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

Submission from The Physiological Society and the British Pharmacological Society
June 2014

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

Comment:

The Physiological Society and the British Pharmacological Society agree with and support the response submitted by the UK Bioscience Sector Coalition (UKBSC) and now wish to emphasize some points and include other aspects where they are relevant to our membership.

As stated in the impact assessment:

> "S24 was included in ASPA to provide assurance to individuals and establishments applying for authorisations, and subsequently carrying out projects, that confidential information and intellectual property provided to the competent authority would be protected."

The requirement for the protection of this information is still as essential today, as when Section 24 was introduced, as recognised by the Government in the consultation document and impact assessment (IA).

That said, it is clearly not appropriate that the law should hinder the spread of best practice when participants are willing for the information to be shared; nor that government officials may not release information that is already in the public domain. Such aspects need to change.

It has also become legally unclear whether s24 applies only to government or also to the parties submitting sensitive information to government. This is a highly unsatisfactory situation, as detailed by UKBSC.

The Physiological Society and the British Pharmacological Society therefore supports reform of Section 24.

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

Comment:

This policy option would meet the government's aim of increasing openness and transparency. However, it does not satisfy the Government's aim of protecting the UK bioscience sector as elucidated in the Impact Assessment.

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:

We agree with the UKBSC that this option is open to interpretation with regard to the term "malicious", and does not adequately protect owners or IP, as deemed necessary in the Impact Assessment, for the following reasons:

Without a clear definition of "malicious intent" it is not possible to accurately determine what is covered by this legislation.

This option fails to adequately specify the cover of people, places and IP, which are the three strands of sensitive information that require specific protection under the amended legislation.

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 agree with the analysis in the impact assessment (p14), that this policy option –

> "does little to address the uncertain application of FOIA exemptions to the information which it is agreed should be protected: i.e. people, places and intellectual property. It would therefore do little to reduce the risk of challenge arising from not providing information relating to the use of animals in scientific research when requested under FOIA."

If both appropriate application of FOIA exemptions and resources to defend against potential challenges are required to protect sensitive information, then it is clear that this policy option doesn't provide appropriate protection. While FOIA provides basic protection, there are practical limitations to its application in this unique situation of sensitive material prepared solely to satisfy government regulation; the UKBSC submission provides more detail on this important aspect point.

We welcome the invitation in the consultation document to provide a definition of what constitutes IP. However, we disagree with the consultation document's assertion that "All information that may be withheld under exemptions within the FOIA would be covered, including intellectual property."

IP, considered in the academic sense, is not clearly defined in the FOIA, which instead refers to "commercial interest" and "information provided in confidence". We are therefore very clear that this policy option does not provide adequate protection of IP as defined in the UKBSC submission in the broader sense as including research plans, ideas and novel hypotheses. Members of the Physiological Society and British Pharmacological Society are largely engaged in preclinical research, most of which does not at that stage (and may never) provide "commercial interest" in the generally accepted meaning of "commercial". We are therefore particularly concerned that the definition/interpretation of IP should be broadened, both in the operation of FOIA and in the revised ASPA.

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:

Implementation of this option may not in itself cause a change in processes, but it would rapidly highlight the necessity for changes to be made.

We do not believe FOIA, as it has been implemented to date, in itself capable of protecting sensitive information in a cost-effective manner. Therefore, if FOIA exemptions are to be relied upon for adequate protection of sensitive information, ASRU would have to make significant changes to existing processes for this policy option to be remotely practical.

In order to protect IP, particularly when IP is considered in the terms most appropriately applied to pre-commercial stage academic IP as held by most of our membership (see Qu 4 and 8), there would be a need for a significant reduction in the amount of detail currently required in the paperwork submitted to ASRU. We believe that such a reduction in detail would still allow a full harm / benefit analysis to take place, and would be entirely commensurate with the Directive and ASPA. This would also have the important benefit of increased harmonisation across the EU and would adhere to the principles of better regulation.

Where establishments have some discretion over paperwork (such as in licence-associated processes such as AWERBs and other management committees) there would most likely be a reduced detail of their records kept so as to mitigate the consequences of any unplanned release. That is not in the best interests of either science or animal welfare.

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

Comment:

As indicated in the impact statement, it is widely agreed that information relating people, places and IP should be protected. This policy option theoretically could provide the necessary protection for sensitive information while allowing the release of all other forms of information, thereby meeting the government's stated aims.

In that context The Physiological Society and British Pharmacological Society wish to endorse the UKBSC's explicit statement that we have no wish to prevent release of information relating to the welfare of animals used in regulated procedures.

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

Comment:

It is unfortunate that neither the Consultation document nor the Impact Assessment clarifies to whom the legislation applies. The legislation must apply equally to all parties with responsibilities under ASPA – that is not only to those receiving such information (e.g. ASRU) but also the providers of such information, such as academic licensees and establishments.

Without a formal definition of malicious intent, it is impossible to be sure what is covered by the legislation. While it is clear that genuinely malicious release is covered, harm can also come about not only through well-intended release of information (for example by persons who genuinely believe that certain information should be in the public domain) but also through negligent or careless release of information. Taking these considerations into account, who and what is covered by the legislation is not at all clear. It is essential that this be rectified in the legislation.

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

Comment:
We believe that this policy option has the potential to provide appropriate protection for sensitive information.

Protection for people and places is provided under FOIA, although with some deficiencies relating to the need to demonstrate the potential for release of such information to cause harm (see UKBSC response to Qu 13 for further detail on this).

However in the absence of a formal definition, the protection afforded for IP is less clear. We strongly welcome the recognition in the impact assessment (p 7) that IP is not restricted to commercially sensitive information, and that academic IP also requires protection. Current Project Licence applications require detailed programmes of work extending (at the time of writing) at least five years into the future, including hypotheses and in many cases named compounds or high levels of details on procedures. Information is also included on hypotheses, in obviously commercially sensitive areas such as development of novel treatments, or in less obvious areas such as clear understanding of system functions, or potential contributions of cellular mechanisms to whole system dysfunction. In addition, unpublished findings, novel targets, molecules, drugs, functions and ideas are frequently included in these documents at the behest of ASRU. Academic research in physiology and pharmacology is, almost by definition, at the pre-commercialisation stage, and therefore demonstration of 'commercial application' of included information, as under FOAI, has been problematic.

It is essential, therefore, that any resultant legislation defines IP to include activity from first research idea to final publication of the results, irrespective of whether there is any commercial application.

). Notwithstanding this it should be recognised that very early stage ideas have great *potential future* commercial value to Universities in terms of attracting external revenue in the form of grants, and in underpinning spin-out commercial ventures. This potential is the

reason why Universities protect such early IP before overt external commercial investment is forthcoming. IP, defined in these broader terms, is not adequately protected under current FOAI definitions. [While we are aware of, and appreciate, current government moves to clarify the definition of IP in relation to FOIA, such clarification is not complete. In any event it needs to be similarly defined in a broad context within ASPA].

A key point for consideration is that researchers and Institutions may be the only people fully aware of the potential sensitivity of information held in documents submitted to ASRU. Early stage hypotheses may not be recognised by a less specialist reader as being sensitive information, and therefore any FOAI request to ASRU will also require input from the originator of the document to identify sensitive information.

This could impact our members and the wider UK/international research base in numerous ways.

1. Our members are largely employed in academic institutions. In addition to their research commitments, many of them have heavy teaching, assessment and administrative burdens. This leaves them with very little time for the increased bureaucracy that would result from an increased number of FOAI requests.
2. The UK academic science base does not exist in isolation from the rest of the world. We collaborate with and are funded by UK industrial partners (e.g. the pharmaceutical industry), and overseas funders (e.g. NIH, EU). Additional barriers to conducting research involving animals have already resulted in some of our partners relocating overseas. If bureaucracy is increased still further, particularly relating to IP, industrial and/or overseas partners would be disinclined to collaborate with us, and to fund research in the UK.
3. ASPA requirements already take our members considerable time, for example writing a complex PPL application which can extend to ~100 pages, involve multiple meetings with Home Office Inspectors and multiple reiterations can take well over a year to finalise and receive approval. Further bureaucracy adding to this burden would result in our membership increasing their overseas collaborations in these areas in order to avoid the inflexibility, and time commitment of working under ASPA. This would be detrimental to the UK science base, as funding would follow the research to our overseas collaborative partners.
4. This would incur considerable additional cost to academic institutions (see detailed response in Qu 15).

It is likely that substantial changes to the procedures and ASRU forms would be required for this policy option to feasible in practice (see Qu 10).

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:

We are clear that FOIA does not provide appropriate protection for sensitive information (see responses to Qu 3, 4 & 8), and under some circumstances for people and places (see UKBS submission Qu. 13), and therefore a statutory prohibition is required. We agree fully with the

UKBSC on the detrimental impact that inadequate protection of sensitive information would have on the UK science base (UKBSC submission Qu 9).

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:

Due to the highly technical nature of license application forms and the interspersion of IP content with non-IP content, redaction for the purposes of a FOIA request usually requires significant effort from both the lead scientist and legal advisors.

Therefore without substantial changes to the license application forms, we risk a situation whereby the process of redacting IP becomes so burdensome that the value of these necessary protections almost becomes meaningless.

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

Comment:

Clearly this option maximises the amount of information that can and would be released into the public domain, subject to FOIA.

We are clear that this option would not provide the necessary protection for sensitive information, as also stated in the Impact Assessment. The limitations of FOIA applied to detailed and sensitive material collected and submitted solely to satisfy government regulation is not well catered for by FOIA, as discussed above and in the UKBSC submission.

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:
The availability of FOIA to UK and overseas nationals is well known. As mentioned, the coverage and protections under FOIA do not, however, clearly cover key aspects covered in the Impact Statement, namely the duty to fully protect people, places and (especially) the early stage research IP undertaken by most of our members.

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:

We are clear that FOIA does not always provide adequate or appropriate protection for sensitive information regarding either people or information (please see responses to Qu 3, 4, 8 & 9).

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:

It is clear to us that options 2 and 3 would necessitate change to ASRU processes, particularly relating to the structure of and detail contained in licence applications and associated paperwork.

There would be a major difficulty with option 3 unless ASRU substantially simplified the level of detail currently required in licence applications. Relying on FOIA rules to edit current licences to FOIA-compliant protection would be extremely difficult, time consuming and expensive.

Establishments would inevitably minimise the records held, which is not helpful, either to research or to animal welfare. While the sector would strongly regret such moves, it would be difficult to condemn such practice, given the potential burden that might be placed upon institutions and individuals reliant solely on FOIA for protection.

Please also refer to comments in Q5 and 10 and the detailed response from UKBSC to this question.

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 IA grossly underestimates the true cost of FOIA requests. Redaction of protected information from project license applications requires significant time from both the lead scientist and legal advisors. As such the estimated £160 – £180 costs do not remotely reflect the direct financial cost of FOI requests. For example, the base cost of academic time for redaction would be at least £70/hr, for legal advice ~£250/hr, and support staff time ~£50/hr; estimated costs would therefore be exceeded by one hour of work by all necessary parties on an FOAI request. Redaction of a single PPL by an academic alone could be estimated to take several days, bearing in mind that these documents can be over 100 pages in length.

We also believe it entirely reasonable to expect that a significant increase in FOIA requests will occur once Section 24 is reformed. Combined with our view that the IA document vastly underestimates the actual financial cost of animal research related FOIA requests by potentially 20 fold (based on an estimated time of 7 hr legal time, 7hr administrative time and 3 days academic time= ~£4,000), we expect that the increased financial and time burden on both the Home Office and other establishments is likely to be considerable.

The potential effect of the time burden imposed by increased numbers of FOIA on the UK science base should not therefore be underestimated. The impact of the time investment required by scientists, support and legal staff for these requests could significantly damage UK research due the loss of research activity. That is exacerbated by the tight deadlines enforced by FOIA, which mean that other pressing work has to be side-tracked.

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:
The Physiological Society and British Pharmacological Society agree with the majority of the risks and assumptions made in the impact assessment.

We would like to re-emphasise the following:
All of the proposed options carry significant risks. We have tried to make suggestions as to how some of these could be minimised by appropriate changes or tightened legal definitions;

The assumptions in the impact assessment significantly underestimate the costs likely to be associated with proposed changes. We have included an example of the potential real costs of such an FOIA request;
The assumption that the FOIA currently gives adequate protection for information relating to people and places (e.g. where information) is flawed, as it may be difficult to prove prospectively that release of such information release would endanger safety or health;
The assumption that the FOIA adequately protects IP is also flawed as IP can have a much broader definition that than currently found in the FOIA;
The assumption that only malicious release could be potentially harmful is flawed, as release could be reckless, negligent, thoughtless or even well-intentioned, and still cause significant harm to individuals, institutions and their IP.

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?

Comment:
We address the likely increase in costs of FOI requests in Qu 15, the factors contributing to the likely increase, and make some suggestions as to how these might be mitigated.

As espoused in the impact assessment, the greater risk is that the UK is perceived as providing insufficient protection for IP, which is likely to result in science and investment moving overseas.

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.

Comment:

Purposefully divulging names and places without the consent of the licence holder would always be malicious.

Many of those who would choose to release protected information believe that this information should be in the public domain. Release by them would therefore not be 'malicious' in intent, but would still be highly damaging to those affected by the release.

Information could also be released due to carelessness or recklessness. Such release might not be malicious (at least in the view of the releaser), but should also be considered as relevant to the review of section 24 due to the potential for harm that this might cause.

"Whistleblowing", where an individual genuinely believes the law has been contravened, must be supported. However, this cannot be allowed to be used as a method to side-step the controls required in the legislation. For instance the deliberate release of whole project licenses would clearly be a malicious action, even were there to be a contravention of the law in the operation of that licence.

Any whistleblowing provision must recognise and respect innocence until guilt is proved. The release should therefore be restricted to the legal supervisors of animal use – ie ASRU - rather than to the press – at least until a legal infringement is proved.

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

Comment:

As stated in our response to Qu 8, we strongly welcome the description of IP in the impact assessment (p 7), and the recognition that in an academic setting IP may not have direct commercial value, but "must be protected so long as it remains sensitive".

We appreciate government's moves to clarify and broaden the interpretation of IP under FOIA. It will be important for the FOIA and ASPA definitions not to be contradictory.

We agree that "protocols and procedures" can be valuable IP for a research scientist. In some cases there are standard procedures and protocols which have no IP value. However, in preclinical physiological and pharmacological research there are many occasions where novel procedures, or a novel combination of a number of standard procedures, will have considerable IP value. In addition, we also consider ideas, hypotheses, experimental plans, often required by ASRU staff as components of licence application, to be valuable IP also in need of protection. Only the scientists involved in the project will be able to make the judgement as to what constitutes value, and therefore a broad definition of IP will be required.

As stated in our responses to Qu 5, 10, & 14, unless the format of the project licence application form is modified to reduce the amount of detailed information required and/or altered as to facilitate redaction, it is unclear how protection of IP could be achieved without resulting in a considerable, additional regulatory burden being imposed on license holders and their establishments. One option might be restructuring of licence applications into protected and unprotected material, as has long been suggested by the sector.

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?

Comment:

As previously stated we do not believe that FOIA exemptions provide appropriate protection of sensitive information. Section 24 was considered by the sector to provide protection over and above FOIA until the Information Commissioner's Office started to interpret it as applying only to ASRU. From that point, public organisations involved in the production of this information have had to rely on FOIA, which has been highly unsatsifactory.

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?

Comment:

The Physiological Society and British Pharmacological Socierty's preferred option would be 2b, provided the legislation is amended to address the risks detailed throughout this submission.

The Physiological Society and British Pharmacological Society welcomes the comment in the Impact Assessment that, *"*It is not our objective to provide information so the public or other external bodies can conduct their own harm / benefit analysis as to whether a particular project should be initiated*."*

Nothing in the above should be taken to imply dissent with the submission by the UK Biosciences Coalition, to which we have contributed and with which we agree fully. We wish to emphasize in particular that

1. The Physiological Society and British Pharmacological Society support the best welfare in the research undertaken by our members, and in our publications accept only research undertaken to UK welfare standards and detailed in accordance with the ARRIVE guidelines.

2. There is already much information available to the public in formal and appropriate formats, such as the non-technical summaries of all Project Licenses and the annual statistics on the ASRU website; individual researchers', funding agencies and academic institution web sites; talks given to the media and (increasingly) visits by the media to animal facilities. We fully subscribe to, and indeed contributed to the development of, the Concordat on Openness, which will provide additional information. We welcome the addition in the annual statistics from 2014 of information on the actual harms experienced by animals used in procedures. All these provide an increasingly realistic and appropriate view of, and the continuing importance of, the use of animals in research.

3. In that light, we urge government to ensure that revision of s24 does not cause costs and damage to the UK's bioscience sector in a manner that greatly outweighs the value of any additional release of what is often highly technical information that may be of limited value to the public, but the release of which could cause great harm to research.

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): Learned Society

Name of organisation if relevant: The Physiological Society and the British Pharmacological Society