The Academy of Medical Sciences' response to the Home Office's consultation on the review of Section 24 of ASPA

June 2014

In June 2014, the Academy responded to the Home Office's consultation on options for updating Section 24 of the Animals (Scientific Procedures) Act 1986 (as amended) (ASPA). Our response was submitted via an online survey. Questions in the consultation were grouped by the options being considered for Section 24 in the consultation document, as described below.

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

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

Comment

The Academy of Medical Sciences promotes advances in medical science and campaigns to ensure that these are translated into healthcare benefits for society. Our elected Fellowship includes the UK's foremost experts drawn from a broad and diverse range of research areas. The use of animals is essential for a significant amount of scientific, medical and veterinary research, and a great number of advances in human and animal health have resulted from this research.

The Academy of Medical Sciences warmly welcomes the Home Office's consultation on Section 24 of the Animals (Scientific Procedures) Act 1986 (as amended) (ASPA), with the aim of making the conduct of animal research more transparent. We are glad to have the opportunity to respond to it and help to develop the legislation in a way that will facilitate the exchange of information in the research community and between researchers, relevant Government departments and the public.

In the Academy's view, transparency and increased public awareness is more likely to come from greater openness and this is reflected in the recently-released Concordat on Openness on Animal Research, to which the Academy is a signatory.[1] We do not feel that Section 24 of ASPA is currently in accordance with these aims. It has neither allowed transmission of information in material relating to animal research held by Government where this could be permissible (i.e. there would be no objections by information providers or Government, and no breach of sensitive information), nor given sufficient protection of personal safety, proprietary rights and intellectual property (IP) in material provided to Government, as originally intended. We therefore do not believe Section 24 should be retained in its current form.

[1] Understanding Animal Research (2014). *Concordat on Openness on Animal Research.* http://www.understandinganimalresearch.org.uk/policy/concordat-on-openness-on-animal-research

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

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.

<u>Very much so</u>
To some extent
Not at all
Don't know

Comment

The repealing of Section 24 would be very likely to result in the release of more information held by Government. It would therefore increase openness and transparency on many regulatory aspects of animal research. However, such a move could be in conflict with another core aim of the Government's agenda, outlined in page 1 of the consultation's impact assessment: to protect the competitiveness of the UK bioscience sector. Repealing Section 24 without other appropriate safeguards would not guarantee the protection of the sector's sensitive information (defined as the people, places and IP involved in research). The impact of criminalising malicious disclosure of information is unknown (in part because the definition of 'malicious' is unclear—see our response to Q3), but it is unlikely that it will provide sufficient protection for the sector.

The Academy would like to ensure that the UK maintains its leading position in bioscience because of the health and wealth benefits that the sector delivers in the UK and beyond, as economic analyses suggest.[2] [3] We are anxious to see a more efficient regulatory environment, in particular one that does not hinder the continued recruitment of world-leading scientists to the UK bioscience effort. If Government were to repeal Section 24, we would recommend that it ensures that the IP of all researchers is protected sufficiently under the Freedom of Information Act (FOIA), particularly in terms of the release of new ideas and projects that are currently included in Project Licence applications. We believe that part of this solution could be readily achieved by a more streamlined format of the Project Licence.

[2] Health Economics Research Group, Office of Health Economics, RAND Europe (2008). *Medical Research: What's it worth? Estimating the economic benefits from medical research in the UK.* <u>www.wellcome.ac.uk/economicbenefits</u>

[3] Glover M, *et al.* (2014) *Estimating the returns to UK publicly funded cancer-related research in terms of the net value of improved health outcomes.* BMC Medicine **12**, 99. <u>http://www.biomedcentral.com/1741-7015/12/99</u>

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

Comment

This option clarifies that the protection of sensitive information would fall under FOIA exemptions, but the Academy is not satisfied that this option gives sufficient protection to the sensitive information, and particularly the IP, of biomedical researchers.

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

Comment

We are pleased to see that Government recognises the value of IP to the sector, and agree that it has a responsibility to protect this, as discussed in the following statement in the impact assessment (p6):

> ASPA is unique in that it requires duty-holders to provide detailed information about their most valued assets – their ideas and scientific hypotheses – in order to be permitted to pursue these ideas within the scientific research in question. This places especial responsibility on Government to ensure the absolute protection of this information.

We do not think that this option provides the necessary assurance that IP will be protected. It is not clear how 'malicious intent' is to be defined, and what protection this would grant. It may introduce legal confusion. We feel that IP requires a clearer definition. The Academy strongly believes that the definition used for intellectual property should include information such as novel ideas, scientific hypotheses, procedures, protocols and research plans. These may constitute commercially sensitive information, but also valuable intellectual property for individual researchers and institutions. A lack of protection for such information would impact badly on the competitive edge of UK researchers and institutions.

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

Comment

Under ASPA, record keeping is of major importance: these records are being used to assess the impact of the 3Rs (the replacement, refinement and reduction of animals in research) on animal welfare and assess the actual level of severity involved in a given procedure. If this option were adopted, excessive use of FOIA may force establishments to minimise the records that they hold, which could be detrimental to both animal welfare and the overall research effort. The Academy is committed to promoting the 3Rs as a key principle for maintaining and improving high animal welfare standards, without compromising scientific and medical advances.
This issue would likely be a major difficulty unless ASRU substantially streamlined the level of detail currently required in Project Licence applications. The content of the Project Licence should reflect key issues related to animal welfare and to the harm-benefit analysis, and we believe that this can be achieved with a streamlined Licence format, that substantially reduces the need to explain in great detail the ideas and hypotheses upon which the planned project depends. Relying on the FOIA to edit current licences to FOIA-compliant protection would be extremely difficult, and time and resource consuming (see Q13 and Q15).

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.
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

Comment

People, places and IP (as defined in the consultation document) are the three core aspects that require protection from unauthorised release. This option permits the release of all other information, in keeping with the sector's intentions, and would increase openness and transparency on material held by ASRU.

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

It is necessary to add further clarification as to whether or not the statutory prohibition would apply to both Government and to those supplying information to ASRU. Such a measure would need to apply to all stakeholders involved in the production or holding of sensitive information for this information to be protected sufficiently.

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

As described in our response to Q4, the definition of IP is crucial for protecting the information sufficiently and not impacting negatively on the competitive edge of UK bioscience. As described in Q7, without extending the statutory prohibition to those producing sensitive information, this will not be adequately protected.

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

Comment

Yes, provided it covers all stakeholders associated with holding or producing the information, as described in our response to Q7 and IP has the broader definition described in Q4. Therefore this wording is essential but it does not in itself provide the protection envisaged by the Impact Assessment.

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

Comment

Please see the response to Q5.

Option 3: Repeal Section 24.

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

Comment

The Academy agrees that this option would generate the maximum transparency permitted under FOIA. However, it fails completely to provide the reassurance that UK researchers and institutions require that their intellectual property contained within documents submitted under the Act will not be released, e.g. by ASRU when challenged under a FOIA request, as appropriately elucidated in the Impact Assessment. This could compromise sensitive information in the material.

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

Comment

It is clear that FOIA would cover information held by both ASRU and the providers of the information.

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

Comment

The Academy agrees that people and places can be adequately protected under FOIA. However, FOIA, as currently constituted, can be ambiguous over the protection of IP. IP *per se* is not defined and is referred to in guidance relating to various exemptions including Section 41 (Confidential Information) and Section 43 (Commercial Sensitive Information). The term 'IP' is often used in the context of having commercial value, whereas in scientific terms the protection is needed for the ideas and future work of scientists even when there is no clear or immediate commercial value at stake. The Academy is anxious to see this form of IP protected.

A further point is that, in many cases, only the technical author of a Project Licence (the applicant) can understand the full potential impact of release, yet only a lawyer dealing with FOIA requests can understand how FOIA can be used to provide protection. There is significant time pressure to respond to FOIA requests, and it can become difficult, in the short time available, to reach agreement between scientist and the lawyer as to what can be protected under which section of FOIA. This process means extensive, time-consuming and expensive discussions and a high risk of it failing to give adequate protection. The Academy's Fellows have direct experience of just such instances in which there were insufficient time allowances to ensure the information released had been properly redacted.

In general, we do not think that this is a satisfactory means for ensuring the safety of the UK's research IP.

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

Comment

Please see the response to Q5.

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

Comment

The experience of many UK universities over recent years is that there has been a large rise in FOIA requests related to their use of animals in biomedical research, and to the Project Licences relevant to that research. The cost of responding to these FOIA requests has grown in proportion. As pointed out above, the redaction process needed to protect people, places and IP can be technically demanding, time-consuming and expensive. No extra costs are allowed for the time taken for such redaction.

As noted above (Q2 and Q5), the Academy suggests streamlining the Project Licence application, in order to reduce the number and complexity of these redactions.
The Academy welcomes the statement in the impact assessment (p9) that recognises that "these sectors make a significant contribution to the UK economy. This contribution to the UK economy may be at risk if the UK is perceived as too high-risk an environment to operate in, both in terms of a perception of insufficient protection of sensitive information and / or being placed under a disproportionate regulatory burden."
We trust that the legislation will minimise the risk of potential damage to UK biomedical science.

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

Comment

We believe that unless there is demonstrable and material public benefit in the release of technical documents held under ASPA, any slight benefit of release will not outweigh the direct costs incurred by doing so (see Q15) and the associated risks of the inadvertent release of IP and the failure of the Government's aim to support the competitiveness of UK biomedical science.

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?

The Academy believes that potentially large and unquantifiable costs related to additional regulatory burdens, together with increased risks of release of IP, could dissuade commercial investment in the UK's bioscience sector, and impede recruitment of leading biomedical researchers to the UK science base. Given the sums quoted in the impact assessment, such a consequence would have significant consequences for the sector and its many employees.

Further questions

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

The Academy supports the statement in the impact assessment regarding IP, but as described in our response to Q4, a detailed description encompassing broader aspects of innovation, that are currently required to be included in the Project Licence application, must be considered for inclusion as IP.

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?

The recent experience of several universities in the UK is that Section 24 provided no such protection for their IP.

Question 21: Are there are 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?

The Academy strongly supports efforts made by Government and the sector to strike a balance in a regulatory between the need to implement high standards of animal welfare and the requirement to facilitate research. It is of particular importance to note that the Academy would not support any new regulations that prevent release of details that are directly related to animal welfare.

This response was prepared by Dr Dylan Williams (Policy Officer) and informed by the Academy's Fellows. For further information, please contact Dr Rachel Quinn (rachel.quinn@acmedsci.ac.uk; +44(0)20 3176 2163).

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