

UK Bioscience Sector Coalition – ASRU meeting

29 November 2018

UKBSC-only pre-meeting

1. Run-through of the meeting agenda
2. Interaction with external stakeholders

[UKBSC](#) aims to represent the collective views of the bioscience sector with an interest in the use of animals in research and will strengthen its communications with the community of stakeholders outside of UKBSC membership, such as individual representatives from academia, industry and expert groups. The group welcomes communications in the form of receipt of up-to-date evidence and expert opinion from this community, for example via submission of evidence to the UKBSC Secretariat at ukbscsecretariat@rsb.org.uk. Submissions will be taken into consideration as suggestions for UKBSC discussions with the regulator.

ASRU meeting Agenda (14:00 – 16:00)

1. Welcome and apologies
2. Developments of the **future e-licensing system**

The head of the Animals in Science Regulation Unit (ASRU) presented an update on the development of the new e-licensing system. The plan to redesign the e-licensing software is motivated by the vision to achieve a more user friendly and agile system, which is easier to interact with than ASPeL and improves the licence application process. At the same time, the system must allow the required level of scrutiny and legal requirements under ASPA.

a. **PEL** updates

The development of the PEL module has continued over the summer and it is the most advanced of all licence modules under development. The developers of the new e-licensing system engaged broadly with scientists, named people, HOLCs, inspectors and ASRU team members. They also gave a presentation of the new PEL module at the last HOLTIF meeting and at the pELH forum at the LASA meeting, while receiving feedback by participants and users. UKBSC members involved in the agile development of the new system acknowledged a fast turn-over of changes and implementations of their suggestions given to the developers at meetings with stakeholders. The developers publish a [weekly report of new prototypes online](#). The new PEL module is easy to search and allows for faster update of information and more straightforward management of licence holder accounts. Establishments can manage access rules for users at a local level and the HOLL acts to support local governance at establishments. The head of ASRU also presented the roll-out plan for the new system, which will take place over the first half on 2019. ASRU plans to hand-hold establishments and provide detailed communication as they are migrated on to the new system. UKBSC members and the ASRU team discussed in more detail the timeline and critical points of the transition to the new e-licensing system.

b. **PPL updates**

ASRU Head of Policy gave an update about project licences and the redesign of the PPL application process as ASRU plans to achieve the following goals:

- good quality applications (the right information with the right level of detail)
- to maintain the rigour of the harm-benefit analysis
- a user-friendly system
- consistent, timely and high quality assessment (risk (complexity)-based and proportionate)
- clear, concise and unambiguous authorities
- improved openness and transparency

The annotated application form and the advice collected during the 2017 PPL workshops are being used to design the new process. Other solutions to be implemented are: (1) only to display questions that are appropriate for a specific type of application (there will be a set of initial criteria to pre-select the type of application); (2) to minimise repetition in questions; and (3) to auto-populate fields wherever technically possible. Extensive individual user testing is underway to highlight 'pain points' to resolve. There will be messaging and updates from ASRU operations team across the first half 2019.

There was a discussion about non-technical summaries and reporting of 3Rs implementations. ASRU was still thinking about the best way to create NTSs, and has been involved in ongoing discussions at EU-level on how to improve the NTSs. The AWERB knowledge hub administered by the secretariat of the Animals in Science Committee can also share useful guidance on how to write NTSs.

ASRU has also devised a plan for new applicants, who will be preparing to submit their application while the new system is under development. The developers are creating a PPL drafting tool, which will be used by new applicants according to a precise timeline communicated to establishments. ASRU plans to release a PPL drafting tool in early 2019. They will also launch dedicated guidance and a website at the same time.

3. **PPL application and granting times**

ASRU presented summary statistics of PPL granting times over the last year and the progress towards one high quality draft. ASPeL records time spent by applicants and inspectors on individual PPL applications and number of drafts before reaching the state of complete and correct. There appears to be a slight increase in the number of applicants reaching complete and correct after only one iteration in draft stage or by direct submission. The future e-licensing system will provide additional useful KPIs. ASRU also hopes to stratify data from the sector and different types of licenses in a more meaningful way on the new system.

In a second graph, ASRU showed the time spent by applicants and inspectors on PPLs over the past year. There appears to be a shift for inspectors having faster turn-around times. Guidance to applicants asking for the submission of a high quality draft (issued around Feb '18), could have played a part in this change¹.

¹ At least some of the seasonal difference could be due to conflicting commitments of academic applicants during exam time and at the start of the academic year.

4. **Fees** increase

ASRU proposed an increase in fees for the FY 2019/20 as part of their discussion with HM Treasury, as the Unit now operates in full cost recovery mode. This was announced in the [October 2018 ELH newsletter](#). The fees will pay for the new and improved e-licensing system and to support the Unit. ASRU will keep investing on the IT system in order to tune it further in the coming years. A fixed element in the unit's income comes from the PEL fees while the PIL fees provide a more variable element. ASRU used a model of steady-state flow and stock to predict the necessary increase in fees. The model has been used to predict ASRU finances for the next two years. ASRU has taken up the recommendation of UKBSC to forecast further in the future and will develop a five-year window model.

ASRU gave an update about the Unit's organogram. A Head of Policy has been appointed and the policy team consists of three members.

5. ASRU publications

a. Annual report

Its publication was imminent (update: the [report](#) has been published). The report contains a collection of non-compliance cases, which UKBSC and ASRU discussed. It is a positive manifestation of a culture of compliance that most of the cases have been self-reported by establishments (93% in 2017).

Failure to provide food and water is still a major cause of non-compliance. Common types of non-compliance are:

- (1) procedures conducted without license authority
- (2) a failure to provide food and/or water
- (3) the unauthorised re-use of animals

ASRU inspectors will carry out themed inspections during 2019 on:

- (1) mouse handling
- (2) single use needles
- (3) food and water

The goal of the inspections is to monitor and support uptake of consolidated best practices but also to gather further evidence about new refinements developed locally at an establishment.

b. Genetic animal breeding tool

The updated version of the document was circulated to stakeholders and will be published soon.

c. Retrospective Assessment (RA) advice note

ASRU is taking suggestions on board but it is a work in progress. The RA should be written in lay language but also provide enough useful detail for inspectors. The process under discussion at ASRU should ensure that published RAs follow a consistent template.

d. Education and training advice note

The draft advice note was circulated to stakeholders and the accreditation bodies for comment. Its publication is imminent.

- e. Zebrafish protocols for project licence applicants
Publication is imminent.
 - f. Publication of Non-Technical Summaries
NTSs for 2017 are in preparation for publication. ASRU is also involved in an EU Commission project on NTS/RA.
6. **ASRU statistics** – PEL standard condition 8
- [Additional statistics](#) based on data collected by establishments under PEL standard condition 18 were released on 8 November 2018. The data were collected to be published as national statistics for the first time. Information in the report should have clarified why these animals are purposefully bred and not used as part of scientific procedures. UKBSC and ASRU had a discussion about the published figures and their significance.
7. **Brexit**
- a. General updates
At the time of the meeting, the Withdrawal Agreement and Political Declaration had been endorsed by EU leaders and the UK Parliament was expected to vote on a deal on 11th December. Animals in science regulation in the UK will continue as usual and only minor changes to the Animals (Scientific Procedures) Act have been drafted into a [statutory instrument](#) (SI).
 - b. ASRU participation in inter-departmental groups
Senior members of ASRU have been involved in meetings with Defra. ASRU has also been involved in workshops in Brussels on project evaluation. Guidance on this will be released by the EU Commission in due course.
8. **ASRU Approval** of format for public minutes from **July 2018 UKBSC-ASRU meeting**.
Approved and [published after the meeting](#).
9. **AOB**
- [ASRU – NC3R signed a Memorandum of Understanding](#), which aims to pull-through 3Rs development and recommendations by NC3Rs. It will also favour a feedback process from ASRU to NC3Rs based on observations collected by inspectors on the ground. The goal is to foster the right exchange of information to drive progress in implementing the 3Rs.
10. Future meetings scheduled:
- a. The 16th Animal Science Meeting to take place in December 2018

Appendix – Animal Science Acronym Buster

A collection of frequently encountered abbreviations during UKBSC meetings

February 2019

3Rs	The principles of replacement, reduction and refinement
AMS	Academy of Medical Sciences (ASG observer)
ASAB	Association for the Study of Animal Behaviour (ASG member)
ASPA	The (Scientific Procedures) Act 1986 as amended by the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012
ABPI	Association of the British Pharmaceutical Industry (ASG member)
APPG	All-Party Parliamentary Group
ASC	Animals in Science Committee
ASG	Animal Science Group
ASRU	Animals in Science Regulation Unit (Home Office)
AWERB	Animal Welfare and Ethical Review Body
BAS	British Andrology Society (ASG member)
BALR	British Association for Lung Research (ASG member)
BAP	British Association for Psychopharmacology (ASG member)
BBSRC	Biotechnology and Biological Sciences Research Council (ASG member)
BEIS	Department for Business, Energy and Industrial Strategy
BIA	The BiIndustry Association (ASG member)
BNA	British Neuroscience Association (ASG member)
BPS	British Pharmacological Society (ASG member)
BS	Biochemical Society (ASG member)
BSAS	British Society of Animal Science (ASG member)
BSI	British Society for Immunology (ASG member)
BSP	British Society for Parasitology (ASG observer)
BTS	British Toxicology Society (ASG member)
CAP	Common Agricultural Policy
CaSE	Campaign for Science and Engineering
CEH	Centre for Ecology and Hydrology
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CRO	Contract Research Organisation
CSA	Chief Scientific Advisor
DEFRA	Department for the Environment, Food and Rural Affairs
DfE	Department for Education
DfH	Department for Health
EARA	European Animal Research Association
EC	European Commission
EFB	European Federation of Biotechnology
EFPIA	European Federation of Pharmaceutical

	Industries and Associations
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EU directive	European Directive on the protection of animals used for scientific purposes (2010/63/EU)
FEAM	Federation of European Academies of Medicine
FOI	Freedom Of Information
FRSB	Fellow of the Royal Society of Biology
FSA	Food Standards Agency
GA	Genetic Alliance
GAA	Genetically-Altered Animals
GDP	Gross Domestic Product
GMO	Genetically Modified Organism
HFEA	Human Fertilisation and Embryology Authority
HO	Home Office
HoC	House of Commons
HoL	House of Lords
HOLC	Home Office liaison contact (this title is often used by establishment licence holders to denote one or several key contacts for communication with the Home Office)
HOLTIF	Home office Liaison, Training and Information Forum
IAT	Institute of Animal Technology (ASG member)
IoP	Institute of Physics
LABA	Laboratory Animal Breeders Association (ASG member)
LASA	Laboratory Animal Science Association (ASG member)
LAVA	Laboratory Animals Veterinary Association
LeSPAR	Learned Societies Partnership on Antimicrobial Resistance
MEP	Member of the European Parliament
MO	(RSB) Member Organisations
MRSB	Member of the Royal Society of Biology
MRC	Medical Research Council
MS	Microbiology Society (ASG member)
NACWO	Named Animal Care and Welfare Officer
NC3Rs	National Centre for the Replacement, Refinement and Reduction of animals in research
NCO	Named Compliance Officer (a term sometimes used for the Named Person Responsible for Compliance)
NERC	Natural Environmental Research Council
NIO	Named Information Officer
NPRC	Named Person Responsible for Compliance (the preferred term, also sometimes referred to as a Named Compliance Officer)
NS	Nutrition Society (ASG member)
NTCO	Named Training and Competency Officer
NTS	Non-technical summary
NVS	Named Veterinary Surgeon
OLS	Office for Life Sciences

PEL	Establishment licence (a licence granted under section 2C of the Act, also known as a 'section 2C licence')
PEL holder	The holder of a section 2C (establishment) licence under ASPA
PET	Progress Educational Trust
PETA	People for the Ethical Treatment of Animals
PIL holder	The holder of a personal licence under ASPA
POLE	Place other than a licensed establishment
POST	Parliamentary Office for Science and Technology
PPL holder	The holder of a project licence under ASPA
PS	Physiological Society (ASG member)
PSRE	Public Sector Research Establishment
RCVS	Royal College of Veterinary Surgeons
REF	Research Excellence Framework
RS	The Royal Society (ASG observer)
RSC	Royal Society of Chemistry
RSPCA	Royal Society for the Prevention of Cruelty to Animals
RVC	Royal Veterinary College
SE	Society for Endocrinology (ASG member)
SEB	Society for Experimental Biology (ASG member)
SfAM	Society for Applied Microbiology
SIG	Special Interest Group
SMC	Science Media Centre (ASG observer)
SPAN	Science Policy Advisor Network
SPoC	Single Point of Contact
SRF	Society for Reproduction and Fertility (ASG member)
STFC	Science and Technology Facilities Council
TEF	Teaching Excellence Framework
T-Levels	Technical qualifications at level 3, equivalent to A-levels
UAR	Understanding Animal Research (ASG member)
UFAW	Universities Federation for Animal Welfare (ASG member)
UKBSC	UK Bioscience Sector Coalition
UKPSF	UK Plant Sciences Federation
UKRI	UK Research and Innovation
WT	Wellcome Trust (ASG member)
ZSL	Zoological Society of London