Animals in Science Committee Minutes of the 36th Meeting: 12th September 2022 Microsoft Teams Meeting

Welcome, Introductions and Conflicts of Interest

- 1. Professor David Main, Chair of the Animals in Science Committee (ASC), welcomed Members to the third meeting of 2022. No apologies had been received. No conflicts of interest were declared. A full list of attendees can be found at Annex A.
- 2. The Chair also welcomed officials from the Home Office Animals in Science Regulation Policy Unit (ASRPU).
- 3. The Chair explained that minutes from the previous meetings were in the process of being completed but noted that a mechanism for the timely production of minutes should be included in the Ways of Working document.

Chair's Update

Roundtable meeting with Minister and stakeholders

- 4. The Chair informed the Committee about a meeting between the Home Office Minister, Home Office representatives, as well as several other stakeholders. It had been a productive meeting with discussions including the rationale for regulatory reform, the need for improved communication with stakeholders and greater public engagement. It was agreed that there would be a follow-up meeting in approximately 6 months' time.
- 5. In order to support delivery of the regulatory reform programme of work, the Head of ASRPU explained that there would be a new member of staff joining the team to lead this work. This would be part of a multi-step programme, beginning with setting the regulatory requirement, then designing the operating model and finally ASRPU and the Animals in Science Regulation Unit (ASRU) working together to agree the new organisational design for ASRU.
- 6. ASRPU advised the Committee that they would be provided with a status update at the next plenary meeting. To help assess the impact of regulatory reform, the Chair had also suggested the ASC undertake a self-commissioned area of work to assess the role of named individuals in establishments and alignment with the audit process.

Visits and stakeholder meetings

7. The Chair updated the Committee on his and another Member's visit to the Animal Replacement Centre of Excellence in Queen Mary's University London. This was an interesting visit focusing on opportunities to replace the use of animals in science.

- 8. The Chair had attended a Home Office conference for members of arms-length bodies which focused in improving diversity in public bodies. He had also met with the Home Office Deputy Chief Scientific Adviser to discuss cross-government working and future ASC recruitment.
- The Chair had met with the National Centre for Replacement, Reduction and Refinement (NC3Rs) and UK Research and Innovation to discuss a more structured engagement process.
- 10. The Chair also informed Members that he would attend the Laboratory Animal Science Association Establishment Licence Holder forum in November to present on the role of the ASC. He had also been invited to the Researching Animal Research conference, hosted by the Animal Research Nexus Programme (AnNex), in March 2023. The conference would mark the end of the AnNex's Wellcome collaborative award.

Other matters

- 11. The Chair drew attention to the most recent commission¹ for advice from the Minister, which had been published on the ASC website, noting that the prioritisation of the delivery of the work programme would be agreed with the ASRPU.
- 12. Members raised an issue about potential delays for research applicants on new licences. ASRPU reassured the Committee that delays were being mitigated, and potential issues had now been resolved. ASRPU also advised there was a potential overall processing time of 9 months for licence applications, so applicants were being advised to submit first applications as early as possible. However, it was noted that legislative timeframes would not be affected.
- 13. The Committee reiterated that it would be beneficial to run another Ipsos MORI survey on public attitudes to animal research. They also felt it would be appropriate to include questions around public engagement with Animal Welfare Ethical Review Bodies (AWERBs).
- 14. The ASRPU advised that this had been raised with the Department for Business, Energy, and Industrial Strategy (BEIS), who had responsibility for the survey.

Ways of Working

- 15. The Chair opened discussion on the drafting of the Ways of Working document. The purpose of the document was to set future ways of working, including stakeholder engagement, and was based on ideas set out in the Code of Practice for Scientific Advisory Committee 2021². The Committee was informed by the Secretariat that the document was still in the early stages of drafting.
- 16. The Committee discussed the level of detail required, including the capturing of the relationship between the Committee and the Home Office as well as other stakeholders,

¹ Animals in Science Committee: ministerial commission - GOV.UK (www.gov.uk)

² Code of Practice for Scientific Advisory Committees and Councils: CoPSAC 2021 - GOV.UK (www.gov.uk)

timeliness of response and levels of engagement between the ASC and Home Office, more clarity around the methodology of evidence collection and sources of data. The evidence required would also depend on the nature of the commission from the Department and the advice sought. In the interests of openness and transparency, both commissions of work from the Home Office and the ASC's responding advice should be published.

17. ASRPU agreed, explaining that ASRPU would clarify governance processes between ASRPU and ASRU. This would enable the ASC to be used in a more effective way in evidence gathering and, consequently, ASC advice to be used more effectively in policy making. The overall framework for this was still being discussed, and the Committee would be provided with a progress update at the next plenary.

Action: Secretariat to update Ways of Working draft to reflect issues discussed

Animals in Science Regulation Policy Unit Update

Policy programme

- 18. ASRPU provided the Committee with an update on progress with developing the policy programme. They advised that governance frameworks for communications, transparency, and ASRU were being created. As the positioning of animal science policy in the Home Office was an interim measure, a cross-government group was being created to look at the where best in government the policy should be placed in the longer term.
- 19. An update was also provided on potential future commissions of work for the ASC along with expected timelines for each commission.

Retained EU Legislation

20. ASRPU advised that, in light of the government's wider commitments to legislative reform following EU exit, they had commissioned detailed legal advice on changes needed to the Animals (Scientific Procedures) Act 1986 (ASPA) to resolve retained references to EU Directive 2010/63/EU. The Committee would be kept updated on progress.

ASPA in Northern Ireland

21. The Committee were informed that although ASPA is a UK-wide act, policy and regulatory delivery responsibility had been transferred (devolved) to Northern Ireland (NI). Therefore, NI would need to agree to any amendments to ASPA that impact NI. ASRPU would continue to liaise with NI on policy matters. The Committee should also ensure processes were in place to keep NI updated as the ASC develops any advice.

Litigation

22. The Committee were updated on the status of the challenge under judicial review, centring around cosmetic regulation and process. At the time of the update witness statements were being gathered and a hearing would take place in January 2023.

Operational update from ASRU

- 23. The Committee received a progress update on the development of the new reporting metrics, compliance recording, licensing times, protection, and welfare initiatives.
- 24. The Committee also heard further details on Standard Condition 18 reports received by ASRU and plans to improve the retrospective review system. Further to this the Committee felt it would be beneficial to receive some further information on any themes emerging from the Standard Condition 18 reports.

Animal Welfare Ethical Review Bodies Subgroup

- 25. The Committee was provided with an update from the Chair of the AWERB Subgroup regarding ongoing workstreams, including moving the planned AWERB Hub workshop to a virtual event and a proposal on retrospective assessments (RA).
- 26. The publication of RAs alongside the non-technical summary (NTS) would allow people to see what the project intended to achieve, what was achieved, and would help identify any benefits, refinements, and unexpected harms.
- 27. The Committee's discussion focused on identifying the potential drawbacks and security issues that might arise and where the key learning opportunities were for RAs such as the AWERB process and how that can be capitalised on without adding extra burden to licence holders.

Action: AWERB Subgroup to consider how to make the information/learning from retrospective assessments better available.

28. ASRPU informed the Committee that ASRU were working on producing a method of publishing NTSs and RAs in the new year on a periodic basis and would value input from the Committee on this topic.

Action: ASRPU to consult with the Committee on publication of non-technical summaries and retrospective assessments.

Project Licence Strategic Review Subgroup

Non-Human Primates bred for use in scientific purposes report

- 29. The Project Licence Strategic Review (PLSR) Subgroup Chair opened discussions on the draft report, 'Non-Human Primates (NHPs) bred for use in scientific purposes'. It was noted that agreement of the technical detail of definitions was needed.
- 30. There was discussion on the difficulties surrounding the global supply issue as a result of the pandemic and China stopping exporting animals for research. It was noted that although there were some alternatives, these would be difficult to adopt in Europe due to the legislation around animal related imports, outside of Europe.
- 31. There were some concerns about the 2024 timeline set out in the report, however the Subgroup Chair explained that this had been carefully considered. It was considered to

- be important that the recommendation was not left open-ended. It would now be for the Minister and ASRPU to consider the proposed timelines.
- 32. The Committee acknowledged that the 2024 date did not align with the EU's scheduled introduction of similar changes (to occur sooner, in November 2023), but felt it was necessary to implement a phased plan that could act as encouragement for overseas breeders to set up closed, self-sustaining colonies. The Committee was aware of the various issues relating to NHPs capture, and this phased approach took into consideration public expectation, animal welfare concerns, scientific requirements, and actual feasibility in terms of a timeline for change.
- 33. The Committee agreed that there were two issues which needed to be addressed: the quality of published data and getting it corrected if necessary and the actual definition of classifying F1 and F2 NHPs. Once these had been resolved, the Committee would approve the report for publication.

Action: ASRPU to provide clarification on the F2 non-human primates definition.

Forced Swim Test report

- 34. The Chair of the PLSR Subgroup provided the Committee with an update on the review of project licences which involve the forced swim test procedure. The methods outlined for data collection mirrored those used in the antibody production report, with the addition of a questionnaire to be sent out to licence holders and an additional questionnaire for stakeholder groups.
- 35. Responding to a question on the availability of an alternative tests as a replacement for the forced swim test, the Subgroup Chair explained that the forced swim test was not used in isolation but was usually one of a large bank of tests listed on the licence, and often it was not clear in the licence whether the forced swim test would actually be used. The questionnaire to licence holders should provide more information on this.
- 36. In response to a question, it was confirmed that Medicines and Healthcare Products Regulatory Agency (MHRA) did not 'require' the forced swim test, but did require the most appropriate test to be used, and the forced swim test was typically included in licences for screening anti-depressants, for example.
- 37. It was noted that the formal commission for the review had yet to published ASRPU was asked to expedite this.

Action: ASRPU to work with the Secretariat to ensure that the commission for the review of licences involving the forced swim test to be published as soon as possible.

Futures Working Group

38. The Futures Working Group Chair updated the Committee on the futures capability report. The report was in its final draft, awaiting some edits to the annex. The main recommendation of the paper was to have a standing horizon scanning portal with an

- associated template through which horizon scans could be submitted online by any interested individual or organisation, forming a consistent input and feedback mechanism.
- 39. The ASC Chair queried who the recommendations were directed towards. The Committee agreed that the recommendations were for the ASC to implement and therefore it needed to be made clear that it was an internally facing report.
- 40. It was noted that awareness of the futures portal should be raised for other stakeholders to feed into, it was suggested that it could be embedded into mainstream Home Office activities.

Action: Futures Working Group Chair to re-draft report to reflect issues discussed.

Brain Organoids, Reanimation, and Sentience Group

- 41. The Brain Organoids, Reanimation, and Sentience Group Chair provided a progress update on the report. The Subgroup Chair informed the Committee that they would circulate the interim report for the Committee for feedback.
- 42. It was noted that some of the recommendations would benefit from re-wording to ensure clarity that these recommendations fell within the Committee's remit.
- 43. The Committee noted that the topic was of interest to other government departments and discussed how this could be addressed.

Action: Secretariat to circulate interim report with Members for comments and Brain Organoids, Reanimation, and Sentience Subgroup Chair to update as needed to reflect feedback.

Committee Matters and AOB

Recruitment

44. The Chair advised the Committee that the recruitment process had been delayed. The Chair also informed Members that other government departments would be involved in the recruitment process to ensure that the Committee had the necessary expertise for the forthcoming work commissions.

Action: Members to send Chair any suggestions for potential co-opted members and recruitment of certain roles for upcoming commissions.

Annex A

Committee Members

Professor David Main (ASC Chair)

Mrs Wendy Jarrett

Dr Donald Bruce

Dr Sally Robinson

Mr Barney Reed

Professor Clare Stanford

Professor Andrew Jackson

Professor Johanna Gibson

Dr Hannah Clarke

Professor Stephen May

Linda Horan

Secretariat

Caroline Wheeler

Zahi Muhammad Sulaiman

Ana Ali

Animals in Science Regulation Policy Unit

William Reynolds

Gideon Winward

Priya Sharma

Apologies

None