

Response from the UK Bioscience Sector Coalition on the consultation on the review of Section 24 of the Animals (Scientific Procedures) Act 1986

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 UKBSC welcomes this review and was pleased to contribute proactively at an early stage to the development of the current thinking on Section 24 revisions. We welcome the opportunity to respond to this consultation.

1. In February 2013, the UK Bioscience Sector Coalition proactively approached ASRU, the Department for Justice and the Office of the Information Commissioner with an extensive review of Section 24. In summary, the sector proposed a modification of Section 24, with consideration of the need for protection of Intellectual Property (including ongoing research), researchers and facilities. It also recommended a review of how and when it would be appropriate to release information contained in Project Licences.

2. The sector welcomes an approach that would enhance exchange of information between research participants and that facilitates the spread of best practice. It also welcomes an environment in which Government officials are able to share information they have received about topics already in the public domain. Such moves would support our objectives of improving animal welfare and advancing scientific knowledge, which go hand in hand. We are also supportive of greater openness around the use of animals in research, as advocated in the sector's recently-released [Concordat on Openness](#).

3. Section 24 performed the role the sector expected it to until it became progressively less clear to whom it applied. There has been sector-wide major concern since Section 24 started to be interpreted by the Information Commissioner as applying to ASPA information held by government but not to that held by those obliged in law to generate and supply that information to government. The legal situation has not been clarified as to who may release which information under Section 24, and so it currently fails to provide establishments with either clarity or the protection of people, places and Intellectual Property (IP) that is required.

4. To offer effective protection, any revised regulations should apply to the information itself and not be applied only to a limited subset of the stakeholders involved in generating and/or holding that information. However, to support the government's openness agenda, and the research process more generally, it will be important to ensure that the named supplier of the information (usually the project licence or establishment licence holder) retains the right, in the normal conduct of their research, to release the information they supplied whenever they deem it appropriate, whether on websites, in grant applications or in research publications etc.

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:

- 1. Much more information would be likely to be released and in that sense it satisfies the government's openness agenda. It does not however meet the criteria of the Impact Assessment (IA) in protecting and supporting the efficient operation of the bioscience sector. See response to Q9 for our evaluation of the additional protection needed for sensitive information and Q19 for a definition of the breadth of IP (Intellectual Property).*
- 2. Whether this option would be at all workable would depend on how the legal definition of 'malicious' is applied. The difficulty arises that the releaser may sincerely believe that release is morally right; in that sense they might not be behaving 'maliciously' in divulging protected information. This is further discussed in our response to Q18.*
- 3. Scientists talking about their research involving animals, and appropriate visitors being given access to research facilities, are likely to enhance public awareness and knowledge more than the release of long technical documents. Such activities are advocated in the sector's recently-released [Concordat on Openness](#). The sector has concerns (based on prior experience) that technical documents could be misinterpreted or misrepresented, or the information be released out of context. Whether due to lack of technical familiarity or otherwise, there is a risk that that would lead to more polarised debate rather than to well informed discussion.*

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:

- 1. Under this option, the protection of sensitive information (people, places and IP) would rely on exemptions under FOIA. The operation of FOIA to date has not made it clear to the sector how IP is defined nor how it can be efficiently protected. This option therefore fails to offer adequate surety for the protection of the owners' safety, security or IP, and thus fails the government's intention to assure*

the sector of the protection of UK research and researchers. For further discussion of this see responses to Q9, Q19 and Q21.

2. The option makes clear that disclosure with “malicious intent” may result in criminal prosecution, but it is not clear how “malicious intent” will be defined. There would remain serious legal difficulty over the balance between ‘intent’ (which might not be ‘malicious’, at least in the eyes of the releaser) and the potential adverse consequences of release. It is likely that clarity would only arise from case law, which would be an unacceptably protracted means for generating clarity over the security of scientists’ IP and safety, and would require significant expenditure on legal advice, which might be beyond the financial means of some establishments.

Many of those who would like information to be released believe that the information should be in the public domain, without realising that release of this information could be highly damaging to the owner’s IP and (directly or indirectly) result in harm to personnel and places.. A release by them would therefore not be ‘malicious’ in intent but could well be reckless. Such reckless release would need to be prevented under the modified legislation. See responses to Q9 and Q18 for further explanation.

3. The only means for controlling release with minimal adverse consequences is for release to be authorized only by those who are in a position to understand the consequences of that release. The only party that can understand the value of embedded IP is the original supplier of the information (usually the licensee or establishment). Therefore the supplier needs to be involved in, and approve of, any release of information involving people, places or IP.

4. Any FOIA request to ASRU would therefore require both parties (ASRU and supplier) to agree in order for the various risks to be minimised or the information safeguarded as appropriate. In many cases legal opinion on the operation of FOIA exemptions would also be required. That overall process would take time and realistically would not be routinely achievable within FOIA timescales. It would also be expensive to operate. This situation would not be in anyone’s best interests.

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:

1. We draw particular attention to the statement (IA, p14) that:

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 are very clear that this government responsibility would not be achieved by option 2a, which does not provide adequate protection for people, places or IP. See responses to Q9 and Q19 for fuller explanation.

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:

1. *We remain unclear of the intended meaning of this question in that the option would of itself not change processes. It would however require significant change of current processes to be in any way workable.*

2. *UKBSC agrees with the IA where it states (p6)*

It should be noted that ASPA, under which the Animals in Science Regulation Unit operates, is unique in that it requires by law applicants to disclose details of high value assets – such as intellectual property or commercially valuable research ideas – in order to gain authorisation to perform the scientific research in question. Consequently, balancing a commitment to openness with the provision of the requisite protection for sensitive information is of paramount importance.

Achieving the “provision of the requisite protection” would require changes to processes but these could only be achieved by ASRU altering its requirements, not by licensees who are obliged to follow the predefined format. It would, for instance, be necessary to adapt the Project Licence application form so as to simplify the redaction of IP. UKBSC would be very willing to help develop such changes. A delicate balance would be needed to provide sufficient information to facilitate harm benefit analysis, while ensuring confidentiality of IP.

3. *Relying on FOIA would generate a disparity between public bodies (which are subject to FOIA) and industry (which is not) in the level of information on animal use liable to release. That would not support the Government’s agenda for openness on the use of animals.*

4. *Relying on FOIA exemptions to keep sensitive information confidential will also inevitably result in a reduction in the detail kept in institutional records so as to minimise the adverse impact of any unplanned release. That is not in the interests of either science or best animal welfare.*

For a fuller explanation of the potential consequences see response to Q14.

5. *It is difficult to assess whether a reduction in detail might also apply to ASRU paperwork (such as inspection reports), but again it is not in the interests of either good science or animal welfare for ASRU staff to feel constrained over what is put on paper.*

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:

1. UKBSC agrees that people, places and IP are the three core aspects that require protection from unauthorised release.
2. This option permits the release of all other information, which is consistent with the sector's intentions. In particular UKBSC is supportive in principle of information relating to animal welfare being released. However there is a perceptual difficulty in that the current Project Licence format requires applicants to describe a worst case scenario rather than providing the most likely welfare outcome. Verbatim release of Project Licence details would therefore not provide a realistic picture of the harms to be experienced; there would be a need to provide additional explanation so that the information is presented to the public in an appropriate context. UKBSC welcomes the fact that the actual harms experienced by animals will, from 2014, be reported to ASRU and subsequently published in their annual statistics.

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:

1. Neither the consultation document nor the Impact Assessment makes clear whether the statutory bar is intended to apply formally only to government or also to those supplying the information to ASRU. We note that it is exactly this uncertainty that is causing problems with the current Section 24; repetition of this uncertainty must be avoided.
2. As indicated under Q1 above, UKBSC is clear that to offer effective protection, any regulations should apply to the information itself and not be applied only to a limited subset of the stakeholders involved in generating and/or holding that information. As also indicated under Q1, it will remain vital for the suppliers of the information to retain the right to release it, at their discretion, in the normal conduct of their research.

3. *The option makes clear that disclosure with “malicious intent” may result in criminal prosecution, but the legislation will need to make clear both how “malicious intent” will be defined, and who will make this determination. See answer to Q3 and Q18 for a fuller discussion of this and the need to control reckless as well as malicious release.*

4. *Further definition of “people”, “places” and “IP” is needed. See answer to Q19 for discussion of the breadth of coverage needed for IP.*

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:

1. *The protection provided for people, places and IP will depend on how each of these is defined within the legislation. See response to Q13 and Q19 for the uncertainties in the definition of IP that will need to be resolved.*

2. *See response to Q13 for further information about why protection over and above that provided by FOIA is required for people and places.*

3. *In terms of what information would be of potential value to academic or commercial competitors, and is therefore IP to be protected, in some circumstances only the provider of information is in a position to advise and decide on this. In some instances the IP might be simple facts (e.g. the pathways to be investigated) but in others it is the protocol and procedures themselves that constitute the IP (see fuller discussion under Q13). That may make it difficult to define the IP in legal terms, but UKBSC is clear that to protect the UK's bioscience base, it will be paramount to provide flexibility in the interpretation of the IP needing protection.*

4. *In the absence of such additional protection, if a case were to reach a FOIA Tribunal, the owner would have to explain (in public) exactly what would be of value to a competitor. That process can itself reveal some of the IP. See Q19.*

5. *It will be important that the revised legislation overtly supports the EU Directive requirement for confidentiality of the information on people and places gathered during the execution of duties under ASPA, while allowing the individual or establishment concerned to release information about themselves if they so wish.*

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:

1. *We would welcome the opportunity to work with the Ministry of Justice and the Home Office to develop the most appropriate guidance on the protection of sensitive information, including ensuring that the protection covers novel ideas, scientific hypotheses and research plans (see response to Q19)*

for further details about this). Additional protection is essential as the current FOI protection is not entirely clear and can be challenged, which could result in significant expenditure on legal support.

We draw particular attention to the statement (IA, p14) that:

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.

This indicates, and we agree, that ASRU has an absolute obligation to ensure that IP is protected. ASRU therefore needs a statutory bar to assure its ability to prevent enforced release.

2. We strongly advocate that the definition of intellectual property applied under Section 24 should cover information such as novel ideas, scientific hypotheses and research plans. These constitute valuable intellectual property for individual researchers and institutions, but it may not be apparent to ASRU officials what is/is not valuable IP as far as an institution is concerned. A lack of protection for such information would undoubtedly have a negative impact on the competitive edge of individual researchers and institutions.

3. As clarified in the accompanying Impact Assessment, and referred to above, it is vital that the UK's research base be encouraged. That in turn requires (a) full protection of scientists' and institutions' IP and (b) an efficient regulatory environment. Therefore it is vital that the legislation protects the owners of information from inappropriate release, whether or not that release was 'malicious' in intending harm to the owner. Therefore the statutory prohibition is essential but, as indicated above, it does not of itself provide the protection supported by the Impact Assessment for individual institutions and the Home Office.

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:

1. As indicated under Q5, the option does not of itself cause change, but its effective implementation will require changes to ASRU's processes so as to streamline the operation of releasing information in response to third party requests.

2. With this option there would be increased opportunities for redaction of information relating to people, places and IP. That should fulfil the sector's needs, subject to administrative streamlining of the process. See response to Q14 for a fuller discussion.

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:

1. *This will generate the maximum 'transparency' permitted under FOIA.*
2. *However, as correctly elucidated in the Impact Assessment, it fails to provide the protection that the sector requires that there will be no unauthorised release of their intellectual property contained within documents that have been submitted purely to satisfy the requirements under ASPA.*
3. *While it is in theory possible that FOIA exemptions could be applied to provide protection, even if used appropriately by officials at ASRU and research institutions subject to FOIA, they are likely to be subject to challenge, and the sector would be dependent on ASRU and other holders of information being willing and financially able to defend their decisions in multiple expensive and time consuming tribunal cases.*

The number of FOIA requests has increased, by 147% over the last 5 years, suggesting that there is an increasing awareness of the availability of FOIA.¹ Requests have come not only from the UK but also from overseas bodies keen to access the UK's IP. It is therefore essential that the statutory bar in option 2b applies.

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:

1. *The FOIA provides basic protection, but (as indicated under Q13) the sector remains unsure of the extent of the cover of IP; and there are also practical problems associated with trying to protect IP using FOIA exemptions; these include manpower costs, time pressures and the liability to challenge and yet further costs.*

¹ <http://www.jiscinfonet.ac.uk/surveys/information-legislation-management-2013/>

2. *Private companies are not subject to FOIA and therefore there is no formal obligation to release information requested by third parties. However, they frequently collaborate with public establishments, and in these situations FOIA may complicate the collaboration and therefore impinge on their legitimate interests.*
3. *This option would not offer any protection for unauthorised release of information, irrespective of whether the establishment was or was not subject to FOIA.*

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:

1. *There is some protection for people and places under FOIA. The FOIA exemption relating to Health and Safety (Section 38) may be applied, but this relies on proof that to release the information would “endanger the safety” or “the physical or mental health” of an individual – something that is not always easy to demonstrate prospectively. There is the additional concern that individuals could still be identified through triangulation using other information provided in the documents.*
2. *FOIA is ambiguous over the protection of IP. IP per se is not currently defined in FOIA but rather is referred to in Guidance relating to various exemptions including Section 41 (Confidential Information) and Section 43 (Commercially 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 commercial value at stake. This is the case with most academic research – it is, almost by definition, at the pre-commercial stage but it does have economic value to the institution because novel ideas are what gives an academic institution its competitive edge in the application for research funds.*
3. *An aspect that is frequently ignored in the operation of the FOIA in relation to technically-complex material is that only the technical author can understand the potential impact of release, yet only the lawyer can understand which sections of the FOIA can be used to provide protection. Given the time pressures for responding to FOIA requests, it becomes very difficult to assess within the timeframe what can be protected under which section of FOIA. This process means expensive discussions and a high risk of failure to protect adequately. It is not a satisfactory means for ensuring the safety of the UK’s research IP. The same consideration would apply to FOIA requests to ASRU, with the added complication that the licensee would also need to be part of the discussion, given that ASRU officials often do not have the specific knowledge to determine which aspects of licensing documents constitute valuable 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:

1. *Relying on FOIA exemptions to redact current licences to FOIA-compliant protection would be difficult and time consuming. In order to reduce the difficulty inherent in the current redaction process, the UKBSC suggests a restructuring and streamlining of the Project Licence application, into information that could and could not be disclosed. This would facilitate the identification of any IP by ASRU officials.*

The content of the Project Licence should reflect key issues related to animal welfare and to the harm-benefit analysis, and ASRU should substantially reduce the need to explain in great detail the IP-rich ideas and hypotheses upon which the planned project depends.

2. *Given the technical nature of the detail embedded in licence related-documents their public release may not add value to the public. We agree with the statement in the IA (p16) that:*

Currently, licence applications are not written for public consumption and the content could be misleading if released out of context. This apprehension could increase the regulatory burden (of the licensing process) on the UKBS and the Home Office, and associated financial consequences could include both the increased labour costs (both sides) or possible loss of competitive advantage (UKBS) due to the increased time taken.

3. *Under the new ASPA, record keeping by establishments is of major importance: these records are being used to assess both the impact of the 3Rs on animal welfare and the level of actual severity involved in a given procedure (e.g. for the data to be provided in ASRU's Annual Statistics). If such records become entirely subject to FOI requests, there would be a tendency to reduce detail of the records so as to mitigate the consequences of any unplanned release. That would not be in the best interests of either science or animal welfare, as some potentially important details of institutional discussions for advancing better practice in animal welfare and 3Rs would be lost.*

4. *Establishments would almost certainly need to respond to a higher volume of FOIA requests, which would cause a delay to research projects because of the time taken by scientists to respond. Moreover institutions would have to divert significant additional resources (staff and funding) to cover the FOIA requests within the timescales required. If such resources were not available it could happen that IP would be divulged, which would be detrimental to the research.*

5. *Similar problems would apply to ASRU, where the diversion of manpower would lead to delays in licensing decisions, to the detriment of the sector's scientific activity and productivity. It would also divert ASRU from its important function of assuring best animal welfare. We note the statement (IA, p11) that "The new framework should not lead to disproportionate regulatory burdens being placed on public authorities or business." and comment that relying on FOIA for protection of IP would cause just such a regulatory burden. For example, concerns about the potential release of IP or loss of competitive advantage are likely to increase the time and resource needed to prepare Project Licence applications, particularly those in the commercial sector where, due to licenses for the first time becoming subject to release, there would be a need for increased scrutiny of the IP in applications.*

6. *The only means for controlling release with minimal adverse consequences is for release to be authorized only by those who are in a position to understand the consequences of that release. That means restricting it to ASRU in consultation with the provider of the information, usually the licence holder or the establishment, or the provider themselves in the course of their normal scientific activities.*

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:

1. *The costs of FOI requests quoted in the IA are presumably for the time of the public official only. In the case of FOI requests for animal-related information, the costs would be very substantially greater. Many FOI requests have been and are likely to remain related to Project Licences. Given the current format of licence applications, the preservation of IP would require much redaction, which can only be undertaken by the licensee in collaboration with relevant FOI legal advisers. With the text part of Project Licences varying over the range of ~10-100+ pages, such redaction and its justification would often require many tens of hours of work by the licensee and the legal support team. Even this input would not avoid challenges to the redaction, with more costs incurred in dealing with such challenges, particularly if they get to Tribunal stage.*

2. *FOIA does not permit the costs of the various stages of redaction to be charged. The ICO's 2011 'Using the fees regulations'² document states:*

*"Once the documentation containing the information has been located and retrieved, a public authority cannot take into account the time taken, or likely to be taken, to consider whether any of the requested information is exempt. Nor can it take into account the time taken, or likely to be taken, to remove the exempt information in order to leave the information that is to be disclosed in response to the request. The activity "extracting the information from a document containing it" refers to the extraction of the information that has been requested out of a document which contains other information, **not** to the extraction of exempt material from the information that has been requested (known as redaction).*

3. *The costs of such redaction are therefore substantial (in terms both of loss of valuable scientist research time and of the monetary value of salaries and legal advice) and fall entirely on the establishment.*

4. *In order to facilitate these redactions for release in response to FOIA requests, the UKBSC suggests restructuring and streamlining of the Project Licence application to separate information that could and could not be disclosed, enabling the IP to be more readily identified to ASRU.*

5. *We note and approve of the statement (IA p9) 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 this potentially disastrous consequence.

² http://ico.org.uk/for_organisations/guidance_index/~media/documents/library/Freedom_of_Information/Detailed_specialist_guides/using_the_fees_regulations.ashx

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:

1. *The IA is well argued and presented, and UKBSC agrees with the great majority of its statements and conclusions.*

2. *While we agree with the statement on p9 that “A demonstrable commitment to openness will help ensure the public fully understand the rationale behind the continued and necessary use of animals in scientific experiments” we are not convinced that the release of highly technical information in licenses will of itself achieve that laudable aim. Publication on the ASRU website of summary information (such as mandatory non-technical summaries and annual statistics) is more helpful for increasing openness by presenting licenced research in context and in a comprehensible format. Openness also comes from scientists talking about their animal work (on websites, at conferences, in publications and in the media), and from appropriate visitors being given access to research facilities. Such activities are advocated in the sector’s recently-released Concordat on Openness. For those motivated to understand technical documents, the publication of peer-reviewed research reports provide the end point of the work. UKBSC approves of the uptake by progressively more scientific journals of the [ARRIVE guidelines](#), resulting in more published information on how animals have been used in research.*

3. *Unless there is demonstrable and material public benefit in the release of the technical documents, that benefit will not outweigh the direct costs incurred in their release (see Q15) and the associated risks both of inadvertent release of IP and of failure of the aim (IA p5-6) “It is imperative that the amended legislation does not harm the competitiveness of the UK in the life sciences and retains the confidence and trust of the UK life sciences sector (and the public) in our duties as a regulator.”*

4. *We note the statement (IA, p11) that “The new framework should not lead to disproportionate regulatory burdens being placed on public authorities or business” and comment that relying on FOIA for protection of IP would cause just such a regulatory burden. Concerns about the potential release of IP or loss of competitive advantage are likely to increase the regulatory burden on applicants due to the need for increased scrutiny of the IP content of applications.*

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:

1. *The direct costs of compliance with more FOI requests are addressed under Q15.*

2. *The much greater costs, which cannot be quantified, relate to the risks that perceived (even if not actual) additional regulatory costs and burdens, together with increased risks of release of IP, will dissuade investment in the UK’s bioscience sector by both commercial organisations and overseas public funding agencies (such as NIH). Given the sums quoted in the IA, such a consequence would be dire for the sector and its many employees. We strongly concur with the statements on p 5-6 and 9 (quoted above re Q15 and 16) regarding the risks to UK industry.*

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:

- 1. Many of those who would like information to be released believe that the information should be in the public domain; release by them would therefore not be ‘malicious’ in intent (it would not be intended primarily to damage the owner, but rather to protect the animals). However, the release might nonetheless be reckless in that it could well be highly damaging to the owner and the owner’s IP in ways that the releaser could not necessarily predict. Unless clarified in the legislation, even option 2b would inevitably lead to lengthy and expensive legal proceedings, to establish whether the intent was or was not ‘malicious’ and therefore legally culpable. Dealing with these legal cases would cause added difficulties where institutions do not have sufficient financial support for protracted legal action. In any event, valuable specialist scientists’ time would be sidetracked into administering the process.*
- 2. Divulging names and places in a manner not approved by the licensee should always be interpreted as malicious.*
- 3. It is in the interests of research scientists to publicise their advances at the earliest opportunity commensurate with the appropriate protection of their IP and safety. Doing so either earlier or more extensively is therefore highly likely to harm the interests of the licensee and/or their organisation, and should not be permitted.*
- 4. ‘Whistle-blowing’ of misdemeanours should clearly be permitted, but the right to do so must be limited to those aspects that the individual in good faith believes to be contraventions of the law and must not include names or places, at least until guilt is proved. It must not be used to divulge information about authorised procedures that the individual happens to disapprove of; nor much broader information (e.g. an entire Project Licence) to which that individual might well have had rightful access; that would be malicious.*
- 5. The laudable aims of the IA will not be met unless the legislation clarifies that acts that cause actual or likely damage (whether physical, emotional or intellectual) fall under the prohibition, whether defined as ‘malicious’ or (as suggested under Q3) ‘reckless’.*
- 6. It would be essential that ASRU provides formal guidance in lay terms explaining the rights inherent in the revised legislation, so that those considering unauthorised release can be very clear about the limits of their legal rights to do so.*

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

Comment:

- 1. The IA goes a long way to doing this successfully where it states (p7):*

Commercially sensitive information and intellectual property (IP) – these are the ideas of research scientists which, if subsequently proven, may be publishable in academic journals, patentable or become subject to copyright. This includes information describing novel ideas, protocols, procedures, experiments, inventions or other IP (including but not limited to information intended for future publication or commercialisation).
- 2. In this list is the inclusion of “protocols, procedures”. While there are some licences in which standard procedures are used that are of no IP value (e.g. standard protocols used to test the safety of*

new pharmacological agents), even here the combination of protocols can sometimes provide clues to a competitor. In other cases (perhaps more commonly in academia) the detail within, and combinations of individual protocols and procedures may be novel – and are therefore of high IP value. This makes it very difficult to come up with any generic statement about the release of specified sections of current Project Licences.

3. Many of those who would like information to be released believe that the information should be in the public domain, without realising that release of this information is quite likely to be highly damaging to the owner and the owner's IP.

4. The only means for controlling release with minimal adverse consequences for the bioscience sector is for release to be authorized only by those who are in a position to understand the consequences of that release. That means restricting it to ASRU in consultation with the provider of the information, usually the license holder or the establishment, or the provider themselves in the course of their normal scientific activities.

5. The sector would welcome the opportunity to continue working with the Ministry of Justice on its revisions to FOIA guidance on what constitutes IP. We want to ensure that IP protection covers ideas, protocols and hypotheses as proposed by the Minister in the recent discussions of the Intellectual Property Bill³.

The sector would also welcome the opportunity to work with the Information Commissioner's Office on its Guidance for the Higher Education Sector in relation to what constitutes commercially sensitive information, including IP. There must be clarity and consistency between both Ministry of Justice's and ICO's approach to what is covered by IP and commercially sensitive information, and the approach taken on IP by the Home Office when drawing up legislative changes to Section 24 and associated guidance.

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:

1. Until recently the sector had thought that Section 24 applied to information held by all parties having a function under ASPA. As a result there has been sector-wide concern since Section 24 has been interpreted by the Information Commissioner's Office as applying to ASPA information held by government but not to that held by those obliged in law to generate and supply that information to government. In effect Section 24 provides no additional protection for information held and submitted to ASRU by public sector organisations over and above that provided by FOIA exemptions. At the same time, organisations that provide information in response to FOI requests are not clear whether they might be liable to criminal prosecution under Section 24.

2. Currently the consultation and Impact Assessment do not provide any clarity over the government's intentions over the parties covered by option 2b. The new legislation must make it very clear (without recourse to the courts) to which parties it applies.

3. The statutory bar must apply to the Home Office because ASRU officials will not always be well placed to judge whether exemptions under FOIA should be applied – particularly the exemption relating to intellectual property, whether at commercial or pre-commercial stage.

³ <http://www.publications.parliament.uk/pa/cm201314/cmhansrd/cm140312/debtext/140312-0001.htm#14031264000002>

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?

Comment:

The UKBSC welcomes the review of Section 24 and was pleased to contribute proactively and constructively to the development of the current thinking on Section 24 revisions. The Coalition is pleased to respond to this consultation.

The Coalition's preferred option would be 2b, subject to elucidation of a number of important details. These include clarity over whom the statutory bar applies to; proper definition of people, places, and IP; and clarity of the controls over malicious and reckless release.

We wish to reiterate and /or clarify a number of points:

1. In responding, UKBSC is bearing in mind the balance needed to achieve the best science operating in the best regulatory environment using animals kept in the best conditions and supported by the best welfare. We have consistently regarded these as going hand in hand. We particularly wish to make it clear that we would not support any new regulations that prevent release of details that are directly related to animal welfare.

2. We agree with the statement (IA, p1) 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." To do otherwise would seriously dent confidence in the sector, prejudice investment in it and so cause long-term damage.

3. We also agree with the statement (IA, p13) that "There is no intention to introduce the ability for the request of information that was produced before the introduction of the legislation" and agree that "This would introduce a potentially significant cost burden..."

4. We accept the statements (IA pp16 and 17) that:

.....the possibility of extremist activity and a potential need for increased security. It is difficult to assess the likelihood of this scenario although the occurrence of such activity has decreased in the past decade. And:

there is a risk of a perception developing that the UK provides insufficient protection for the health and safety of those involved with animal research and the associated intellectual property. This may lead to an increased risk of loss of investment in the UKBS, with a resultant negative impact on UK economic growth if high quality science were to be driven overseas.

We wish to highlight that substantial extremist activity still exists in other countries (notably within the EU and USA) and could readily resurface in the UK. Vigilance over it, and protections against it, therefore remain important to maintaining confidence within the sector. Therefore adequate protection for both staff and establishment facilities remains paramount.

5. The UKBSC considers that the Government's objective to be transparent on the use of animals in UK research should apply equally to the public and private sectors. That would not be achieved by relying solely on FOIA and is a strong argument for controlling the information flow under ASPA rather than FOIA.

6. The UKBSC wishes to emphasize the costs of relying solely on FOIA to protect its IP. We accept that FOIA provides a core support for IP, and we recognise and appreciate the government's current attempts to clarify the extent of that support. Even with this legal support, however, there would remain major practical problems with using FOIA exemptions as the primary means for protecting the UK's invaluable bioscience IP base: It is expensive in monetary terms (see Q15) largely because of the need for legal opinion. It is highly time-consuming to redact the sorts of long documents currently required under ASPA (see Q15), diverting scientist time from their research. It would be very difficult to achieve redaction satisfactory to all parties within the timescales allowed by FOIA

(see Q3), which might have to result in the untimely release of IP. We therefore consider that relying on FOIA would seriously impair the UK's bioscience base. We also reiterate the IA's important consideration (p14; see also p6) that ASPA is "unique in that it requires duty-holders to provide detailed information about their most valued assets"; the information in documents submitted to ASRU under ASPA would not be collated without this regulatory requirement. This unique regulatory situation, together with the importance of the UK's bioscience sector to the national economy, requires specific support not anticipated or addressed in FOIA.

7. The sector also wishes to emphasise just how much information on the use of animals in research is already publicly available. Apart from the Project License non-technical summaries on the ASRU website, ASRU publishes annual statistics of animal use and an annual report of its regulatory activities. The statistical report will from 2014 become more helpful with the overdue introduction of statistics on the actual harms experienced by animals. From the scientist perspective, not only are research results published as soon as they are sufficiently robust to pass peer review for publication, but previews of research activity are published on researchers', establishment and funding agencies' websites to the extent that IP and personal safety allow.

The sector's recent Concordat on Openness is already having the effect of persuading more establishments to allow the media in to record and publicise what animal facilities are actually like.

Taken together, this body of data already provides extensive insight into how and why the UK bioscience sector uses animals in its world-leading and welfare-conscious 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): *Umbrella organisation*

Name of organisation if relevant: *UK Bioscience Sector Coalition*

On behalf of The Association of the British Pharmaceutical Industry (ABPI), Association of Medical Research Charities (AMRC), The Academy of Medical Sciences (AMS), Biotechnology and Biological Sciences Research Council (BBSRC), UK Bioindustry Association (BIA), British Neuroscience Association (BNA), British Pharmacological Society (BPS), Institute of Animal Technology (IAT), Laboratory Animal Breeders Association (LABA), Laboratory Animal Science Association (LASA), Medical Research Council (MRC), The Physiological Society, Society of Biology (SB), Understanding Animal Research (UAR) and the Wellcome Trust.

The UKBSC Secretariat is hosted by the Society of Biology. For any more queries to this response please contact: Society of Biology, Charles Darwin House, 12 Roger Street, London WC1N 2JU - Tel: 020 7685 2572 or ukbsc@societyofbiology.org.