Animals in Science Committee

Minutes of the 42nd Meeting: 12th March 2024 Hybrid Meeting

Welcome, Introductions and Conflicts of Interest

- Professor David Main, Chair of the Animals in Science Committee (ASC), welcomed everyone to the first meeting of 2024. In particular, the Chair extended his welcome to the nine new Members of the ASC to their first meeting. Apologies were received by Chris Matthews (Northern Ireland) and Dr Vicky Robinson (National Centre for the Replacement, Refinement and Reduction of Animals in Research; NC3Rs). No conflicts of interest were declared. A full list of attendees can be found at Annex A.
- 2. The Chair welcomed officials from the Home Office Animals in Science Regulation Policy Unit (ASRPU) and a representative from the Department of Health, Northern Ireland (NI), who joined the meeting online.
- 3. The Chair advised that most of the actions from the December plenary had been completed with the remaining few awaiting the new Membership to take forward. It was also noted that following the announcement from the Department for Science, Innovation, and Technology (DSIT) regarding policy responsibility for alternative methods to animals in science, it would be helpful to arrange a meeting with DSIT to discuss future DSIT/ASC engagement processes.

Chair's Update

Ministerial commission 2024

4. The Chair noted that the Minister's commission of work for 2024¹ had been published; Members had been informed of the commission ahead of the meeting. The Chair explained that ASRPU were in the process of deciding on a priority for the topics as well as drafting detailed individual commissions for each area. More information would be provided by the ASRPU as part of their update.

Futures Working Group report

5. The Chair confirmed that the report² from the Futures Working Group would shortly be published on the ASC website. He thanked the Subgroup Chair and Members for their work on the report.

Home Office Science Advisory Council - review of Scientific Advisory Bodies

¹ Animals in Science: ministerial commission 2024 - GOV.UK (www.gov.uk)

² The future of futures: participatory futures research in the ASC - GOV.UK (www.gov.uk)

- 6. The Chair advised the Members that the Home Office Chief Scientific Adviser had commissioned the Home Office Science Advisory Council (HOSAC) to review all Science Advisory Bodies that come under her responsibility.
- 7. The Chair advised the Committee that the review would look at the processes for the commissioning and provision of advice. The review would also consider departmental responses to advice, potential areas for improvement and what support would be needed to facilitate delivery and improvements.
- 8. The Committee would be contacted by HOSAC for their input into the review.

Public attitudes to animal research survey

9. In 2023, the Committee had discussed the need for the reinstatement of the public attitudes to animal research survey, previously conducted by Ipsos MORI, and had written to DSIT Minister Andrew Griffith regarding this³. The Committee was pleased to note the announcement of its reintroduction by the DSIT Minister during the animal testing debate at Westminster Hall on 19 February 2024.

Forced Swim Test advice – Minister's response

- 10. The Chair updated the Committee on the Minister's response to the Forced Swim Test (FST) report⁴ which had been published by the ASC in July 2023⁵. The Committee were informed that the Minister had accepted all recommendations and had agreed to further restrict the use of the FST, with more scrutiny to be applied to any future proposals of use. It was expected that this would be implemented by the end of March 2024.
- 11. The Chair advised that the response had also included the Minister's plans to work towards the goal of replacing the FST, once viable alternatives were available. As such, the Minister had written to DSIT and UKRI requesting that they expediate research to find validated replacements.

Animal testing debate (Westminster Hall, February 2024)

- 12. The Chair invited Members to comment on the recent animal testing debate held in Westminster Hall on 19 February 2024. Ahead of the meeting, Members had the opportunity to review the debate and its announcements. The key announcements noted were:
 - a. Additional £10 million funding to support the accelerated uptake of alternative methods to animals in science;
 - b. Announcement of a plan on accelerating the development, validation and uptake of alternative methods, to be published by a cross-government group, in the summer of 2024;
 - c. The reintroduction of the public attitudes to animal research survey;
 - d. Increase in the project licence fee being charged by the Home Office; and

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³ Public attitudes to animal research: letter to Andrew Griffith (accessible) - GOV.UK (www.gov.uk)

Advice on the use of the forced swim test: letter from Lord Sharpe - GOV.UK (www.gov.uk)

⁵ Advice on the use of the forced swim test - GOV.UK (www.gov.uk)

- e. A Home Office review of project licence duration to determine whether a shorter licence period would be more appropriate.
- 13. The Chair raised that he felt it was appropriate to write to Minister Andrew Griffith to express enthusiasm for the announcements made during the debate, and to offer the ASC's assistance in their enactment.
- 14. The Chair shared his thoughts on the most important elements to consider going forward:
 - a. The need to consider the research environment, the culture, and careers elements so that the appropriate reframing of questions can occur.
 - b. The need to scrutinise the decisions that are made in association with animal testing in an industry context and focus on what decisions need to be made around safety and use of alternative methods.
 - c. The need to prioritise and focus on the animals that were the most affected, requiring further funding to enable continued support.
 - d. The need to consider the interaction/intersection between support for the development of alternative methods and the regulatory framework. Ensuring the regulator asks the right questions and pushes back on project licences where appropriate.
- 15. One Member highlighted that the amount announced for alternative methods funding would be insufficient to make significant advances in their development. ASRPU advised that the £10 million was intended to be used to develop an environment and architecture that can facilitate and sustain the development of alternative methods rather than fund individual opportunities.
- 16. The Chair noted Members' comments and agreed to include this in the letter. In addition, the Chair recommended highlighting that, although the ASC agreed with the vision set out, long-term engagement between the ASC and DSIT policy officials would be important to achieve that vision.
- 17. One Member also highlighted the importance of ensuring that the reinstated public attitudes to animal research survey was reviewed and updated to reflect the modern context of the landscape. The Chair agreed to include this point in the letter.

Action: Chair to write to Minister Andrew Griffith regarding the animal testing debate.

Action: Secretariat to organise a meeting between the Chair and Minister Andrew Griffith.

<u>Animal Welfare Committee Review into Livestock Breeding and Breeding Technologies</u>

18. The Chair informed the Committee that he and another Member had been approached, in their capacity as ASC Members, to contribute to the Department for Environment Food and Rural Affairs (DEFRA) Animal Welfare Committee's 2024 review into livestock breeding and breeding technologies in the UK. Having reviewed the questions in the 2024 review, they had agreed to

forward the ASC response to DEFRA's 2021 consultation on the regulation of genetic technologies, as a number of the issues overlapped.

Animals in Science Regulation Policy Unit Update

19. ASRPU provided the Committee with an update on the key areas of the policy programme, ministerial commission, and ASRU operations.

Ministerial commission

- 20. ASRPU advised the Committee that there had been two items from the previous ministerial commission that were yet to be completed. These were the implication of the recognition of decapods as sentient beings for the regulation of the use of animals in science, where the ASC was awaiting formal commissioning, and the Minister's response to the ASC's advice on non-human primates bred for use in scientific purposes⁶. These were now being moved forward in addition to the newly commissioned items.
- 21. ASRPU advised they would be providing detailed information for each item on the commission. This may include providing responses from the call for evidence⁷ which was carried out for the decapods project.
- 22. A question was raised on whether Section 24 of ASPA could potentially affect any recommendations made by the Committee when looking at the forthcoming commission on non-technical summaries (NTS) and Retrospective Assessment (RA). ASRPU advised that this was unlikely to be an issue but could have a further discussion with the Committee on this if needed.
- 23. The Chair advised the Committee that the work on the Commission related to leading practice would be the initial focus as the outputs from this would potentially inform any future work of the Committee.

Decapods

- 24. The call for evidence on decapods closed on 13 October 2023 and received responses from across the UK. ASRPU advised that they were exploring whether to regulate the use of decapods in science and the various options this, mindful of the approach being taken by DEFRA. The Committee were informed that ASRPU would be seeking advice on this matter from the ASC later in the year.
- 25. In response to a question by the Committee, ASRPU advised that much of the current research involving decapods may not meet the threshold to be governed by ASPA.

Non-Human Primates bred for use in scientific purposes report

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⁶ Non-human primates bred for use in scientific purposes - GOV.UK (www.gov.uk)

⁷ Call for evidence: background - GOV.UK (www.gov.uk)

- 26. This workstream was being actively progressed and the ASRPU were assessing feedback from the sector and recommendations made by the ASC in their Non-Human Primates bred for use in scientific purposes report⁸.
- 27. ASRPU advised that their main focus was on evaluating options for the effective implementation of restrictions in the use of non-human primates, taking into account industry challenges like supply shortages.
- 28. Members noted that there had been some confusion around whether or not a lack of supply of non-human primates would be acceptable as 'scientific' justification to use non-human primates from a non-self-sustaining colony. ASRPU agreed that clarity for the sector would be an important factor in their approach to addressing this topic.

Forced Swim Test report

29. ASRU was in the process of implementing the relevant recommendations made by the ASC in their Forced Swim Test report⁹.

Section 24

- 30. The Committee were provided with background on Section 24 and the steps taken by ASRPU to ensure transparency. The Committee were advised that the Minister had decided not to review Section 24 of ASPA at that time, and that stakeholders had been informed.
- 31. The Committee advised that there was still confusion amongst establishments about the scope of Section 24. It was noted by the Committee that there would be potential scope in the NTS & RA work to provide some clarity on this issue.

Action: ASRPU to clarify with the AWERB Subgroup the scope of Section 24 ahead of their work on the NTS & RA.

Retained EU legislation

32. The draft statutory instrument to restate the current retained EU law into ASPA had been delayed due to legal complexities but would be laid before Parliament later in the year.

Genetic Technology (Precision Breeding) Act 2023

- 33. ASRPU had been continuing to engage with DEFRA to gather evidence that would inform the understanding of the implications of the Genetic Technology (Precision Breeding) Act 2023 for ASPA.
- 34. ASRPU advised that they expected to commission advice from the ASC on this topic in 2025.

Cosmetics regulatory testing

35. There had been ongoing work across government on the longer-term administration of the licensing ban and that licences were not being authorised for chemicals that were exclusively used as ingredients in cosmetics.

⁸ Non-human primates bred for use in scientific purposes - GOV.UK (www.gov.uk)

⁹ Advice on the use of the forced swim test - GOV.UK (www.gov.uk)

36. Following discussion, Members clarified their understanding of the current position to be: if a UK regulator required animal testing for a product to be manufactured in the UK, that the animal testing for that product could not happen on UK shores. ASRPU confirmed that this was the current position.

<u>Fees</u>

37. ASRPU had received approval to raise ASRU's licensing fees by 10% from 6 April 2024. The statutory instrument for this would be laid in Parliament on 14 March 2024 and stakeholders had been informed about the increase on 14 November 2023.

Training and continuous professional development guidance

- 38. ASRU had been developing operational guidance to support the new guidance for training and continuous professional development (CPD) under ASPA. ASRPU explained that the guidance published in 2023 set out clear documented roles and responsibilities and how the Home Office would assure training provision.
- 39. Following a question on whether ASRU would assess whether people are trained or whether they are competent, ASRPU advised that ASRU assess training undertaken before granting licences but that assessing competency and CPD would be a matter for establishments with establishment systems for doing so audited by ASRU.

Regulatory Reform

- 40. ASRPU provided the Committee with an update on the regulatory reform programme and highlighted key areas of change including streamlining the licence application process, organisational design, and the compliance process.
- 41. ASRPU also provided the Committee with an update on their work on external governance of the Regulator and the performance framework.

ASRU Enhanced Performance Framework

- 42. ASRPU advised that this project would focus on improving how ASRU tracks and measures performance and impact. It would do this by:
 - a. Enhancing ASRU's performance measurement framework.
 - b. Considering the potential for short-term technology and systems improvements to support tracking and measurement.
 - c. Focusing metrics on demonstrating impact in two key areas:
 - i. Animal protections through compliance with ASPA.
 - ii. Service to the science sector through areas such as timeliness of service.
- 43. Though still in its initial stages, ASRPU invited feedback from Committee Members on the proposed programme of work.
- 44. Feedback from Members included:

- a. the addition of a way to measure the time taken by the regulated community to submit their applications.
- b. capturing the actual experience of the animals, though difficult, was important and ways of doing this should be considered.
- c. ASRU should be looking to assess the commitment to the 3Rs and to a trajectory of improvement rather than focusing specifically on compliance.
- d. that there was no consideration of the measurement of harms, which had been previously highlighted by the Committee.
- e. the need to ensure that ethics had been considered in the guidance.
- 45. In response, ASRPU advised that, as measuring regulatory impact was known to be challenging, ASRU would need to start with relatively simple measures and build on these to develop more complex measures over time. Measuring harms was known to be particularly complex.
- 46. It was highlighted by a Member that although harms could be subjective, it would be wrong to assume that all important measures are numerical.
- 47. Summing up, the Chair felt that the framework aims needed to be more ambitious in relation to animal welfare metrics, acknowledging that the leading practice work would contribute towards that aim. The Chair also acknowledged that the points made were in relation to the Harm Benefit Analysis (HBA) work that the Committee felt should be a priority. ASRPU advised that work on the HBA was planned to occur later in 2024.

ASRU external oversight

- 48. ASRPU provided the Committee with an update on their work on external governance. They advised that they had reviewed ASRU's external governance structure to determine the support provided to enable the Regulator to perform effectively. The review included consideration of whether there was sufficient oversight, support, challenge, diversity of perspectives, and 'holding to account' for the Regulator.
- 49. ASRPU had also undertaken extensive research into other regulators' best practices and governance to provide some guidance. This research had highlighted the importance of having an external perspective. As a result, ASRPU would consider establishing a regulatory advisory board for ASRU, to provide advice, support, and external challenge on decision making but would have no formal powers in decision making.
- 50. Members noted a potential for overlap of responsibilities between the proposed board and the ASC. Responding, ASRPU advised that clear terms of reference would be established to ensure there would be clear delineation between the roles and responsibilities of the ASC, as an independent Science Advisory Committee to government, and the board, whose advice on regulation would be internal to the Regulator. ASRPU would aim to establish the Board to start operating in 2025, if authorised.
- 51. A further question was raised around the proposed body being called an 'advisory board' when its responsibility would be directed towards governance.

ASRPU would consider how the role of the Board should be appropriately reflected in its name.

Action: ASRPU to review the name of the regulatory advisory board.

Animal Welfare Ethical Review Body (AWERB) Subgroup

Co-option of Members

- 52. The interim Subgroup Chair provided the Committee with an update of the Animal Welfare Ethical Review Body Subgroup (AWERB) Subgroup's ongoing work. The Committee were advised that the Subgroup Members working on the NTS report, and who had demitted from the ASC on 31 December 2023, had been co-opted to the Subgroup to complete this work. The NTS report was undergoing its final edits, once finalised, as part of the usual process, the report would be sent to the ASC Chair for approval and then to the Minister and for publication.
- 53. Thanking the interim Chair for their support, the ASC Chair confirmed a new Subgroup Chair would be appointed from the new Membership.

Workshops

54. The interim Chair advised the Committee that the report from the October 2023 AWERB Hub Network workshop had been published¹⁰. Members of the Hub Network had been advised that there would not be an AWERB Hub workshop in April 2024 due to the changeover in Subgroup Members. However, Hub Network members had been contacted with a request for potential topics for the next workshop scheduled for October 2024.

AWERB Hub Network

55. The interim Chair advised Members that some Hubs in the Network had been struggling to maintain momentum in arranging Hub meetings and, due to a lack of volunteers within Hubs, had encountered difficulties when trying to rotate the Hub Chair role to another establishment. It was suggested that the new Subgroup Membership consider the structure and function of the Hub Network and how to provide additional support.

Project Licence Strategic Review (PLSR) Subgroup

Non-Human Primates used in service licences report

- 56. The Subgroup Chair updated the Committee that demitted Members had been co-opted to the Subgroup until the Non-Human Primates used in service licences report had been completed.
- 57. The Non-Human Primates used in service licences report was in the final stages of drafting and the Subgroup Chair expected the report to be ready for ASC ratification at the next plenary meeting, in June 2024.

¹⁰ ASC and AWERB Hub workshop report: October 2023 - GOV.UK (www.gov.uk)

Annex A - List of Attendees

Committee Members

Professor David Main (ASC Chair)

Professor Jonathan Birch

Mrs Caroline Chadwick

Professor Johanna Gibson

Dr Stuart Greenhill

Professor Andrew Jackson

Mrs Wendy Jarrett

Professor Martin Knight

Professor Stephen May

Mrs Tina O'Mahony

Professor Hazel Screen

Dr Dharaminder Singh

Professor Christine Watson

Dr Carl Westmoreland

Dr Lucy Whitfield

Secretariat

Caroline Wheeler

Jessica Stone

Emily Townley

Animals in Science Policy Regulation Unit

William Reynolds

Gideon Winward

Chloe Jenkins

Mamataj Begum

Bernie Godson

Rebecca Newman

Lucy Duncan

Alice Whiteman

Nicholas Were

Department of Health, Northern Ireland (NI)

Karen Somerville

<u>Apologies</u>

Chris Matthews (NI)

Dr Vicky Robinson (NC3Rs)