

Animals in Science Committee

Minutes of the 26th Meeting: 17th February 2020

1. Welcome, Introductions and Conflicts of Interest

- 1.1. The Chair welcomed attendees to the 26th meeting of the Animals in Science Committee (ASC).
- 1.2. Apologies were received from Dr Noelia Lopez-Salesansky. Dr Andrew Jackson joined the meeting via teleconference. A full list of attendees is provided at Annex A.

2. Minutes and Actions from the previous ASC meeting.

- 2.1. Minutes from the last meeting had been agreed and awaited publication.
- 2.2. Actions were complete with the following exceptions:
 - 2.2.1. The Animals in Science Regulation Unit (ASRU) to send the Project Licence Applications (PLA) responses to the ASC. (See para 5.2.1)
 - 2.2.2. ASRU to provide the ASC with their procedure for auditing and assuring the accurate reporting of retrospective severity. (See para 5.2.3)
 - 2.2.3. ASRU to consider the development of a policy position on brain reanimation research. (See para 5.4)
 - 2.2.4. ASRU to provide ASC with the numbers of regulatory licences that apply to animals listed under 'protected species' by Animals (Scientific Procedures) Act (ASPA). (See para 5.6.3)
 - 2.2.5. ASRU to provide advice about use of recognised animal husbandry on animals and where this intersects with ASPA to ensure institutions are in compliance with ASPA guidance. (See para 5.7)

3. Chair's Update

3.1. Meeting with ASRU and NC3Rs

- 3.1.1. The Chair and AWERB Subgroup Chair met with Jenny Stewart (Head of Science and Technology Strategy Delivery), Will Reynolds (Head of ASRU) and Vicky Robinson (CEO NC3Rs) on 30th January 2020.
- 3.1.2. The meeting focused on two issues:
 - i The ASC's role in providing assurance on compliance with ASPA;

- ii The role of ASRU, NC3Rs and the ASC as leaders in public policy wider than ASPA compliance.
- 3.1.3. Governance issues impacting the use of Animals in Science involved organisations beyond the ASRU, ASC and NC3Rs. The Department for Business, Energy and Industrial Strategy (BEIS), UK Research and Innovation (UKRI) and the Department for Environment, Food & Rural Affairs (DEFRA) were key stakeholders with interests broader than ASPA. It was unclear who holds responsibility for oversight of governance and overall strategy.
- 3.1.4. The Chair informed the Committee of the following actions from that meeting:
- i The ASC would write to the Minister to set out the technological and innovative benefits of developing a broader oversight approach for the use of animals in science.
 - ii ASRU would discuss this proposal with Home Office (HO) Chief Scientific Advisor (CSA) and reach out to other Government departments to garner support for the initiative.
- 3.1.5. Follow up meetings would take place every three months, with midway progress reports scheduled via teleconference.

Action: Secretariat to draft a letter to the Minister to set out the technological and innovative benefits of developing a broader approach for the use of animals in science.

Action: The ASC Chair to update the committee on progress made regarding broader policy leadership and compliance with legislation at the next meeting.

3.2. Minister's response to the Harm Benefit Analysis (HBA) report recommendations

- 3.2.1. The Minister had responded accepting all the HBA report recommendations directed by the ASC for implementation by ASRU.
- 3.2.2. Committee members queried how and when ASRU planned to implement the HBA recommendations. Members felt that a recommendation delivery timeline would be useful.
- 3.2.3. Members were informed that ASRU were in the process of putting together their strategy which incorporated the response to the HBA Report. ASRU would provide further detail on their implementation and delivery plans once finalised.

Action: ASRU to provide an update on implementation of the HBA at the next ASC meeting

3.3. Letter from the Institute of Animal Technology

- 3.3.1. The Chair informed the Committee that the ASC had received a letter from the Institute of Animal Technology (IAT) expressing concern that the ASC lacked animal technician expertise.
- 3.3.2. The Chair had responded to the IAT explaining the recruitment process for appointees to public bodies and welcoming the IATs input to future working groups as appropriate.
- 3.3.3. The Chair also informed the Committee that the Chair of IAT Council had been invited to attend the ASC AWERB Hub Workshop in March.

3.4. Laboratory Animal Science Association PEL Spring Forum Meeting.

- 3.4.1. The Chair informed the Committee that he would be speaking at the LASA PEL Spring forum on 'Oversight & Leadership for Animals in Science'.

3.5. Media Reports about Contract Research Organisation (CRO)

- 3.5.1. The Chair thanked members for their comments concerning the German CRO involved in an exposé piece. This topic had been discussed previously and members were updated that the CRO involved had been closed down as a result.

4. ASC Futures Capability

- 4.1. The Chair advised the Committee that ASC member Johanna Gibson had agreed to Chair the Futures Capability working group.
- 4.2. The Chair of the Futures working group provided an update on work so far including that initial Terms of Reference had been drafted and were awaiting ratification by the ASC.
- 4.3. The Subgroup Chair outlined their initial thoughts on the scope and remit of the working group and reminded members that although the subgroup would be responsible for the logistical elements of the work all committee members would be welcome to participate in the discussions held.

Action: ASC members to review and ratify the draft Terms of Reference.

5. Update from the Animals in Science Regulation Unit (ASRU)

5.1. ASRU response to a whistle-blowing incident

- 5.1.1. The ASRU Head of Unit (HoU) advised the ASC that a response had been drafted and would be published once issues concerning Section 24 of the ASPA had been addressed.

5.2. Project Licence Application (PLA) Referrals to the ASC.

- 5.2.1. The ASRU HoU advised the ASC that 11 of the 13 responses had been passed to the Secretariat.
- 5.2.2. ASRU HoU noted that the responses had been delayed and informed members of the intention to expedite processes to avoid this in the future.

Action: ASRU to provide the ASC with the remaining responses to the PLA Subgroup before the next PLA Review meeting on 31st March 2020.

- 5.2.3. At its last plenary meeting the ASC had been advised that the ASRU was developing its strategic review which, within a continued programme of work, would include a review of the use of retrospective severity for audit and future applications. Members requested an update on work concerning the accuracy of reporting of retrospective severity, including the processes applied. This piece of work was being led on by the ASRU Head of Policy who was unable to attend the meeting to provide an update.

Action: ASRU to provide the ASC with a timescale setting out procedures for auditing, and assuring the accuracy of reporting retrospective severity by its next plenary meeting on 18th May.

- 5.2.4. The ASC Chair reported that he had written to the ASRU to request that they seek, where applicable, each applicant's permission for the PLA subgroup to have access to the assessment outcomes provided by funding organisations including the NC3Rs, Wellcome and Medical Research Council. Concern was noted by members that applicants might feel obligated to give permission, even when it would be clearly put forward as non-mandatory.
- 5.2.5. The ASC requested that ASRU support a system for ASC to request assessment outcomes from applicants, including a mechanism for sharing with the PLA subgroup along with a suggested starting date.

Action: ASRU to support a system for NC3Rs, Wellcome and MRC application assessment sharing, with a suggested starting date.

- 5.2.6. Members noted their generic concern with regard to the timeliness of ASRU reporting and responses and queried whether this was a consequence of insufficient resources and whether additional resources would remediate the situation. Members were informed that ASRU were almost at full capacity in terms of its resource funded by the full cost recovery model. It was agreed that the Head of Operations (HoO) would review and prioritise current resource to expedite delivery.

Action: ASRU to review system to expedite delivery of response to the ASC.

5.3. ASRU Inspector training

- 5.3.1. ASRU had previously invited ASC Committee members to attend sections of their structured Inspector training programme to provide members with insight into how the Inspectorate functioned.

- 5.3.2. Members were informed that the ASC Secretariat had collated members' expressions of interest in the training courses and sent these to the ASRU Head of Policy, who would update the Secretariat with details of training course availability.

Action: ASRU to provide Secretariat with dates of Inspector training course availability.

5.4. Post mortem reanimation of pigs' brains

- 5.4.1. Members were advised that ASRU had considered this matter but had not defined a new policy position on the authorisation of research using reanimated brains. ASRU confirmed that should an application regarding reanimation be received by ASRU, it would be referred to the ASC for consideration under current policy.
- 5.4.2. Members had previously noted their concern about the ethical implications of research in this field, including organoids.
- 5.4.3. Noting the complexity and ethical implications ASRU requested that the ASC discuss the issue further and advise ASRU on the outcome of their deliberations.

Action: ASC to advise ASRU on the legal and ethical implications concerning the reanimation of pigs' brains and utility of organoids.

5.5. Animal Sentience

- 5.5.1. ASRU reported that the proposed legislation from DEFRA, which may have included recognition of decapod crustaceans as sentient, remained on hold following Parliament's prorogation last Autumn.
- 5.5.2. ASC members agreed that this topic should be included with their discussions regarding reanimation of pigs' brains and organoids.

Action: ASC to include this item with their proposed work on organoids and reanimated pigs' brains.

5.6. Non-Technical Summaries and New e-Licensing System (ASPeL)

- 5.6.1. ASRU HoO informed the committee that the Non-Technical Summaries (NTSs) from early 2017 had been published and that the remainder from 2017 would be published by the end of March 2020. NTSs for 2018 through to early 2020 would be published by June 2020.
- 5.6.2. ASRU HoU informed the committee that they would be reformatting their performance summary (dashboard) and once developed they would share the metrics with the ASC.
- 5.6.3. ASRU were compiling information on the number of regulatory service licences granted for the use of non-human primates as a 'protected species' under ASPA.

Action: ASRU to provide the ASC with the number of regulatory licences issued for non-human primates under ASPA.

5.7. Animal Husbandry

- 5.7.1. This topic was being handled by the ASRU Head of Policy who was unable to attend the meeting. The Chair requested an update on this topic at the next ASC Plenary meeting.

Action: ASRU to provide an update at the next plenary meeting.

6. Presentation from ASRU on Strategic and Business Updates

6.1. The committee received the following updates:

- 6.1.1. Development of the ASRU Strategy was progressing;
- 6.1.2. Changes to the ASPA had been made in advance of the United Kingdom leaving the European Union. Changes had been modest and ASRU would continue to refer to the Directive 2010/63/EU on the protection of animals used for scientific purpose
- 6.1.3. ASRU noted that a Memorandum of Understanding (MoU) had been agreed with the Northern Ireland (NI) Regulatory Unit, offering training support and guidance to NI Inspectors.
- 6.1.4. Members were also informed of ASRU's MoU with the NC3Rs.
- 6.1.5. ASRU updated the ASC on the number of Parliamentary Questions and Freedom of Information requests it had received to date in 2020.
- 6.1.6. ASRU informed the ASC on the current and completed cases of non-compliance and updated the committee on its inspection program.
- 6.1.7. Members were provided with an update on its new e-licensing system including current developments, planned changes and information on the format of the Government Digital Services planned review of 200 licences. The ASC requested that a committee member be involved in the review process.

Action: ASRU to request that the Government Digital Services include an ASC member in its review panel.

7. Animal Welfare and Ethical Review Body Subgroup Update

7.1. AWERB Hub Update

- 7.1.1. The Subgroup Chair updated the committee on the current status of the Hub Structure.

- 7.1.2. Members were informed that the Home Counties North East Hub no longer wished to serve as an AWERB Hub. AWERBs originally assigned to the Home Counties North East Hub had been offered alternative Hubs to join.

7.2. Hub Chair Workshop 2020

- 7.2.1. The Subgroup Chair confirmed that the agenda and presentation topics for the Hub Chair workshop had been finalised and circulated to attendees.
- 7.2.2. In preparation for the workshop, feedback forms requesting views on the current value of the network had been circulated, alongside pre-work relating to the role of Animal Technicians in AWERBs. Feedback would be used to inform the subgroup's later work 'Assessing the Value of the Hub Network' and to update the Hub Chair Support Note.

7.3. AWERB Subgroup Work Programme

- 7.3.1. The Subgroup Chair outlined the 2020 work programme which would focus on:
- i HBA recommendations
 - ii The Non-Technical Summary Guidance
 - iii Mechanisms to assess the value of the Hub Network
 - iv Support note
- 7.3.2. The committee had been provided with a written update containing more detail on each item, prior to the meeting.

- 7.4. As part of their work on the NTS guidance, the AWERB Subgroup Chair requested that ASRU consider providing applicants with a copy of the questions posed in the ASPeL system rather than these being revealed sequentially as the ASPeL form was completed. Foresight of the questions would allow applicants to prepare the NTS earlier potentially resulting in improvement.

Action: ASRU to consider the option of putting the ASPeL system questions on their website as a separate reference document.

- 7.5. ASRU HoO offered ASC members access to the training area of the new ASPeL system in order to familiarise themselves with the new process.

Action: ASRU to provide ASC members with access to the new e-licensing system.

- 7.6. The Subgroup Chair noted that the Knowledge Hub network was a valuable resource and now had close to 150 members.

7.7. HBA recommendations for AWERBs

- 7.7.1. Members agreed that while the HBA recommendations for AWERBs were well written and informative the number and scope might prove daunting for AWERB Chairs. This could be rectified by the addition of some implementation examples.

- 7.7.2. Members suggested requesting feedback on the report from a small number of AWERBs. An AWERB Subgroup member agreed to seek feedback from their partner AWERB Hub prior to wider dissemination.

Action: AWERB Subgroup members to obtain feedback on the report from a select number of AWERBs.

8. Task and Finish Groups

8.1. Non-Human Primate Welfare Assessment (NHPWA) Subgroup

- 8.1.1. The Subgroup Chair noted that the NC3Rs had been working on this subject, but that the scope of the work had yet to be confirmed.
- 8.1.2. The ASC Chair advised that he would liaise with the NC3Rs to discuss sharing the information gleaned more widely as part of an inclusive community sharing exercise. Given NC3R's lead in this area the ASC NHPWA was put in abeyance.

Action: ASC Chair to obtain more background information on the work being carried out by NC3Rs on NHP Welfare Assessments.

8.2. Licence Analysis (LA) Subgroup Update

- 8.2.1. A review of the first draft of the Licence Analysis (LA) Report had revealed areas that required further clarification, including the section referring to service licences.
- 8.2.2. Members agreed that the LA Subgroup would liaise with other ASC members after the meeting to reach consensus on the most appropriate wording of section 7. The difficulties of regulating the implementation of HBAs in a service licence environment were considered and it was agreed that local oversight could provide some assurance.

Action: The LA subgroup to liaise with ASC members to agree final wording of section seven of the Licence Analysis Report.

9. AOB

9.1. ASC Letter to the Minister

- 9.1.1. At the December ASC plenary, members had agreed to write to the Minister to provide:
- i details of progress against the 2018-19 commission;
 - ii an update to changes made to the ASC work programme.

- 9.1.2. Members agreed to include the ASC's intention to begin self-commissioned work including Futures and the ethical debate re the use of reanimated brains, organoids and sentience;

Action: Secretariat to include the ASC's intention to begin a new item of work on reanimated pigs' brains, organoids and animal sentience in the Minister's letter.

9.2. Project Licences (PPL) – ASRU's outstanding responses

- 9.2.1. The Chair thanked ASRU for expediting the responses to ASC recommendations concerning PPLs. Members agreed that it would be beneficial to set in place an agreed process and timeframe for the response to future PPL recommendations.

Action: Secretariat to organise a meeting with the lead Inspector to discuss future ASRU PPL responses to the recommendations made by the PLA Subgroup, before the next PLA meeting.

- 10.1. The next ASC meeting would be held on 18 May 2020.

Annex A

Animals in Science Committee Members

Dr David Main (Chair)

Mrs Wendy Jarrett

Professor Stephen May

Dr Donald Bruce

Dr Virginia Warren

Professor Christine Watson

Dr Sally Robinson

Mr Barney Reed

Professor Clare Stanford

Mrs Susan Sparrow

Professor Andrew Jackson

Professor Johanna Gibson

ASRU

Mr Will Reynolds (Head of Unit, ASRU)

Dr Martin Whiting (Head of Operations, ASRU)

Science Secretariat

Dr Joanne Wallace (Head of Science and Technology Advisory Networks)

Ms Jessica Daly (ASC Secretariat)