

Animals in Science Committee

Minutes of the 23rd Meeting: 20th May 2019

1.0 Welcome, Introductions and Conflicts of Interest

- 1.1. The Chair welcomed attendees to the 23rd meeting of the Animals in Science Committee (ASC). The Chair extended a warm welcome to new Committee members: Professor Andrew Jackson, Professor Johanna Gibson, Dr Noelia López-Salesansky, Professor Stephen May, Susan Sparrow, Dr Virginia Warren and Professor Christine Watson.
- 1.2. Apologies were received from Susan Sparrow. A full list of attendees is provided at Annex A.

2.0 Actions from the previous ASC meeting

- 2.1. In respect of the action “*Recirculate project licence applicant guidance note to ASC members.*” members suggested updating the guidance note to better reflect their review processes as published on the ASC website¹.

Action 1: Secretariat to update the project licence applicant guidance note for ratification by the Project Licence Application subgroup

- 2.2. The Chair requested the Secretariat maintain an action log to keep the Committee and ASRU informed of the progress against outstanding issues.

Action 2: Secretariat to circulate an action log on progress against outstanding issues.

3.0 Chair’s Update

3.1. Demitting Committee members

- 3.1.1. The Chair thanked the Committee members who had recently demitted from the ASC: Dr John Landers (former Chair), Professor Gail Davies, Professor Malcolm Macleod, Ken Applebee, Dr Gerlinda Stoddart and Anna Rowland; informing the Committee he would send each a formal letter of thanks.

Action 3: Chair to send formal letters of thanks to demitting members.

¹

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/680009/Licence_Referral_Review_for_publication_v2_pub.pdf

3.2. Licence Analysis (LA) Subgroup (SG) membership

3.2.1. The Committee agreed that Dr Donald Bruce should assume the role of LA SG Chair and that Dr Gilly Stoddart should be co-opted onto the SG until the completion of the project, expected Autumn 2019.

3.3. Meeting with the Royal Society of Biology (RSB)

3.3.1. The Chair reported that in July he would meet with Professor Dominic Wells, Chair of the RSB Animal Science Group (ASG). This would be an annual meeting between the ASC and the ASG to share information including common areas of interest, upcoming activities and emerging priorities. The Chair invited members to submit to the Secretariat any topics or issues they would like raised as part of the meeting.

Action 4: Committee members to send topics for discussion to the Secretariat.

3.4. European Union (EU) National Committee meeting

3.4.1. The Chair thanked Dr John Landers, in his absence, for his report on the recent meeting of EU National Committees in Stockholm.

3.4.2. Key points from the meeting included:

- Dutch representatives had led on the need to transition to non-animal research, noting this would require a three-tier approach of political initiative, social support and educational effort. The focus for change should be young researchers.
- Whilst differences in the jurisdiction of individual member states meant it was not possible to establish a uniform mode of implementation for the Directive, it would be desirable to harmonise (where possible) some aspects of licensing, such as severity grading.
- “Regulatory tourism” (applications rejected in one jurisdiction being resubmitted in another) was discussed, with consideration given on how to address this within the bounds of current legislation.
- Going forward, the National Committees agreed that meetings would be held once or twice a year, hosted by member countries. The next meetings would take place in Rome, followed by Berlin and then Budapest.
- Meetings would focus on two topics, one nominated by the host country and the second by agreement of the membership.
- Improvements to the current website would be helpful to further promote co-operation and information sharing.

3.4.3. Members were informed that the ASC would continue to contribute to these meetings after the UK exits the EU.

4.0 Task and Finish Group Update (part 1)

4.1. Licence Analysis Subgroup Update

- 4.1.1. The SG Chair reported that the review of the eleven licences had been completed and the report drafted. Findings had been discussed with the Animals in Science Regulation Unit (ASRU) and a further meeting had been held to discuss regulatory licensing (licences required by UK regulations other than Animals in Scientific Procedures Act (ASPA)) as well as the new e-Licensing system which was for launch Summer 2019. Topics discussed included the use of project plans, experimental design, power calculations and the content and quality of non-technical summaries.
- 4.1.2. In preparing the final report, Committee members suggested it would benefit from clear and attributable recommendations.

Action 5: Dr Bruce to assume the role of Chair to complete the LA Report.

Action 6: Dr Stoddart to be co-opted to the SG to complete the LA Report.

5.0 Presentation

5.1. ASRU New E-Licensing System

- 5.1.1. ASRU Head of Operations gave a presentation on the new ASRU e-licensing system which will be launched during Summer 2019. He explained there were three types of licence: an establishment licence to enable the establishment to carry out the work on its premises; a personal licence for the researcher carrying out the work; and a project licence for the research being carried out. The new system would produce all three licences in a simpler, more intuitive and easier to amend format and would hold details of all licences: approximately 155 establishment licences; 18,000 personal licences; and 3,000 project licences.
- 5.1.2. The system build had produced and utilised publicly available open source code to reduce development costs and maintain consistency with other Government Digital Services. In the interests of openness and transparency and to keep stakeholders updated on progress, each phase of the system's development had been made available on the Home Office website in weekly reports.
- 5.1.3. A common issue from stakeholders was the difficulty in understanding the Regulator's expectations. Therefore, project licence applicants would be required to respond to more structured questions than the previous licensing system, which would be more specific and easier to answer. To help applicants familiarise themselves with the new project licence application system, a drafting tool had been released early in 2019 with feedback addressed in the next iteration of the system. The Committee was informed that during 2020

ASRU would audit the effectiveness of the new project application from using applicants' responses to questions and determine whether any changes needed to be made to improve responses.

- 5.1.4. Turning to the specific issues raised by the LA SG, the Head of Operations explained new sections had been added where applicants would: provide greater clarity around numbers of animals; number of uses of each animal, when re-use is authorised; and, the experimental design and add details of the scientific justification, including the research questions and hypothesis being tested.
- 5.1.5. Committee Members queried whether changes could be made to the NTS section ahead of the Summer launch and were informed that, the NTS template was set out by the EU Commission and ASRU did not intend to deviate from this other than to add sub questions to improve the quality of answers. However, there may be an opportunity to add questions following the 2020 audit.

6.0 Task and Finish Group Update (part 2)

6.1. Non-Human Primate (NHP) Welfare Assessment Subgroup

- 6.1.1. The SG Chair explained that the purpose of the project was to understand how individuals working with NHPs assess and identify normal and abnormal NHP behaviours and whether the methods used would be improved by enhancing the behavioural training resources available.
- 6.1.2. The workstream had taken time to become established, however the group had now co-opted seven additional NHP experts from industry and academia. The group would begin collecting data to construct the survey questionnaire with the aim of engaging survey participants from as wide a field as possible including scientists, technicians, veterinarians, research assistants etc.
- 6.1.3. It was suggested that the construction of the questionnaire would benefit from the input of a research psychologist; the SG Chair confirmed that Prof Gail Davies (former ASC member), had agreed to review the draft questionnaire.

6.2. Comparative Study of Regulation Subgroup

- 6.2.1. Following the SG's contribution to the EU survey on the implementation of Directive 2010/63 EU (Autumn 2018), work on the second part of the programme, a review of other areas of UK regulation and its relevance to ASPA, had slowed. This was as a result of the SG and ASRU finding little common ground between ASPA and other UK regulatory authorities. Consequently, SG members considered that pursuing the original objectives might prove futile.

- 6.2.2. The Committee noted the SG's assessment and discussed the potential benefits of better understanding other regulatory regimes, in particular how they influence compliant behaviour, observing that compliance was a marker for the quality of science. Members noted that many institutes undertake research outside of the UK and that an understanding of the regulation processes of other jurisdictions may benefit establishments in making decisions to carry out research abroad.
- 6.2.3. It was concluded that the workstream should be paused and revisited at the September ASC meeting, at which time ASRU would be better positioned to discuss how the project could develop to provide appropriate challenge and support to current operations.

Action 7: Comparative Study of Regulation workstream to be paused and revisited at the September ASC meeting.

7.0 Animal Welfare Ethical Review Bodies (AWERBs) Subgroup Update

7.1. Hub Chair Workshop

7.1.1. Following a review of the AWERB Hub Regional Network, the original fourteen Hubs had been consolidated down to eleven. The chairs of the eleven Hubs met on the 13 March 2019 for their annual meeting. The key actions from that meeting would help form the AWERB SG work programme over the next 18 months, (see paragraph 7.2). The Hub chairs' meeting report would be published on the ASC website and added to the secure online communication platform for AWERBs, the Knowledge Hub.

7.2. AWERB SG workplan for next 18 months

7.2.1. The proposed work programme included:

- i. Update the AWERB Hub Support note guide to assist the Hub Chair role;
- ii. Review the ASC HBA report recommendations and their relevance to AWERBs and provide a short set of practical points for AWERBs to utilise when undertaking harm-benefit analysis;
- iii. Following the publication of the report from the LA SG, to provide guidance on how to write good NTS as recommended;
- iv. Develop a mechanism/metrics to quantify the value of the AWERB Hub Network to participants, and produce a report;
- v. Continue to support and promote the AWERB Knowledge Hub as the communication tool for all AWERB members and to increase AWERB awareness and use of the platform; and

vi. Continue to host the annual AWERB Hub Chairs' workshop.

7.2.2. In taking forward the work programme, the ASC Chair observed the need to distinguish between the respective responsibilities of the ASC and ASRU in providing support for AWERBs, particularly in respect of harm-benefit analysis. The Committee noted that ASRU had the formal/legal requirement to carry out harm-benefit analysis, whereas AWERBs were required to consider the ethical aspects of the research but that incorporated a local discussion involving harm-benefit analysis. It was agreed that the AWERB SG would provide practical advice in a simple format to help AWERBs with their harm-benefit discussions.

Action 8: AWERB SG to provide practical advice, in a simple format, to help AWERBs with their harm-benefit discussions.

8.0 ASRU Update

8.1. Strategic planning

8.1.1. ASRU Head of Unit (HoU) provided an overview of their five-year strategic plan, their five-year resource and workforce plan and their annual business plan. This included an outline of the restructure of their leadership to: Head of Unit, Chief Inspector; Head of Policy and Head of Operations, with additional support from three Principal Inspectors. It was reiterated that ASRU works to a full cost recovery model and that their Annual Report outlines how the fees are calculated and spent. In future ASRU will use the new five-year resource and workforce plan to map their long-term work programme, including any IT development, to the available resource.

8.1.2. Members were informed that ASRU's wider management assurance objectives were achieved through the Departmental management assurance framework which assesses all aspects of ASRU business (policy, finance etc) to set benchmarks for performance.

8.1.3. Responding to a question from the Chair, ASRU HoU confirmed that their strategic plan would outline ASRU's plans for engagement with the ASC and that this would be presented at the September ASC meeting. In advance of that, it was agreed that a bilateral meeting with the ASC Chair would be helpful to discuss the mechanism of engagement.

Action 9: ASC Chair and ASRU to meet to discuss future mechanisms for engagement.

Action 10: ASRU to present their updated strategy at the September ASC meeting.

8.2. Emerging priorities for ASRU Inspectorate

8.2.1. ASRU Chief Inspector (CI) outlined the three key priorities for the Inspectorate:

- i. The implementation of a consistent, proportionate project licence process via the new e-licensing system (ASPEL) along with a standards-based assessment process;
- ii. A further development of outcome-based inspection activities, following the undertaking of a themed inspection programme. Currently, numbers of inspections carried out each year is the main measure of success. ASRU would move towards a more evidence-based programme for 2020.
- iii. Assessing the working practices for staff across the inspectorate to improve well-being and reducing isolation of home-based Inspectors by piloting working in smaller teams to encourage peer learning, wider support and improve consistency.

8.2.2. Reflecting some of the findings of the recent AWERB Hub meeting, the Committee asked if the themed inspections programme would also consider the benefits of learning from near misses, in terms of non-compliance with ASPA. The CI agreed, noting that project licence reviews included near miss discussions in terms of unexpected adverse effects. Near misses may also provide information about culture of care, which is assessed during inspection activities. The reorganisation of Inspectors into peer groups with more regular face to face meetings would provide a further forum to discuss issues such as near misses.

8.2.3. In response to a question from the Committee about the reuse of hypodermic needles in establishments, the CI confirmed that evidence gathering had commenced noting establishments' acceptance that policies and procedures, particularly around the use of hypodermic needles needed to be reviewed in some areas. ASRU also reported, there had also been positive responses to this themed inspection programme which had led to improved practice in several establishments.

Action 11: AWERB SG Chair to send some additional information to ASRU on the reuse of hypodermic needles in establishments.

8.2.4. When questioned about the outstanding response to the recommendations in the ASC's Review of Harm Benefit Assessment report, the CI apologised for the delay and confirmed ASRU would shortly send their response to the Committee.

Action 12: ASRU to send their draft response to the recommendations in the ASC's Harm Benefit Review Report to the Secretariat by end of June 2019.

8.3. **Yale: Post Mortem reanimation of pigs' brains**

8.3.1. The CI commented on recent experiments in the United States to reanimate pigs' brains, post mortem, and the potential ethical and regulatory issues regarding the risk of recovered consciousness of the animals. The threshold of regulation under ASPA was defined by whether a procedure being undertaken

for scientific purposes may cause pain, suffering, distress, or lasting harm to the protected animal. Experiments such as the reanimation of pig brains may raise societal concerns. Whilst ASRU had not yet received any correspondence or project applications requesting authority for such experiments, they would welcome the ASC's views on any actions to take at this stage.

8.3.2. The Committee agreed that this was an area of research that may increase in frequency and therefore a proactive approach would be appropriate. An evidence base was needed to show the degree, if any, of reanimation and suffering. Clarity was also needed about the sentience of reanimated animal tissue and the applicability of ASPA to such research on that tissue, to ensure the research would be appropriately regulated. The Committee recommended that ASRU seek legal advice on the application of the ASPA in the case of reanimated tissue.

8.3.3. ASRU HoU suggested that ASRU present an overview, at the ASC's next meeting, of their horizon scanning.

Action 13: ASRU to consult Home Office Legal Advisors on the status of ASPA in relation to the research on reanimated animal tissue and to report this back to the Committee

Action 14: ASRU to present on their methodology for horizon scanning at September ASC meeting.

8.4. Animal Sentience

8.4.1. ASRU HoU explained that the Department for Environment, Food and Rural Affairs (DEFRA) were developing new legislation that would require animal welfare to be considered during the development of new policy. This change might recognise decapod crustaceans as well as cephalopods, as sentient beings. This in turn may require the eventual amendment of ASPA to be consistent with this new legislation with regard to the animals protected under ASPA. The Committee noted that decapods had been included in the early drafts of Directive 2010/63 EU but had later been removed. This was prior to the evolution of the evidence base concerning animal sentience.

8.4.2. The Home Office would continue to liaise with DEFRA on the progress of the new legislation and keep the ASC updated.

Action 15: ASRU to update Secretariat on Animal Sentience legislation progress.

8.5. Primate Licence matters

8.5.1. The CI updated the Committee on a recent question, from an establishment, about the potential provision of 24 hr Inspector cover as an assurance in the event of an unexpected adverse event during primate research. Consideration of the question had identified the need to: ensure clarity regarding the roles and

responsibilities of named individuals and licensees in ensuring compliance with ASPA and licence authorities; and ensure clarity in the humane endpoint written into licences. The CI would make further enquiries into the issue and provide an update to the Committee.

- 8.5.2. Committee members agreed that licences should be able to provide for unexpected adverse effects of procedures without requiring consultation with an Inspector which may cause a delay leading to adverse welfare impacts on the animal. Members also noted that consultation stipulations had been included in some licences and it would be helpful to understand why this has happened in these isolated cases.

Action 16: ASRU CI to provide an update to the Committee on the issues related to primate licences.

9.0 Committee Matters

9.1. Visit to a Research Establishment

- 9.1.1. Several members of the ASC visited a licenced establishment. They had a useful and informative visit which included a research laboratory and breeding facility. Members had one question about monitoring facilities in the laboratory. ASRU agreed that they would seek a response from the assigned Inspector for the establishment.

Action 17: ASRU to contact the named Inspector and reply to the ASC.

9.2. Research Excellence Framework

- 9.2.1. An ASC member reported back on their attendance at the Westminster Higher Education Forum seminar on the Research Excellence Framework (REF). The intention to trial four unit of assessments in eight establishments was reported at the seminar. There were also three additional mini symposia on: equality, diversity and inclusion; open access; and impact. Impact was the issue on which the ASC had made their main contribution to the REF 2020 consultation in respect of the 3Rs.
- 9.2.2. Members noted that the difficulty of finding effective mechanisms to measure the impact of research had long been an issue, with journal publications tending to focus on research outcomes rather than 3Rs advances. Measures of quality include changes in behaviours and societal benefits such as an improved understanding of the value of science etc. They also noted that assessing impact should not be restricted to the REF but should include a wider range of science bodies, including funders. Members agreed this was an area to keep under review.

10.0 ASC Work Plan

- 10.1. Members discussed the ASC work programme for the next eighteen months agreeing that membership of the specific subgroups would be discussed individually with each new member.
- 10.2. Addressing the specific areas in the Minster's Commission letter, the Chair suggested that 'issues that may raise societal concerns' was one that could be consolidated as part of a futures/horizon scanning programme. The Chair proposed that he discuss this with ASRU and report back at the September ASC meeting.
- 10.3. Updates on the progress of other working groups are provided above.

11.0 AOB

- 11.1. The next meeting of the ASC would take place on 16th September.
- 11.2. No other business was raised.

Annex A

Animals in Science Committee Members

Professor David Main (Chair)

Dr Donald Bruce

Dr Hannah Clarke

Professor Johanna Gibson

Professor Andrew Jackson

Mrs Wendy Jarrett

Dr Noelia López-Salesansky

Professor Stephen May

Mr Barney Reed

Dr Sally Robinson

Professor Clare Stanford

Dr Virginia Warren

Professor Christine Watson

ASRU

Dr Kate Chandler (Chief Inspector, ASRU)

Mr Will Reynolds (Head of Unit, ASRU)

Dr Martin Whiting (Head of Operations, ASRU)

Science Secretariat

Dr Joanne Wallace (Head of Science Secretariats)

Mrs Caroline Wheeler (ASC Secretary)