Cruelty Free INTERNATIONAL

Target Zero

Animal Experiments in the United Kingdom

crueltyfreeinternational.org

Introduction

Most people, even some of those who carry out animal experiments, say that they would like to see the day when animals are no longer used in research and testing.

The United Kingdom still has one of the highest numbers of animal experiments in the world and, despite warm words, there is no meaningful, pro-active strategy to bring this, even incrementally, to an end. Indeed, the government has recently said that it believes that animal research plays a vital role in providing safety information.[1]

The established position is that animal experiments are a 'necessary evil'. It is thought that science and the market will in time develop replacements. Yet science doesn't operate in a political vacuum. If there is political will, government can direct, incentivise, stimulate and accelerate change. Scientific progress tends to be slow, with researchers wont to spend their lives in singular pursuit of answers to very specific questions, using established methods. Unless driven by changes in funding and regulation, the scientific paradigm that supports the use of animals in research and testing will change glacially.

In today's world of complex human diseases, continued reliance on animal experiments is not only inherently unethical but is holding back progress and answers.

Public support for using animals in testing and research is extremely limited. Reassured by government and researchers that only the most essential experiments are done, and rarely seeing what happens behind laboratory doors, their opposition is often quiet, but it is there.

Policymakers are wedded to the view that like-for-like replacement of animal experiments with non-animal methods is the way forward and will, at least in part, gradually be realised. However, without greatly increased investment in technologies replacing animal experiments – coupled with a commitment to strictly limiting, in the meantime, the number and type of animal experiments – this will not happen for the best part of another century.

The development and implementation of non-animal methods are limited by comparatively low levels of funding, bureaucratic hurdles, poor enforcement and lack of incentives. The current system of authorisation for animal experiments is demand-led, with a cap only on the most egregious experiments. The over three million procedures taking place annually in the UK – and the five million instances of animals bred – are by no measure all essential to medical progress. There is lack of ambition for change, and the malaise and bias in the system must be addressed.

Hastening a future without animal experiments is a challenge that can only be met through policy changes as well as scientific development.

Setting intentional and progressive policy has been accepted as necessary to tackle other socio-economic challenges – climate change, for example – and one that has been used before in animal testing, where setting a date after which ingredients could no longer be tested on animals for cosmetics purposes dramatically hastened the development of non-animal methods.[2] Sadly, this approach has not been extended to other areas of animal use.

In this analysis, we suggest priority actions that should be included in a strategy to accelerate the transition to more humane and human-relevant research and testing, supported by the establishment of targets. **Go to page 18 to read our recommendations**.

[1] *Pow, R. (2023). Written Answer on behalf of the UK government to question 163925, 16 March 2023. Retrieved from: https://questions-statements.parliament.uk/written-questions/detail/2023-03-13/163925.*

[2] *Recent developments in the UK and EU that undermine the cosmetic ingredient animal testing bans (see https://crueltyfreeinternational.org/latest-news-and-updates/uk-government-admits-it-secretly-abandoned-cosmetics-animal-testing-ban for more information) do not negate the fact that the bans stimulated huge advances in the field of animal-free safety science, and the resulting technologies continue to be relied upon to demonstrate the safety of cosmetics.*

Acknowledgements

Cruelty Free International, formed as the BUAV in 1898, works to create a world where nobody wants, or believes that we need, to experiment on animals.

This report was written for Cruelty Free International Trust by Dr Katy Taylor, with input from staff and advisers. It was discussed with a panel of political, scientific, ethical and legal experts, and the final report is informed by their input.

The experts who assisted in panel discussions and were influential in the scope and tone of this final version are:

- Dr Darren Calley
- Dr Maureen O'Sullivan
- Dr Steven McCulloch
- Mr Norman Baker
- Professor Kay Peggs
- Professor Michael Balls
- Sir Nicholas Dakin
- Ms Blanche Koenig
- Dr Helen Lambert
- Professor Stephen Eisenman

Animal testing is old science

Most animal experiments use animals as so-called models of human diseases. Many of these diseases are not naturally seen in the animals, and are therefore artificially induced, or similar diseases are used as indicators of what might happen in humans. Animals may be genetically modified, injected with damaging chemicals or subjected to surgery to mimic aspects of the human disorder. Much research is an attempt to find, understand and improve these models rather than using the models to test effective treatments for humans. In fact, only 5% of animal testing in the UK is the testing of new medicines for humans required by regulators.[3]

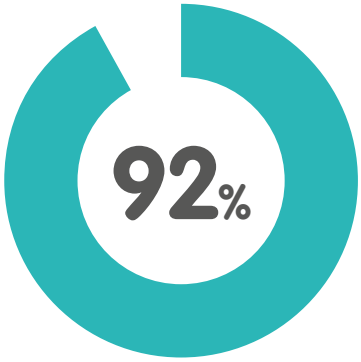
Despite decades of animal research, many debilitating and life-threatening human diseases, such as Alzheimer's, Parkinson's, Multiple Sclerosis and many cancers, remain poorly understood and without effective treatments. **As remaining human afflictions become increasingly complex and unique to humans, animal models are less and less directly relevant. It appears that the use of animals to model human disease has had its heyday – any low hanging fruit there might have been has already been picked.**[4]

The drug industry has been in silent crisis for decades: 92% of drugs fail in clinical trials despite passing extensive pre-clinical tests (including animal tests) which suggested that these medicines were safe and effective.[5] The failure rate for more complex and poorly understood conditions, such as Alzheimer's disease, is even greater.[6] Only a handful of novel medicines (approximately 20) are actually released onto the market every year,[7] and withdrawals and warnings of adverse effects commonly follow as the drug is tested in the wider human population.[8]

However, due in part to drug regulators requiring, or at the very least expecting to see, evidence from animal tests that drugs are safe and effective before they are tested in humans, **the industry is bound to continue conducting animal tests regardless of their scientific relevance or utility**. The inertia is overwhelming, and no-one wants to be the one to challenge the status quo.

Something has to change.

The drug industry has been in silent crisis for decades:



of drugs fail in clinical trials despite passing extensive pre-clinical tests (including animal tests) which suggested that these medicines were safe and effective.[5]

[3] *Home Office (2022). Annual Statistics of Scientific Procedures on Living Animals, Great Britain, 2021.*

[4] *Scannell, J., & Bosley, J. W. (2016). When Quality Beats Quantity: Decision Theory, Drug Discovery, and the Reproducibility Crisis. PLOS ONE, 11(2), e0147215.*

[5] *Biotechnology Innovation Organization (2021). Clinical Development Success Rates and Contributing Factors 2011-2020. Retrieved from: go.bio.org/rs/490-EHZ-999/images/ClinicalDevelopmentSuccessRates2011_2020.pdf.*

[6] *Alteri, E., & Guizzaro, L. (2018). Be open about drug failures to speed up research. Nature, 563(7731), 317-319.*

[7] *Biotechnology Innovation Organization (2021).*

[8] *van Meer, P. J., et al. (2012). The ability of animal studies to detect serious post marketing adverse events is limited. Regulatory Toxicology and Pharmacology, 64(3), 345-349.*

Animal experiments persist as the default method

At approximately three million animals used in procedures every year, **the UK is one of the world's largest users of animals in research and testing, and the largest user in Europe.**

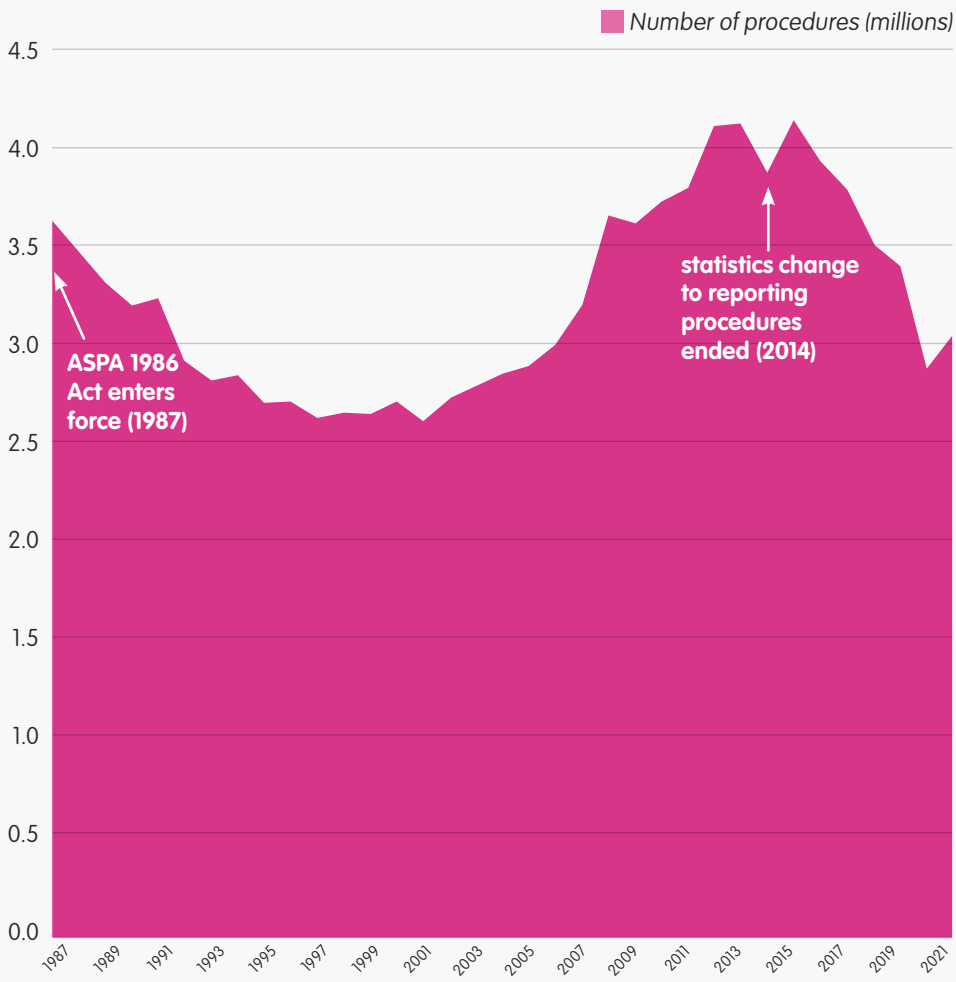


Fig. 1. The number of procedures on animals in Great Britain based on official government statistics from 1987 to 2021.

The last few years may have seen a small decline in animal testing numbers, but they remain greater than in the 1980s, despite progress in replacement methods, greater awareness of animal sentience and consistently high levels of public concern.

In addition, there is nothing in current government policy that gives any confidence that even the current small incremental decline will continue. As the graph shows, the number of animal experiments goes up and down for different reasons. For example, 2020's significant decrease of 15% was, as the Home Office itself stated, largely due to the Covid-19 lockdowns; and the steady increase since 2001 can be attributed to the popularity of the production of genetically modified mice.

Based on the level of decrease from 2010 to 2019 (pre Covid-19 pandemic), animal experiments will continue for the next 89 years, until 2108.

Animal experiments will continue for the next

89

YEARS

until 2108

The prevailing attitude within government is that animal testing is a 'necessary evil' requiring regulation only to curb the worst excesses. This has been the approach since the introduction of the Animals (Scientific Procedures) Act in 1986,[9] and has not changed since.

The law includes a requirement that any experiment for which there is not a suitable alternative method available should use the minimum number of animals and cause the least amount of suffering necessary (the so-called '3Rs' concept of replacement, reduction and refinement). However, there is no requirement in the legislation or elsewhere to ensure that only the most essential experiments take place, or that the number of animals used overall is an absolute minimum. If a researcher can state a good case for the use of animals – as determined by their peers – then it is permitted.

The current approach is therefore a demand-led system,[10] with little or no public policy drive to pro-actively achieve the goal of zero animal experiments.

And as new animal models are also being created, any decrease in the number of animals achieved by replacement of some types of experiments is balanced, or even exceeded, by an increase in new animal experiments.

[9] *UK government (2014). Consolidated version of the Animals (Scientific Procedures) Act 1986. Retrieved from: https://www.gov.uk/government/publications/consolidated-version-of-aspa-1986.*

[10] *NC3Rs (n.d.). Evaluating progress in the 3Rs: The NC3Rs framework. Retrieved from: https://nc3rs.org.uk/sites/default/files/2021-09/Evaluating%20progress%20in%20the%203Rs-%20the%20NC3Rs%20framework.pdf*

The public wants to see an end to animal testing

The UK government has been commissioning Ipsos MORI to conduct an annual opinion survey on animal experiments since 1999. In these attitude surveys, public support for animal testing *for medical research purposes where there is no alternative* has dropped progressively from 76% in 2010 to 65% in 2018.[11,12] In fact, 38% of people thought that animals should not be used in any scientific research on animal welfare grounds.

In addition, when questioned about individual species, any support drops dramatically. In 2018, only 14% of respondents said it was acceptable to use dogs, macaque monkeys and cats, even for medical research that benefits people.

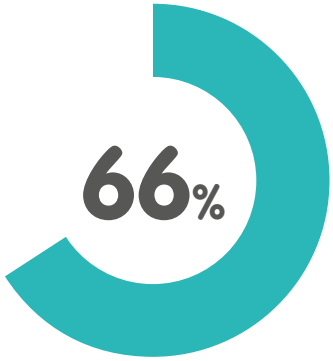
In a 2009 survey,[13] conducted just prior to the revision of EU Directive 2010/63 on the protection of animals used in scientific procedures, of the UK participants, 72% agreed that 'the new law should prohibit all experiments on animals which do not relate to serious or life-threatening human conditions'.

Similar results have been seen more recently in an opinion poll carried out by YouGov for Cruelty Free International: 66% wanted to see a plan to phase out animal experiments with a target date for ending tests in the UK, and 68% would back a government-led investment strategy to accelerate the availability of non-animal alternatives.[14] When asked if, before taking this survey, they were aware that almost three million animal experiments take place in the UK each year, 80% stated that they were not.

According to a poll conducted for Animal Free Research UK in 2021, 68% of Britons want an end to animal experiments in medical research in UK laboratories.[15]

There is, therefore, only very limited support for animal testing in the UK, and even that support is conditional on it being for medical purposes and where there is no alternative method. There is no support for the use of species with which the British public identifies most.

Far more animal testing is being permitted that falls outside of these acceptability criteria than the public realises.



wanted to see a plan to phase out animal experiments with a target date for ending tests in the UK

[11] *Ipsos MORI (2014). Attitudes to animal research – A long-term survey of public views 1999-2014. A report by Ipsos MORI for the Department for Business, Innovation & Skills. Retrieved from: https://www.ipsos.com/ipsos-mori/en-uk/attitudes-animal-research-2014.*

[12] *Ipsos MORI (2019). Public attitudes to animal research in 2018 – A report by Ipsos MORI for the Department for Business, Energy & Industrial Strategy. Retrieved from: https://www.ipsos.com/ipsos-mori/en-uk/public-attitudes-animal-research-2018.*

[13] *BUAV/YouGov (2009). Opinion poll on animal experiments. Report available on request.*

[14] *Cruelty Free International/YouGov (2021). Poll of 1,765 adults across England, Wales and Scotland. Report available on request.*

[15] *Animal Free Research UK/YouGov (2021). Poll: clear majority of Britons want end to animal testing in UK labs. Retrieved from: https://www.animalfreeresearchuk.org/poll-clear-majority-of-britons-want-end-to-animal-testing-in-uk-labs/.*

Animal testing is not working

If policy makers are serious about change, they tend to put in place frameworks with targets. Legally-binding long-term environmental targets will drive action by successive governments to protect and enhance our natural world. They allow for objective scrutiny and accountability of governments' progress to society. The duty to achieve targets rests with central government, but delivery will require action across the economy. [Defra][16]

Targets have been a feature of strategies to tackle a range of complex policy issues such as child poverty and NHS waiting times,[17] and continue to be used today. Currently, targets feature most prominently in action on climate change.

The Climate Change Act 2008, requiring that the net UK carbon account for the year 2050 is at least 80% lower than the 1990 baseline, was recently revised to be net zero by 2050.[18]

The overall target is supported by sub targets or milestones, for example a pledge to cut emissions by 78% by 2035:

This latest target shows the world that the UK is serious about protecting the health of our planet, while also seizing the new economic opportunities it will bring and capitalising on green technologies. [Secretary of State for BEIS, April 2021][19]

The Environment Act (2021) includes measures to help achieve the vision set out in the 25 Year Environment Plan:

An important aspect of the Environment Bill is the power to set long-term, legally-binding environmental targets. Setting targets will provide a strong mechanism to deliver long-term environmental outcomes. [Defra][20]

Why not apply this thinking to animal experiments? Why not pledge that science will continue but in a different way? Why not pledge that the UK will be a forerunner in innovative approaches to science, creating more jobs and furthering treatments and cures for debilitating human diseases along the way?

There is consensus that climate change is inherently bad, but we all need power to live. No one is seriously suggesting that we should switch off the lights, stop driving cars or stop heating our homes to counter it – the implication is that technological advancements are needed to ensure we can still have power (good) whilst fighting climate change (bad).

This approach should be the same for animal experiments. There is consensus that animal testing is a bad thing, but that medical progress is good and necessary. With incentives to invest in new technologies, we can improve medical progress (good) whilst not causing harm to animals (bad).

There is currently nothing in law or policy that will purposefully and deliberatively hasten an end to animal experiments, or accelerate the development and use of alternatives to animal testing.

[16] *Department for Environment, Food & Rural Affairs (2022). Consultation on environmental targets. Retrieved from: https://consult.defra.gov.uk/natural-environment-policy/consultation-on-environmental-targets/supporting_documents/Environment%20Targets%20Public%20Consultation.pdf.*

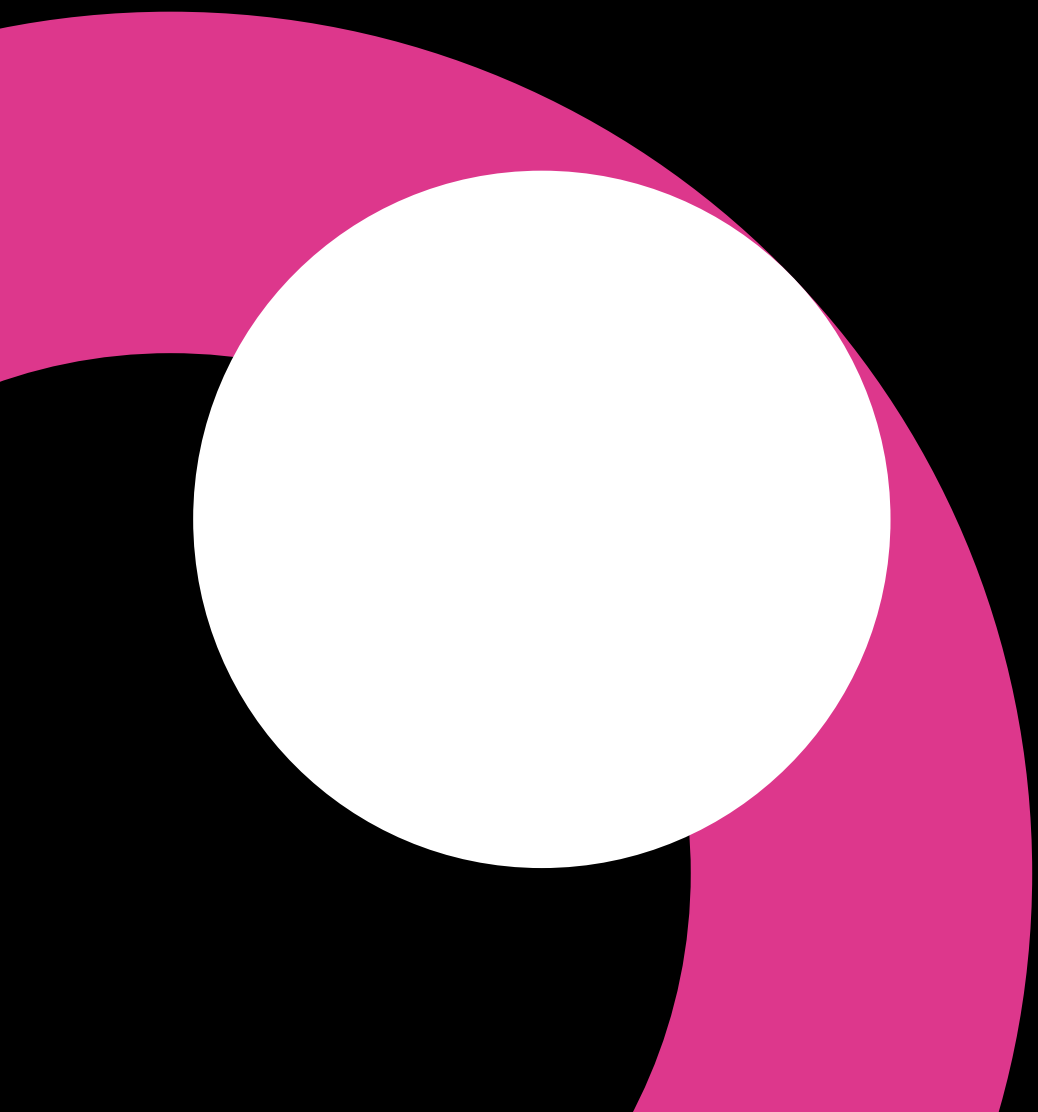
[17] *House of Commons Library Research (2010). Targets as a policy tool. Retrieved from: https://www.parliament.uk/globalassets/documents/commons/lib/research/key_issues/key-issues-targets-as-a-policy-tool.pdf.*

[18] *Hansard. (2019) Debate on Net Zero Emissions Target. Retrieved from: https://hansard.parliament.uk/Commons/2019-06-12/debates/A348AE4C-8957-42C8-8180-0F59E597E3EA/NetZeroEmissionsTarget.*

[19] *UK government. (2021) UK enshrines new target in law to slash emissions by 78% by 2035. Retrieved from https://www.gov.uk/government/news/uk-enshrines-new-target-in-law-to-slash-emissions-by-78-by-2035.*

[20] *Department for Environment, Food & Rural Affairs (2020). Environment Bill – environmental targets. Retrieved from: https://www.gov.uk/government/publications/environment-bill-2020/august-2020-environment-bill-environmental-targets.*

Where to start?



Sub targets and milestones

Once an overarching commitment is put in place, such as net zero for carbon emissions, government officials work with stakeholders and experts to set sub targets and milestones.

This is currently the case for the Environment Act (2021).

Environment Bill targets will help stimulate investments in green technology and innovative practices by providing long-term certainty for business. They will help businesses to plan ahead, including how they rebuild from the Covid-19 crisis.

Defra officials identified four steps to 'enable us to systematically develop this evidence and meet the criteria and principles… so that we can set strong and meaningful targets'. These are deciding on scope, developing fully evidenced targets, public consultation and drafting target legislation. In the context of the Environment Act, sub targets include:

- Support for up to 59,000 jobs in 2024 and up to 120,000 jobs in 2030
- Delivering 5GW of hydrogen production capacity by 2030, whilst halving emissions from oil and gas
- Trebling woodland creation rates in England, contributing to the UK's overall target of increasing planting rates to 30,000 hectares per year by the end of the current Parliament
- 40GW of offshore wind by 2030, including 1GW of floating wind[21]

So, whilst a target zero policy for animal experiments may seem daunting, it would, in reality, start with a review of the current landscape and, via consultation, the setting of achievable milestones in much the same way as is normal in other policy contexts. This could include:

1. **increasing investment in the development of new technologies**
2. **reviewing the current authorisation process to ensure it is fit for purpose**
3. **limiting certain types of experiment – for example, those considered of less importance or utility, or harmful to the public**

[21] *Department for Environment, Food & Rural Affairs (2020). Environment Bill – environmental targets.*

1. Investing in new technologies

Government funding for the development of alternative methods to the use of animals is via the NC3Rs.[22] The core budget of the NC3Rs is between £10.5M and £11M per year, with most coming directly from the Medical Research Council (MRC) and the Biotechnology and Biological Sciences Research Council (BBSRC), and some from charities and industry.

The government, however, does not track how much of this is directed at replacement only, nor does it track the extent of replacement-focused funding outside of the contribution to the NC3Rs.[23] Also, no comparison is made between spending on non-animal methods with any funding of research that uses animals. Without this information, we are working in the dark.

Evidence presented at the All-Party Parliamentary Group (APPG) for Human Relevant Science in 2021 indicated that UK funding for *human relevant* New Approach Methodologies in 2019 amounted to around £2 million per year through the NC3Rs, i.e., projects that were solely relevant to replacing animals, as opposed to projects that supported current animal-based research. The Group's report states that this was less than 0.2% of the total budget for MRC, BBSRC and Innovate UK combined (£1.144B) and ~0.02% of the UK's total public expenditure on R&D of £10.45B.[24]

The APPG recommended that the government start by tracking and then prioritising the funding of replacement technologies over its funding of animal-based research.

The suggestions in the APPG report[25] are a good starting point in this regard.

2. Ensuring the system is fit for purpose

Transparency and accountability

The government-funded IPSOS Mori attitudes survey in 2016 found that most of the British public do not feel well-informed about the use of animals in research – only one third (34%) said they feel either very or fairly well informed.[26] In the 2018 survey, a large proportion of respondents (41%) believed that animal research organisations are secretive and only a few felt that they are well regulated (26%) and stick to good animal welfare standards (15%).[27]

When asked about awareness before participating in a YouGov poll in 2021, 80% stated that they were not aware that three million procedures are carried out on animals in the UK each year.[28]

Approved applications to conduct animal research (over 500 each year) are typically not released to the public, even for publicly funded research. There has been a longstanding campaign to remove the statutory bar on the release of confidential information under section 24 of the Animals (Scientific Procedures) Act which, despite a request for action by the House of Lords in 2002, is still in place.[29] The Freedom of Information Act 2000 can be used in some circumstances but is only relevant to public bodies, and there are frequently time delays or legal battles over the release of any apparently contentious material.

According to a survey of five EU countries (UK, France, Germany, Italy, Sweden and Czechia) conducted by YouGov in 2009, just prior to the revision of Directive 2010/63 on the protection of animals used for scientific purposes, 80% agreed that all information about animal experiments should be publicly available, except information which is confidential or would identify researchers or where they work.

Annual statistics on the numbers of animals used are produced, and summaries of project applications published on the website of the responsible government department, the Home Office. However, until recently, the Home Office was consistently 18 months behind in its publication of these summaries and they are often scant and not easily searchable.

Despite the Freedom of Information Act, the public is living in an information vacuum. Evidence from an exercise conducted by Ipsos Mori in 2013 found that the more people were shown the reality of animal testing, the more they wanted to know and the more they opposed it.[30]

Under UK law, all projects that intend to use animals in research that may cause 'pain, suffering, distress or lasting harm'

[22] *Solloway, A. (2021). Letter from BEIS Amanda Solloway Nadhim Zahawi 01/02/21. Retrieved from: https://www.humanrelevantscience.org/all-party-parliamentarygroup/correspondence-with-government-ministers/.*

[23] *Freeman, G. (2021). Written Answer on behalf of the UK government to question 76012, 24 November 2021. Retrieved from: https://questions-statements.parliament.uk/written-questions/detail/2021-11-16/76012.*

[24] *All-Party Parliamentary Group for Human Relevant Science (2022). Bringing Back the Human: Transitioning from animal research to human relevant science in the UK. Retrieved from: https://www.humanrelevantscience.org/all-party-parliamentary-group/bringing-back-the-human-transitioning-from-animal-research-to-human-relevant-science-in-the-uk/.*

[25] *Ibid.*

[26] *Ipsos MORI (2016). Public attitudes to animal research in 2016. Retrieved from: https://www.ipsos.com/sites/default/files/publication/1970-01/sri-public-attitudes-to-animal-research-2016.pdf.*

[27] *Ipsos MORI (2019).*

[28] *Cruelty Free International/YouGov (2021).*

[29] *Animal Procedures Committee (2004). Report of the Animal Procedures Committee for 2003.*

[30] *Ipsos MORI (2013). Openness in Animal Research Dialogue. Retrieved from: https://webarchive.nationalarchives.gov.uk/ukgwa/20170110112420/http://www.sciencewise-erc.org.uk/cms/openness-in-animal-research-dialogue/.*

must undergo a harm-benefit analysis (HBA), where the harms caused to the animals are weighed against the likely benefits to humans, other animals or the environment. Following this evaluation, the projects are approved, almost without exception. However, the outcome of the HBA is not made public, and there is no publicly available list of experiments that the government will not authorise.

Greater transparency is often a contributor to greater reform. However, in the area of animal experiments, transparency remains woefully lacking. Without genuine transparency there cannot be genuine public debate and engagement. This must be resolved, not only because the government authorises animal experiments on behalf of society, but also because most animal research is funded by the British taxpayer.

Independence in the system

The system used to authorise animal experiments and enforce governing legislation is complex and opaque. Surprisingly, after decades of complaints to that effect by animal protection organisations, last year the Home Office itself finally recognised that the current system is at '**very high risk of regulatory failure due to regulatory capture both at an operational and strategy level**'.[31] Inspectors were inspecting the very experiments they had authorised and were too close to the institutions they inspected.

The unit responsible at the Home Office has been undergoing a 'change programme', but stakeholders' input has not been sought, nor has advice from their own Animals in Science Committee,[32] and not all issues are being addressed.

One particular issue that has not yet been tackled as part of the programme is that project evaluation and authorisation are carried out by very few individuals, the majority of whom are proponents of animal research, with no layperson involvement required under the current rules.

In the UK:

- The initial assessment is done by a small body based within the institution where the experiment is to be undertaken. This body is only required to contain one of the establishment's Named Animal Care and Welfare Officers (NACWO), one of the Named Veterinary Surgeons (NVS) and a scientific member.[33]
- The final project evaluation (and authorisation) is typically done by a single Home Office inspector who, according to the law, must be a veterinary surgeon or a medical practitioner.
- Contentious projects may be referred to another inspector, a group of inspectors or the Animals in Science Committee, which, in practice, sees only a handful of projects each year.[34]

This compares poorly with systems in other European countries:[35]

- **Sweden**: Projects are evaluated and authorised by regional ethical committees composed of scientists, animal technicians and laypersons, as well as a chair with relevant judicial experience. Half of the members must be laypersons who are there to represent society's point of view regarding the benefit and necessity of research versus ethical justification of the harm inflicted to the animals. Two of the laypersons must represent animal welfare organisations.
- **Denmark**: Projects are evaluated and authorised by the national Danish Animal Experimentation Council which consists of 11 experts on laboratory animal science and animal welfare. The chair must be a judge, and four members are appointed after consulting animal welfare organisations.
- **France**: Projects are evaluated by local ethics committees, at least one member of which must represent civil society. Projects are then authorised by the relevant Ministry.
- **Netherlands**: Projects are evaluated by regional animal experiments committees made up of at least seven members. Half of the members must be independent of the institution, and the committee must include an expert in ethics. Projects are then authorised by the Central Committee on Animal Testing which currently has seven members appointed by the Secretary of State.

For several years, the UK government has

[31] Regulatory capture is when a regulatory agency created to act in the public interest advances the concerns of the regulated industry or parts within. The Home Office's Animals in Science Regulation Unit expressed this view in a presentation to stakeholders on 27 May 2021.

[32] Main, D. (2022). ASRU change programme: letter to Baroness Williams. Retrieved from: https://www.gov.uk/government/publications/animals-in-science-regulation-unit-change-programme/asru-change-programme-letter-to-baroness-williams-accessible-version.

[33] Home Office (2014). Guidance on the Operation of the Animals (Scientific Procedures) Act 1986. Retrieved from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/662364/Guidance_on_the_Operation_of_ASPA.pdf.

[34] According to the most recent figures available, the Animals in Science Committee saw three licences in 2013 and four in 2014 (https://www.gov.uk/government/publications/the-animals-in-science-committee-annual-report-2013-to-2014). There is now a project licence subgroup that looks at a slightly larger number on an ad hoc, retrospective basis but does not provide advice on licensing.

[35] European Commission (2020). Report From the Commission to the European Parliament and the Council 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 (COM/2020/15 final).

[36] Ipsos MORI (2019).

[37] Animals in Science Committee (2017). Review of harm-benefit analysis in the use of animals in research. Retrieved from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/675002/Review_of_harm_benefit_analysis_in_use_of_animals_18Jan18.pdf.

[38] Williams, S. (2020). Letter from Baroness Williams to the Chair of the Animals in Science Committee. Retrieved from: https://www.gov.uk/government/publications/harm-benefit-analysis-review-ministers-reply-to-the-ascs-recommendations.

been tracking the public's view on animal research,[36] but it is yet to incorporate those views into its decision making, despite the Animals in Science Committee recommending that it did so in its 2017 review of the HBA.[37] The Minister agreed with the recommendation but failed to commit to any change in approach.[38]

The failure to incorporate public opinion, either directly or indirectly, and the dominant involvement of supporters of animal experiments, render the system – as the Home Office admitted – at extremely high risk of regulatory capture and failure. It risks the process being a bureaucratic exercise only.

The quality of the assessment is also likely to be affected if those with the requisite expertise are not included. With the Home Office licensing, on average, 500 projects each year, Animals in Science Regulation Unit (ASRU) inspectors cannot be expected to be experts in all the areas of research they authorise, most crucially in the possibilities for replacement.[39]

It is not surprising, therefore, to find that the Home Office has a long history of not rejecting project applications.[40,41]

The Home Office itself has acknowledged that this is a 'red flag' that shows that the system is failing.[42]

Rigour in the system

As well as lack of independence and lack of transparency, the HBA is flawed in several other ways:[43]

- there is no agreement on what should be included in the assessment
- the weighing of harms and benefits is entirely subjective
- there are no rules for what constitutes a pass or fail
- there is no broader consideration of whether a completely different, non-harmful piece of research (likely to be done by a different researcher) might be as likely to deliver similar benefits
- generic licences are permitted for regulatory testing without a requirement to specify the substances being tested, preventing not only assessment of the possibility to use alternative methods but also the evaluation of the societal benefit of the substance.[44]

Regulatory testing, mainly to determine the safety of products, accounts for only 10% of all animal experiments in Great Britain.[45]

As a result, about 90% of animal experiments in Great Britain are done entirely voluntarily, with no regulatory or legal requirements demanding that they be undertaken.

If a commitment were made to reduce animal testing, there would be wide scope to tackle the 90% of testing that has a much greater voluntary element. The HBA could be strengthened to be the tool that it was intended to be and limit animal testing to only that considered to be the most essential. The public are currently being misled that the HBA is more than an exercise in bureaucracy. If those conducting project evaluation were steered to take a more critical view of the potential benefits of each project, perhaps under a quota system, then it is possible that the least useful projects would not go ahead, with no detriment to society.

In 2003, the government's advisory committee on animal experiments said that '*negotiating and setting targets for implementation of best practice and for phasing out procedures that generate concern over the level of suffering they cause would help in moving thinking on and avoiding inertia*'. They suggested that they themselves embark on a more detailed investigation of the possibilities; this did not take place.

[39] *NC3Rs (2023). The role of review and regulatory approvals processes for animal research in supporting implementation of the 3Rs. Retrieved from: https://nc3rs.org.uk/role-review-and-regulatory-approvals-processes-animal-research-supporting-implementation-3rs-2023.*

[40] *Atkins, V. (2021). Written Answer on behalf of the UK government to question 161856, 8 March 2021. Retrieved from: https://questions-statements.parliament.uk/written-questions/detail/2021-03-02/161856/.*

[41] *Featherstone, L. (2011). Written Answer on behalf of the UK government to question 83720, 30 November 2011. Retrieved from: https://publications.parliament.uk/pa/cm201011/cmhansrd/cm111130/text/111130w0003.htm.*

[42] *The Home Office's Animals in Science Regulation Unit expressed this view in a presentation to stakeholders on 27 May 2021.*

[43] *Taylor, K. (2018). Harms versus Benefits: A Practical Critique of Utilitarian Calculations. In: Linzey A. and Linzey C. ed. The Ethical Case against Animal Experiments. University of Illinois Press, pp. 148-159.*

[44] *Animals in Science Committee (2020). Report of the Licence Analysis Subgroup. Retrieved from: https://www.gov.uk/government/publications/licence-analysis-review-report-by-the-animals-in-science-committee.*

[45] *Home Office (2022). Annual Statistics of Scientific Procedures on Living Animals, Great Britain, 2021.*

3. Limiting certain types of experiment

Here we suggest some areas of current animal research that are ripe for scrutiny under a more rigorous system.

Experiments of low benefit

Examples of research and testing that could be of perceived **lower benefit from the outset due to their non-essential nature** include:

- Procedures carried out purely for higher education and training purposes
- Research into:
  - behaviour
  - ageing
  - warfare
  - effects of recreational substances like tobacco, alcohol and drugs
  - improving exploitative industries like horse racing and intensive food production
- Testing with a view to:
  - making food product health claims
  - making pet food product health claims
  - marketing aesthetic medical products, for example botulinum toxin and fillers
  - marketing non-medical products like household product ingredients and weed killer

Here are just a few examples of animal models that have been heavily criticised scientifically and are of **low potential benefit because they do not generate reliable and relevant data**:

- Alzheimer's disease (e.g., APP and tau transgenic mice)[46]
- Stroke (e.g., cerebral artery occlusion model)[47]
- HIV (e.g., SIV model)[48]
- Multiple sclerosis (e.g., EAE induced models)[49]
- Rheumatoid arthritis (e.g., collagen-induced arthritis model)[50]
- Cancer (e.g., graft models)[51]
- Xenotransplantation[52]

Experiments of high harm

Severe procedures are defined as those where the animals are likely to experience severe pain, suffering or distress or long-lasting moderate pain, suffering or distress, as well as procedures that are likely to cause severe impairment of the well-being or general condition of the animals.[53] These can include tests where the animals are expected to experience severe behavioural or physical deficits as the result of a surgery or disease being induced. It also includes tests where the researchers expect some of the animals to die as a result of the intervention. For genetically modified animals, this would include breeding of animals who experience severe physical defects such as paralysis, seizures, fractures, severe developmental abnormalities or expected pre-weaning death.

There were 86,785 uses of animals in Great Britain in 2021 that caused severe suffering. This includes some regulatory tests, including the notorious botulinum toxin batch potency tests for Botox products that causes the death by suffocation of 50% of the mice in each test. It also includes basic medical research, including neurological and cancer research involving brain surgery, water deprivation, restraint, and growth of tumour masses.

The general public does not support the use of animals in experiments that cause severe suffering. In a 2009 survey[54] conducted just prior to the revision of the EU Directive 2010/63 in 2009, of the UK participants, 77% agreed that 'the new law should prohibit all experiments causing severe pain or suffering to any animal'.

The public has also long been concerned with the use of particular species in harmful experiments. Public demonstrations led to the introduction of the Dogs (Protection) Bill in 1919 that aimed, unsuccessfully, to end testing on dogs. Public distaste with the use of

[46] *ScienceDaily (2012). New model of Alzheimer's disease developed. Retrieved from: https://www.sciencedaily.com/releases/2012/07/120716163243.htm.*

[47] *Gladstone, D. J., et al. (2002). Toward wisdom from failure: lessons from neuroprotective stroke trials and new therapeutic directions. Stroke, 33(8), 2123-2136.*

[48] *Trivedi, B. (2010). The primate connection. Nature, 466, S5.*

[49] *Behan, P., et al. (2002). The Pathogenesis of Multiple Sclerosis Revisited. J R Coll Physicians, 32, 244-265.*

[50] *Firestein, G. (2009). Rheumatoid arthritis in a mouse? Nat Rev Rheumatol, 5(1).*

[51] *Edwards, J. C., et al. (1999). Do self-perpetuating B lymphocytes drive human autoimmune disease? Immunology, 97(2), 188-196.*

[52] *Taylor, K. (2010). Rapid Response: Xenotransplantation not a solution. Retrieved from: http://www.bmj.com/rapid-response/2011/11/02/xenotransplantation-not-solution.*

[53] *Home Office (2014). Advisory notes on recording and reporting the actual severity of regulated procedures. Retrieved from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/810118/NotesActualSeverityReporting.pdf.*

[54] *BUAV/YouGov (2009).*

non-human primates has resulted in bans on the use of great apes and wild caught primates, and closer scrutiny of continued use.

However, the use of dogs and monkeys in particular – partly because they are traditionally used in the testing of new drugs – is still significant and not necessarily decreasing.

In 2021, researchers in the UK conducted 4,227 tests on dogs and 2,795 tests on monkeys.

In the government's ISPOS Mori survey of 2018, only 14% of respondents said that it was acceptable to use dogs, 14% that it was acceptable to use macaque monkeys and 14% that it was acceptable to use cats for medical research, even to benefit people.[55] In a YouGov poll in 2021, 80% found it unacceptable for animal experiments to be carried out on dogs and cats, and 76% on monkeys.[56]

This opposition to the use of these animals is presumably based on our affinity with them and therefore a greater appreciation of their capacity to suffer. Whilst it is not necessarily true that these species suffer more than any other – there is growing evidence of the emotional lives of rodents and the intelligence of pigs, for example – in any reduction strategy these species would be a good place to start.

Wastage in the system

Most animals used in research and testing are bred for that purpose. In that endeavour there will inevitably be some animals who are bred and not used, because they are the wrong sex or otherwise unsuitable, or because production outstrips demand.

In 2017, for the first time under the EU Directive 2010/63, the UK had to report how many animals had been bred that year for scientific procedures but were killed or died without being used in procedures.[57] The answer was an astonishing 1.81 million animals.

According to the report, these animals had been used for breeding of other animals, to provide tissues, were the wrong sex for a particular purpose or were a 'necessary' surplus resulting from the breeding of animals to ensure adequate supply for scientific purposes. No more details were provided. It is possible that there is considerable scope to reduce this wastage.

Based on the 2017 figure, we estimate that, of all animals in laboratories in any given year, 33% will simply be bred and then killed.

This is in addition to the huge number of animals who are genetically modified and then not used – an area of animal use that has mushroomed in the last 20 years. As a regulated procedure in its own right, as it may lead to pain, distress or lasting harm in the animal who is subsequently bred, the breeding of genetically modified animals **who are not used in further procedures** now constitutes 43% of all procedures in Great Britain (1.3 million animals) **What are all these genetically modified animals being bred for?**

[55] *Ipsos MORI (2019).*

[56] *Cruelty Free International/YouGov (2021).*

[57] *Home Office (2018). Additional statistics on breeding and genotyping of animals for scientific procedures, Great Britain 2017. Retrieved from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/754408/breeding-genotyping-animals-scientific-procedures-2017-hosb2718.pdf.*

Use of alternative methods

There is a legal obligation that an animal test must not be conducted if there is a non-animal alternative that would achieve the scientific outcomes sought. However, through correspondence with ASRU and answers to MPs' written parliamentary questions, Cruelty Free International has observed several problems with the current approach:

- There is no legal obligation on the researcher or the government to *develop* alternatives; only to use them once they exist.
- Project licence applications are very large, usually covering several experiments to be conducted over five years. They may not include the fine details of the experiments and, where relevant, do not usually include information about the specific substances or products to be tested. This information would enable the ASRU inspector to determine whether an alternative approach could be used (which is often specific to the substance being tested).[58] This makes it very hard for anyone other than the researcher to judge the genuine opportunities to replace animals.
- Home Office inspectors tend to be veterinary surgeons and have limited expertise in alternative methods.[59,60]
- The responsibility to ensure alternative methods are used over the course of a project is currently delegated to the project licence holder.[61]

Government attitudes to the replacement of animal tests remains passive, delegating the responsibility largely to project licence applicants, most of which will be contract testing laboratories with an obvious commercial conflict of interest in wanting freedom over which tests they offer.

Government declines to make public statements when alternative methods come on board to require and enforce their use, preferring to allow industry to run down the animal tests as awareness of the alternative method grows and international regulations fall in line.

Animals are still being used in tests (over 100,000 in 2021) that are redundant or have been replaced by methods that have gained, or are close to gaining, approval by regulators (see Table 1). Due to the opaque nature of the system, it is unclear why most of these are still being permitted, and repeated questions to that end go unanswered.

[58] *Animals in Science Committee (2017).*

[59] *Ibid.*

[60] *NC3Rs (2023).*

[61] *Pursglove, T. (2022). Written Answer on behalf of the UK government to question 121943, 21 February 2022. Retrieved from: https://questions-statements.parliament.uk/written-questions/detail/2022-02-09/121943.*

Table 1. Animal tests being conducted in the UK that have valid replacement methods or strong evidence of redundancy.

Animal test	Estimated number of animal tests in 2021	Replacement method
Creation of antibodies for use in therapeutics or research[62]	**27,263**	Phage-display technology
Target and general animal batch safety of veterinary vaccines	Unknown	Improvements in the manufacturing process and post-market surveillance have made animal batch tests redundant
Batch potency test of botulinum toxin (Botox)[63]	**56,804**	The major toxin manufacturers have now developed a cell-based test to replace the batch test for their Botox products
Topical toxicity tests (skin irritation, skin sensitisation)	**375**	Reconstituted human tissue models and a battery of chemical and cell-based methods
Acute toxicity tests (LD50 and LC50 tests in rodents, birds, fish)	**11,758**	Cell-based tests or tests using fish eggs
90 day (sub-chronic) repeated dose test in a second species (dogs or monkeys)	**910**	Strong evidence of redundancy in these tests, including by the NC3Rs[64]
Developmental reproductive toxicity test in a second species (rabbits)	**3,003**	Strong evidence of redundancy in these tests, including by the Dutch authorities[65]
Carcinogenicity test in rodents	**3,036**	Strong evidence of redundancy in these tests, including by international drug regulators[66]

[62] In 2021, there were 52,986 'routine production: blood based products' uses, of which we conservatively estimate that half were for antibody production. In addition, there were 770 uses for monoclonal antibody production (none of which involved the ascites method). Home Office (2022). Annual Statistics of Scientific Procedures on Living Animals, Great Britain, 2021.

[63] Batch potency tests on mice to meet requirements of human medicines legislation in Britain in 2021, assumed to be all for botulinum toxin. Information obtained from the Home Office via an FOI request.

[64] Prior, H., et al. (2020). Opportunities for use of one species for longer-term toxicology testing during drug development: A cross-industry evaluation. Regulatory Toxicology and Pharmacology, 113, 104624.

[65] Braakhuis, H. M., et al. (2019). Testing developmental toxicity in a second species: Are the differences due to species or replication error? Regulatory Toxicology and Pharmacology, 107, 104410.

[66] ICH (2012). Concept Paper S1: Rodent Carcinogenicity Studies for Human Pharmaceuticals. Retrieved from: https://database.ich.org/sites/default/files/S1%28R1%29%20Concept%20Paper.pdf.

Recommendations

A statement of intent

A clear statement by ministers that the government is committed to taking action to drive down the numbers of animals used in experiments, with a view to ending the practice altogether, is an essential first step that should apply across all relevant government departments.

A transformation strategy

This commitment needs to be supported by an ambitious transformation strategy, outlining how the government intends to deliver.

A transformation strategy could include:

- Prioritisation of funding of replacements for animal tests, with simultaneous divestment of funding from animal experiments.
- Introduction of targeted reform of R&D tax incentives to promote the reduction of animal tests.
- Establishment of a cross-government taskforce to review all relevant UK regulations and agency practices to:
  - create an improved, consistent approach to animal testing and its alternatives
  - review the evaluation of projects using animals to ensure it is robust, thorough and reflects public opinion
  - evaluate the scope for a targets-based end to the requirement for sector specific animal tests.
- Elimination of unnecessary excessively-harmful and redundant tests, and reduction of wasteful practices.

With no detriment to scientific progress, there is scope to reduce the number of animals used now.

Government should seize these opportunities immediately by strengthening the harm-benefit analysis process, setting targets to end severe experiments and those conducted on dogs and primates, devising a plan to tackle wastage in the system and maintaining a list of tests that will not be authorised because they are redundant or have accepted replacements.

Ministerial responsibility

A government minister solely dedicated to leading a transition to animal-free science, with responsibility for driving policy across government departments.

A non-animal science innovation hub

Draw on the example of the Dutch government by establishing a partnership between government departments, businesses, civil society and academia, to drive innovation and adoption of specifically non-animal approaches to science.

Cruelty Free INTERNATIONAL

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