

Transparency in Animal Research – Time to Look at the Bigger Picture

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Abstract

Animal research has been a contentious subject for many decades. Passionate views about animal welfare and ending animal use in research and testing are balanced against the ongoing need for consumer protection, the advancement of medicine, and the speed of scientific innovation.

Transparency in animal research has therefore been difficult to achieve, with stakeholders such as those conducting or regulating animal research being understandably cautious or reluctant to share information with the wider public. Without adequate transparency, it is difficult to understand where and how animals are being used in research and testing. As a result, it is more challenging to determine where gaps in replacing animals with alternative methods lie and if replacement opportunities are being missed.

In the United Kingdom, the Animals (Scientific Procedures) Act 1986 (ASPA 1986)¹ exists to provide protection for animals used in research and testing, and provide protection to those who use animals. It is not designed to further scientific innovation and the development of non-animal methods. ASPA 1986 is, however, the only legal framework that covers the replacement of animal research, through its inclusion of the 3Rs - replacement, reduction, and refinement.² Replacement requires that, wherever possible, a scientifically satisfactory method or testing strategy not entailing the use of protected animals must be used. Replacement by this definition includes not just non-animal approaches, such as *in vitro* cell-based research, computer modelling, or the use of big data sets, but also the use of a spe-

cies not protected by ASPA 1986. Reduction necessitates the use of the fewest number of animals that are scientifically necessary. Refinement is to refine experimental procedures, husbandry, and care of the animals used, to reduce their suffering and improve their welfare.³

Recent evidence from a 2023 National Centre for the 3Rs (NC3Rs) commissioned report 'The role of review and regulatory approvals processes for animal research in supporting implementation of the 3Rs', clearly shows that replacement of animal research is not being reviewed or challenged as it should within the regulatory processes of ASPA 1986.⁴ This is potentially resulting in animal projects being granted licences without sufficient justification for animal use, as opportunities to avoid or replace procedures on animals are being missed.

This article considers how the frameworks of ASPA 1986 could be more robustly implemented to increase transparency around animal research, and some of the barriers that prevent this today. This includes improvements to the 'Annual Statistics of Scientific Procedures on Living Animals in Great Britain' publication, improvements to Non-Technical Summaries (NTS) as part of an animal research project licence application form, and enabling greater analysis of animal research projects by repealing Section 24 of ASPA 1986. We will discuss potential improvements that we have identified as part of our approach at Replacing Animal Research, to strengthen policy around the use of animals in research, particularly areas that could have a considerable impact on transparency. Acknowledging and address-

³ *ibid.*

⁴ Francis Rawle, 'The role of review and regulatory approvals processes for animal research in supporting implementation of the 3Rs' (February 2023) <<https://nc3rs.org.uk/sites/default/files/2023-02/Rawle%20project%20report.pdf>> accessed 25 Jul 2024.

¹ Animals (Scientific Procedures) Act 1986

² Animals (Scientific Procedures) Act 1986, s 2A

ing these issues would improve transparency around decisions to use animals in research, increase public trust, and better inform future work to replace animals.

Introduction

Animal research can be a polarising and emotive subject for many, with varying public opinion around animal welfare and the use of animals in science. Some believe animals should not be used in any research or testing,⁵ whilst others accept or endorse the use of animals as necessary for understanding disease and developing new drugs.⁶ Meanwhile, many regulators continue to require animal testing data to help prove the safety of new medicines, chemicals, and consumer products. This has caused it to be a contentious issue for many decades.⁷ These contrasting ethical views on animal research have led to transparency being difficult to achieve in the public domain. There has, historically, been a reluctance to share animal research information with the public due to high levels of activism from animal rights organisations and those wishing to end animal experiments.⁸ Whilst activism has clearly demonstrated an appetite for change, it has also had the unfortunate effect of reducing information and transparency around animal research, for fear of negative responses or retribution.⁹ To support the progress of animal-free science and bring effective change, it is important to facilitate ongoing open dialogue and create a framework for increasing transparency without unnecessary judgement.

In the UK, animal research is regulated under the Animals (Scientific Procedures) Act 1986

5 Nuno Henrique Franco, 'Animal Experiments in Biomedical Research: A Historical Perspective' (2013) 3 *Animals* 1

6 Pru Hobson-West, 'The role of 'public opinion' in the UK animal research debate' (2009) 36 *JME* 46

7 *ibid.*

8 Elena Link and others, 'Public controversy and citizens' attitude formation about animal research: A case for scholarship and recommendations on conflicts at the science-society interface' (2004) 19 *PLoS One* e0295503 < <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10763933/#:~:text=Activist%20groups%20attack%20animal%20research,whereas%20scientists%20often%20remain%20silent.> accessed 24 Jul 2024.

9 Larry Carbone, 'Open Transparent Communication about Animals in Laboratories: Dialog for Multiple Voices and Multiple Audiences' (2021) 11 *Animals* 2

(ASPA 1986).¹⁰ Whilst ASPA 1986 is often considered to be one of the most stringent pieces of legislation outlining how animals may be used in science,¹¹ there are flaws around its implementation, which are hampering openness and transparency.

In this article, we will explore issues and avenues to improve the legislation, focussing on the standard of information required by law, and the release of information into the public domain. This includes: (1) Missed opportunities in the 'Annual Statistics of Scientific Procedures on Living Animals in Great Britain' publication; (2) Strengthening non-technical summaries of the project licence application; (3) Section 24 of the Animals (Scientific Procedures) Act 1986.

Acknowledging and addressing these issues would improve transparency around decisions to use animals in research, increase public trust, and better inform future work to replace animals.

The law

In British society, causing unnecessary harm or suffering to an animal is generally not accepted by the public,¹² and is subject to sanction under the Animal Welfare Act 2006.¹³ However, animals may be subjected to harm or suffering when used in scientific research or testing. Because of this, legislation exists to outline under what circumstances harm is permitted and steps that must be taken to limit this.

ASPA 1986 regulates the use of protected animals in scientific, educational, or any other experimental procedures that may cause pain, suffering, distress, or lasting harm, higher than, or equivalent to, the insertion of a needle under good veterinary practice. Procedures meeting these criteria are known as 'regulat-

10 ASPA 1986 (n 1)

11 Simon Festing and Robin Wilkinson, 'The ethics of animal research: Talking Point on the use of animals in scientific research' (2007) 8 *EMBO reports* 526

12 Animal Aid, '71% of people think causing pain and suffering to animals is wrong, Animal Aid poll shows' (animalaid.org.uk, 4 April 2022) <<https://www.animalaid.org.uk/71-percent-poll/>> accessed 6 January 2025

13 Animal Welfare Act 2006

ed procedures'.¹⁴ Protected animals are those species covered by the legislation, which currently includes any living vertebrate other than man, and, as of 2013, any living cephalopod, such as octopus and squid.¹⁵ The addition of cephalopods was made in line with the EU Directive 2010/63/EU on the protection of animals used for scientific purposes, which states that 'there is scientific evidence of their ability to experience pain, suffering, distress and lasting harm', and should therefore fall under ASPA 1986 protections.¹⁶

ASPA 1986 outlines a three-tier licensing system, requiring an establishment licence, a personal licence, and a project licence to be held before any research procedure on an animal can be undertaken.¹⁷ Establishment licences are required by any establishment where regulated procedures are carried out, including establishments that breed and supply animals for research.¹⁸ Personal licences are required by anyone who wishes to conduct regulated procedures using animals. This type of licence specifies the work that will be conducted and why.¹⁹ Project licences are required for any research project requiring regulated procedures to be conducted. This type of licence specifies the work that will be conducted within this study.²⁰

Failures to address replacement

One of the key failures of ASPA 1986 currently is around ensuring the correct and robust exploration and review of replacement. In their project licence applications, researchers must illustrate how they have explored and adhered to the legal requirement of the 3Rs of replacement, reduction, and refinement, with the principle of replacement being the priority of the three.²¹

14 Animals (Scientific Procedures) Act 1986, s 2
15 Animals (Scientific Procedures) Act 1986, s 1
16 Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes [2010] OJ L276/33
17 Animals (Scientific Procedures) Act 1986, s 2C
18 *ibid.*
19 Animals (Scientific Procedures) Act 1986, s 4
20 Animals (Scientific Procedures) Act 1986, s 5
21 Home Office, 'Guidance Notes for Project Licence Applications' (February 2024) < <https://assets.publishing.service.gov.uk/media/65cb31ff103de2000eb8f33f/Guidance+Notes+for+Project+Licence+Applications.pdf> > accessed 29 July 2024.

Despite the replacement of animal use being a legal requirement where possible, there has been formal acknowledgement that the current legal frameworks and processes are insufficient in ensuring that replacement is being addressed. In October 2022, a UK Home Office review of antibody licences (licences where researchers plan to use antibodies obtained from animals) granted over the previous 5 years showed that 'many licences did not provide sufficient demonstration that it is not currently scientifically possible for the antibodies ... to be produced by non-animal methods'.²² Furthermore, February 2023 saw the publication of an independent report entitled 'The role of review and regulatory approvals processes for animal research in supporting implementation of the 3Rs', commissioned by the Government-funded National Centre for the 3Rs (NC3Rs). This report is based on interviews and surveys with stakeholders within the animal research community and found that 'replacement does not seem to be covered well by any of the review processes'.²³

Issues with the Animals (Scientific Procedures) Act 1986, and avenues for improvements

1. Missed opportunities in Great Britain's 'Annual Statistics of Scientific Procedures on Living Animals'

The first area of concern relates to the annually published statistics on animal use in Great Britain. Under the ASPA 1986, it is a legal requirement to collect and record data on the use of animals in scientific procedures. This is collated and published by the Home Office annually, in the 'Annual Statistics of Scientific Procedures on Living Animals in Great Britain'.²⁴ This report outlines several pieces of basic data, including the total number of procedures using animals, the number of proce-

22 Animals in Science Committee, 'Antibody report by the Project Licence Strategic Review subgroup' (October 2022) < <https://www.gov.uk/government/publications/review-of-antibody-licences-report-by-the-animals-in-science-committee/antibody-report-by-the-project-licence-strategic-review-subgroup-accessible> > accessed 25 Jul 2024.
23 Rawle (n 4)
24 Home Office 'Animals in science statistics' (www.gov.uk, 9 September 2013) < <https://www.gov.uk/government/collections/animals-in-science-statistics> > accessed 25 Jul 2024.

dures carried out for experimental purposes, the number of procedures carried out for the creation and breeding of genetically altered animals, the number of procedures that used specific species, and severity levels of procedures. Alongside the report, data tables are published which show the statistics in more detail. Most of the categories contain information from 2014 to the present year.

The annual statistics are vital for transparency in order to accurately understand where and how animals are used in research. The primary responsibility of researchers under the 3Rs principles is to replace animal use in individual procedures and projects. The desired year-on-year trend to reflect this should therefore be a fall in the total number of procedures on animals. More specifically, the statistics help identify exactly where, why, and how animals are still being used in science and can help identify where animal use is being effectively replaced. This in turn can inform the development of alternatives to help address areas of science still heavily reliant on animals. Whilst the current statistics provide some useful insight, some simple additions and alterations could improve transparency and provide more information on the animals involved in research.

In March 2023, the UK Office for Statistics Regulation published a letter containing the results of a compliance check that they had conducted on the annual statistics.²⁵ This compliance check was conducted in response to concerns that were raised by the public, focusing on errors that had been found in previous statistics publications. Errors in the published statistics bring the validity of the statistics and the data collection process into question. The subsequent compliance check focused on four main areas - quality assurance, revisions and corrections, clarity and insight, and user engagement.

Recommendations:

25 Mark Pont, 'Annual Statistics of Scientific Procedures on Living Animals, Great Britain' (March 2023) < <https://osr.statisticsauthority.gov.uk/correspondence/mark-pont-to-jon-simmons-annual-statistics-of-scientific-procedures-on-living-animals-great-britain/> > accessed 25 Jul 2024.

Based on our work at Replacing Animal Research, there are several changes or additions that could be made to the annual statistics that would improve their transparency, scope, and usability.

Inclusion of animals bred and killed before use in a regulated procedure: There is currently no requirement to record the number of animals that are killed or die each year without being used in a regulated procedure, with the exception of genetically altered animals and specially protected species. This means that a large number of animals that are bred for research but not used are slipping through the system and not being accounted for, making the overall statistics inaccurate. Under EU Directive 2010/63/EU, data on animals under these circumstances must be published every five years.²⁶ The UK previously published this data in line with EU Directive 2010/63/EU in 2017, but is no longer legally obliged to do so as it is no longer a member of the EU.²⁷ Not publishing this data is, at best, compromising the use of the annual statistics to accurately reflect the full scale of animal use, and at worst, actively misleading the public on the total number of animals involved in all points of research and testing. As a minimum, the UK could continue the collection and publication of this data, at least every five years in line with the EU. However, ideally, this data could be included in the annual statistics to more accurately represent the number of animals involved in research each year.

Re-inclusion of establishment type: Establishment types include universities, public health laboratories, non-profit organisations, and government departments. Prior to the 2021 statistics, the type (and number) of licensed Home Office Establishments were published

26 European Commission 'Commission Staff Working Document – Union overview on the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes in the Member States of the European Union in 2018 – 2022' (July 2024) <https://d8aaf127-0203-427a-b8b6-1f1b942cd1af.usrfiles.com/ugd/d8aaf1_3673afd-6252b4ebe824da451eb1f8c53.pdf> accessed 3 December 2024.

27 Home Office 'Additional statistics on breeding and genotyping of animals for scientific procedures, Great Britain 2017' (November 2018) < <https://www.gov.uk/government/statistics/additional-statistics-on-breeding-and-genotyping-of-animals-for-scientific-procedures-great-britain-2017> > accessed 30 July 2024.

annually.²⁸ In 2021, the Home Office removed the breakdown of establishment type from the annual statistics publication, stating that “establishment type is not an indicator of the type of procedures carried out and often establishments could be categorised as more than one establishment type.”²⁹ This means that there is no longer information available on which types of establishments are the biggest users of animals, and has reduced transparency around where animals are being used in an area that has no impact on privacy or identification of individual establishments. Knowing which establishment types hold the highest number of licences and conduct the most procedures is vital for transparency and monitoring changing trends. It would also highlight the extent to which certain establishments use animals in research, meaning frameworks to support change can be focused on specific areas.

Inclusion of animals that are 'rehomed': Currently, there is no data published on the number of animals that are 'rehomed' annually, or to where they are 'rehomed.' The Guidance on the Operation of ASPA encourages consideration of 'rehoming' opportunities and contains information to aid this,³⁰ yet data on successful 'rehoming' is not published in the annual statistics. Under the legislation, 'rehoming' is defined as several different actions, including being moved to a new home (as a pet, to a farm, to an aquarium or zoo), being transferred to a slaughterhouse, or being moved to another research establishment abroad.³¹ As

28 Home Office 'Statistics of scientific procedures on living animals, Great Britain 2020' (July 2021) <<https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2020>> accessed 30 July 2024.

29 Home Office, 'Statistics of scientific procedures on living animals, Great Britain: 2021' (June 2022) <<https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2021>> accessed 25 July 2024.

30 Home Office, 'Guidance on the operations of the Animals (Scientific Procedures) Act 1986' (October 2024) <https://assets.publishing.service.gov.uk/media/6700017e080bdf716392ee63/Guidance_on_the_operation_of_ASPA_-_December_2023.pdf> accessed 3 December 2024.

31 Animals in Science Regulation Unit 'Advice Note: 03/2015 Animals (Scientific Procedures) Act 1986 Re-homing and setting free of animals' (October 2015) <https://assets.publishing.service.gov.uk/media/5a82e2ab-40f0b6230269d373/Advice_Note_Rehoming_setting_free.pdf> accessed 20 July 2024.

such, this definition is highly misleading. The word 'rehomed' implies that an animal has been removed from the research system. Alternative terms could be used to reflect the animals' destination more accurately. As an example 'discharged' (from the Act) is a more reflective term that has been used historically within ASPA 1986.³² Adding information on 'rehoming' would improve public understanding of the fate of animals used in research, specifically where animals are 'rehomed', and how many are 'rehomed'. Understanding the fate of animals used is important when considering the welfare of animals used in research. If they are 'rehomed' to another research establishment, they may be used in further scientific procedures with added potential to suffer.

Improved data collection and auditing: Whilst there is a legal requirement to collect data on how, where, and why animals are used in research,³³ we know from discussions with various stakeholders, that at research establishments, how data is collected in establishments is not standardised. Establishments and individual researchers can collect and record data any way they choose, be that electronically, or on paper. This leaves room for mistakes to occur too easily, as shown by the multiple errors that have previously been found in the statistics, leading to the compliance check. This not only brings into question the validity of the published statistics but also indicates that the data are not being audited properly. A simple solution would be to engage external auditors to hopefully identify and reduce the number of errors prior to publication. We know that some improvements are being made regarding data collection, with the introduction of the online licensing system Animals in Science Procedures e-Licensing system (ASPeL), which has built-in systems for end of year data collection.³⁴ Project licence holders, however, are still responsible for managing their data throughout the year before inputting them into ASPeL, leaving room for information to be lost, misplaced, or inaccurately recorded. To help prevent errors, ASPeL, or another online data capture system could be utilised to allow data to be

32 The Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012, SI 2012/3039

33 Animals (Scientific Procedures) Act 1986, s 21A

34 Pont (n 25)

collected throughout the life of a project licence. There could also be the introduction of a regulatory requirement to collect data in this manner at key stages of animal use within a project, such as the total number of animals bred or obtained, the number of animals actually used for certain procedures, and the end fate of all the animals.

2. Strengthening replacement requirements in the Non-Technical Summary of project licence applications

The second area of concern is the current project licence application processes, and its failure to ensure rigorous scrutiny of replacement. Project licence applications in the UK are completed through ASPeL, an online system that replaced the previous paper system for licensing. ASPeL covers all aspects of the proposed animal research project and procedures. The first main section of the application is the Non-Technical Summary (NTS).³⁵ NTS' are published publicly for all licensed projects involving procedures on animals.³⁶ They should provide a clear, lay summary of why, and how, the research project is being carried out. This section of the application contains questions on the project's aim, what the benefits and harms are likely to be, and how the 3Rs have been implemented. This is the only section of the licence application form that contains questions relating to how the 3Rs are being addressed.

Ensuring the 3Rs have been correctly applied is the responsibility of the researcher applying for the licence and should be addressed in the early stages of project planning, particularly exploring opportunities to avoid the need for regulated procedures on animals (replacement). Within a project licence application, applicants must demonstrate how they have searched for alternatives and explain why they were not suitable. However, the accompanying guidance document for project licence applications contains limited

information on how to conduct a search, and no minimum evidence requirement to show this has been done.³⁷ Whilst the responsibility for exploring and assessing replacement opportunities sits with the researcher, licences are also reviewed at establishment and government level, with these bodies having the potential to adjust, improve or reject the application.

It is a requirement of ASPA 1986 that all research institutions with an establishment licence must have an Animal Welfare and Ethical Review Body (AWERB). The purpose of the AWERB includes advising on all matters related to animal welfare and the 3Rs, reviewing all proposed projects involving procedures on animals at the establishment, and providing a forum for ethical discussion. AWERB reviews take place before project licence applications are submitted to the Home Office for review at government level. This includes reviewing the implementation of replacement to ensure all alternatives have been fully explored before procedures on animals are approved. Once the Home Office has completed its review and is satisfied that the work is appropriate and in alignment with the law, the licence is granted, and animal work can commence.

Despite the implementation of the 3Rs being a legal requirement and reviews taking place, we know, as stated in the 2023 NC3Rs report, that the review of replacement is not always fulfilled as robustly as it should be by funders, AWERBs or the Home Office.³⁸ The reasons for this given in the report include, that suggesting replacements after the funder has approved an animal project is too late in the process, and a lack of access to in-depth replacement expertise on all review panels.

In February 2024, the Animals in Science Regulation Unit published updated guidance notes for project licence applicants.³⁹ This includes more detailed information on what to include in the replacement section of the licence application. Researchers must now provide evidence-based choices of the animal 'models' they intend to use, a structured review of alternative non-animal approaches they con-

35 Home Office (n 21)

36 Home Office, 'Transparency and freedom of information releases' ([www.gov.uk](https://www.gov.uk/search/transparency-and-freedom-of-information-releases?parent=/business-and-industry/animal-research-and-testing&topic=85f606cf-741b-4aa3-8480-f92f6ce7b3b8&content_store_document_type%5B%5D=transparency&order=updated-newest)) https://www.gov.uk/search/transparency-and-freedom-of-information-releases?parent=/business-and-industry/animal-research-and-testing&topic=85f606cf-741b-4aa3-8480-f92f6ce7b3b8&content_store_document_type%5B%5D=transparency&order=updated-newest accessed 29 July 2024.

37 Home Office (n 21)

38 Rawle (n 4)

39 Home Office (n 21)

sidered, the databases and search methods that they used to find them, and show that their research will not include unnecessary duplication of animal use. Whilst these updates to the guidance are an important step in the right direction, they could, and should, go further to ensure replacement is fully explored, opportunities for replacement are not being missed, and reviewers have enough information to assess this in the application.

Recommendations:

There are various ideas for ensuring replacement is being robustly scrutinised during the application process. For example, some have called for a committee or panel of non-animal methods experts to review all project licence applications before a licence is granted.⁴⁰ One simple and practical approach is to make changes to the project licence application form itself, ensuring this evidence is presented in sufficient detail, to enable reviewers to make effective judgements or offer advice.

This could be achieved by adding more specific sub-questions to the application form to ensure that applicants provide all the information required by the guidance. This will provide applicants with space to break down the details in their answers, ensuring the different steps and thought processes that led them to decide to use animals over non-animal approaches are fully described. Prompts and hints for what applicants should include in each section could also be added to the replacement section questions. The updated guidance document already includes equivalent prompts as part of the reduction and refinement sections, but there is currently nothing equivalent as part of the replacement section. This makes little sense.

The current NTS' replacement questions are:

1. Why do you need to use animals to achieve the aim of your project?
2. Which non-animal alternative did you consider for use in this project?
3. Why were they not suitable?

As an example for question 1, we suggest

⁴⁰ HC Deb 16 January 2023, col 5W

adding four sub-questions, and the following prompt:

"You must demonstrate that you have considered all possible alternatives for your programme of work by describing the steps you have taken to actively research non-animal methods."

- a. Can any part of your proposed work using animals be replaced?
- b. Summarise the evidence base for your choice of animal model in this project. Please provide 2-3 references for your answer.
- c. How does your project avoid unnecessary duplication?
- d. Do you plan to publish this research or share the data in another format to avoid duplication of animal use in future?

As well as changes to the questions within the licence application form, some additional simple non-specialist questions could also be asked, to provide information that would guide both researchers and reviewers of applications, to ensure a thorough exploration of opportunities to avoid animal use has been performed, such as the 'Replacement Checklist'.⁴¹

In addition to improving the detail and consistency within and between individual NTS', as the only public record of project licences granted for animal work, the format in which they are published could be more accessible. Currently in the UK, NTS' are published in large PDF documents, covering several months at a time.⁴² By comparison, EU NTS' are published in an online database allowing for searching and filtering by country, project title, keywords, species, purpose, year and language.⁴³ To further promote transparency in NTS', the UK could also publish the NTS' in a similar database, or if possible, combine them with the EU database to allow for easier searching and

⁴¹ Juliet Dukes and others, 'Reviewing Current Guidance for the 'R' of Replacement and Rethinking it with the 'Replacement Checklist' ATLA

⁴² Home Office (n 36)

⁴³ European Commission, 'ALURES – Animal Use Reporting – EU System EU NTS Database on the Use of Animals for Scientific Purposes Under Directive 2010/63/EU (webgate.ec.europa.eu) < <https://webgate.ec.europa.eu/envdataportal/web/resources/alures/submission/nts/list> > accessed 29 July 2024.



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benchmarking across the EU and the UK.

3. Section 24 of the Animals (Scientific Procedures) Act 1986

The third area of concern relates directly to the law itself. Section 24 is a section of ASPA 1986⁴⁴ that protects confidential information, meaning that the Home Office cannot release any information received in confidence under the Act, even if the provider of the information has no objection to its disclosure. Whilst basic data is published around the use of animals in science, including annual statistics and NTS', Section 24 prevents more detailed information, such as full licence applications and licensing reviews, from being accessed. This means detailed information on procedures is not available to the public. Section 24 is incompatible with previous government commitments on openness and transparency⁴⁵ and the central principles of the Freedom of

Information Act 2000 (FOI 2000), which allows for public access to information held by public authorities.⁴⁶ ASPA 1986 predates FOI 2000 by 14 years. Section 24 also goes against the trend seen in recent years to improve transparency around animal research through initiatives such as the Concordat on Openness on Animal Research in the UK, launched by the organisation Understanding Animal Research,⁴⁷ and the European Animal Research Association's Be Open About Animal Research Day.⁴⁸ These initiatives have been developed by organisations supporting animal research to encourage transparency and build public trust in animal research.

This lack of transparency is an issue that has been identified and raised in UK Parliament several times over the last two decades, resulting in several government reviews. When

44 Animals (Scientific Procedures) Act 1986, s 24
45 Matt Hancock and others, 'Open and transparent government' (March 2016) <<https://www.gov.uk/government/speeches/open-and-transparent-government>> accessed 6 January 2025.

46 Freedom of Information Act 2000
47 Understanding Animal Research 'Concordat on Openness on Animal Research in the UK' (concordatopenness.org.uk) <<https://concordatopenness.org.uk/>> accessed 29 July 2024.
48 European Animal Research Association '#BOARD24 Celebrating openness about animal research' (EARA.EU) <<https://www.eara.eu/board24>> accessed 29 July 2024.

initially raised in Parliament in 2001, the Government argued that Section 24 was in place to protect individual scientists and their institutions from the actions of animal rights extremists.⁴⁹ However, since, and including this response, the Government has stated that it remains committed to creating a position of greater openness and transparency within the use of animals in scientific procedures, with Section 24 being a key barrier to this, and has provided very few arguments in support of retaining Section 24.⁵⁰

The first governmental review was conducted in 2002 by a House of Lords Select Committee which recommended that the section be repealed.⁵¹ The Government replied to the Select Committee's report in 2003 stating that they would 'consult further with the scientific community before reaching a final decision.'⁵² In 2004, Section 24 was reviewed again by the Home Office, but concluded that due to concerns from the scientific community around the impact of repealing Section 24, the section should be retained, with the potential to be re-reviewed in 2 years.⁵³ Between 2004 and 2014, several MPs questioned whether repealing the section would be reconsidered, however, there were no reviews during this time. In 2014, the Government published the 'Working to reduce the use of animals in scientific research' delivery plan.⁵⁴ In response to this, the Minister of State for the Home Department stated that the Government was actively reviewing Section 24 in line with the delivery plan and their policy on openness and transparency, leading to a public consultation being conducted between May and June 2014.⁵⁵

49 HC Deb 17 July 2001, col 129W

50 HC Deb 24 May 2002, col 708W; HC Deb 1 March 2011, col 289W; HC Deb 20 June 2011, col 3W; HC Deb 5 February 2013, col 46W

51 Select Committee on Animals in Scientific Procedures Volume I – Report (HL 2001-02 150-I) paras 9.11-9.18

52 Secretary of State for the Home Department, The Government Reply to the Report of the House of Lords Select Committee on Animals in Scientific Procedures Session 2001-2002 HL 150-I (Cm 5729, 2003)

53 HC Deb 1 July 2004, vol 423, col 17W

54 Home Office, Department for Business Innovation & Skills, Department of Health, 'Working to reduce the use of animals in scientific research' (February 2014) < <https://www.gov.uk/government/publications/working-to-reduce-the-use-of-animals-in-research-delivery-plan> > accessed 30 Jul 2024.

55 Home Office 'Consultation on the review of Section 24 of the Animals (Scientific Procedures) Act 1986' (May 2014) < [The consultation proposed four options for amending Section 24:](https://assets.publishing.service.gov.uk/media/5a7e-</p></div><div data-bbox=)

- Option 1: Retain Section 24 of ASPA
- Option 2a: Repeal Section 24 and amend ASPA by creating a criminal offence of malicious disclosure of information about the use of animals in scientific research
- Option 2b: As option 2a, but with the amended legislative framework to include a statutory prohibition on disclosure of information relating only to people, places and intellectual property
- Option 3: Repeal Section 24 of ASPA, allowing all information to be publicly disclosed unless exempt under the Freedom of Information Act

The preferred government option during the consultation was option 2b.⁵⁶ Despite the consultation ending and being reviewed in 2014, no results have been published and Section 24 remains in place as it was originally legislated. The Home Office stated in March 2024 that there are currently no plans to further review Section 24.⁵⁷

Recommendations:

Considering the work that has been done up to this point, the previous recommendations provided for moving forward, and the lack of governmental arguments in support of retaining the section over the previous two decades, this is a missed opportunity to increase transparency.

As a fundamental principle of an open democracy, there should always be an assumption of transparency, unless there is clear evidence that any risk of disclosure outweighs the public interest. This is what the FOI Act 2000 is designed to do, and its existence and protections render Section 24 obsolete.

0ba7e5274a2e87daf307/Consultation_on_the_review_of_Section_24_of_ASPA.pdf> accessed 30 July 2024.

56 *ibid.*

57 Animals in Science Committee 'Minutes of the 42nd Meeting: 12th March 2024' (July 2024) < https://assets.publishing.service.gov.uk/media/66a7af0b49b9c0597fdb0685/ASC+meeting+minutes_+12+March+2024.pdf > accessed July 2024.

In light of previous recommendations to this effect, we believe that Section 24 should be repealed to allow access to information that is currently protected, without increased risk to confidentiality. This would increase transparency around animal research, particularly project licences, by allowing opportunities for further scrutiny of successful applications and the scientific procedures that take place on animals. Option 2b from the 2014 consultation, the preferred government option, would allow the controlled release of information for independent auditing, review, and scrutiny, whilst protecting the identities and intellectual property of the researchers who were involved.

Repealing Section 24 in this way would be particularly beneficial to better understand the information provided by project licence applicants, especially around replacement, and the way that licences are reviewed at both government and establishment levels. This would help inform and develop training and resources, both for those applying for licences, and reviewers.

Conclusion

Despite being a legal obligation under the Animals (Scientific Procedure) Act 1986 to replace animal use where possible, it is clear that the consideration of scientific alternatives prior to animal use is not being carried out consistently or effectively, and that a lack of transparency is a key factor enabling this. Whilst the overarching requirements of the legislation are clear, the frameworks and processes for upholding them are lacking, making transparency difficult to achieve, and meaning that opportunities for animal replacement are being missed.

As outlined in this paper, we believe several simple changes could be made to improve the implementation of the legislation. Improvements and additions to the Annual Statistics of Scientific Procedures on Living Animals in Great Britain, strengthening Non-Technical Summaries of project licence applications, and repealing Section 24 of ASPA 1986 will each have a considerable impact on transparency, and in turn, will improve how the replacement of animal use in science is con-

sidered and addressed, as well as improving the public's understanding of animal research and growing public trust in both scientists and the government.