Animals in Science Committee Minutes of the 44th Meeting: 9th September 2024 Hybrid Meeting

Welcome, Introductions and Conflicts of Interest

- Professor David Main, Chair of the Animals in Science Committee (ASC), welcomed Members to the third plenary meeting of 2024. Apologies were received by Mrs Tina O'Mahony and representatives from the Department of Health, Northern Ireland (NI). 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 the Chief Executive of the National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3Rs), who joined the meeting as an NC3Rs representative.
- 3. The Chair updated that the minutes from September 2023, December 2023 and March 2024 had been published and were now available on the ASC website¹. The Chair reminded Members that the minutes from June 2024 had been circulated for comment.
- 4. Following an action taken at the June 2024 plenary to write to officials from the Department for Science, Innovation and Technology (DSIT) regarding 'NAMs' terminology, the Chair confirmed that this letter had been sent on 25 June 2024, and that all Members should have received a copy. A DSIT representative would be attending later in the meeting to provide an update on this.
- 5. Following an action taken at the June 2024 plenary to consider whether a funding council representative should be invited to attend a future plenary, the Chair updated that the points raised in this discussion would be considered as part of the Leading Practice Subgroup workstream.
- 6. Following an ongoing action for ASRPU to provide a formal response to the recommendations of the Licence Review report, published in September 2020, ASRPU updated that the Head of Regulatory Reform would draft a letter to the ASC outlining how the recommendations of the report had informed work undertaken as part of the regulatory reform programme.

Action: Head of Regulatory Reform to write letter to ASC responding to the Licence Review report.

7. More broadly, the Committee discussed the need to better track the recommendations made by the ASC and, if accepted, the actions taken by ASRPU to address them.

¹ Membership - Animals in Science Committee - GOV.UK (www.gov.uk)

Action: Secretariat and ASRPU to collaborate on ASC recommendations tracker.

Chair's Update

Recruitment

8. The Chair updated that, as his second term as Chair of the Animals in Science Committee would be concluding on 31 May 2025, a recruitment round for the new Chair would shortly be commencing. Members would be notified when the advert went live.

Meeting with UKBSC

- 9. The Chair informed the Committee that he had met with the co-chairs of the UK Bioscience Sector Coalition (UKBSC), Dr Sarah Bailey and Dr Joanne Storey, on 8 July 2024.
- 10. UKBSC presented a summary of their recent strategy and objective setting review, which would define the direction of their work in future. The Chair had provided an update on the work of the ASC, including the upcoming workstreams as outlined in the Ministerial commission 2024. The Chair reflected in particular that the discussions surrounding how UKBSC might support the ASC's work on leading practice had been particularly productive.

SAC review recommendations

- 11. Following the recent internal, non-statutory review undertaken by the Home Office Science Advisory Council, commissioned by the Home Office, on how the department commissions, uses and feeds back on advice from its independent Science Advisory Committees (SACs), the Chair updated on their findings and recommendations. He then informed the Committee that he intended to provide a written response to the review and requested any initial comments to be included.
- 12. A Member reflected that the recommendations highlighted as long-term priorities appeared to be those that should be addressed more urgently. They further considered that not all of the recommendations would be relevant to each of the SACs, as some of the actions were common practice in the ASC's systems.
- 13. Another Member raised that the measuring of effectiveness and impact appeared to be missing. ASRPU responded that appropriate metrics could be considered as part of the earlier action taken to produce an ASC recommendations tracker.

Action: Chair to provide a written response to the findings of the review of Science Advisory Committees.

BBSRC forward look consultation

14. The Chair drew Members' attention to a consultation that had been launched by the Biotechnology and Biological Sciences Research Council (BBSRC) to review their Forward Look for UK Bioscience. One of the key objectives had been listed

- as: "Enable the development of new models and approaches to reduce the use of animals in research and provide more effective and representative tools for studying animal and human biology", which may be relevant to the ASC.
- 15. The consultation questions had been shared with the ASC to decide whether a collective response should be submitted. Following discussion, it was agreed that the ASC would not submit a response as an organisation, but individual Members were welcome to respond on behalf of their own organisations.

NCOB neural organoids call for evidence

- 16. The Chair also highlighted the Nuffield Council on Bioethics (NCOB) had launched a call for evidence seeking expert opinions on further ethical guidance needed for research using neural organoids.
- 17. The ASC, through its previous Brain Organoids, Reanimation and Sentience Group, had produced a summary report on neural organoids in August 2022. The Chair proposed that this report should be submitted as evidence, in particular for the "regulation and governance" section of the consultation. Following discussion, it was agreed that the report should be updated to maximise its relevance to the call for evidence and submitted on behalf of the ASC.

Action: Professor Christine Watson and Professor Jonathan Birch to update neural organoids summary report, to be submitted to the Nuffield Council on Bioethics call for evidence by the Secretariat.

Department for Science, Innovation and Technology Update

- 18. The Chair welcomed a representative from DSIT, who joined the meeting to provide strategic updates on matters within their remit relevant to the ASC, including alternative methods.
- 19. DSIT updated that, following their update at the previous plenary on the draft alternatives strategy, they were currently engaging with new Ministers postelection to determine next steps to take forward the relevant government manifesto commitment².
- 20. DSIT informed the Committee that the Minister for Science had hosted a series of roundtables with various stakeholders, across industry and government, to discuss their views on this issue, and confirmed that there would be a meeting arranged between the Minister and the Chair in due course to discuss this further. The Committee would be kept updated on the next steps.
- 21. DSIT additionally thanked the Committee for their letter on 'NAMs' terminology. DSIT had actioned this feedback and would be instead using the term 'alternative methods' to avoid the inconsistency associated with the 'NAMs' acronym.

² "We will partner with scientists, industry, and civil society as we work towards the phasing out of animal testing." (Change Labour Party Manifesto 2024)

- 22. A Member reflected that alternative methods were often compared with preclinical animal models accepted by regulators, but that this assumed that animal models were the most accurate proxy for human biology, which was not necessarily the case. DSIT responded that they were aware of challenges with uptake of alternatives due to international regulations, and that they planned to engage with international regulators to address this issue.
- 23. NC3Rs expressed their support for a coordinated strategy that accounted for the breadth of UK expertise to promote knowledge sharing and strengthen UK presence on the international stage. A Member shared this optimism for the future of the science of alternative methods, but highlighted that the governmental challenge, where different regulators and scientific groups in different countries may have varied attitudes to alternative methods. DSIT agreed with the importance of cross-government working and international engagement.
- 24. A Member asked whether alternative methods was a priority for the Minister for Science. DSIT considered that, whilst the remit of the Minister was large, he had shown engagement with the issue through the hosting of these roundtables, which they would consider to be a positive signal.
- 25. Members highlighted the importance of distinguishing between, and educating about, different types of animal research: toxicity testing; efficacy testing; and fundamental research. The first two correspond to use within industry associated with testing chemical products and therapeutics, whilst the latter is more university based. Alternative methods to date appeared to focus mostly on toxicity testing, which was positive, but the government should also be aware of the benefits of increased translation of alternative approaches to the other two areas. It was also noted that the hurdles for this were considerably lower than for toxicity testing and that the potential to reduce animal usage in these sectors was greater due to the larger numbers involved.

Alternative Methods Masterclass

- 26. The Chair had invited three Members with the relevant expertise to upskill the ASC via a masterclass on alternative methods.
- 27. Two Members delivered a joint presentation focused on organ-on-a-chip and other *in vitro* models from an academic perspective. The key points covered were:
 - a. Types of alternatives
 - b. Reasons to reduce reliance on animals in science
 - c. Issues and barriers with replacing animals in science
 - d. Terminology
 - e. Organ-on-a-chip technology
 - f. Confidence in and uptake of alternative methods

- 28. One Member delivered a presentation on alternative methods from an industry perspective. The key points covered were:
 - a. Definitions of alternative models
 - b. Reasons to focus on alternative methods
 - c. Benefits of developing alternative methods over current technologies
 - d. Key stakeholders with an interest in alternatives
 - e. Future direction of alternatives

Animals in Science Regulation Policy Unit Update

29. ASRPU provided the Committee with an update on the key areas of the policy programme, regulatory reform programme, and Animals in Science Regulation Unit (ASRU) operations.

Ministerial update

- 30. Following the general election and new Ministerial appointments, ASRPU confirmed that the Minister responsible for animals in science would be Lord Hanson of Flint.
- 31. The detailed commissions were being prepared for submission to the Minister and would be published in due course, subject to approval.
- 32. A Member asked whether the Minister had expressed his view on the potential review of Section 24. ASRPU responded that this had not yet been discussed with the Minister.

Decapods

33. ASRPU were continuing to engage with the Department for Environment, Food and Rural Affairs (DEFRA) on the inclusion of decapods in the Animal Welfare (Sentience) Act 2022. The Committee would be updated as this progressed.

Non-Human Primates bred for use in scientific purposes report

34. ASRPU were in the process of testing their proposed policy approach in response to the recommendations of the ASC report. They planned to advise the Minister on this matter in autumn 2024.

Forced Swim Test report

- 35. ASRU had reviewed all licences authorising the use of the forced swim test (FST) to implement the recommendations made by the ASC³.
- 36. The Home Office were now engaging with the relevant licence holders to ensure that the recommendations of the ASC were being implemented for these licences.

Licence duration review

37. Following the announcement by the previous Minister for Science, Research and Innovation at the Westminster Hall debate on animal testing on 19 February

³ Forced swim test report (publishing.service.gov.uk)

2024, ASRPU were currently engaging with the new Minister on the potential licence duration review. The Committee would continue to be updated.

Retained EU legislation

38. ASRPU were preparing to lay a statutory instrument and revised Code of Practice to clarify UK law in Spring 2025. ASRPU updated that they intended to publish Section 3 of the Code of Practice separately to enable more streamlined updating of leading practice, which would be discussed further during the update on the regulatory reform programme.

Precision breeding

- 39. DEFRA had commissioned a research project to gather evidence on the linkages between the requirements under the Genetic Technologies (Precision Breeding) Act 2023 and the Animals (Scientific Procedures) Act 1986 (ASPA), due to be completed by the end of 2024. The evidence gathered would likely inform a commission for advice from the ASC in 2025.
- 40. The Chair queried whether the Committee should expect further consultation on this work in the short-term. ASRPU responded that DEFRA would be able to confirm whether the Committee should be further engaged as the workstream on animals progressed. The Committee expressed a desire to be engaged early to avoid issues further down the line, and ASRPU agreed to pass this sentiment on.

Regulatory reform programme

41. ASRPU updated the Committee on the progress and next steps of the regulatory reform programme.

42. The key updates were:

- a. Work had been progressing internally on enhancing ASRU governance, and ASRPU would continue to aim to implement these changes in 2025.
- b. Following recommendations made by PricewaterhouseCooper (PwC), ASRPU would be announcing changes to ASRU's organisational design in autumn 2024 to facilitate the transition towards its target operating model.
- c. The Code of Practice for the housing and care of animals bred, supplied or used for scientific purposes⁴ was due to be updated and republished in 2025 (see paragraph 38). The key changes would include correcting minor errors, removing references to EU Directive 2010/63 and removing out-of-date information. This would align the document to the restatement of retained EU law in ASPA. Additionally, ASRPU would be republishing Section 3 of the Code of Practice, on leading practice, as a separate document to enable more streamlined updating as the landscape evolved. The ASC would be invited to review the updated draft.

⁴ Code of practice for the housing and care of animals bred, supplied or used for scientific purposes - GOV.UK (www.gov.uk)

- 43. ASRPU would be briefing the Minister on the regulatory reform programme in mid-September to inform next steps.
- 44. On the Code of Practice update, the Committee highlighted the need for careful dissemination, as it could be interpreted as a downgrading of standards. ASRPU assured the Committee that they were aware of this risk and planning communications and engagement accordingly. The Chair commented that coordination with the ASC's leading practice workstream would help to mitigate this risk.
- 45. On the proposed governance arrangements, the Committee provided the following feedback:
 - a. There was a need to ensure that governance arrangements had a more operational delivery view, and that those responsible had the appropriate skills and expertise.
 - b. Whilst it would be appropriate to have clear separation between the ASC and ASRU's governance to avoid misconceptions about the ASC's role and responsibilities, there should be open channels of communication to promote effective ways of working and maintain a broader view of the strategic and operational landscapes.
 - c. Both the academic and industry regulated communities should be considered, as they may be impacted differently by changes.

Operational update

- 46. ASRPU provided an update on the operations of ASRU, including business performance, stakeholder engagement and publications. ASRPU then gave an overview of the licensing and compliance data for the previous quarter.
- 47. As requested at the previous plenary, ASRPU updated that the omission of the distinction between self-reported and detected non-compliance from the previous ASRU annual report was due to a review of the process for recording and quality checking these cases. This process had now been updated and the data would be included in the 2023 annual report.
- 48. The Chair raised the need to define appropriate measures of success for ASRU's operations, which ASRPU confirmed was currently in progress.
- 49. The Committee questioned whether there was a resourcing risk with the number of ASRU inspectors declining. ASRPU responded that there had been contingency planning to ensure that ASRU could continue to operate, and that the risk would more broadly be addressed by the regulatory reform programme.
- 50. One Member queried a discrepancy in the number of Standard Condition 18 reports received versus those open, in progress or closed. ASRPU agreed to raise this with ASRU and share the response with the Committee.

Action: ASRPU to discuss Standard Condition 18 reporting figures with ASRU.

National Centre for the Replacement, Refinement and Reduction of Animals in Research Update

- 51. The Chief Executive of the NC3Rs provided an update to the Committee on work of interest to the ASC.
- 52. The key funding updates were:
 - a. The NC3Rs provided an update on the additional £5 million of funding that they had received for alternative methodologies within the 2024/25 financial year, for which they had launched two grant calls. 35 applications had been received for the £4 million infrastructure grants, and 14 applications for the £1 million validation studies for non-animal derived products and reagents grants. They were in the process of finalising assessment and successful applicants would be notified shortly. The NC3Rs further reflected that the level of response, despite the short timeframe, indicated the community's appetite for progress in this space.
 - b. £2.9 million had been awarded in recent project grant awards, which primarily focused on replacement. The NC3Rs highlighted that they planned to encourage future applications focused on refinement.
 - c. The CRACK IT challenges for 2024 had recently been launched. One focused on replacing avian toxicity testing⁵, which had four chemical/agrochemical sponsors. The other focused on improving post-operative recovery in rodents through the design of a new shelter⁶, which was sponsored by AstraZeneca.
- 53. The NC3Rs would be hosting an online event for their annual 3Rs prize on 11 September 2024. This year's prize had been awarded to a researcher from Merck for a publication describing work to develop an *in vitro* assay for potency testing of follicle-stimulating hormone. Another researcher, from Emulate Inc., was highly commended for their paper analysing the predictability of an organ-on-a-chip device to determine liver toxicity.
- 54. One Member asked whether the annual statistics of scientific procedures on living animals, which were due to be published on 11 September 2024, would feature in the event, or whether there had been any media planning to bring these together. The NC3Rs responded that, as the event was international, the statistics would not necessarily be relevant to all attendees, but that they were in the process of looking at any potential media engagement.
- 55. The NC3Rs updated that their 3Rs self-assessment tools would be taken down shortly and that they were in the process of developing new tools, for which the Committee's input would be sought.

⁵ Wings of Change | Innovation Platform (nc3rs.org.uk)

⁶ Rodent Shelter | Innovation Platform (nc3rs.org.uk)

- 56. A paper on the animal and economic cost of new endocrine disruptor regulations under REACH⁷ had recently been published by the NC3Rs, which may be of interest to the Committee.
- 57. Finally, the NC3Rs reminded the Committee that they were due to undergo their quinquennial review, for which they were currently preparing their submission due in November 2024. They were expecting to receive a decision by early spring 2025.

Leading Practice Subgroup

- 58. The Chair of the Leading Practice (LP) Subgroup provided the Committee with an update on their workstream.
- 59. The LP Subgroup had been convened following the publication of the annual Ministerial commission 2024. The Subgroup Membership had been finalised and published on the ASC website.
- 60. Based on the information given in the annual commission, the Subgroup had undertaken some preparatory research and discussion. The report would likely focus on the themes of setting leading practice standards, assessment against leading practice standards, and incentivising the uptake of leading practice. It would be focused on principles rather than defining specific leading practice techniques. Stakeholder engagement would be undertaken to inform the recommendations.
- 61. The Subgroup were awaiting the publication of the detailed commission to inform next steps.

Animal Welfare Ethical Review Body Subgroup

62. The Chair of the Animal Welfare Ethical Review Body (AWERB) Subgroup provided the Committee with an update on their workstreams.

AWERB Subgroup newsletter

63. The AWERB Subgroup newsletter, which had been circulated to the ASC at the previous plenary meeting, had been circulated to the AWERB Chairs mailing list on 28 June 2024. The next newsletter would be sent in January 2025.

AWERB Hub workshop (October 2024)

- 64. The next AWERB Hub workshop would be held on 16 October 2024. There had been 100+ registrations, and advertising would continue through the AWERB networks in the coming weeks.
- 65. The key agenda items would be:

Resource and animal use implications of the proposed REACH information requirements for endocrine disruptor assessment - PubMed (nih.gov)

- a. Update on the work of the Animals in Science Committee
- b. Skills and training needed by an AWERB
- c. Benefits of an active AWERB Hub.

AWERB Hub/Member pairings

66. The Subgroup were planning to complete a short-term piece of work defining the role of the ASC Member within their paired AWERB Hub to clarify responsibilities and reduce uncertainty. This would likely be circulated within the next newsletter.

Project Licence Strategic Review Subgroup

- 67. The Chair of the Project Licence Strategic Review (PLSR) Subgroup provided the Committee with an update on the status of the Non-Human Primates used in service licences report.
- 68. The report had been finalised by the PLSR Subgroup. Following the review and discussion of the draft report at the previous plenary, the Subgroup Chair was now seeking ratification from the Committee. The Subgroup Chair gave an overview of the changes that had been made since the report had last been presented to the Committee.
- 69. Following discussion of the rationale behind the changes made, the Committee were content to ratify the report, with one minor amendment to the phrasing of one of the report's recommendations.
- 70. The next steps would be to seek a formal accuracy check from ASRPU ahead of submission to the Minister and publication on the ASC website.

Committee Matters and AOB

RSPCA correspondence

- 71. The Chair updated the Committee that he had received a letter from the RSPCA, also addressed to the Head of ASRPU and the Head of ASRU, on reducing severe suffering in fishes in regulatory toxicology. The letter outlined three recommendations and asked that the ASC consider how they might engage with these.
- 72. Following discussion with ASRPU and the Committee, the Chair agreed that the recommendations would be most appropriately responded to by ASRPU. The Secretariat would outline this in a brief response via email and request to be copied into all further correspondence.

Action: Secretariat to respond to RSPCA via email on behalf of Chair.

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

Professor Hazel Screen

Dr Dharaminder Singh

Professor Christine J Watson

Dr Carl Westmoreland

Dr Lucy Whitfield

Secretariat

Emily Townley

Animals in Science Regulation Policy Unit (ASRPU)

William Reynolds

Chloe Jenkins

Mamataj Begum

Alice Whiteman

Nicholas Were

National Centre for the Replacement, Refinement & Reduction of Animals in

Research (NC3Rs)

Dr Vicky Robinson

Department for Science, Innovation and Technology (DSIT)

Colin Wilson

Apologies

Mrs Tina O'Mahony

Christine Henderson (NI)

Karen Somerville (NI)