House of Commons Library

Debate Pack

Number
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Animal Testing

1 Background

E-petitions calling for Government to Ban Animal Testing (581641) and to phase out animal experiments (590216) will be debated in Westminster Hall on Monday 25 October at 6pm. E-petition 581641 , which closed on 12 October and received 235,897 signatures, states that:

> We would like the Government to ban all animal testing UK, including for the development of cosmetics, household products and medicines. Alternatives need to be actively funded. Many products that are tested on animals end up not being suitable for humans. Animal testing is outmoded and should end.[1]

E-petition 590216 on phasing out animal experiments, closes on 7 January 2022. On 21 October 2021 it had received 83,655 signatures. It states that:

> The Government must recognise the urgent need to use animal-free science and publish a clear and ambitious action plan with timetables and milestones to drive the phase-out of animal experiments. As well as preventing animal suffering, this will benefit public health and business.[2]

The Government outlined its stance on animal testing in its response to e-petition 581641 published on 4 August 2021:

> Scientific research using animals is vital in understanding how biological systems work in health and disease. Government oversees development of 3Rs techniques and delivery of robust regulation.[3]

The principles of the 3Rs, (replacement, reduction and refinement) were first presented in 1959 and provide a framework for providing more humane animal research.[4]

The Government response highlighted that testing of cosmetics on animals has been banned in the UK since 1998 and that it is illegal to test cosmetic products, or their ingredients, on animals to meet the requirements of the Cosmetics Regulations 2009.

The petition response also outlined Government funding that has been allocated for research into the 3Rs:

> Since the NC3Rs [National Centre for the Replacement, Refinement & Reduction of Animals in Research] was launched it has committed £100

1 Parliament.uk, Ban Animal Testing - Fund, accept & promote alternatives to animal testing, closed 12 October 2021
2 Parliament.uk, Plan to phase out animal experiments, closes 7 January 2021
3 Parliament.uk, Ban Animal Testing - Fund, accept & promote alternatives to animal testing, closed 12 October 2021
4 NC3Rs, The 3Rs

million through its research, innovation, and early career awards to provide new 3Rs approaches for scientists in academia and industry to use. This includes almost £27 million in contracts through its CRACK IT Challenges innovation scheme to UK and EU-based institutions, mainly focusing on new approaches for the safety assessment of pharmaceuticals and chemicals that reduce the use of animals. The MHRA works closely with the NC3Rs in bringing together stakeholders in academia, industry, government and animal welfare organisations to facilitate the exchange of information and ideas, and the translation of research findings into practice that benefits both animals and science.[5]

The Government response to e-petition 590216 was also published on 4 August 2021 and can be viewed here.

Further information and the latest data on scientific procedures involving animals are available in the Commons Library briefing on Animal Experiment Statistics published on 4 August 2021.

1.1 Legislation and regulation

The Animals (Scientific Procedures) Act 1986 (ASPA) regulates the use of protected animals in any experimental or other scientific procedure which may cause pain, suffering, distress or lasting harm to the animal. The Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 made several changes to the ASPA, including the addition of cephalopods as 'protected' animals. Government guidance on the operation of ASPA was published by the Home Office in March 2014. This states that "under the Act, protected animals are any living vertebrate other than man and any living cephalopod."[6]

Revised legislation came into force in 2013, transposing EU Directive 2010/63/EU. This also required EU Member States to submit data on specific indicators annually to be synthesised and published by the European Commission.

In the light of the UK's departure from the EU, the Animals in Science Regulation Unit (ASRU), the body responsible for enforcing ASPA, has stated that "other than minor changes to references to the Directive [EU Directive

[5] Parliament.uk, Ban Animal Testing - Fund, accept & promote alternatives to animal testing, closed 12 October 2021

[6] Home Office, Guidance on the Operation of the Animals (Scientific Procedures) Act 1986, March 2014 PDF 2.20 MB

2010/63/EU] that are embedded in ASPA, no further legislative action is needed for animals in science regulation around EU exit".[7]

The UK continues to collect and publish statistical information on the use of protected animals in regulated procedures annually in order to meet the requirements of the Animals (Scientific Procedures) Act 1986.[8]

The Government response to the e-petition provided further details and context for the existing legislative framework:

> Animal testing of cosmetics has been banned in the UK since 1998. Under UK law it is illegal to test cosmetic products, or their ingredients, on animals to meet the requirements of the Cosmetics Regulations 2009. Animal testing of chemicals is required under UK law, depending on the chemical itself and the quantity manufactured, to protect the safety of workers manufacturing or exposed to such material in high amounts and protect the environment when such chemicals may find their way into waterways, soil or the atmosphere.[9]

Regulation and regulatory bodies

Administration and enforcement of ASPA in England, Scotland and Wales is the responsibility of the Animals in Science Regulation Unit (ASRU), which is part of the Home Office. Its activities include:

- providing advice on the regulations
- operating the licensing system required by ASPA
- assuring the compliance of licence holders with ASPA and the terms of their licences[10]

The Northern Ireland Department of Health carries out this role in Northern Ireland and reports its activities separately.

The Animals in Science Committee (ASC) is an independent committee which advises the Home Secretary on matters relating to animal testing in the UK. Prior to 2013, this was done by the now-disbanded Animal Procedures Committee (APC). Further information and reports from the ASC can be found online.

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7 Home Office, Animals in Science Regulation Unit Annual Report 2017, 3 December 2018

8 Home Office, Animal testing and research: guidance for the regulated community, updated 29 September 2021

9 Parliament.uk, Ban Animal Testing - Fund, accept & promote alternatives to animal testing, closed 12 October 2021

10 Home Office, Animals in Science Regulation Unit, 2 July 2021

The Government response to the e-petition also set out that animal testing is a requirement of medicines regulators. The response stated that:

> Animal testing is required by all global medicines regulators, including the UK's Medicines and Healthcare products Regulatory Agency (MHRA), to protect human health and safety. Without the testing of potential medicines on animals the development, registration and marketing of new, safe, and effective medicines would not be possible. The animal species for testing of potential medicines are specifically chosen to give as much human relevant information as possible and to avoid species specific reactions which would not predict human effects. Many products which would [be] unsafe or ineffective in humans are detected through animal testing thus avoiding harm to humans. Potential medicines fail in development for many reasons but the fact that medicines are stopped in development for reasons other than unsatisfactory animal testing does not mean that the testing is not essential.[11]

1.2 Previous debate

Animal testing has been the subject of previous parliamentary debates. The most recent of these took place in Westminster Hall on Tuesday 1 May 2018. The debate on Cosmetics Testing on Animals was opened by Dr Lisa Cameron (SNP) who requested that the House consider a global ban on cosmetic animal testing:

> The public overwhelmingly want cosmetics testing on animals to end worldwide. More than 5.5 million people to date have signed a petition, jointly with the Body Shop and Cruelty Free International, for a global end to cosmetics testing on animals, which can be achieved by adopting an international agreement reflecting the combined will of United Nations member states to map a harmonised framework that would end the use of animal tests for cosmetic products and continue the development and international validation of non-animal methods.[12]

The then Minister for Agriculture, Fisheries and Food, George Eustice, responded:

> We recognise that in some instances animals can be an important tool in scientific research and can build on our understanding of how biological systems work. However, animals are not used lightly in that work, and the Government maintain a rigorous regulatory system under the Animals (Scientific Procedures) Act 1986. That regulatory system ensures that animal research and testing is carried out only where there are no

[11] Parliament.uk, Ban Animal Testing - Fund, accept & promote alternatives to animal testing, closed 12 October 2021

[12] HC Deb c103WH, 1 May 2018

> practical alternatives and under controls that keep suffering to a minimum.
>
> ...the UK has played a leading role globally in supporting the development and adoption of scientific techniques to replace, reduce and refine the use of animals, known as the three Rs. The three Rs principle is robustly applied to every single research proposal that requires the use of animals, to ensure that animals are replaced with non-animal alternatives wherever possible, that the number of animals is reduced and that procedures are refined as far as possible to remove any suffering that animals might incur during those tests.[13]

Wider debate and further reading

On Thursday 23 May 2019 a Westminster Hall debate took place which looked at supporting clinical trials and the UK's future clinical research capability. The Commons Library briefing published ahead of the debate includes information on advances in clinical testing techniques for the development of medicines.

An area of research highlighted in the briefing is the use of Complex Cell Models (CCMs) as they have potential to make preclinical research more likely to predict a drug's effects in clinical trials. CCMs, such as 3D biological models and testing systems using human tissue, have the potential to replace traditional 2D cell cultures and animal testing in pre-clinical research.

Further information on CCMs and advances in clinical trials is available in the Commons Library briefing on supporting clinical trials and the UK's future clinical research capability.

A POST note on advances in vaccine technologies published on 29 September 2021 contains information on the use of animal studies in the development of vaccines. The POST note highlights that new vaccines are often developed for veterinary use before being adopted for humans. Supporting veterinary research and medicine has a key role in epidemic preparedness, as 75% of emerging infectious disease threats to humans are of animal origin.

The World Health Organisation (WHO) has a factsheet on zoonoses with further information. This defines a zoonosis as "any disease or infection that is naturally transmissible from vertebrate animals to humans."[14]

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[13] HC Deb c111WH, 1 May 2018

[14] WHO, Zoonoses: key facts, 29 July 2020

1.3 Stakeholder views

The National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), funded under UK Research and Innovation (UKRI), promotes the acceleration of the 3Rs (replacement, reduction and refinement) in animal research. However, the organisation supports the use of animals in scientific research in certain situation. Their policy on this states that:

> The NC3Rs only supports the use of animals where the justification is scientifically compelling, where the experimental plans are robust and will provide meaningful results which are reported in line with the ARRIVE guidelines, and where appropriate measures are taken to minimise any suffering. Animal research supported by the NC3Rs must comply with the principles set out in *Responsibility in the use of animals in bioscience research* and other guidance including specific terms and conditions associated with grant awards.
>
> Wherever possible we ensure that animals are not used specifically for NC3Rs projects but instead "piggy-back" onto existing ongoing studies to minimise the use of animals. For our projects to develop tools and approaches that replace the use of animals it may be necessary to test these against animal models for comparative purposes. In the majority of these cases, historic animal data are used. [15]

Cruelty Free International is a campaign group seeking to end animal experiments worldwide. According to research carried out by YouGov on behalf of the organisation, 65% of people in Great Britain "want to see a binding plan in place to phase out animal testing." [16] Speaking about the research, the organisation's Director of Public Affairs Kerry Postlewhite, stated that:

> Our research with YouGov shows that the public is overwhelmingly supportive of bringing animal testing to an end in the UK with deadlines applied. We are calling on the Government to bring forward a pro-active strategy for ending reliance on outdated and unreliable animal experiments. Like those deployed in other important policy areas such as climate emissions and pollution, the roadmap should contain agreed milestones, targets and timetables. [17]

A page on the Cruelty Free International website provides access to their reports and scientific research papers published in peer-reviewed journals.

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[15] NC3Rs, Who we are and what we do

[16] Cruelty Free International, Poll: Two thirds of Brits want to see animal tests phased out and a deadline set, 4 October 2021

[17] Cruelty Free International, Poll: Two thirds of Brits want to see animal tests phased out and a deadline set, 4 October 2021

These cover issues such as the use of animals in medicine and chemical testing and testing on primates.

2 Press

Police spend tens of thousands of pounds protecting transport of puppies to labs for experiments

Independent, 8 October 2021

EU rules could bring back animal testing

The Times, 4 October 2021

Covid: Immune therapy from llamas shows promise

BBC News, 22 September 2021

Hundreds of UK and EU cosmetics products contain ingredients tested on animals

The Guardian, 19 Aug 2021

UK could allow animal tests for cosmetic ingredients for first time since 1998

The Guardian, 11 Aug 2021

3 Parliamentary Questions

Animal Experiments: Rodents

Asked by: Grahame Morris | **Party:** Labour

To ask the Secretary of State for the Home Department, what assessment she has made of the correlation between the availability of non-animal alternatives and the number of skin sensitisation tests carried out on mice between 2015 and 2019; and for what reason those tests increased by 375 per cent in 2020 compared with 2019.

Answered by: Damian Hinds | **Department:** Home Office

The Home Office has made no such assessment of non-animal alternatives and the number of skin sensitisation tests carried out on mice between 2015 and 2019; and for what reason those tests increased in 2020.

The requirements for regulatory testing are set by regulatory bodies across Government. The Home Department regulates the use of animals in science through administration and enforcement of the Animals (Scientific Procedures) Act 1986 (ASPA) which describes that the evaluation of a programme of work is favourable if it is required by law.

The Home Office assures that, in every research proposal: animals are replaced with non-animal alternatives wherever possible; the number of animals are reduced to the minimum necessary to achieve the result sought; and that, for those animals which must be used, procedures are refined as much as possible to minimise their suffering.

23 Sep 2021 | Written questions | Answered | House of Commons | 51671

Animal Experiments: Dogs

Asked by: Fleur Anderson | **Party:** Labour

To ask the Secretary of State for Business, Energy and Industrial Strategy, what recent steps she has taken to reduce the use of dogs for research purposes.

Answered by: Amanda Solloway | **Department**: Department for Business, Energy and Industrial Strategy

The NC3Rs has recently launched a £2.6 million call for the development of a virtual dog for assessing the safety of new medicines during drug development. The call is part of the NC3Rs CRACK IT Challenges competition and aims to build virtual canine tissues and organs using advanced computational and mathematical modelling approaches, ultimately to help replace the use of dogs. The Challenge builds on an international project led

by the NC3Rs that has demonstrated that there are opportunities to use one rather than the standard two species for some studies in drug development.

09 Sep 2021 | Written questions | Answered | House of Commons | 38431

Animal Experiments

Asked by: Kenny MacAskill | **Party:** Alba

To ask the Secretary of State for Business, Energy and Industrial Strategy, what plans his Department has to (a) prioritise and (b) progress on delivering the recommendations of the 2015 Innovate UK NAT Roadmap.

Answered by: Amanda Solloway | **Department:** Department for Business, Energy and Industrial Strategy

The recommendations in the Non-Animal Technologies (NATs) roadmap continue to be delivered. For example, the NC3Rs CRACK IT programme which is accelerating the development and commercialisation of NATs.

There is ongoing work led by the NC3Rs to review the impact of the £7m invested as part of the NATs programme for commercial feasibility and collaborative R&D projects. The findings of this review will be used to inform future activities in this area.

23 Jul 2021 | Written questions | Answered | House of Commons | 33344

Animal Experiments: Dogs

Asked by: Sobel, Alex | **Party:** Labour

To ask the Secretary of State for the Home Department, with reference to the publication of the annual statistics of scientific procedures on living animals in Great Britain for 2020, what harms were experienced by the 10 dogs who were genetically altered with a harmful phenotype.

Answered by: Victoria Atkins | **Department:** Home Office

The Home Office assigns severity classification to protocols in accordance with the Animals (Scientific Procedures) Act 1986 (as amended) which is published at:

https://www.legislation.gov.uk/ukpga/1986/14/contents(opens in a new tab). The classification takes account of the highest severity likely to be experienced by any animal used in the protocol and takes account of the pain, suffering, distress and lasting harm that an animal is likely to experience, after applying all the appropriate refinement techniques. The severity classification for the 10 dogs with a harmful genetically altered phenotype was ‘Moderate’.

The Home Office assures that, in every research proposal animals are replaced with non-animal alternatives wherever possible, the number of animals are reduced to the minimum necessary to achieve the result sought, and that, for those animals which must be used, procedures are refined as much as possible to minimise their suffering.

22 Jul 2021 | Written questions | Answered | House of Commons | 35874

Animal Experiments

Asked by: Kenny MacAskill | **Party:** Alba

To ask the Secretary of State for Business, Energy and Industrial Strategy, what assessment he has made of the effectiveness of the strategies of his Department to increase the number of commercial service providers or research laboratories skilled in New Approach Methodologies (NAMs) data interpretation to deliver the Government's commitment to reduce and replace animal testing.

Answered by: Amanda Solloway | **Department:** Department for Business, Energy and Industrial Strategy

We recognise how data from New Approach Methodologies (NAMs) could be used for regulatory decision-making to enable a shift away from using animals in testing.

The commercial capability in this area is increasing and, for example, UK companies such as XCellR8 have developed OECD test guideline compliant NAMs assays for use in skin sensitisation studies.

21 Jul 2021 | Written questions | Answered | House of Commons | 34616

Animal Experiments

Asked by: Kenny MacAskill | **Party:** Alba

To ask the Secretary of State for Environment, Food and Rural Affairs, what assessment he has made of the effectiveness of the strategies of (a) his Department and (b) the Health and Safety Executive to increase the number of commercial service providers or research laboratories skilled in New Approach Methodologies (NAMs) data interpretation to deliver the Government's commitment to reduce and replace animal testing for UK REACH.

Answered by: Rebecca Pow | **Department:** Department for Environment, Food and Rural Affairs

UK REACH sets out what information is needed to satisfy each hazard endpoint. This includes specifying in some, but not all cases, what studies are required, including non-animal methods where they are available. New test

methods will be included through amendments to the Test Methods Regulation after development and validation through the OECD. The responsibility then lies on registrants to commission any studies they need to fulfil their UK REACH information requirements, following Good Laboratory Practice.

The responsibility to reduce and replace animal testing with alternative methods, including New Approach Methodologies (NAMs), lies with industry (within the confines of the appropriate legislation). We would anticipate that commercial service providers will develop and expand their services accordingly, as and when demand for these methods increases. The Health and Safety Executive (HSE) has an active role with a number of organisations to advise, influence and support those looking to develop and apply these alternative methods. Where animal studies are unavoidable the Home Office is responsible for licensing testing houses and individual procedures.

HSE regulatory scientists, including toxicologists, are actively involved in monitoring and influencing the development of NAMs at both the domestic and international level which involves discussions and engagement with external experts in this field. HSE has recently appointed several independent experts who are familiar with NAMs to its UK REACH Independent Scientific Expert Pool to provide independent expert advice on the safety and regulation of chemicals and support its scientific opinions.

19 Jul 2021 | Written questions | Answered | House of Commons | 33341

Animal Experiments

Asked by: Mike Amesbury | **Party:** Labour

To ask the Secretary of State for Business, Energy and Industrial Strategy, whether he has made a recent assessment of the potential merits of holding a public scientific hearing on animal experimentation.

Answered by: Amanda Solloway | **Department:** Department for Business, Energy and Industrial Strategy

The use of animals in research is carefully regulated and remains important in ensuring new medicines and treatments are safe. At the same time, the Government believes that animals should only be used when there is no practicable alternative and it actively supports and funds the development and dissemination of techniques that replace, reduce and refine the use of animals in research (the 3Rs). This is achieved primarily through funding for the National Centre for the 3Rs, which works nationally and internationally to drive the uptake of 3Rs technologies and ensure that advances in the 3Rs are reflected in policy, practice and regulations on animal research.

15 Jul 2021 | Written questions | Answered | House of Commons | 28309

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