



Home Office

# Consultation on the review of Section 24 of the Animals (Scientific Procedures) Act 1986

## Ministerial Foreword



1. In February this year, the Coalition Government published a Delivery Plan<sup>1</sup> outlining the commitment to 'Working to reduce the use of animals in scientific research'. This plan seeks to build on the UK's leading position in the adoption of the 3Rs: Replacement of animals with non-animal methods as appropriate; Reduction of the numbers of animals used; and Refinement of procedures to minimise harm to the animals involved.
2. Within the Delivery Plan we outlined our duty to promote understanding and awareness of the use of animals where no alternative exists - this is part of our work on openness and transparency. In the Plan the Coalition Government has committed to a public consultation for the review of Section 24 of the Animals (Scientific Procedures) Act. Section 24 prevents openness on information we hold in connection with our regulatory activities under the Act. It is incompatible with Coalition Government policy on openness and transparency, including the public right of access to information held by public authorities that is provided by the Freedom of Information Act 2000.
3. The public offers conditional support for the use of animals in research, but rightly expects that any harm to animals must be more than balanced by benefits to humans, animals or the environment. To maintain public trust we must be as open and transparent as possible about activities under the regulatory framework.
4. An important part of our work is supporting ways in which the use of animals in science can be made more open and transparent. In October 2012, 40 organisations from the academic sector, health charities and industry signed a Declaration on Openness on Animal Research, committing to develop a Concordat setting out how they would be more open about the ways in which animals are used in scientific, medical and veterinary research in the UK.

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<sup>1</sup> <https://www.gov.uk/government/publications/working-to-reduce-the-use-of-animals-in-research-delivery-plan>

5. Similarly, the Coalition Government has a responsibility to be more open about the information it holds. Section 24 of the Animals (Scientific Procedures) Act 1986 prevents openness on information held in relation to activities under the Act.
6. The confidentiality requirements of Section 24 are out of step with Coalition policy on openness and transparency. The current provisions of Section 24 mean we cannot disclose information the Home Office receives in confidence, even in circumstances where the provider of the information subsequently has no objection to us releasing it. This paper therefore sets out the Government's proposed options for amending Section 24.
7. We have conducted early discussions and facilitated workshops with the diverse range of our key stakeholders to assist our thinking on the proposals. We are seeking views on our proposals and invite suggestions as to whether they are appropriate, how they may work in practice and any alternatives available. We also seek your advice to help quantify the potential impacts associated with the chosen options.
8. The Coalition Government believes the existing Section 24 should be replaced and I am fully committed to making a change. Maintaining public trust in this field is essential. By being more open and transparent we will establish greater public understanding and engender a more informed and balanced debate.
9. Following analysis of the responses to this consultation, we will work quickly to propose a final option with which to proceed. I look forward to hearing your views.



**Norman Baker MP**

## About this consultation

### Topic of this consultation

This consultation is on the review of Section 24 of the Animals (Scientific Procedures) Act 1986.

### Scope of this consultation:

This paper sets out the Government's proposals for the review and indicates our preferred option. This consultation is seeking views on our proposals and invites suggestions as to whether they are appropriate, how they may work in practice and any alternatives available. We also seek advice to help quantify the potential impacts associated with the chosen options.

### Geographical scope:

UK wide.

### Impact assessment:

An impact assessment has been published alongside the consultation.

### To:

This consultation is open to the public.

### Duration:

This is a 6 week consultation, starting on 1 May 2014 and closing on 13 June 2014.

### Enquiries and responses:

Our expected and preferred means of response to this consultation is via the online survey at:

<http://www.homeofficesurveys.homeoffice.gov.uk/s/111295XIPYF>

If you are unable to submit your response online, you may send a hard copy response to:

Section 24 consultation  
Home Office  
Animals in Science Regulation Unit  
4<sup>th</sup> Floor Peel Building  
2 Marsham Street  
London, SW1P 4DF

Please contact the Home Office ([www.gov.uk/government/organisations/home-office](http://www.gov.uk/government/organisations/home-office)) if you require information in any other format, such as Braille, large font or audio.

### After the consultation:

Responses will be analysed and a 'Response to the Consultation' document will be published. This will explain the Government's final policy intentions. All responses will be treated as public, unless stated otherwise.

### Consultation co-ordinator:

If you have a complaint or comment about the Home Office's approach to consultation, you should contact the Home Office Consultation Co-ordinator, Barima Asante. Please DO NOT send your response to this consultation to Barima Asante. The Co-ordinator works to promote best practice standards set by the Code of Practice, advises policy teams on how to

conduct consultations and investigates complaints made against the Home Office. He does not process your response to this consultation.

The Co-ordinator can be emailed at: [Barima.Asante@homeoffice.gsi.gov.uk](mailto:Barima.Asante@homeoffice.gsi.gov.uk) or alternatively write to him at:

Barima Asante, Consultation Co-ordinator  
Home Office 3rd Floor Peel Building  
2 Marsham Street  
London SW1P 4DF

**Getting to this stage:**

The Home Office has made initial engagement with, among others; animal welfare groups and animal protection groups, the UK life sciences sector, research funding bodies, practitioners such as veterinarians and animal care staff, and others with an interest in the use of animals in scientific research. Additionally, we have gathered evidence and views of internal stakeholders in other Departments; the Ministry of Justice (Freedom of Information Act), the Department for Business, Innovation and Skills and Home Office Legal Adviser's Branch. We have also consulted with the Information Commissioner's Office.

**Previous engagement:**

The initial engagement was carried out through a series of facilitated workshops, focus groups and 1:1 meetings. A previous public consultation published by the Home Office, on options for the transposition of European Directive 2010/63/EU, asked for suggestions for amending Section 24 in line with the policy objectives outlined in this consultation.

**Next steps:**

Following the consultation, we will analyse the responses and publish a Government Response to the Consultation. We will seek to make amendments as required.

# Introduction

## Context

1. The use of animals in scientific research within the UK is regulated under the Animals (Scientific Procedures) Act 1986 (ASPA). Experimentation is only permitted when there is no practical alternative research technique and the expected benefits outweigh any possible adverse effects. The Home Office, and in Northern Ireland the Department of Health, Social Services and Public Safety, have responsibility for authorising and regulating all work performed under ASPA within the UK
2. The Coalition Government is firmly committed to increasing openness and transparency, in all areas of public service. As part of this commitment we have a duty to keep the public informed of the continued use of animals in scientific research, while ensuring we uphold our high standards of animal welfare. Section 24 of ASPA prevents openness on all information we hold that is provided to us in confidence in connection with our regulatory activities under ASPA.
3. As part of the Coalition commitment titled 'Working to reduce the use of animals in scientific research', the Coalition Government has committed to the review of Section 24 of ASPA. The intention is to design a more framework that will protect proprietary rights, intellectual property and personal safety, provide greater transparency to assist public understanding, and not harm the competitiveness of the UK in the Life Sciences.

## Why is the Home Office reviewing Section 24?

4. The current provisions under Section 24 mean that the Home Office cannot release any information received in confidence under ASPA, even when the provider has no objection to its disclosure. Section 24 is incompatible with the Government's policies on openness and transparency and the central principles of the Freedom of Information Act (2000) (FOIA).
5. The FOIA is an Act of Parliament that provides a public right of access to information held by public authorities. It does this in two ways; public authorities are obliged to publish certain information about their activities, and members of the public are entitled to request information from public authorities. However, Section 44 of the FOIA states that information is exempt from public disclosure if its disclosure is prohibited by or under any enactment e.g. that described in Section 24 of ASPA. This exemption overrides the normal public right of access that is provided by the FOIA.
6. Our review should be seen in the context of changes to the information rights landscape since 1986. ASPA predates the FOIA and was therefore designed without a right to request information held by public authorities in mind. Our review must recognise the changed information rights landscape and take account of the protection provided to sensitive information by the FOIA, and ensure that the two pieces of legislation sit comfortably along side each other.
7. The primary objective of the review of Section 24 is to increase openness and transparency in order to assist public understanding of the use of animals in scientific procedures, while not putting people or property at risk or disclosing genuinely commercially confidential information and intellectual property on which UK jobs depend.

We are committed to increasing openness in order to facilitate the construction of an informed public dialogue and to help mitigate public anxieties; ideally fostering a culture of openness and understanding.

8. This review supports the Coalition Government's commitment to promoting a climate of openness and transparency. In February of this year, we published a Delivery Plan for the Coalition Commitment: Working to reduce the use of animals in scientific research. This document provides a narrative of the rationale for the use of animals in scientific research and a framework of actions to progress the commitment. One of our strategic priorities within this Plan is to promote an understanding and awareness about the use of animals where no alternatives exist – of which the review of Section 24 is a fundamental part.
9. We are also committed to building on the Declaration of Openness launched last year, driven by the academic sector, health charities and industry. This commits those engaged in research to foster an environment of openness around the ways in which animals are used in scientific research in the UK. One of the requirements of the recent transposition of the European Union Directive (2010/63/EU) is that the UK must publish non-technical summaries of all authorised project licences. These are lay summaries that detail the objectives of all research projects that involve animals, and list the potential benefits and adverse effects of the research. These summaries also detail how the licence applicant has considered the 3R's. These summaries will commence being published online during 2014. The review of Section 24 provides an opportunity to continue the progression to an increasingly open and transparent environment in which the Home Office is the monopoly regulator.
10. The greater amount of information that would potentially be publicly accessible following this review may increase awareness among the scientific community of current research involving the use of animals. This may help to provide a constructive dissemination of technical knowledge, minimising the potential for duplication of animal experiments.
11. The Home Office (Animals in Science Regulation Unit), and in Northern Ireland the Department of Health, Social Services and Public Safety, have sole responsibility to regulate the use of animals for experimental or other scientific purposes within the UK. Three licences are required by ASPA before testing on animals is permitted; a personal licence for each person carrying out procedures on animals; a project licence for the programme of work; and an establishment licence for the place at which the work is carried out. The drive for a more transparent regulatory system allows us the additional opportunity to minimise the confusion over the application of the current Section 24 legislation, including who and what it applies to. Consequently, there is a possibility of minimising the effort associated with the application, assessment and authorisation of licences required to perform scientific research involving animals. This will make it easier for individuals and organisations to carry out their duties, increasing the efficiency of our regulatory processes.
12. An assured degree of confidentiality is still required. Protecting health and safety is a particular concern for people and places involved in animal research and confidentiality remains obligatory for people or place names. The Government also reaffirms its legal responsibility towards safeguarding confidentiality of information that constitutes intellectual property, whilst supporting a more open and transparent environment surrounding the use of animals in scientific research and increasing public understanding of the use of animals where no alternative exists. Stakeholder views are invited on the kinds of information that should or should not be automatically protected from disclosure on grounds of commercial confidentiality.

## Objectives of the review

13. The solution to the review of Section 24 must not detract from the primary intent of ASPA which is to provide for the protection of animals used in scientific procedures. We must provide greater transparency to provide information and assist public understanding about the use of animals in scientific procedures and retain the public confidence and trust in our duties as a regulator. However, our commitment to openness must be balanced by the provision of appropriate protection for sensitive information, such as personal details and intellectual property, in order both to safeguard personal privacy / safety and to promote the economic growth and success of the UK in the life sciences.
14. As a regulator, we are unique in that we are legally obliged to collect large amounts of detailed information about research scientists' most valued assets – their ideas and scientific hypotheses – in order to grant authorisation for researchers to pursue those ideas and hypotheses for their livelihood. This places especial responsibility on Government to ensure the appropriate protection of this information. Any amendments we make to Section 24 should not harm the competitiveness of the UK in the life sciences.
15. The harm / benefit analysis of a project licence application is a process conducted to weigh whether a project using animals should be authorised. It is not the intent of this review to amend Section 24 such that we provide information so the public or other external bodies can conduct their own harm / benefit analysis as to whether a particular scientific research project involving animals should be authorised. It is only possible to conduct a harm / benefit analysis with access to all the information provided about the project licence application, some of which (e.g. intellectual property) would be prohibited from public disclosure. Therefore, the Home Office must remain the competent authority for taking decisions on licence applications.

## Getting to this stage and next steps

16. There is a diversity of views about animal research in general. As part of the initial stage of the review, the Home Office has engaged broadly with stakeholders from across the spectrum of opinion, from anti-vivisectionists to duty holders performing functions under ASPA. We have consulted with, among others; animal welfare groups and animal protection groups, the UK life sciences sector, research funding bodies, practitioners such as veterinarians and animal care staff, and others with an interest in the use of animals in scientific research.
17. Additionally, we have set up a cross-Government steering group to garner the views of internal stakeholders in other Departments. Views have been sought from the Ministry of Justice (FOIA), the Department for Business, Innovation and Skills and Home Office Legal Adviser's Branch; we have also consulted the Information Commissioner's Office, responsible for regulating the use of Section 24 to prevent disclosure under the FOIA.
18. Through our initial engagement we have developed policy options which are the focus of this consultation. Engagement with stakeholders has demonstrated confusion over who Section 24 applies to and what information is permitted for public disclosure. There was general agreement across all those consulted that information relating to people, places and intellectual property should be protected from disclosure in a reliable manner.



19. The Government wants to ensure that appropriate measures are put in place to continue the progression to an increasingly open and transparent environment, both in the use of animals in scientific research and overall Government policy. However, before committing to any action it is imperative that we have identified all the relevant issues pertaining to our proposed policy options.
20. To that end, this consultation seeks views on whether and how the Government's proposals should be implemented, in particular our preferred option. We would also welcome views on any additional issues that should be considered when proposing amendments to the regulatory regime.
21. Following the consultation, we will analyse the responses and publish a Government Response to the Consultation. We aim to progress quickly, finalising a chosen option and amending ASPA through Parliamentary process if required.

# The proposals and questions

## Background

22. Section 24 of the Animals (Scientific Procedures) Act 1986 provides for the protection of information received in confidence that is provided in connection with the Home Office's regulatory activities under the 1986 Act. The lists below itemises some of the information which might be covered by Section 24. However, the list is not exhaustive, and not all of the types of information listed below are equally covered. For instance, Section 24 may cover only some parts of a licence assessment.

### a) Licensing

- Licence applications (personal, project and establishment), supplementary information and associated correspondence.
- Assessments of licence applications by inspectors.
- Animals in Science Committee (a non-departmental advisory body) and external assessor advice on licence applications.
- Non-compliance correspondence.
- Review papers / proceedings (including legal advice and final reports).

### b) Inspections

- Inspection visit reports.
- Risk assessments of establishments.
- Non-compliance reports.
- Other information provided by licensees and establishments.
- Information provided by (and about) overseas suppliers and our assessment.

### c) Other

- Animals in Science Committee records.
- Ministerial and policy advice.

## Options

23. Initial stakeholder engagement has assisted in the development of proposed policy options which are the subject of this consultation. The proposed options for amending Section 24 are as follows:

### **Option 1:** *Retain Section 24 of the Animals (Scientific Procedures) Act 1986 (ASPA).*

- This currently provides a statutory prohibition on disclosure of information provided in confidence to the Home Office. Information can only be publicly disclosed if it does not contain information provided in confidence. Technically, this prevents disclosure of information even when the provider has no objection to its disclosure.
- Information that does not directly contain information provided in confidence is publically accessible, provided it is not exempt from release under the FOIA.<sup>2</sup>

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<sup>2</sup> The Freedom of Information Act (FOIA) contains exemptions to the right of access. The exemptions listed in Part II of FOIA set out the circumstances in which public authorities may decline to provide information in response to any request: if information is exempt then individuals do not have a right of access to it under the Act. For more information, please see Annex A of the accompanying Impact Assessment.

**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.*

- All information that may be withheld under exemptions within the FOIA would be covered, including intellectual property.
- Definitions of what constitutes intellectual property (and information that might become commercially valuable in the future) may also be required and we would welcome stakeholder views on this.
- The instances covered by the term “malicious disclosure” will be defined in the prospective legislation, but may, for example, cover where information was disclosed with the intent to cause harm or for financial gain.
- This option would allow for controlled release of information in required circumstances, in addition to non-malicious disclosure of confidential information, e.g. to highlight malpractice and / or threats to animal welfare.
- Under this option, when considering a request made under the FOIA it would be necessary to rely solely on exemptions within that Act to protect sensitive information where appropriate. If information was disclosed with malicious intent, it would be a criminal offence.

**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.*

- All information could be disclosed provided it was neither exempted from release under FOIA nor specifically contained information about people, places or intellectual property. FOIA exemptions would be available to protect other information not relating to people and place details and intellectual property where necessary. If information was disclosed with malicious intent, it would be a criminal offence.

**Option 3:** *Repeal Section 24 of the Animals (Scientific Procedures) Act 1986 (ASPA).*

- This option would completely remove the current Section 24 legislation, and no further amendments would be made to ASPA. All information could be publicly disclosed unless exemptions in the FOIA were relied upon to protect it.

24. Option 1 is the ‘do nothing’ option which we consider untenable. Under options 2a, 2b and 3, a significantly greater amount of material will be disclosable than under the current regime. The difference between the options lies not in the amount of material which is disclosable but in the criminal sanction which will apply in the event of malicious disclosure of “protected” material (under options 2a and 2b, but not 3) and the presence of a statutory prohibition on disclosure in option 2b. This statutory prohibition is intended to give certainty to the minimum scope of the “protected” material into the future.

25. Our preferred way forward lies in option 2b. We believe there would be significant benefit if the amended legislative framework were to include a statutory prohibition on disclosure of ‘protected’ information in limited and defined categories (relating only to people, places and intellectual property), while also allowing disclosure of such information if the provider is content.

26. The option under 2b would allow all information to be disclosed, provided it is not specifically information about people, places or that containing intellectual property. If information is disclosed with malicious intent, it will be a criminal offence. This option would allow for controlled release of information in required circumstances, in addition to non-malicious disclosure of confidential information, e.g. to highlight malpractice and / or threats to animal welfare. A full list of costs, benefits and risks of the proposed options is detailed in the Impact Assessment published alongside this consultation.

# Questions

## Option 1: Do nothing. Retain Section 24 in its current form.

27. Under the current legislation, information can only be released where it does not contain information provided in confidence. Technically, this prevents disclosure of information even when the provider has no objection to its disclosure.

**Question 1: Do you believe we should retain Section 24 in its current form? Please provide comments to explain your answer.**

- Yes
- No
- Don't know

## Option 2a: Repeal Section 24 and amend ASPA, creating a criminal offence of malicious disclosure of information about the use of animals in scientific research

28. All information may be disclosed provided it is not exempted from release under the Freedom of Information Act 2000 (FOIA). If information is disclosed with malicious intent (defined in the legislation), it will be a criminal offence. (This option does not include the statutory bar as under option 2b).

**Question 2: To what extent do you believe, if at all, that this option meets the Government's primary objective of increasing openness and transparency about the use of animals in scientific research? Please provide comments to explain your answer.**

- Very much so
- To some extent
- Not at all
- Don't know

**Question 3: To what extent do you believe, if at all, that this option appropriately clarifies who and what is covered by the legislation? Please provide comments to explain your answer.**

- Very much so
- To some extent
- Not at all
- Don't know

**Question 4: To what extent do you believe, if at all, that this option provides appropriate protection for sensitive information (e.g. people and place details and intellectual property)? Please provide comments to explain your answer.**

- Very much so
- To some extent
- Not at all
- Don't know

**Question 5: Would this option change any processes – directly or indirectly – associated with operating under ASPA, compared to the current regime? (For example, a change in the way a licence application is constructed). If you consider yes, please provide comments to explain your answer.**

- Yes
- No
- Don't know

**Option 2b: As option 2a. The amended legislative framework would additionally include a statutory prohibition on disclosure of information relating only to people, places and intellectual property.**

29. All information may be disclosed provided it is neither exempted from release under FOIA nor specifically contains information about people, places or intellectual property. If information is disclosed with malicious intent, it will be a criminal offence.

**Question 6: To what extent do you believe, if at all, that this option meets the Government's primary objective of increasing openness and transparency about the use of animals in scientific research? Please provide comments to explain your answer.**

- Very much so
- To some extent
- Not at all
- Don't know

**Question 7: To what extent do you believe, if at all, that this option appropriately clarifies who and what is covered by the legislation? Please provide comments to explain your answer.**

- Very much so
- To some extent
- Not at all
- Don't know

**Question 8: To what extent do you believe, if at all, that this option provides appropriate protection for sensitive information (e.g. people and place details and intellectual property)? Please provide comments to explain your answer.**

- Very much so
- To some extent
- Not at all
- Don't know

**Question 9: Do you agree that the additional statutory prohibition on disclosure is necessary to protect certain types of sensitive information? Please provide comments to explain your answer.**

- Very much so
- To some extent
- Not at all
- Don't know

**Question 10: Would this option change any processes – directly or indirectly – associated with operating under ASPA, compared to the current regime? (For example, a change in the way a licence application is constructed). If you consider yes, please provide comments to explain your answer.**

- Yes
- No
- Don't know

### **Option 3: Repeal Section 24.**

30. All information may be disclosed unless it is exempted from release under FOIA. There would be no additional, or alternative, protection provided for confidential information other than that provided by the exemptions within FOIA.

**Question 11: To what extent do you believe, if at all, that this option meets the Government's primary objective of increasing openness and transparency about the use of animals in scientific research? Please provide comments to explain your answer.**

- Very much so
- To some extent
- Not at all
- Don't know

**Question 12: To what extent do you believe, if at all, that this option appropriately clarifies who and what is covered by the legislation? Please provide comments to explain your answer.**

- Very much so
- To some extent
- Not at all
- Don't know

**Question 13: To what extent do you believe, if at all, that this option provides appropriate protection for sensitive information (e.g. people and place details and intellectual property)? Please provide comments to explain your answer.**

- Very much so
- To some extent
- Not at all
- Don't know

**Question 14: Would this option change any processes – directly or indirectly – associated with operating under ASPA, compared to the current regime? (For example, a change in the way a licence application is constructed). If yes, please provide comments to explain your answer.**

- Yes
- No
- Don't know

## **Impact Assessment**

**Question 15: Are there any additional costs or benefits that have not been identified in the impact assessment but should be taken into consideration? If yes, please state what they are, your reasoning for including them and any information which would help to quantify the impact, where possible.**

- Yes
- No
- Don't know

**Question 16: To what extent do you agree or disagree with the risks and assumptions made in the impact assessment? Please provide comments to explain your answer.**

- Strongly agree
- Agree
- Disagree
- Strongly disagree
- Don't know

**Question 17: Can you provide any further information which may help to quantify the scale or direction of the costs or benefits, as identified in the impact assessment, as a result of these proposals?**



## **Further questions**

**Question 18: With regards to options 2a and 2b, in what instances do you believe disclosure of information about the use of animals in scientific research is malicious? Please provide comments to explain your answer, using clear examples where possible.**

**Question 19: What do you believe should be covered by the term 'intellectual property'? Please provide comments to explain your answer.**

**Question 20: Do you consider that Section 24 of ASPA, being a statutory bar and an absolute exemption, provides greater protection for intellectual property than other qualifying FOIA exemptions?**

**Question 21: Are there any other views or comments that you would like to add in relation to the review of Section 24 that were not covered by the other questions in this consultation?**

**Question 22: Which of the following best describes the organisation or professional interest that you represent? Please state the name of the organisation in the box below.**

- Academia
- Commercial
- Charity
- Other Government department
- A representative of an animal welfare organisation
- A representative of an animal protection organisation
- A member of an animal welfare organisation
- A member of an animal protection organisation
- An individual with a professional interest
- A member of the public
- Other (please specify):

**Name of organisation if relevant:**

