



Dr John Landers
Animals in Science Committee Secretariat
2 Marsham Street
London
SW1P 4DF

13 July 2018

Dear Dr Landers,

Animals in Science Committee – Commission of work

I am writing to you, in capacity as Chair of the Animals in Science Committee (ASC), to provide the ASC with a commission of work for the next 18 months. This commission sets out the Government's requirement for specific advice in this important policy area.

I would like to take this opportunity to thank you and your colleagues for your recent achievements. This year, the Committee delivered an important piece of work: the Harm Benefit Analysis (HBA) review paper. The harm benefit analysis process is the cornerstone of our project evaluation process and is a key part of the robust decision making required. It is essential we continue to reflect on how this analysis is undertaken, to ensure that our process remains fit for purpose and provides assurance for the public, whilst facilitating the UK biosciences and supporting the UK as a global leader in this area. This was an important review, which will shape the Animals in Science Regulation Unit's (ASRU's) future work.

It is important that the Committee continues to make valuable contributions to the Government's priorities in animals in science and, in this letter, I have outlined the key priorities where I would welcome your expertise over the next 18 months. This commission aims to balance essential priorities with sufficient space for the Committee to work on other relevant issues of its own choosing.

I encourage you to continue dialogue with ASRU officials to ensure that we remain sighted of the Committee's thinking as policy is being developed and reviewed.

My commission for work is as follows:

1. Societal Concerns

In your HBA review paper, you propose a review of the working criteria used to identify issues of societal concern and suggest that these criteria should be published. I would welcome such a review from the ASC. The outputs should provide advice on the criteria used to identify projects or procedures of societal concern. This could inform ASRU's work on how they identify societal concerns in project licence applications, the categories within their internal referral system, identification of applications that should be referred to the Committee, and could support ASRU in publishing revised methods and criteria.

2. Licence Analysis

As part of the Committee's Licence Analysis project, I understand you intend to examine a small sample of project licences across a range of species and severity ratings to gain a broader view of the licences received and processed by ASRU. Your views on the severity classification of non-human primate protocols in project licences are of particular importance, because it is an area of significant concern to the public and the scientific community. ASRU officials are drafting an Advice Note on prospective severity classification, planned for publication in 2018, so this work may be particularly relevant at this time.

I would also welcome the views of the Committee on any other matters that arise during this licence analysis and whether they merit action on the part of ASRU or others.

3. Non-animal alternatives and the 3Rs

The principles of the 3Rs (Replacement, Reduction and Refinement) are central to A(SP)A and to ASRU's delivery. ASRU seeks assurance from applicants that the 3Rs are fully implemented both during the assessment process and throughout the life of the project. It is important that as non-animal alternative (NAA) technologies are developed and validated there are mechanisms for knowledge dissemination throughout the UK. This enables applicants and licence holders incorporate new technologies as quickly as possible. ASRU are continuing to review ways in which the 3Rs are implemented. I seek the Committee's advice on identifying ways of highlighting Replacement in our regulatory processes, without obstructing legitimate research that requires animal testing and ensuring that human safety can still be assured. Specifically, I ask the Committee to advise on how information on the 3Rs can be shared across the UK via the Animal Welfare Ethical Review Bodies hub network. This will complement ASRU's work on implementation of the 3Rs.

4. Project Licence application process in other jurisdictions

Your Committee is undertaking a comparative study of global animals in science regulation. Importantly, the European Commission is also conducting a survey on Member State regulatory frameworks throughout 2018, as a requirement of Article 54(1) of Directive 2010/63/EU and has recently asked Member States to contribute detailed information. Results of the survey will be published in a Report in 2019. I therefore urge the Committee to consult with ASRU officials regarding this Commission survey, to ensure work is not repeated unnecessarily. Since ASRU are building an updated electronic licensing system and are reviewing their project evaluation and licensing process this year, I would expect that information from your study or the Commission's review could usefully inform their work, with a view to maintaining high quality, efficient assessment of licences with appropriate and proportionate scrutiny.

5. Non-Technical Summaries (NTSs)

I consider NTSs to be a vital tool in delivering better openness and transparency. High quality NTSs inform the public of how animals are used in science to deliver societal benefit within our robust regulatory framework. ASRU recently ran a stakeholder survey regarding NTSs and, as a result, is reviewing how NTSs could be published to make them more accessible and useful. ASRU has also published advice on how to improve NTS quality, in their annotated PPL form. This year, ASRU expects to make changes to improve the promptness of publication and will continue to encourage the submission of good quality NTSs. ASRU may ask the Committee for their views on this work as it proceeds. It would be helpful if the Committee could review a sample of NTSs as part of their Licence Analysis project, and assess them against the requirements set out in the annotated PPL form.

6. Project licence referral

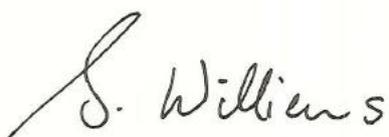
I appreciate the Committee's ongoing provision of advice regarding the more novel, contentious or severe project licence applications. This is a valued part of the proportionate project licence assessment process. It is important that independent scrutiny is given to the licensing process to provide public assurance whilst ensuring rigour and scientific quality.

7. Future work

There are a number of other areas of Home Office work in the coming year which the Committee will wish to note.

- The legitimate use of non-human primates in neuroscience attracts particular regulatory attention due to the sentience of the species used, their status as specially protected species and the duration and severity of procedures. In 2018, ASRU plans to engage with relevant stakeholders to review how non human primate neuroscience contributes to the wider neuroscientific landscape, and to the needs of scientists, patients and other beneficiaries.
- The UK exit from the EU has implications for the use of animals in UK science. ASRU are making plans for a smooth transition: maintaining our robust legislation; developing stakeholder engagement strategies for relevant business and academic sectors; and, developing outward communication plans. I will ask the Committee to comment on relevant issues as they emerge over the next year.

There are a number of other projects which I may seek your advice later in the year. These include Home Office policy on the testing of tobacco products, and the development of ASRU's new electronic licensing system.



Baroness Williams of Trafford