performed as specified by PPL (more injections administered than authorised)	Mouse	4	PPL SC1, PIL SC19	Inspector advice
Regulated procedure not performed as specified by PPL (injection route and monitoring frequency)	Mouse	15	PPL SC1, PIL SC2, 19	Inspector advice

Table A2: Failure to provide adequate care

Description	Animal type involved	Number of animals involved	Section of ASPA or SC breached	Action taken by regulator
Animal left singly housed and without food/water for ~48 hours; subsequently Schedule 1 killed	Mouse	1	PEL SC4(1) (3)(5)	Letter of Reprimand
Unauthorised mortality and concerns regarding monitoring of anaesthetised animals	Rat	64	PEL SC1	Compliance Notice
Facilities had fallen below the standard specified in the Home Office Code of Practice for the Housing and Care of Animals Bred, Supplied or Used for Scientific Purposes	Cat	2	PEL SC4(1)	Inspector advice
Animal was drawn through a siphoning tube, resulting in death	Fish	1	PEL SC4(1) (4)	Letter of Reprimand
Animals were left in unmarked cages for 48 hours and were not checked as required	Mouse	3	PEL SC4(1)	Inspector advice
Animal escaped from cage	Mouse	1	PEL SC4(1)	Inspector advice
Animals under procedure exceeded weight loss limit due to dehydration	Mouse	2	PEL SC4(1)	Inspector advice
Fault with water valve resulting in dehydration of animal	Mouse	1	PEL SC4(5)	Inspector advice
Lack of food in hopper resulted in animals dying and others were killed by Schedule 1 method	Mouse	6	PEL SC 4(3) (5)	Letter of Reprimand
Animals accidentally kept overnight in a pen that was too small, and one animal was singly housed	Dog	4	PEL SC4(7)	Inspector advice
Malnutrition due to unidentified malocclusion	Mouse	1	PEL SC4(5)	Letter of Reprimand
Neonates left without parents, access to food, water and warmth for 22 hours	Mouse	4	PEL SC 4(1) (3)	Inspector advice
Fish escaped tank as baffle was not the appropriate size	Fish	27	PIL SC2	Letter of Reprimand

Description	Animal type involved	Number of animals involved	Section of ASPA or SC breached	Action taken by regulator
Animal was trapped by tail for up to 16 hours, necessitating euthanasia	Mouse	1	PIL SC2	Inspector advice
Fish died when a system fault led to exposure to chlorine	Fish	394	PEL SC 4(3) (4)	Letter of Reprimand
Animals were without access to water	Mouse	3	PEL SC 4(1) (3)(5)	Letter of Reprimand
Leaking water valve resulted in flooded cage overnight and animals found dead	Mouse	26	PEL SC4(1)	Letter of Reprimand
Animal mistakenly put in waste bag	Hamster	1	PEL SC4(1	Letter of Reprimand
Animals unable to feed from mother and consequently died	Mouse	10	PEL SC4(1)	Inspector advice
Significant issues of concern regarding farm and large animal facilities	n/a	n/a	PEL SC4(7)	Compliance Notice
Animal found suspended from cage lid by tail, without access to food and water	Mouse	1	PEL SC4(1)	Letter of Reprimand
Animal under procedure was found in the food hopper without access to food and water	Mouse	1	PIL SC2	Inspector advice
Animal found trapped between cage and food hopper; found alive but humanely euthanised	Mouse	1	PEL SC4(1)	Letter of Reprimand
Animal found dead with malocclusion	Mouse	1	PEL SC4(5)	Letter of Reprimand
Fault with boiler leading to fluctuations in temperature and humidity	Mouse and rat	13,952 and 1,625	PEL SC4(4) (7)	Letter of Reprimand
Animal euthanised after being found trapped by its tail by cage lid for approximately 20 hours	Mouse	1	PEL SC4(1)	Letter of Reprimand
Animals held in genotyping tanks for prolonged period on liquid diet rather than solid food	Fish	63	PEL SC4(1) (5), PIL SC2	Letters of Reprimand
Animal found with tail trapped between lid and base of cage	Mouse	1	PEL SC4(1)	Letter of Reprimand
Delay in killing resulting in unnecessary suffering for animal	Rat	1	PEL SC4(1), PEL SC21	Letter of Reprimand

Description	Animal type involved	Number of animals involved	Section of ASPA or SC breached	Action taken by regulator
Injections accidentally administered to the wrong animals	Mouse	6	PIL SC1	Inspector advice
Animal left in new cage without food for 3 days	Mouse	1	PEL SC4(1) (3)	Letter of Reprimand
Mother removed from cage and killed, resulting in unweaned pups starving to death	Mouse	7	PEL SC4(1) (5)	Letter of Reprimand
Tank found to have no water or air supply	Fish	12	PEL SC4(1)	Letter of Reprimand
Animals unintentionally left without food for 24 hours	Mouse	28	PEL SC4(1)	Inspector advice
Animal's tail trapped in cage and damaged, necessitating euthanasia	Rat	1	PEL SC4(1), PIL SC1	Letters of Reprimand
Schedule 1 procedure carried out without appropriate training or authority	Mouse	62	ASPA 2	Inspector advice
Upon delivery, transport box fell to the ground resulting in death of some animals	Mouse	6	PEL SC4(6)	Letter of Reprimand
Unauthorised blood sample taken	Rat	4	PIL SC1	Inspector advice
Animal swallowed an oral gavage needle; unauthorised procedure performed to retrieve it	Mouse	1	PIL SC2	Inspector advice
Animal's tail tip was momentarily trapped in the cage door after having a training telemetry jacket removed	NHP	1	PEL SC4(1)	Inspector advice
Missing animal found alive in a waste bag within the cage wash area; animal was euthanised	Mouse	1	PEL SC4(1)	Letter of Reprimand
Froglets escaped from their tank when it overfilled/overflowed	Frog/ Xenopus	26	PEL SC4(1)	Letter of Reprimand
Animal was found dead, with its tail trapped between the lid and base of the cage	Mouse	2	PEL SC4(1)	Letter of Reprimand
Animals not monitored as required by PPL controls	Mouse	1	PIL SC2	Inspector advice

Description	Animal type involved	Number of animals involved	Section of ASPA or SC breached	Action taken by regulator
Incorrect water accidentally added to tanks containing fish, resulting in 15 deaths	Fish	36	PEL SC4(1)	Letter of Reprimand
Moribund mouse pups were found in cages in the cagewash area, without the dam	Mouse	4	PEL SC4(1)	Letter of Reprimand
Animal found with tail trapped in lid of cage	Mouse	1	PIL SC2	Inspector advice
Animal sustained thermal injury while on a faulty heat mat	Rat	1	PEL SC4(4)	Inspector advice
Administrative errors led to protected animals not receiving adequate care	Fish	5	PEL SC4(1)	Inspector advice
Inappetence in animal not noted early enough, resulting in malnutrition and emaciation	Rabbit	1	PEL SC4(1) (5)	Letter of Reprimand
Fish accidentally left in tank at end of a study	Fish	1	PIL SC2	Inspector advice
Animal accidentally left in transfer box for 7 days (with food/water gel)	Mouse	1	PEL SC4(1)	Inspector advice
PIL holders had not completed the competency assessments before procedure undertaken	Rat	6	PPL SC6, PIL SC17	Inspector advice
Animal sustained injury from cage water hopper	NHP	1	PEL SC4(4)	Letter of Reprimand

Table A3: Failure to provide food/water

		Number	Section of	
Description	Animal type involved	of animals involved	ASPA or SC breached	Action taken by regulator
Animals were without water, period of time uncertain but up to 5 days	Mouse	2	PEL SC4(3)	Letter of Reprimand
Animals without food in cage for 3 days	Mouse	2	PEL SC4(3)	Letter of Reprimand
Water bag nozzle for cage became blocked with bedding resulting in dehydration in animals	Mouse	2	PEL SC4(1) (3)(5)	Inspector advice
Animals were without food for approximately 40 hours, which daily checks failed to detect	Mouse	2	PEL SC4(3) (5)	Inspector advice
Animals were without food for approximately 40 hours	Rat	7	PEL SC4(3)	Inspector advice
Animals were without food and water	Bat	2	PEL SC4(3)	Letter of Reprimand
Animals were without food for 42 hours, which was missed by daily checks	Mouse	5	PEL SC4(3) (5)	Inspector advice
Animals were without food	Bat	3	PEL SC4(3)	Letter of Reprimand
Animals without food overnight, as agreed processes were not followed by PIL	NHP	2	PIL SC2	Inspector advice

Table A4: Failure to have appropriate personal licence (PIL) authority

Description	Animal type involved	Number of animals involved	Section of ASPA or SC breached	Action taken by regulator
Procedure carried out on species without PIL authority	Guinea pig	13	ASPA 3(a), PIL SC19	Inspector advice
Animals mistakenly given additional dose of hormone	Mouse	3	PIL SC1	Inspector advice
Procedure carried out by a non-licensee	Mouse	1	ASPA 3(a), PEL SC20	Inspector advice
Animal killed by a non-approved Schedule 1 method	Mouse	12	ASPA 3(b)	Inspector advice
PIL holder did not have licence authority to perform procedures on species	Fish	3	ASPA 3(a), PIL SC19	Inspector advice
Regulated procedures carried out without PIL authority	Cattle	63	ASPA 3(a), PIL SC19	Inspector advice
Regulated procedures carried out without correct PIL authority	Mouse	12	PEL SC20, PIL SC19	Inspector advice
Licensee conducted regulated procedures in animals without relevant PIL authority	Mouse	739	PEL SC20, PIL SC19	Inspector advice
Regulated procedure performed without appropriate PIL authority	Mouse	3	ASPA 3(a)	Inspector advice
Regulated procedures performed without the necessary PIL authority (species not authorised)	Rat	14	ASPA 3(a), PIL SC19	Inspector advice
Regulated procedures performed without the PIL authority (intraperitoneal injections)	Mouse	2	ASPA 3(a)	Inspector advice

## Table A5: Unauthorised location: Performing procedures or keeping animals in area not specified on PEL

Description	Animal type involved	Number of animals involved	Section of ASPA or SC breached	Action taken by regulator
Animal left in room not authorised for overnight holding and without water	Mouse	1	PEL SC13, PIL SC2	Inspector advice
Animals underwent a minor surgical procedure in room not approved on the PEL for aseptic surgery; plus one PIL holder did not have the correct PIL authorisation	Mouse	56	ASPA 3(a), PEL SC13	Inspector advice

## **Table A6: Inadequate PEL records**

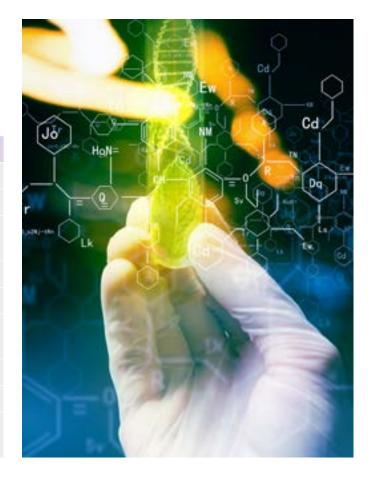
Description	Animal type involved	Number of animals involved	Section of ASPA or SC breached	Action taken by regulator
Administrative issues identified at facilities audit; neither directly impacted animal welfare	n/a	n/a	PEL SC2, 13, 15	Inspector advice
At audit, it was discovered that there was no Killing Register	n/a	n/a	PEL SC2	Inspector advice

## Annex B

## Reporting period of 1 January 24 to 31 December 2024

## Table B1: Licence applications and amendments, 2024

	Totals
PILs <sup>1</sup> granted	2,164
PILs amended	738
PILs in force at 31 December 2024	13,311
PELs <sup>2</sup> granted	2
PELs amended	3,440
PELs in force at 31 December 2024	134
PPLs³ granted	472
PPLs amended	905
PPLs in force at 31 December 2024	2,315

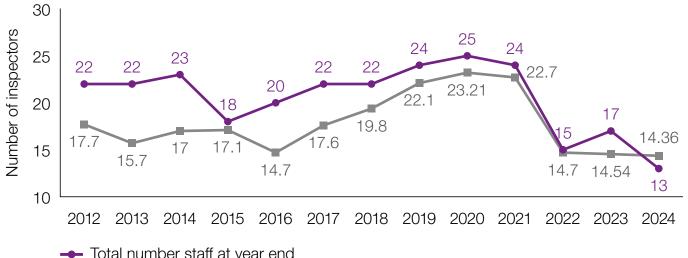


#### Notes:

1,2,3. The numbers here relate to the Glossary on page 30.

## Reporting period of 1 January 24 to 31 December 2024

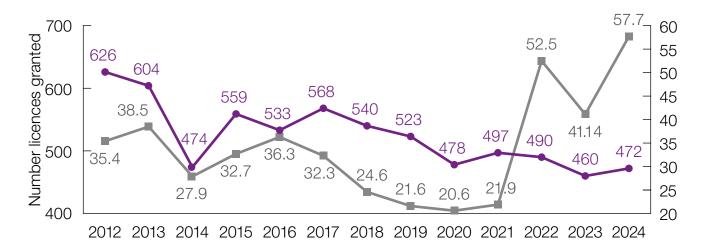
Table B2: Inspectorate staff years, ending March 2011 to 2024



- Total number staff at year end
- Average FTEs through year

Note: FTE = full-time equivalent averaged across the year

Table B3: Project licences granted, years ending March 2011 to 2024



- Licences granted (total)
- Licences granted (per inspector FTE)