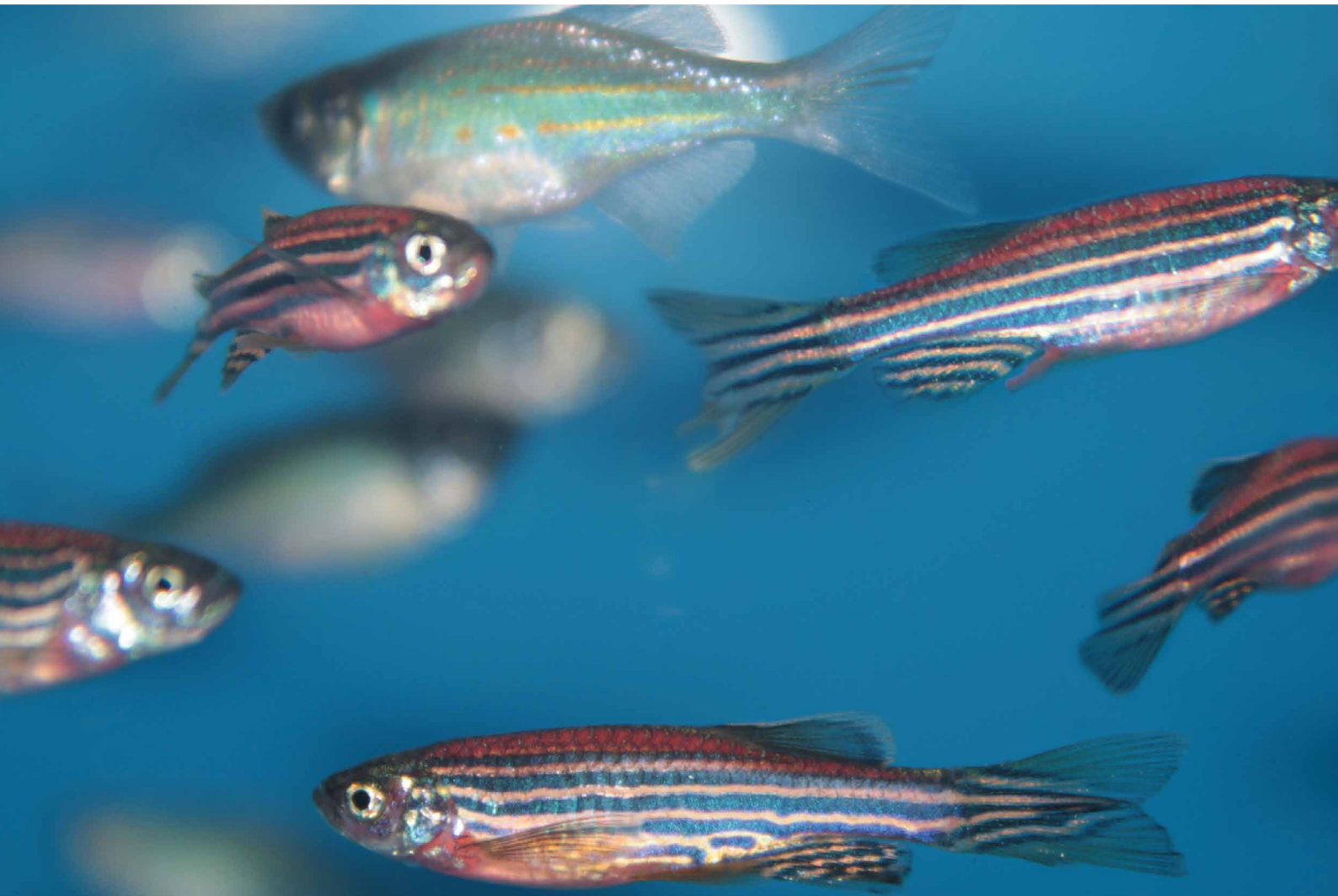




Home Office

Animals in Science Regulation Unit

Annual report 2023



Published December 2024



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Contents

Foreword	3	Section 5: Audit	18
		Audit approach	18
Section 1: The Animals in Science Regulation Unit	4	Description of audit types	19
Introduction	4	Number of audits	20
Licensing function	4	Audit reports	20
Compliance assurance function	6	Risk management	20
Processes and standards function	7	Investigating allegations made to ASRU	20
Business support function	7		
Section 2: Regulatory Reform Programme	8	Section 6: Management of non-compliance	21
Background	8	Compliance policy	21
Regulatory reform in 2023	10	Potential remedies for non-compliance	22
		Summary of non-compliance cases in 2023	24
Section 3: Stakeholder engagement	11	Number and type of animals	25
Stakeholder engagement framework	11	Adverse welfare outcomes	26
Stakeholder meetings	13	Remedies	27
Relationship management	13	Trends in non-compliance cases over time	28
Publications	14	Key learnings from 2023 non-compliance cases	29
Correspondence	14		
Section 4: Licensing	15	Section 7: Standard Condition 18	31
The framework	15		
Licensing activities	16	Section 8: Financial Report – income and expenditure for 2023	32
Animals in Scientific Procedures		Financial Report	32
e-Licensing	16	ASRU income and expenditure for the years 2020-21, 2021-22, 2022-23 and 2023-24	33
The Animals in Science Committee (ASC)	17	Fee income	33
		Expenditure	34

Annex A: Non-compliance cases	36
Failure to comply with PPL authorities	36
Failure to provide adequate care	41
Failure to provide food/water	47
Failure to have the appropriate personal licence (PIL) authority	49
Unauthorised location: Performing procedures or keeping animals in area not specified on PEL	50
Annex B: Tables and figures	51

Foreword

UK life sciences research delivers critical scientific and health benefits to humans, animals and the environment, making vital contributions to healthcare, economic growth and innovation. Some of this research requires the use of animals, and it is essential that we provide protections to those animals. It is also crucial to maintain and build public confidence that where animals are used in scientific research, that their use is fully justified. The Animals in Science Regulation Unit (ASRU) assures 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. ASRU 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, alongside maintaining compliance with the Animals (Scientific Procedures) Act 1986 (ASPAs).

ASRU implemented several business improvements throughout 2023, demonstrating ongoing commitment to continuous improvement and effective regulatory delivery. These include improvements to the Standard Condition 18 process and audit report process.

2023 also marked the continuation of the animals in science regulatory reform programme which included a review of ASRU's operating model, aiming to strengthen how we deliver our purpose while providing quality regulatory services. Further improvements are expected to be implemented in 2024 and 2025.



The on-site audit programme continued and audit reports for establishments were further improved following feedback, aimed to strengthen the systems in place to protect animals at establishments and improve compliance with ASPAs.

We look forward to making more improvements to our operating model through regulatory reform in 2024, and beyond, to deliver our purpose of protecting animals in science by maintaining compliance with ASPAs.

A handwritten signature in blue ink that reads "K. Chandler".

Kate Chandler,
Head of the Animals in Science Regulation Unit

Section 1: The Animals in Science Regulation Unit

Introduction

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

ASRU regulates the use of animals in science according to ASPA. ASPA is UK law, approved by Parliament, which permits the use of animals in scientific research and provides the restrictions around which animals can be used and for what purpose. 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 needed
- 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:

- advising on the regulation
- operating the licensing system required by ASPA
- assuring the compliance of licence holders with ASPA and the terms and conditions of their licences

ASRU delivers these responsibilities through its licensing and compliance assurance functions, supported by additional functions delivering business support and overseeing processes and standards. As of 31 December 2023, 35.32 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 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), which 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) which 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 an establishment licence.

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

The principles of replacement, reduction and refinement (the 3Rs) as set out by the NC3Rs:¹

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 as a consequence 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 so as 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 exploiting the latest in vivo technologies to minimise pain, suffering and distress and improve understanding of the impact of welfare on scientific outcomes.

How the 3Rs are applied

Personal licence holders' responsibilities for the 3Rs:

- The responsibilities conferred on PIL holders through standard licence conditions include the requirement 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).

¹ <https://nc3rs.org.uk/who-we-are/3rs>

Establishment licence holders' responsibilities for the 3Rs:

- The first Standard Condition of the establishment licence 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 2023, the licensing functions work included:

- issuing establishment, personal and project licences, and amending these
- providing regulatory advice to licensed establishments
- maintaining ASRUs e-licensing system, ASPeL (Animals in Scientific Procedures e-Licensing)

As of 31 December 2023, the licensing function of ASRU comprised of one FTE senior leader, 11.18 FTE inspectors, three FTE executive officers and two FTE administration officers.

Compliance assurance function

The compliance assurance function delivers all activities which provides oversight and assurance to the public of licence holders' compliance with ASPA and their licence conditions.

In 2023, the compliance assurance functions work included:

- investigating potential non-compliance cases and the proportionate application of sanctions, as described in the published compliance policy
- managing the delivery of the 2023 audit programme undertaken by ASRU
- reviewing reports submitted to evidence compliance, such as Standard Condition 18 and other reporting requirements required by a specific licence
- responding to compliance assurance related regulatory advice queries

As of 31 December 2023, the compliance assurance function of ASRU comprised of one FTE senior leader, 4.60 FTE inspectors, one FTE senior executive officer, one FTE higher executive officer and three FTE executive officers.

Processes and standards function

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

In 2023, the process and standards function work included:

- mapping out internal process for all ASRU business activities
- monitoring and maintaining procedural documents
- monitoring published regulatory guidance and advice

As of 31 December 2023, the processes and standards function of ASRU comprised of two FTE members of staff.

Business support function

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

In 2023, the business support functions 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 return of procedures for the publication of the annual statistics

- managing procurement and all financial activities
- collecting annual licence fees

As of 31 December 2023, the Business Support function of ASRU comprised of one FTE senior leader and 1.54 FTE executive officers.



Section 2: Regulatory Reform Programme

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 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
- greater efficiency

The initial reform programme has delivered:

1. The creation of a separate animals in science policy function against which the regulator is structurally aligned.

In April 2022, the Animals in Science Regulation Policy Unit was established in the Home Office, as a separate entity from ASRU. The Policy Unit advises ministers on policy relating to regulating the use of animals in science, principally under ASPA.

More widely, a range of policies and legislation led by other government departments influence the use of animals in scientific procedures, and therefore the work of ASRU. These range from regulatory safety testing requirements to the funding of scientific research. The table below outlines the key departments that influence the use of animals in science and their areas of responsibility.

Department	Areas of responsibility
Home Office	Regulation of the use of animals in science under ASPA, including licensing and compliance. Policy of regulation of animals in science.
Department for Science, Innovation and Technology	Policy on the development and validation of alternatives that cause less harm or do not use animals (under ASPA section 20B). Government funding for alternatives (through UK Research and Innovation and the National Centre for the 3Rs (NC3Rs)). Funding for basic and applied research. Public attitudes to animal research survey. Strategic support to the life sciences sector to promote research, innovation and the use of technology to improve health and care.
Department for Environment, Food & Rural Affairs	Protection of the natural environment. Chemical regulation (REACH). Precision breeding. Health and preservation of species. Veterinary medicine. Animal welfare standards (excluding animals in science) and sentience.
Department for Health and Social Care	Medicines and healthcare products policy and regulation. Higher education and training for surgeons.
Department for Business and Trade	Product safety and standards. Cosmetic regulations.

2. Changes to ASRU's operating model to align with leading practice.

In July 2021, ASRU made changes to 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. 'Bridging Ways of Working' was embedded in ASRU throughout 2022.

In 2022, the regulatory reform programme paused to gather feedback from establishments and the wider sector, and to consolidate new processes and develop the Policy Unit.

Further details on the regulatory reform programme changes in 2021 and 2022 can be found in the 2022 annual report.

Regulatory reform in 2023

Regulatory reform was reinitiated in May 2023 to further bolster the regulator's ability to employ best practice standards to effectively achieve its purpose of protecting animals used in science. In addition, reform was aimed at adopting best practice standards to enable the regulator to best deliver for the science sector, in order to facilitate the benefits of scientific progress. Reform considerations aimed to increase resilience and flexibility to future-proof the organisation, setting it up for long-term success.

In 2023, ASRU undertook a comprehensive exercise to review its operating model and organisational design. ASRU identified and designed where further improvements could be made to enhance effective regulatory delivery. This included consideration of ASRU's licensing, compliance assurance and guidance functions, as well as ASRU culture and broader internal systems, against requirements of robustness, proportionality and efficiency. Further, the review included a focus on enhancing transparency and accessibility of information to make it as simple and straightforward as possible to understand how animals should be protected according to the law, thereby improving animal protections and removing unnecessary complexity for the regulated community.

A review of the operating model and organisational design was intended to ensure that ASRU has the right skills and structures to effectively deliver its purpose in the context of scientific advances and an increasingly data-driven economy.

Implementation of improvements to ASRU is planned for 2024, following stakeholder engagement where appropriate.

Continuous improvement remains core to ASRU's mode of operation to ensure it continues to deliver high standards for animals, the public and the regulated community into the future.

Section 3: Stakeholder engagement

Stakeholder engagement framework

ASRU engagement with the regulated community addresses the three tiers of requirements:

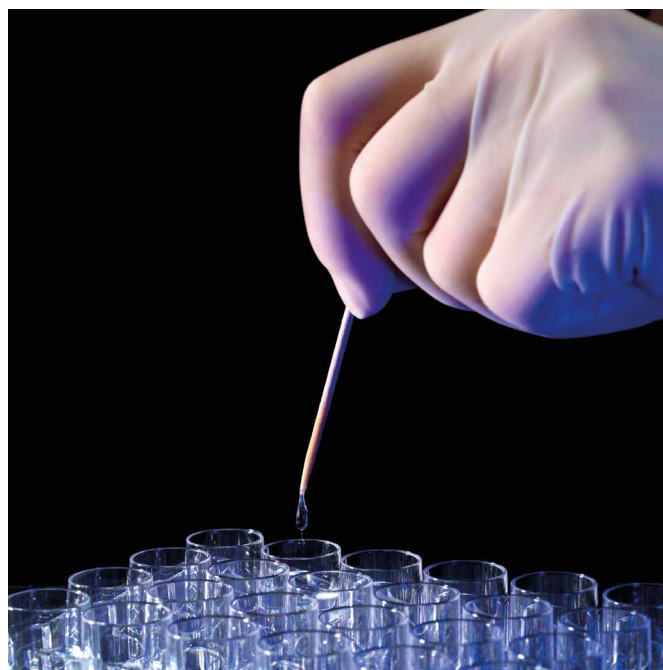
- relationship needs, e.g. establishment service delivery standards
- operational needs, e.g. compliance questions
- strategic needs, e.g. policy implementation

ASRU engagement with the regulated community aims to be:

- focused and clear about outcomes
- differentiated and tailored to the needs of those in the regulated community to ensure value for those we engage with

Overall, the ASRU's engagement with the regulated community is vital to ensure ASRU:

- reviews and issues licences and licence amendments in a consistent and timely way
- reviews compliance of licence holders in a consistent and timely way
- has a forum to inform the regulated community of regulatory changes that impact them
- understands the impact of the regulation on the regulated community
- has a forum to answer questions from the regulated community about the regulation and regulatory delivery



Engagement mechanism(s)	Key areas for engagement	Output of engagement	
Individual establishment engagement for relationship management, customer service and operational delivery.	1. Individual Establishment Discussion with Home Office Liaison Contact (HOLC)/ASRU liaison officer for review or concerns about individual issues. Ad hoc and/or quarterly periodic one-to-one virtual meetings, depending on business requirements.	Meeting expected service standards.	Providing a consistent service.
	2. Individual Establishment Email queries. Queries triaged.	Compliance with ASPA.	Operational – enabling the smooth functioning of the regulatory framework.
All establishment operational engagement.	3. Home Office Liaison, Training and Information Forum (HOLTIF) Providing updates, clarification and information. Three to four times a year.	Improving understanding of regulated community.	Transparency and enabling regulated community to comply.
All establishment strategic engagement.	4. Regulator Engagement Forum ASRU engagement with the Establishment Licence Holders Committee. A representative establishment group for input and review of guidance and service standards. Three to four times a year.	Understanding impact on the regulated community.	Avoiding unnecessary regulatory burdens.

Stakeholder meetings

The Home Office met three times with counterparts in establishments through HOLTIF in 2023. The meetings were an opportunity to discuss service delivery, for ASRU to receive feedback and to solve any associated issues. The main external attendees are the HOLCs, who undertake many of the administrative functions required under ASPA at each establishment, and support licence applicants and existing licence holders. Up to 60 HOLCs attend the HOLTIF and meetings have been held virtually since 2020.

Meetings were chaired by an ASRU senior leader. These meetings were used to update HOLTIF members on the reform programme and operational matters.

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

Relationship management

In 2021, the role of operational relationship management lead (one FTE) was created with the responsibility of engaging with the regulated community in a co-ordinated and centralised way. In addition, the new role of internal and external engagement lead (one FTE) was created. An operational relationship management mailbox was also set up in 2021 and continued to be used through 2023 as a first port of call for stakeholders to contact ASRU, including responding to any complaints. Additional mailboxes were maintained for each function, managing regulatory advice queries and potential reporting of non-compliance.

Publications

In 2023, ASRU published:

- ASRU operational newsletters²
- The Animals in Science Regulation Unit annual report 2022³ and corrections to the 2019 to 2021 annual report⁴
- potential non-compliance notification form⁵
- non-technical summaries and retrospective assessments for projects granted 2019 to 2023⁶

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 the regulation of animals in science.

In 2022, the Policy Unit handled 79 FOI requests, 105 items of ministerial correspondence and 62 other pieces of correspondence.

In 2023, the Policy Unit handled 105 FOI requests, 81 items of ministerial correspondence and 48 other pieces of correspondence.

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
- ASRU's reform programme
- the use of non-animal alternatives in research
- audits of establishments licenced under ASPA

2 [Animals in Science Regulation Unit: newsletters – GOV.UK](#)

3 [Animals in Science Regulation Unit annual report 2022 – GOV.UK](#)

4 [Animals in Science Regulation Unit annual report explanatory note – GOV.UK](#)

5 [Animals in Science Regulation Unit Potential Non-Compliance Notification Form – https://assets.publishing.service.gov.uk/media/662b7e5f5b89e6a356bf931d/Potential_Non-Compliance_Notification_Form_March_2024_final.docx](https://assets.publishing.service.gov.uk/media/662b7e5f5b89e6a356bf931d/Potential_Non-Compliance_Notification_Form_March_2024_final.docx)

6 [Animals in Science Regulation non-technical summaries – GOV.UK](#)

Section 4: Licensing

The framework

Under 'Bridging Ways of Working', the principles, processes and standards used in licence assessment, in accordance with ASPA requirements, remained unchanged.

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). We prioritise licence applications using timelines that are aligned within the statutory timelines as 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/55 days for complex applications
- new PPL amendment review and any returned project amendment review: 40 days

The three-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

ASRU administers and issues the following 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) that qualify the holder to apply regulated procedures to animals specified in the licence

As of 31 December 2023, ASRU licensed and regulated 134 establishments. These establishments include universities, pharmaceutical companies and contract research laboratories. As of 31 December 2023, there were 1,870 active PPLs and 11,504 active PILs.

Licensing activities

Establishment licences

During 2023, one PEL was granted, two were revoked, and 4,480 amendments were made. This includes detailed amendments, changes to Named Person, and approved area changes.

Project licences

During 2023, 460 new PPLs were granted, and 945 amendments were made. This is a slight decrease compared to 2022.

Personal licences

During 2023, 2,336 new PILs were granted, and 740 PIL amendments were made. This is a slight increase compared to 2022. Overall, there are fewer PILs at the end of 2023, compared to 2022.

Animals in Scientific Procedures e-Licensing

In 2019, ASRU rolled out ASPeL, a refreshed digital e-licensing system, to improve:

- consistency
- efficiency
- compliance

The ASPeL system ensures that personal licence and Named Persons holders can easily access the information they need to do their work, reducing 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 continue to be improved and has committed to ongoing development of ASPeL to ensure it continues to meet user needs, both internally and externally. Other improvements have been made in ASPeL, including:

- PILs are visible quickly and easily to licence holders, Named Persons and administrators, enabling them to ensure that appropriate authorisations are held – PIL licensing tasks are also easier for ASRU to administer, and 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
- being able to upload the Harm Benefit Assessment into ASPeL for new PPLs and amendments
- introducing financial and invoicing information for PELs and PILs, which began in January 2022, has provided establishments greater transparency over their financial data
- 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, built in a way that it can be continually improved and upgraded as technology advances
- referrals to the Animals in Science Committee

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 provides independent, balanced and objective advice to the Secretary of State on issues relating to regulating animals in science. At all times, the ASC must consider both the legitimate requirements of science and industry and protecting animals from avoidable suffering and unnecessary use in scientific procedures.

The ASC has a website detailing its activities.⁷

The ASC also advises on specific categories of project licence 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 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'⁸

⁷ [Animals in Science Committee – GOV.UK](#)

⁸ [Home Office Guidance on the use of human material in animals – GOV.UK](#)

Section 5: Audit

Audit approach

The new audit approach was first rolled out in 2021 to 2022 and has continued in 2023 to replace the previous old-style inspection programme.

An audit is a process which 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 the requirements of ASPA and the relevant conditions specified in licences. ASRU advises duty holders on how to comply with ASPA requirements and will enforce non-compliances.

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.

More specifically, 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 Purposes⁹
- 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

⁹ Code of practice for the housing and care of animals bred, supplied or used for scientific purposes – GOV.UK

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 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 2023:

- **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, e.g. facilities audit and on-site licensing assessment work.

The criteria used to assess establishments is published online.¹⁰

Audit activity	Onsite visit duration	Number of inspectors attending
Facilities	1 day	1 to 3 inspectors
Facility assessment for establishment licence amendment	1 day	1 inspector
For cause audit	Minimum 1 day	Minimum 2 inspectors
Dual purpose audits	1 day	1 to 2 inspectors

¹⁰ Animals in Science Regulation Unit Full System Audit Process – 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 2023, ASRU audited 69 establishments. This consisted of 65 facilities audits, three dual purpose audits, and one for-cause audit.

Of these audits, 14 audits were unannounced to the establishments.

The audit programme will be undergoing review in 2024 as part of regulatory reform with implementation of further changes expected in 2025.

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 of a review of the national risk profile and local establishment factors. ASRU undertakes reviews 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

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, including by initiating for-cause audit, if appropriate. 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 6: Management of non-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 is responsible for ensuring 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). 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 and guidance on the operation of the ASPA.

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.

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 five years. All letters are also sent to 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.

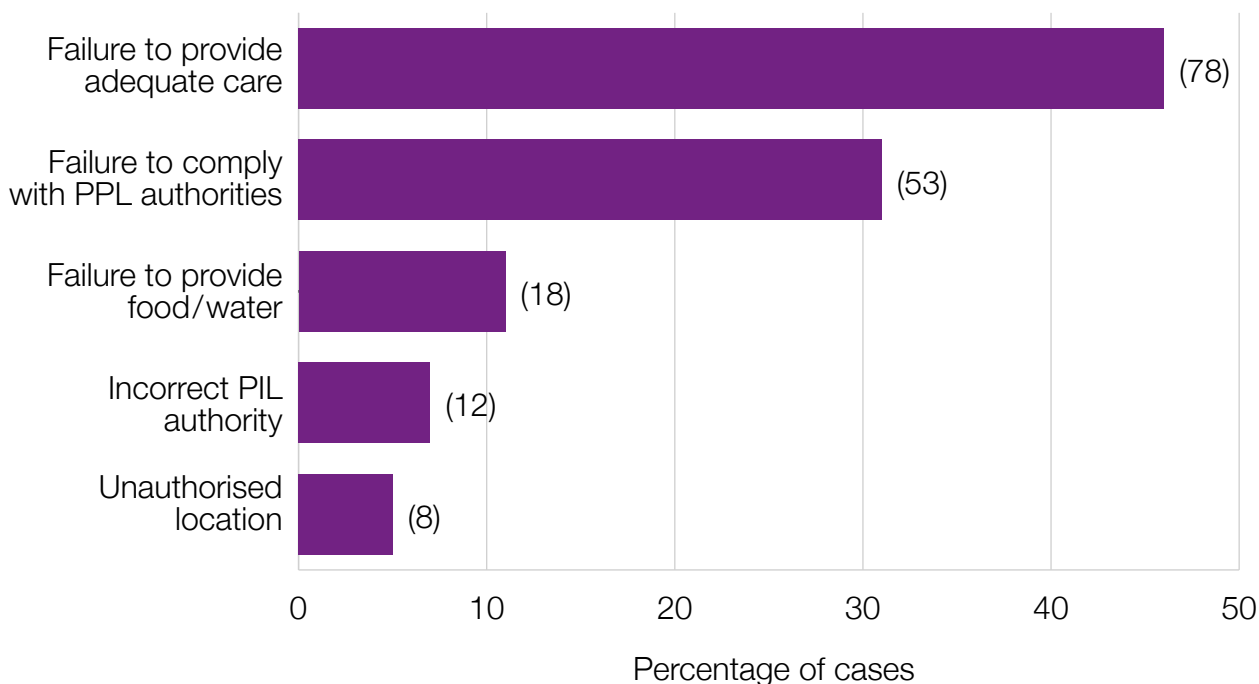
6. Prosecution

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 2023

In 2023, 169 cases of non-compliance, in 48 different establishments, were confirmed and finalised. Of these, 96 (57%) were related to the failure to provide adequate care (including food, water, and suitable facilities) while the other 73 (43%) were related to the failure to have or adhere to licence authorities. See Figure 1, below.

Figure 1: Breakdown of the types of non-compliance



Note: Actual number of remedies in brackets.

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

In 2023, 148 (88%) of the cases closed as confirmed non-compliances were self-reported by establishments as potential non-compliances; 16 (9%) were identified by ASRU from PPL Standard Condition18 reports, three (2%) by the Licensing Team and two (1%) during an audit.

Number and type of animals

In 2023, of the 169 cases of non-compliance, animal numbers were reported in 165 cases. These 165 cases involved a total of 154,904 animals. There are four cases in which the number of animals were not reported. The number of animals reported in the 165 cases, by species is shown in Table 1.

Table 1: Number of animals involved in non-compliance cases, 2023

Animal type	No. of animals
Bird	35
Bird (eggs)	9,140
Dog	6
Ferret	384
Fish	3,052
Guinea pig	2
Hamster	1
Mouse	38,107
NHP	54
Rabbit	980
Rat	102,960
Other	3
Xenopus	180
Total	154,904

Out of the 165 cases, there were two which involved a large number of animals:

- **Case 1:** 102,775 animals were involved – rats (101,231), rabbits (966), mice (578). This occurred due to lack of adherence to project licence authorities. In this case, specifically the number of animals used on the experimental protocol exceeded that authorised by the PPL.
- **Case 2:** 20,000 mice were involved. This occurred due to an air handling unit failure in mice holding rooms which resulted in increased temperature and humidity and likely contributed to 37 animals dying. There were no additional adverse welfare outcomes.

In four cases, the number of animals involved were either not relevant or, not known (as the breach was administrative only). The reasons for this are:

- **For two of the cases:** an administrative breach occurred – no animals were directly involved.
- **For the other two cases:** a breach occurred over a prolonged time-period, e.g. lighting issues in multiple holding rooms.

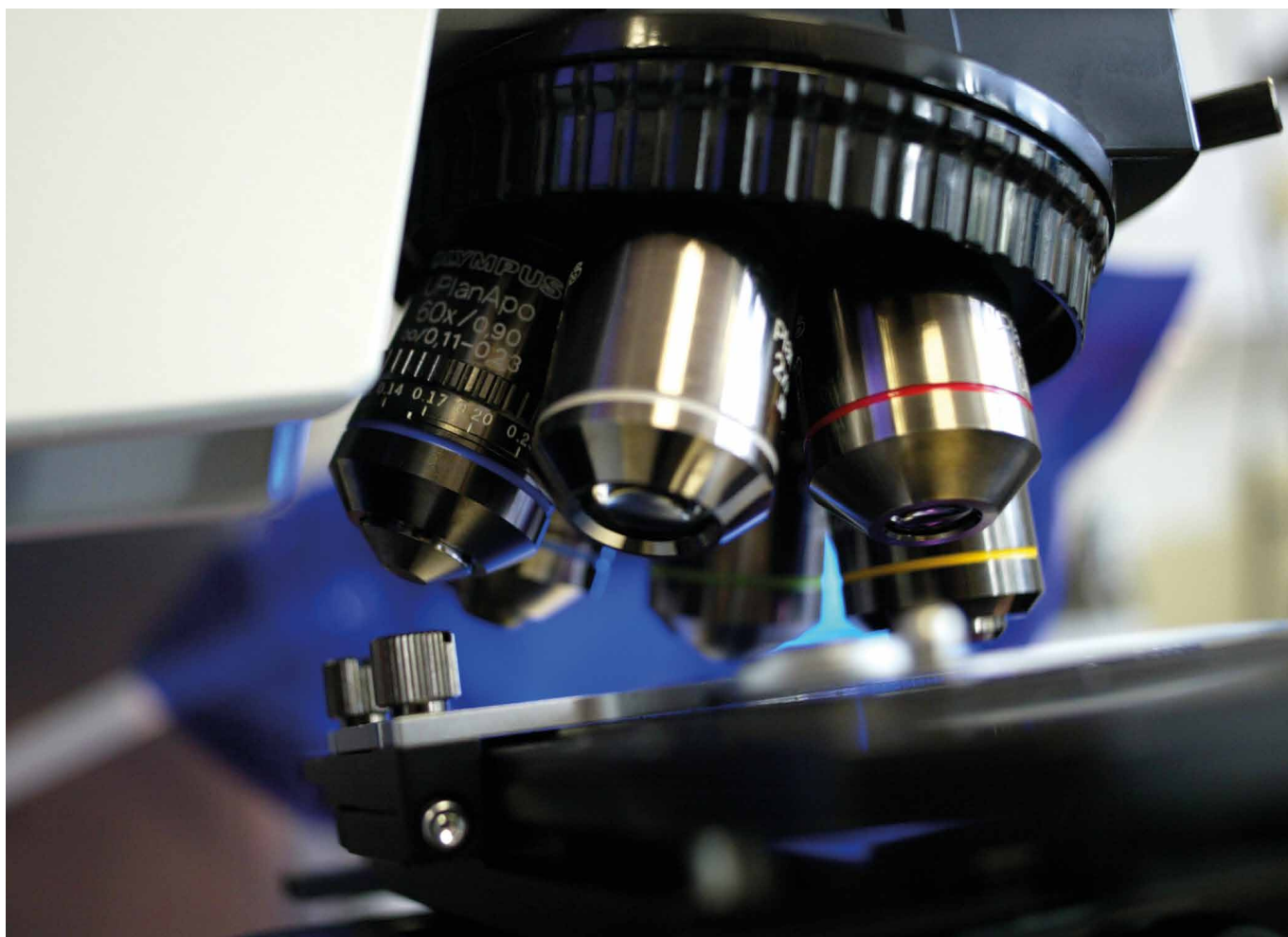
Adverse welfare outcomes

An animal is assessed as experiencing an adverse welfare outcome as the result of a non-compliance if they experienced more pain, distress, suffering or lasting harm than was authorised and which is greater than minor. 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.

In 2023, 553 animals experienced adverse welfare outcomes because of non-compliance (Table 2). There has been an evident reduction of adverse animal welfare cases reported by way of comparison to the cases reported in 2022. In 2022, there were 1,063 adverse animal welfare cases reported which evidences a 47.98% reduction in adverse welfare cases reported in 2023.

Table 2: Number of animals with adverse outcomes by type

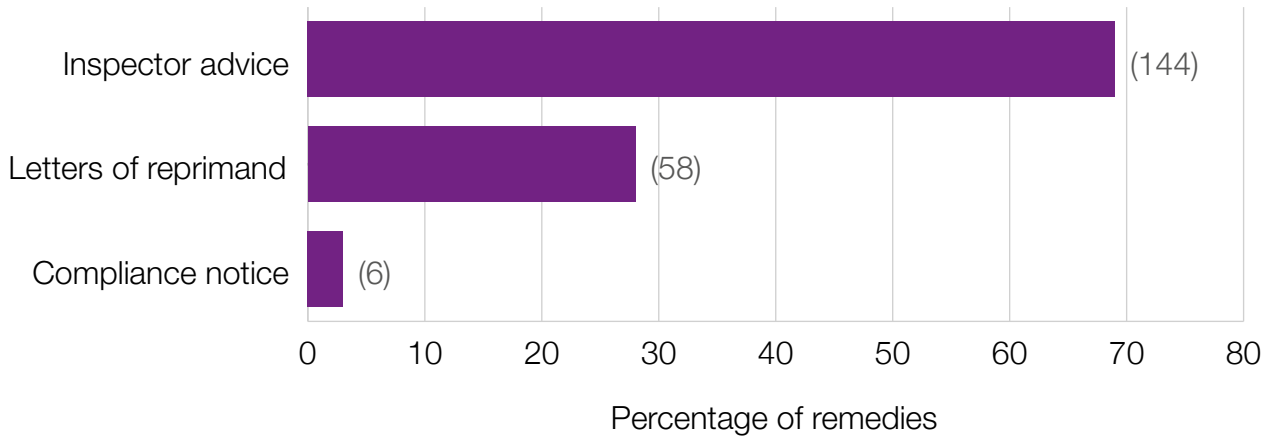
Animal type	No. of animals
Bird	7
Fish	145
Mouse	240
Rat	7
Xenopus	154
Total	553



Remedies

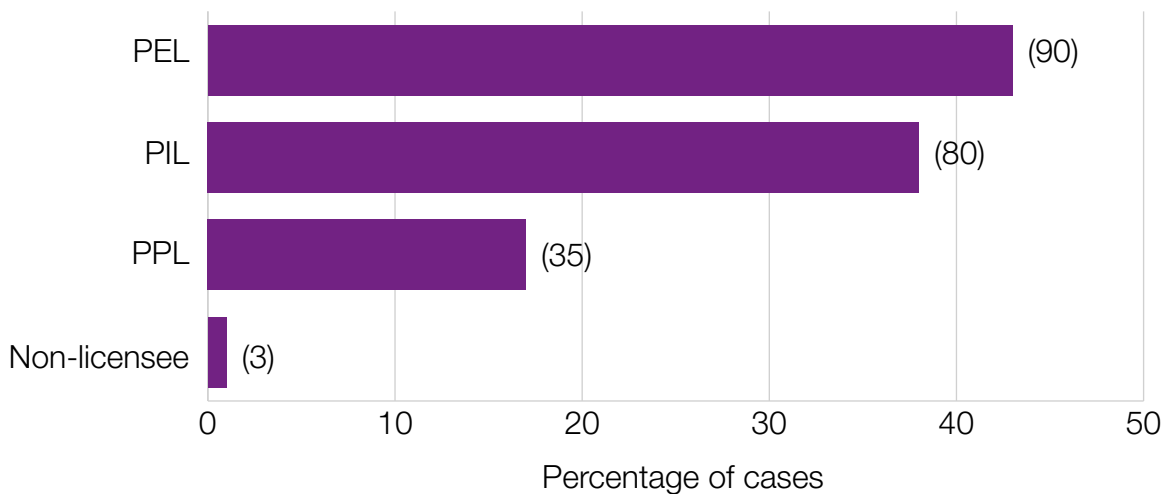
It should be noted that in a single case of non-compliance, there can be several different remedies applied to a variety of individuals. Therefore, the number of remedies is not the same as the number of cases.

Figure 2: Percentage and type of remedies issued



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

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



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

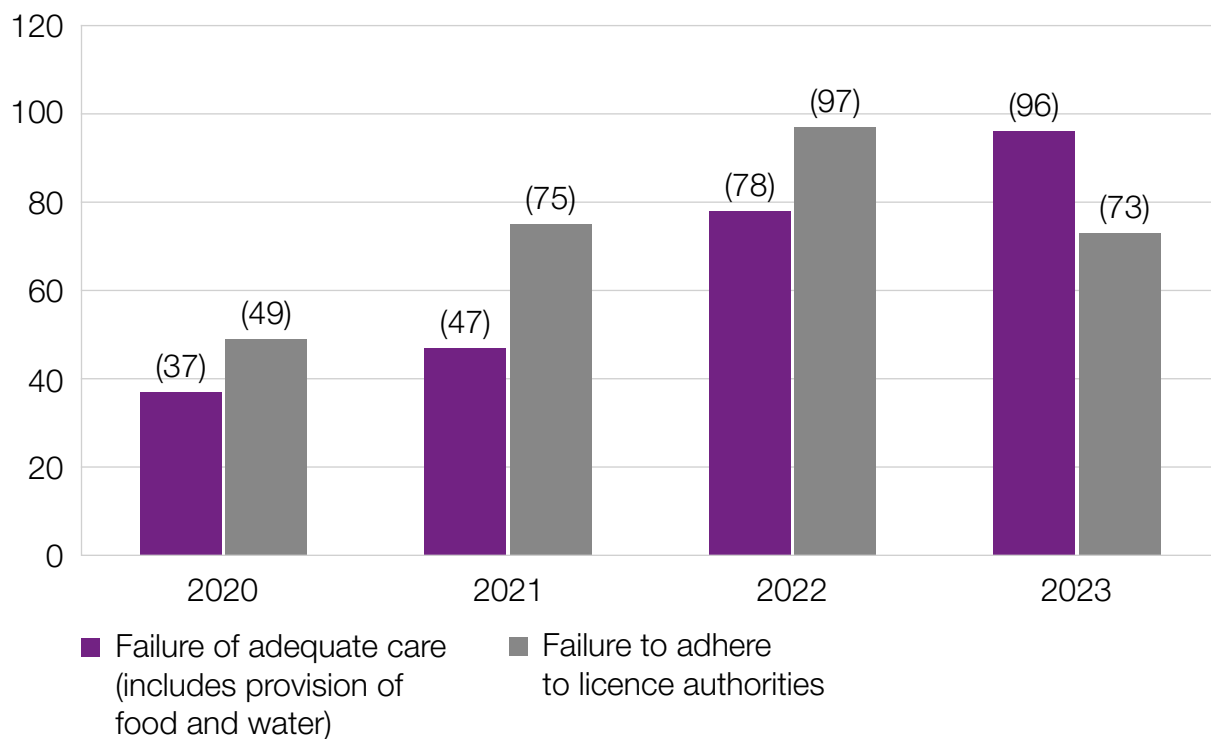
There were 108 cases (64%) for which the sole remedy was inspector advice.

Summaries of all the non-compliance cases completed in 2023 are in Annex A. 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 could identify the establishment

Trends in non-compliance cases over time

Figure 4: Number of non-compliance cases by overarching category by year, 2020 to 2023



Note: Number of cases in each category is shown at the end of each bar in brackets.

The overall number of cases of non-compliance closed in 2023 is comparable with that closed during the previous year (169 and 175, respectively).

Key learnings from 2023 non-compliance cases

Failure to comply with project licence authorities

In 2023, 53 (31%) of the 169 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 PPL 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 2023, there were 78 cases (46%) 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 2023, of the 169 cases of non-compliance, 18 (11%) 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 non-compliance 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 2023, 12 (7%) 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 2023, eight (5%) 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 2023 there were no cases of non-compliance in this category.

Section 7: 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 2023, ASRU received 2,530 Standard Condition 18 reports from establishments.



Section 8: Financial Report – income and expenditure for 2023

Financial Report

Since the year ending 31 March 2015, 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.

Table 3: Summary of income and fee-funded expenditure, by budgeting year, including capital spend, years ending March 2015 to 2024

Year	Income	Expenditure		Variance
		Running budget	Capital ²	
2014-15	£4,380,206	£4,378,929	–	£1,277
2015-16	£4,692,833	£4,207,503	–	£485,330
2016-17	£4,482,578	£4,467,404	–	£15,174 ¹
2017-18	£4,421,361	£4,777,455	–	£356,094
2018-19	£4,752,912	£4,579,303	£1,625,492 ³	£173,609
2019-20	£4,943,224	£4,947,844	£1,800,230 ⁴	(£4,620)
2020-21	£5,012,744	£5,408,987	–	(£396,243)
2021-22	£5,067,060	£5,163,588	(£100,992) ⁵	(£86,528) ⁶
2022-23	£4,729,602	£4,829,571	–	(£99,969)
2023-24	£4,725,171	£5,391,009	–	(£665,838)

Notes:

Some figures given above may be different to previously reported figures. This is due to final costs landing as financial year closes and all accounting activities are recorded.

- 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.
- 6 This figure was previously reported as (£96,528), this was due to an administrative error.

ASRU income and expenditure for the years 2020-21, 2021-22, 2022-23 and 2023-24

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, ASRU 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.

In 2022 to 2023, ASRU had a delegated budget from the Home Office in anticipation of the fee income of £4.72 million; by the close of the year ASRU remained within 2.11% of the assigned budget.

In 2023 to 2024, ASRU had a delegated budget from the Home Office in anticipation of the fee income of £4.72 million; by the close of the year ASRU remained within 14% 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.

Table 4: Annual licence fees, years ending March 2015 to 2024

Annual fee ¹	2015-18	2018-19	2019-20	2020-24
Personal licence	£242	£257	£275	£299
Establishment licence	£631	£757	£826	£915

Notes:

- 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 2023 is collected in the following year.

The 2023 to 2024 fees have remained the same as 2022 to 2023.

Expenditure

Details of the expenditure for years ending March 2021, 2022, 2023 and 2024 are shown in Table 5.

Table 5: Summary of expenditure by budgeting year, years ending March 2021 to 2024

Category	2020-21	2021-22	2022-23	2023-24
Pay and recharges	£3,397,001	£3,187,412	£2,775,603	£3,355,614
Consultancy	–	(£45)	–	£716,508
Travel	£7,742	£29,933	£27,327	£23,499
Office supplies	£4,593	£6,888	£8,437	£12,378
Training and recruitment	(£3,626)	£13,696	£17,018	£15,190
Conferences	(£1,545)	(£29)	£31,755	£16,676
Estates	£56,903	£1,771	£214	£10
IT and comms	£1,231,632	£775,639	£793,171	£177,208
Marketing	£719	(£719)	£5,353	–
Legal	£12,143	£14,453	£869	£6,682
Special payments	–	–	–	–
Other	£3,427	£8,034	£113,207	£10,627
Direct costs	£4,708,987	£4,037,032	£3,772,954	£4,334,392
Overheads	£700,000	£516,556	£456,617	£456,617
Expenditure total	£5,408,987	£4,553,588	£4,229,571	£4,791,009
Depreciation	–	£600,000	£600,000	£600,000
Income	(£4,913,145)	(£5,067,060)	(£4,729,602)	(£4,725,171)
Variance	£204,158	(£86,528)	(£99,969)	(£665,838)

Notes:

Some figures given above may be different to previously reported figures. This is due to final costs landing as financial year closes and all accounting activities are recorded.

- 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.
- In 2022 to 2023, approximately £2.77 million of the total pay costs were salary costs, of which £369,273 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 support. ASRU salary costs decreased in 2022 to 2023 as a result of a previous recruitment freeze and as a result ASRU carried up to 15% vacancies.

- In 2023 to 2024, total pay costs increased in line with recruitment. Additionally, the legacy e-licensing system (ASPeL) hosting and support services was brought in house and costs were re-charged to ASRU as staff payroll costs.
- 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.
- The majority of IT and telecommunication costs for 2020 to 2021, 2021 to 2022 and 2022 to 2023 include the hosting and support of the legacy e-licensing system (ASPeL).
- In 2023 to 2024, the hosting and support of the legacy e-licensing system (ASPeL) was brought in house and accounted as payroll costs.
- 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, travel costs increased due to the easements of COVID-19 restrictions.
- In 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.
- Training costs in 2020 to 2021 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 four 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.
- From 2021 to 2022 and 2022 to 2023 training was aligned with the requirements of the change programme and the requirements of a regulator aligned to the Regulators Code.
- In 2023 to 2024 training was aligned with the requirements of the Regulatory Programme and the Regulators Code.
- Legal costs in 2021 to 2022 and 2022 to 2023 included the costs of handling appeals against licensing decisions taken.
- 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.
- 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 five years.
- In 2023 to 2024, ASRU commissioned out work to external consultants to design a new operating model and advise on organisational design.

Annex A: Non-compliance cases

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

Failure to comply with PPL authorities

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached	Regulator action taken
Zebrafish kept alive longer than the 18 months authorised on the PPL.	Fish	20	PPL SC 1	Inspector advice
Animals not monitored as required by PPL; four found dead and another 16 euthanised.	Mouse	20	PIL SC 2 and 19	Letter of reprimand
Animals used for behavioural testing not authorised by the PPL protocol they were under.	Mouse	30	PPL SC 1, PIL SC 19	Inspector advice x2
Reports required by the additional PPL condition were not submitted in the timeframe required.		n/a	PPL additional condition	Inspector advice
PPL expired with animals still held on the licence.	Rat	24	PPL SC 1	Inspector advice
Irradiation of older animals than authorised (n=5) and others kept alive longer than authorised by the PPL (n=209).	Mouse	214	ASPA 3(b), PPL SC 1	Inspector advice x2

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached	Regulator action taken
Number of animals used on experimental protocol exceeded that authorised by the PPL.	Mouse	84	PPL SC 1	Inspector advice
Animals were administered larger volume, by intramuscular injection, than authorised by the PPL.	Rat	3	ASPA 3(b)	Inspector advice
Procedure performed which was not authorised by the PPL.	Rat	38	ASPA 3(b), PIL SC 19	Inspector advice
Animals re-used, which was not authorised by the PPL.	Mouse	3	ASPA 14, PIL SC 19	Inspector advice
Number of animals used on experimental protocol exceeded that authorised by the PPL.	Mouse	1,236	PPL SC 1	Letter of reprimand
Animal exceeded age authorised by PPL.	Mouse	1	PPL SC 1	Inspector advice
Animal not weighed adequately post-surgery and exceeded weight loss humane end-point.	Mouse	1	PIL SC 2	Inspector advice
Number of animals used on experimental protocol exceeded that authorised by the PPL.	Rat	1,378	PPL SC 1	Inspector advice
Number of animals used on experimental protocol exceeded that authorised by the PPL.	Rat	103	PPL SC 1	Inspector advice
Volume of blood sampling exceeded volume authorised by the PPL.	Rat	6	PPL SC 1, PIL SC 19	Inspector advice x4
Animals exceeded age limit authorised by the PPL.	Fish	60	PPL SC 1	Inspector advice
Animals injected twice, where only once was authorised by the PPL.	Xenopus	2	ASPA 3(b)	Inspector advice
Animals, over a prolonged period of time, underwent an additional anaesthesia for pre-surgical preparation, which was not authorised by the PPL.	Mouse	unknown	ASPA 3(b), PIL SC 19	Inspector advice
Animals experienced an unnecessary regulated procedure; mydriatic eye drops applied in error.	Rat	6	PPL SC 1	Inspector advice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached	Regulator action taken
Regulated procedure undertaken that was not authorised by the project licence.	Mouse	30	ASPA 3(b), PIL SC 19	Inspector advice
Number of animals used on mild severity breeding protocol exceeded that authorised by the PPL.	Mouse	879	PPL SC 1	Inspector advice
Regulated procedure undertaken that was not authorised by the project licence.	Mouse	4	PIL SC 2 and 19	Inspector advice x2
Appropriate action was not taken when the humane endpoint specified on the PPL was reached.	Hamster	1	PPL SC 1 and 18	Inspector advice
Animals experienced unnecessary regulated procedures: oral gavage dosing.	Rat	42	PEL SC 1	Inspector advice
Regulated procedure not performed as specified by the project licence.	Mouse	7	PIL SC 19	Inspector advice
Refinement (as specified in the PPL) to reduce likelihood of adverse effects was not applied, which resulted in adverse effects in one animal.	Rat	3	PIL SC 19	Letter of reprimand
Animals experienced an unnecessary regulated procedure: mydriatic eye drops applied in error.	Rat	40	PEL SC 5	Inspector advice
Substance administered by a route not authorised by the PPL.	Mouse	136	ASPA 3(b), PPL SC 1, PIL SC 19	Inspector advice x7
Animals kept singly housed for 14 weeks, whereas the PPL only authorised 12 weeks.	Mouse	2	PPL SC 1 and 11, PIL SC 19	Inspector advice x2
Number of animals used on breeding and experimental protocols exceeded that authorised by the PPL.	Mouse	1,585	PPL SC 1	Inspector advice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached	Regulator action taken
Monitoring for humane end-points was not performed as specified by the PPL, which led to one animal exceeding the end-point; tumour size.	Mouse	4	PIL SC 2, 14 and 19	Inspector advice
Regulated procedure undertaken that was not authorised by the project licence; suturing non-surgical wound.	Mouse	1	ASPA 3(b), PIL SC 19	Inspector advice
Surgical procedure undertaken that was not authorised by the project licence; attaching probe to skull.	Mouse	1	PPL SC 1, PIL SC 19	Inspector advice x2
Surgical procedure undertaken that was not authorised by the project licence; insertion of second minipump subcutaneously.	Mouse	8	ASPA 3(b), PPL SC 1, PIL SC 19	Inspector advice x2
Animals experienced an unnecessary regulated procedure; substance administered in error.	Mouse	10	PPL SC 4	Inspector advice
Number of animals used on experimental protocols exceeded that authorised by the PPL.	Mouse	3,948	PPL SC 1	Inspector advice
Animals euthanised by a non-schedule 1 regulated procedure and without PPL authority.	Mouse	322	ASPA 3(a) and 3(b), PIL SC 17	Inspector advice x4
Animals administered drug doses for a longer period than authorised by the PPL.	Mouse	9	PPL SC 1, PIL SC 19	Inspector advice
Regulated procedure undertaken that was not authorised by the project licence.	Mouse	3	ASPA 3(b), PEL SC 20, PPL SC 1	Inspector advice x3
Animal exceeded age authorised by PPL.	Fish	100	PPL SC 1, PIL SC 16 and 19	Inspector advice x2
Number of animals used on experimental protocols significantly exceeded that authorised by the PPL.	Rat, rabbit, mouse	101,231 rats, 966 rabbits, 578 mice	PPL SC 1	Letter of reprimand

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached	Regulator action taken
Number of animals used on experimental protocol exceeded that authorised by the PPL.	Mouse	269	PPL SC 1	Inspector advice x2
Animal not provided with water for the period specified by the PPL.	NHP	1	PPL SC 1, PIL SC 2	Inspector advice x2
Regulated procedure undertaken that was not authorised by the project licence.	Rat	1	ASPA 3(b), PIL SC 19	Inspector advice x2
Animals kept on procedure for longer than authorised by the PPL.	Mouse	4	PPL SC 1, PIL SC 19	Inspector advice
Minor regulated procedure undertaken that was not authorised by the project licence, over a period of 1.5 years. Also, the most refined method was not used.	Mouse	907	PPL SC 1, PIL SC 19	Inspector advice x3
Animals were kept alive with adverse effects that were not authorised by the PPL.	Mouse	9	PPL SC 1 and 23, PIL SC 19	Inspector advice x2
Appropriate action was not taken when the humane endpoint specified on the PPL was reached.	Dog	2	PIL SC 19	Inspector advice
Genetically altered animals undergoing a regulated procedure were found to be pregnant, which was not authorised by the PPL.	Mouse	2	PIL SC 1	Inspector advice
Regulated procedure undertaken that was not authorised by the project licence.	Mouse	19	ASPA 3(b), PPL SC 1, PIL SC 19	Inspector advice x2
PPL authorities not adhered to.	Mouse	16	PIL SC 19	Inspector advice
Regulated procedure not performed as specified by the project licence.	Rabbit	5	PIL SC 19	Inspector advice

Failure to provide adequate care

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached	Regulator action taken
Animals found in dirty cages after cleaning, without food and water.	Mouse	5	PEL SC 4(3), 4(5) and 5	Letter of reprimand
Mouse with trapped tail found dead.	Mouse	1	PEL SC 4(3), 4(5) and 5	Letter of reprimand
Animals reported missing from their cage: may have entered the waste disposal process.	Mouse	3	PEL SC 4(1)	Letter of reprimand
Air handling unit failure resulting in increased temperature and humidity, which likely contributed to 37 animals dying.	Mouse	20,000	PEL SC 4(3) and 4(7)	Letter of reprimand
Animal found with tail trapped and with no access to food.	Mouse	1	PEL SC 4(3) and 4(5)	Letter of reprimand
Animal found with large tumour on hind leg and euthanised.	Mouse	1	PEL SC 4(5)	Inspector advice
Animals (male, female and infants) left outside in external pens overnight without food and water.	NHP	11	PEL SC 4(1), 4(3) and 4(7)	Inspector advice
Lack of cage label observed during audit.	n/a	n/a	PIL SC 16	Inspector advice
Animals found dead after being transported between buildings.	Mouse	5	PIL SC 2	Inspector advice
Animals found dead and others euthanised, due to poor water quality.	Fish	80	PEL SC 4(1) and 4(3)	Letter of reprimand
Animals housed in pens which did not comply with the Code of Practice.	Dog	4	PEL SC 4(2) and 4(7)	Inspector advice
Non-compliance of facilities and 'killing register' found during facilities audit.	n/a	n/a	PEL SC 2, 4(3) and 4(4)	Compliance notice
Fish died or experienced adverse effects due to low water levels.	Fish	14	PIL SC 2	Letter of reprimand
Time switch fault resulted in animals being exposed to continuous light.	Mouse	150	PEL SC 4(7)	Inspector advice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached	Regulator action taken
Animal was euthanised after being found with its tail trapped between the cage and lid.	Mouse	1	PEL SC 4(1)	Letter of reprimand
Two incidents where animals escaped from their cage: they were unharmed.	Rabbit	2	PEL SC 4(1)	Inspector advice
Animal found dead, trapped between ladder and cage floor.	Mouse	1	PIL SC 2	Letter of reprimand
Animals did not receive daily checks, for one day.	Mouse	8	PEL SC 4(5)	Inspector advice
Animal left in cage wash area overnight, in a cage without food and water.	Mouse	1	PEL SC 4(1)	Inspector Advice
Animals found dead, most likely due to contamination of system water with bleach.	Fish	18	PEL SC 4(4)	Inspector advice
Animal found with tail trapped in the lid of cage and euthanised.	Mouse	1	PEL SC 4(5)	Letter of reprimand
Cage not checked for two days, but animal had access to food and water.	Mouse	1	PEL SC 4(5)	Inspector advice
A faulty valve on the automatic watering system caused two cages to flood, which resulted in the deaths of 16 neonatal mice.	Mouse	19	PEL SC 4(1) and 4(4)	Compliance notice
Daily checks failed to detect an animal that had died.	Mouse	1	PEL SC 4(5)	Inspector advice
A fault with the automatic watering system caused a cage to flood, which resulted in the deaths of 10 neonatal mice and the dam was euthanised.	Mouse	11	PEL SC 4(1) and 4(4)	Letter of reprimand
Animal found dead with malocclusion, which had been missed by daily checks.	Mouse	1	PEL SC 4(5)	Letter of reprimand
Daily checks failed to detect that young animals were unable to access the water supply.	Mouse	5	PEL SC 4(5)	Letter of reprimand
Animal found dead with malocclusion, which had been missed by daily checks.	Mouse	1	PEL SC 4(5)	Letter of reprimand

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached	Regulator action taken
Processes were not followed, leading to the deaths of 20 mice in an overcrowded transport box.	Mouse	30	PEL SC 4(1)	Letter of reprimand
Animal euthanised due to unexpected adverse effects following blood sampling, which had not been performed competently.	Mouse	1	PIL SC 17	Inspector advice
Lack of appropriate care provided by responsible personal licensee for 23 mice and eight pups.	Mouse	31	PIL SC 2	Inspector advice
A piece of bedding became lodged in the automatic watering system nozzle, which caused the cage to flood; five neonatal mice died.	Mouse	22	PEL SC 4(1) and 4(4)	Letter of reprimand
Tank lacked a baffle, resulting in fish escaping the tank, of which two died.	Fish	5	PIL SC 2	Letter of reprimand
Daily checks failed to detect an animal that was trapped behind food hopper within the cage.	Mouse	1	PEL SC 4(5)	Letter of reprimand
A faulty valve on the automatic watering system caused a cage to flood, which resulted in the deaths of 17 neonatal mice.	Mouse	20	PEL SC 4(1) and 4(4)	Compliance notice
Tank lacked a baffle, resulting in fish escaping the tank, of which seven died.	Fish	10	PIL SC 2	Letter of reprimand
Animal found dead trapped behind food hopper.	Mouse	1	PEL SC 4(1)	Letter of reprimand
Tail was injured when trapped in cage: animal was euthanised.	Mouse	1	PEL SC 4(1)	Letter of reprimand
A fault with the automatic watering system caused two cages to flood, which resulted in the deaths of 11 neonatal mice.	Mouse	16	PEL SC 4(1) and 4(4)	Letter of reprimand
A fault with the automatic watering system caused a cage to flood, which resulted in five mice being euthanised.	Mouse	5	PEL SC 4(1) and 4(4)	Compliance notice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached	Regulator action taken
A fault with the automatic watering system caused three cages to flood, which resulted in the deaths of three neonatal mice.	Mouse	12	PEL SC 4(1) and 4(4)	Compliance notice
A fault with the automatic watering system caused a cage to flood, which resulted in five mice being euthanised.	Mouse	5	PEL SC 4(1) and 4(4)	Compliance notice
Animals were without food for approximately 26 hours.	Mouse	2	PIL SC 1 and 2	Inspector advice
Tail was injured when trapped in cage; animal was euthanised.	Mouse	1	PEL SC 4(1)	Letter of reprimand
Animals escaped from their cage; they were unharmed.	Rabbit	2	PEL SC 4(1), 4(4) and 4(5)	Letter of reprimand
Incorrect positioning of sealed cage on rack resulted in lack of air flow.	Mouse	4	PEL SC 4(1) and 5	Letter of reprimand
Birds were caught in bags and were accidentally not released; they were found dead four days later.	Bird	7	PEL SC 4(3) and 4(5), PIL SC 2	Letter of reprimand x2
Inadequate monitoring of water quality led to low oxygen levels, which resulted in the deaths of 150 tadpoles/froglets.	Xenopus	173	PEL SC 4(1), 4(3) and 4(5)	Letter of reprimand
Animals escaped from their cage; they were unharmed.	Rabbit	2	PEL SC 4(1), 4(4) and 4(5)	Letter of reprimand
Animal escaped from cage; it was unharmed.	Rabbit	1	PEL SC 4(1), 4(4) and 4(5)	Letter of reprimand
Animal with malocclusion showed clinical signs and was euthanised.	Mouse	1	PEL SC 4(5)	Letter of reprimand
Animals administered with incorrect drugs to induce general anaesthesia, resulting in the death of one mouse and euthanasia of two mice.	Mouse	3	PIL SC 2	Inspector advice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached	Regulator action taken
An animal escaped from its cage; it was unharmed.	Rabbit	1	PEL SC 4(1), 4(4) and 4(5)	Letter of reprimand
Animals in separate area were not checked over the weekend by the PIL delegate; there was no impact on animal welfare.	Mouse	7	PIL SC 2	Inspector advice
Daily checks not performed by a competent person; no harms were incurred.	Mouse	73	PEL SC 4(5)	Inspector advice
Animals not sufficiently monitored during regulated procedure; two animals died.	Rat	2	PIL SC 2	Letter of reprimand
An animal was without food and water for approximately 45 hours, having been inadvertently placed in a waste bin; it was euthanised due to welfare concerns.	Mouse	1	PEL SC 4(5), PIL SC 2	Letter of reprimand x2
Animal found with tail trapped in the lid of cage and euthanised.	Mouse	1	PEL SC 4(1)	Letter of reprimand
Animal found dead after being trapped within the cage between cage wall and food hopper.	Mouse	1	PEL SC 4(1)	Letter of reprimand
Animal found dead after being trapped within the cage between cage wall and food hopper.	Mouse	1	PIL SC 2	Letter of reprimand
Animal found dead with malocclusion, which had been missed by daily checks.	Mouse	1	PEL SC 4(5)	Letter of reprimand
Juvenile fish were found dead, after they had escaped through small gaps in the tank lid,	Fish	10	PEL SC 4(1)	Letter of reprimand
Animals were left within imaging equipment without food, water and appropriate housing for approximately 72 hours; they were euthanised.	Mouse	3	PIL SC 2	Letter of reprimand

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached	Regulator action taken
GA mouse pups produced in error.	Mouse	19	PEL SC 5	Inspector advice
Animal found dead after being trapped within the cage between cage wall and food hopper.	Mouse	1	PEL SC 4(1)	Letter of reprimand
Animals exposed to constant light due to malfunction of the control system.	Mouse, rat	700 mice and 15 rats	PEL SC 4(7)	Inspector advice
Equipment used that was not suitable for the purpose.	Mouse	6	PEL SC 4(4)	Inspector advice
An animal sustained an accidental injury; it was euthanised.	Rat	1	PEL SC 4(4)	Inspector advice
Animals were not killed when the humane end-point was reached and were left in an area not authorised for overnight holding for approximately 69 hours.	Rat	2	PEL SC 4(1), 4(3) and 13	Letter of reprimand
An animal was left outside, in an area not authorised on the PEL, in a disposable cage, overnight; it did not have access to water.	Mouse	1	PEL SC 4(1)	Inspector advice
The baffle at the back of the tank was missing, which led to fish escaping from the tank.	Fish	19	PEL SC 4(1)	Letter of reprimand
Animal found dead trapped between cage wall and food hopper.	Rat	1	PEL SC 4(1) and 4(5)	Letter of reprimand
Temperature fluctuations occurred, resulting from an overnight power failure.	Fish	1,500	PEL SC 4(4)	Inspector advice
An animal experienced an unnecessary regulated procedure; intraperitoneal injection.	Mouse	1	PIL SC 1	Inspector advice

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached	Regulator action taken
Tank overflowed due to blocked outlet pipe; four animals were missing, presumed dead (plus, one was found and returned to the tank).	Xenopus	5	PEL SC 4(1), PIL SC 2	Letter of reprimand x2
Animals exposed to constant light due to malfunction of the control system; 48 hours.	Ferret	10	PEL SC 4(1)	Inspector advice
Daily checks did not detect the presence of a litter of animals, until they were adults.	Other	3	PEL SC 4(5)	Inspector advice
A fault with the steam plant led to lower air humidity than appropriate for the animals held.	NHP, mouse, rat, bird	42 NHPs, 3,120 mice, 8 rats, 28 birds	PEL SC 4(3), 4(4) and 4(7)	Inspector advice

Failure to provide food/water

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached	Regulator action taken
Eight incidents where cages containing animals were found with no water valves, so they had no access to water.	Mouse	34	PEL SC 4(3), 4(5) and 5	Letter of reprimand
Animals found dehydrated, due to missing water valve.	Mouse	5	PEL SC 4(3) and 4(5), PIL SC 15	Inspector advice x2
Animal was without for food for more than three days and was euthanised.	Mouse	1	PEL SC 4(1), 4(3) and 4(5)	Letter of reprimand
Animals were without food for 28 hours.	Rat	3	PEL SC 4(3) and 4(5)	Inspector advice
Animals were left without water overnight.	Mouse	10	PEL SC 4(3) and 4(5)	Inspector advice
A cage of animals was not provided with food for 26 hours, which was not detected at two checks.	Rat	3	PEL SC 4(1), 4(3) and 4(5)	Inspector advice
Animals were without water for greater than 24 hours, due to a missing water valve.	Mouse	2	PEL SC 4(3) and 4(5)	Letter of reprimand

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached	Regulator action taken
Animals were without water for four days; one died, the other three recovered.	Mouse	4	PEL SC 4(3) and 4(5)	Letter of reprimand
Animal was without food for 25 hours.	Rat	1	PEL SC 4(3) and 4(5)	Inspector advice
Animals were without water for approximately 24 hours, due to missing valve.	Mouse	2	PEL SC 4(3)	Inspector advice
Animals were without water for approximately 2.5 days; they subsequently recovered.	Mouse	2	PEL SC 4(1), 4(3) and 4(5), PIL SC 2	Inspector advice x2
Animals were without food for longer than authorised by the PPL, due to an oversight.	Rat	24	PPL SC 1	Inspector advice
Animals were without food for four days; two were found dead, the third was euthanised.	Mouse	3	PEL SC 4(3) and 4(5)	Letter of reprimand
Animals were without food for five to six days; they were euthanised due to welfare concerns.	Mouse	3	PEL SC 4(3), 4(5) and 5	Letter of reprimand
Animals were without water for approximately 24 hours	Mouse	81	PEL SC 4(3), PIL SC 2	Inspector advice x2
Three mice were without food for 42 hours; they subsequently recovered	Mouse	3	PEL SC 4(3) and 4(5)	Inspector advice
Animals were without food for 4 days; 1 died, the other 3 were euthanised	Mouse	4	PEL SC 4(3) and 4(5)	Letter of reprimand
Animals without food for 19 hours, following regulated procedure	Mouse	3	PIL SC 2	Inspector advice

Failure to have the appropriate personal licence (PIL) authority

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached	Regulator action taken
Regulated procedure performed without PIL authorisation for that species.	Guinea pig	1	ASPA 3(a), PIL SC 19	Inspector advice
Non-licensee performed regulated procedures without PIL authority.	Mouse	4	ASPA 3(a)	Inspector advice
Regulated procedures performed without PIL authority for that species.	Ferret	5	ASPA 3(a), PIL SC 19	Inspector advice
Regulated procedures performed without PIL authority for that species.	Mouse	32	ASPA 3(a), PIL SC 19	Inspector advice
Non-licensee administered intraperitoneal injections to animals without personal licence authority.	Mouse	6	ASPA 3(a)	Inspector advice
Regulated procedures performed without PIL authorisation for that species.	Ferret	369	ASPA 3(a), PIL SC 19	Inspector advice
Regulated procedures on chicken eggs performed with no PIL authority for that species.	Bird (eggs)	8,600	ASPA 3(a), PIL SC 19	Inspector advice x2
Regulated procedure (blood sample) performed, without PIL authority for the species of animal involved.	Rabbit	1	ASPA 3(a)	Inspector advice
Regulated procedures (ear-notching for scientific purpose) performed without PIL authority.	Mouse	5	ASPA 3(a)	Inspector advice
Regulated procedures performed without PIL authority for that species.	Mouse	23	ASPA 3(a), PIL SC 19	Inspector advice
Regulated procedures performed without PIL authority.	Mouse	36	ASPA 3(a), PEL SC 20	Inspector advice x2
Regulated procedures performed without PIL authority.	Fish, mouse	516 fish, 3,168 mice	PEL SC 20, PIL SC 19	Inspector advice x3

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

Description	Animal type involved	Animal numbers involved	Section of ASPA or SC breached	Regulator action taken
Fish larvae underwent regulated procedures in a room not authorised by the establishment licence, over a period of four years.	Fish	700	ASPA 2B(1), PEL SC 13	Inspector advice x2
Fish held in a room not authorised for that species.	Fish	unknown	PEL SC 13	Inspector advice
An animal underwent a surgical procedure in room not approved on the PEL for aseptic surgery.	Rat	1	PEL SC 13	Inspector advice
Regulated activities occurred in rooms not approved on the PEL approved areas schedule.	Rat, mouse	14 rats and 24 mice	PEL SC 13	Inspector advice
Regulated activities occurred in rooms not approved on the PEL approved areas schedule.	Bird (eggs)	540	PEL SC 13	Inspector advice
Animals kept overnight in a room not approved on the PEL approved areas schedule for overnight holding.	Rat	10	PIL SC 2	Inspector advice
Animal kept overnight in a room not approved on the PEL approved areas schedule for overnight holding.	Mouse	1	PIL SC 14	Inspector advice
An animal underwent a surgical procedure in room not approved on the PEL for aseptic surgery.	Guinea pig	1	PEL SC 13	Inspector advice

Annex B: Tables and figures

Table 1: Licence applications and amendments, 2023

	Totals
	2023
PILs granted	2,336
PILs amended	740
PILs in force at year-end	11,504
PELs granted	1
PELs amended	4,480
PELs in force at year-end	134
PPLs granted	460
PPLs amended	945
PPLs in force at year-end	1,870

Notes:

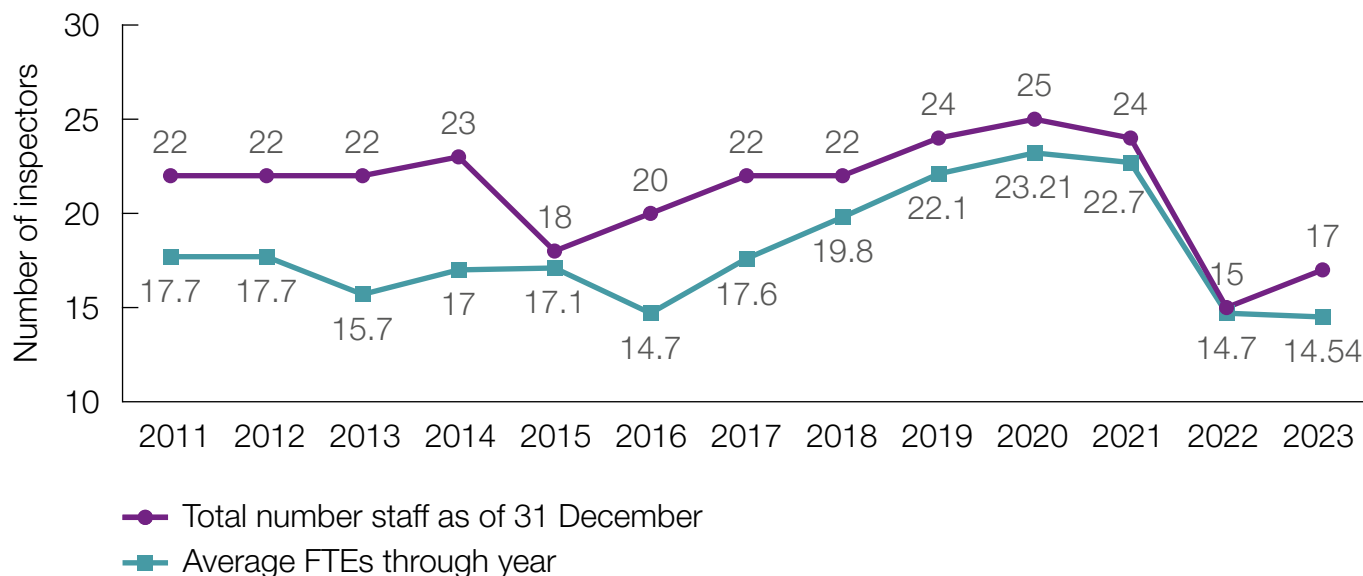
PIL = personal licence.

PEL = establishment licence.

PPL = project licence.

Reporting period is 1 January 2023 to 31 December 2023.

Figure 1: Inspectorate staff 2011 to 2023



Notes:

FTE = full-time equivalent averaged across the year.

Figure 2: Project licences granted 2011 to 2023

