

UK BIOSCIENCE SECTOR COALITION – ASRU MEETING

Summary of meeting notes

9 April 2018

Summary of the pre-meeting discussion (only UKBSC members in attendance)

1. **Future e-licensing system**

UKBSC members commented on the current state of development of the new establishment licence (PEL) module, the first type of licence to be implemented in the new e-licensing system. Direct stakeholder involvement is part of the agile framework chosen by ASRU to develop the future system. It will be a web-based system in which searchability will be a key aspect. The group agreed that, to avoid confusion, the terminology used in this new system should replicate closely that used in the Act and guidance notes.

2. **Review of UKBSC Terms of Reference**

The review of UKBSC Terms of Reference is entering its final phase before circulation to the wider bioscience community. The group discussed the expertise and representation that UKBSC seeks to bring to meetings with ASRU. Moreover, all members believe that representatives of member organizations part of UKBSC should engage actively and regularly in the workings of the group, playing an active part in the sector and have an up-to-date understanding of the issues faced by scientists and others working in the field. UKBSC aims to work with ASRU positively to enable a supportive environment for the bioscience sector in the UK, by observing, discussing and debating ASPA implementation and the development of guidance and regulations that are fit-for-purpose and that meet the needs of the sectors, while maintaining both high standards for the welfare of animals and the competitiveness of UK science.

3. **Ongoing activities to create a public face for the UKBSC**

The one-page summary of the role of UKBSC has been finalised and the Secretariat is receiving UKBSC members' logos to add to a PDF version as a means of sign-off by the membership. As part of the openness agenda, UKBSC policy group confirmed that they wish a summarised, anonymised overview of meetings to be made available on the RSB webpages.

4. **UKBSC engagement with the wider research community**

The group discussed how to interact with the various groups making up the bioscience sector in a productive manner. Particular attention was given to the group of academic stakeholders that had engaged directly with ASRU; spokespersons for the academic stakeholders would be invited to attend the next quarterly meeting of UKBSC policy group, as observers.

5. **The group decided to stress the following aspects in discussion with ASRU:**

- State of progress and timeline for development of the new format of and process for PPL applications;
- Review criteria and conditions that distinguish between animal welfare issues versus non-compliance of the Act, particularly those not having an adverse welfare impact (e.g. standard condition 18 advice note);
- Ask about ASRU timeframe for reviewing advice notes;
- Query the timing of the retrospective assessment of PPLs, particularly in relation to the timing of new applications and the need for assessing and incorporating new techniques.

- *End of the pre-meeting* -

Minutes of the meeting with ASRU (ASRU representatives in attendance, 14:00-16:00)

1. Developments of the **future e-licensing system**

- a. Prototypes for the Establishment Licence (PEL)
- b. Prototypes for the Project Licence (PPL)
- c. Prototypes for the Personal Licence (PIL)

The new e-licensing system will be a true web-based system (rather than a paper system on-line) with a more intuitive design. It will maintain a high regulatory standard with an improved usability. The **new PEL** will be developed first. Over 50 institutions are contributing to the development. Some of the useful suggestions put forward by the stakeholders are: (1) to add a printable version of PEL; (2) the use of terminology and wording that closely follows that of ASPA and the guidance documents (more informal synonyms should be removed to avoid confusion). **New PPL and PIL** will be developed afterwards. In the meantime, contingency plans are being made to maintain ASPeL active until the new system comes online. Currently, ASRU's work is focusing on carving out a slender template for the PPL by including protocols and the right level of appropriate information for different project types to allow for a Harm:Benefit assessment to be carried out. The new PPL will address people, places and IP as required for **Section 24**. The system will also provide a management tool for ASRU and a platform for dealing with FOI requests.

d. Service licences

Work is ongoing to develop templates for different types of service licences, based on:

- Standard wording that can be used across different service licences (e.g. standardised terms for techniques);
- Defined broad categories of services (e.g. cancer models, antibody generation);
- The decision making process and checks that a service provider (e.g. CRO) needs to implement every time it takes on a new commission.

ASRU is gathering ideas about the variety of licences currently approved and the type of work that is currently undertaken by CROs.

2. State of progress on **advice notes**

a. Education and training advice note

This advice note refers to requirements for training and education that have to be met by applicants for PPLs and PILs. A draft was circulated by ASRU direct to stakeholders. However, there are members of UKBSC, such as BPS, with an involvement in training for animal scientists, who would like to see the draft and be involved in the development work.

b. Standard Condition 18

The final text with comments from legal advisers is back to ASRU. Publication is expected within a month (update: [the SC18 is available online](#), publication date: 11 May 2018).

c. Re-homing advice note

Members of UKBSC suggested that the advice note should be amended to better explain the potential options for release from the Act (and terminology involved, with some case studies and examples to provide clarity). Technically, the only options for release from the Act are: rehoming, setting-free and killing. There is an intrinsic difficulty in the terminology used by ASPA. More work will be done to review this advice note.

d. Severity assessment of aged animals

ASRU and some other groups (e.g. LASA and IAT) are working on this. UKBSC suggested that additional expertise from CROs should be sought on this matter. Opinions were collected at a LASA

meeting session dedicated to this topic. ASRU is seeking to form a coherent view about the right checks that should be put in place to monitor the health/welfare of aging animals.

e. **Prospective severity assessment**

The document is work in progress and is with ASRU at the moment. UKBSC will see the draft for review in due course.

f. **Retrospective assessment**

This piece has high priority, and is currently under internal review. To submit a retrospective assessment is one of the conditions at the end of end of certain types of PPL. ASRU wants to make it a single process that should start 6 months before the end of the current PPL. The note in preparation will explain this. UKBSC requested to see a draft of this document, in due course.

3. **ASRU involvement in discussion with DEFRA about the draft Animal Welfare Bill**

ASRU is discussing with BEIS and DEFRA about the development of the Bill. They discussed the species that will come in scope and how the Bill might impact research done on animals that are not currently included under ASPA.

4. **Updates on Brexit related to ASRU work**

From the point of view of regulations for animals in research, the transition should be seamless (Directive 2010/63 was fully transposed into ASPA, with all ambulatory references to annexes of the Directive collected and awaiting transposition).

5. **ASRU return of procedures for 2017**

ASRU collected the data for the annual Return of Procedures from all project licence holders by 31st January 2018. The collected data are undergoing quality assessment and statistical figures will be published later in the summer. In addition to the normal end of year Return of Procedures, this year ASRU has required PEL Holders to provide additional data from each establishment in accordance with PEL Standard Condition 8 (the EU Directive stipulates this extra data collection occurs once every 5 years). The planned publication date for the 5-year dataset should match that set up by the European Commission (November 2018). In terms of extent and quality of reporting, the UK is ahead of other States. So far, ASRU has sought parity with how things are done at the EU level. Members of UKBSC expressed their view that in all scenarios it should be a priority to maintain rigor, improve regulatory processes and reduce administrative burden.

6. **AOB**

- UKBSC informed ASRU about the planned revision of the Terms of Reference of UKBSC and ways to expand engagement with the bioscience community. The new ToR specifies the membership, structure, objectives and working methods of UKBSC. It aims to increase visibility of UKBSC across the sector. The co-chairs explained that UKBSC was initially put together to facilitate a joined discussion between industry, academia, funders and the regulator. The aim was to coordinate views and opinions while reducing confusion in the implementation of the Act. ASRU suggested a formal contact with the PEL Forum to facilitate cross-communication.
- As a follow-up to earlier discussions about guidance given to AWERBs, UKBSC asked ASRU whether they could add a [specific rewording to their newsletter](#) to specify that it is the responsibility of the establishment licence holder, not the AWERB, to ensure that only high quality drafts are submitted to ASRU, and reiterate this message at the PEL Forum meeting.

7. **Future meeting scheduled:**

- a. Next ASRU-UKBSC Co-Chairs meeting is on 7 June 2018
- b. Next ASRU - UKBSC policy group meeting is on 26 July 2018
- c. Future UKBSC – BEIS/OLS meetings TBD