Animals in Science Committee Minutes of the 43rd Meeting: 10th June 2024 Hybrid Meeting

Welcome, Introductions and Conflicts of Interest

- Professor David Main, Chair of the Animals in Science Committee (ASC), welcomed Members to the second plenary meeting of 2024. Apologies were received by Dr Stuart Greenhill and Dr Dharaminder Singh. 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. The Chair also welcomed representatives from the Department of Health, Northern Ireland (NI).
- 3. The Chair updated that the minutes from September 2022, December 2022, March 2023 and June 2023 had been published and were now available on the ASC website¹. The Chair explained that the minutes from September 2023 and December 2023 were ready for publication and would be published shortly. The Chair reminded Members that the minutes from March 2024 had been circulated for comment.
- 4. The Chair reminded the Committee that, due to the announcement of the general election, the ASC (as a non-departmental public body) and the government officials joining the meeting were subject to general election guidance², as published by the Cabinet Office, throughout the pre-election period.
- 5. A Member requested an update on the publication of a response to the Non-Human Primates bred for use in scientific purposes report³. ASRPU updated that the response was in the final stages of drafting and would be published following Ministerial approval.

Chair's Update

Meeting with Minister for Science, Research and Innovation

6. The Chair updated that the meeting with Minister Andrew Griffith from the Department for Science, Innovation and Technology (DSIT), which had been scheduled to take place on 12 June 2024, had been cancelled following the

¹ <u>Membership - Animals in Science Committee - GOV.UK (www.gov.uk)</u>

² General election guidance 2024: guidance for civil servants (HTML) - GOV.UK (www.gov.uk)

³ <u>Non-human primates bred for use in scientific purposes - GOV.UK (www.gov.uk)</u>

announcement of the general election. This would be rescheduled following the election outcome.

Action: Secretariat to reschedule meeting between the Chair and the responsible Minister for Science, Research and Innovation from the Department for Science, Innovation and Technology.

Futures report

7. The Chair reminded Members that the Futures report⁴ had been published on the ASC website and thanked the Chair of the Futures Working Group (FWG) for their work on this. The report had been circulated to the FWG workshop attendees for awareness.

Animal Free Research UK correspondence

- 8. The Chair informed Members that he had received correspondence from Animal Free Research UK regarding the published Animals in Science Regulation Unit (ASRU) annual report 2022⁵ and focusing primarily on non-compliance. The Chair had responded informing Animal Free Research UK that the issues in their letter were matters of policy and therefore should be raised with the Home Office, and agreeing to circulate the letter with Members for awareness, which had been actioned.
- 9. On the topic of the annual report, one Member raised a query as to why there had not been reporting on the proportion of non-compliance cases that were selfreported, as there had been in previous ASRU annual reports. ASRPU agreed to raise this with ASRU and share the response with the Committee.

3Hs Initiative launch event

- 10. The Chair had asked a Member to represent the ASC at the 3Hs (Housing, Handling and Habituation) Initiative⁶ launch event held on 27 March 2024, who was then invited to share their reflections on the event. The Member explained the aims of the initiative and the updates provided at the event, and reflected that they found the programme to be commendable.
- 11. The NC3Rs representative reflected that the key next steps would be considering how the findings from the initiative would be rolled out in practice.

Precision Breeding webinar

12. The Chair had asked a Member to represent the ASC at a webinar held by the Department for Environment, Food and Rural Affairs (DEFRA) on precision breeding on 21 May 2024. The Member reflected that the webinar had primarily focused on plants and therefore had little relevance to the ASC at this time.

⁴ The future of futures: participatory futures research in the ASC - GOV.UK (www.gov.uk)

⁵ Animals in Science Regulation Unit annual report 2022 - GOV.UK (www.gov.uk)

⁶ <u>The 3Hs Initiative (3hs-initiative.co.uk)</u>

13. The Chair reminded Members that a representative from DEFRA was due to attend the meeting during a later item to provide an update on their precision breeding activities.

For a Government Strategy on Non-Animal Methodologies webinar

- 14. The Chair had asked a Member to represent the ASC at a webinar held by the Cosmetic, Toiletry and Perfumery Association (CTPA) on non-animal methodologies on 25 April 2024 who was then invited to provide their reflections on the event. The Member updated on the outcomes and recommendations that resulted from the webinar. They reflected that the event focused primarily on safety, rather than efficacy, testing. They found the cross-government representation and international element to the event particularly interesting, as it enabled a much broader perspective.
- 15. Another Member, who was attending the webinar in their organisational capacity, shared this view on the international element. They further reflected that they found it useful to have a wide range of stakeholder groups represented at the event. This made the confusion surrounding NAMs terminology particularly apparent.
- 16. ASRPU reflected that it was positive to see cross-government engagement on animal alternatives, given the requirement in ASPA Section 20B to develop and validate alternative strategies, but that they agreed with the observations of the Committee and NC3Rs that more work needed to be done surrounding consistency in NAMs definitions and terminology and would take this forward with colleagues.

Ministerial commission 2024

- 17. Due to the announcement of the general election, the Chair updated Members that the detailed commissions arising from the annual Ministerial commission 2024⁷ would be delayed until the election outcome was finalised.
- 18. A Member questioned whether the content of the annual commission might change if there was a change in the responsible Minister. ASRPU responded that this was possible.

Department for Science, Innovation and Technology Update

- 19. The Chair welcomed a representative from DSIT, who joined the meeting to provide an update on the non-animal methods strategy announced by the government in February 2024.
- 20. DSIT had approached the ASC for consultation on the draft strategy. Due to the announcement of the general election, this had been paused. A representative

⁷ Animals in Science: ministerial commission 2024 - GOV.UK (www.gov.uk)

from DSIT had still agreed to attend the meeting to provide an update on the workstream.

- 21. DSIT were leading the cross-government group on the non-animal methods strategy. Timelines were dependent on the election outcome, but DSIT confirmed that the ASC would be consulted on the draft strategy.
- 22. The draft strategy was currently made up of six sections:
 - a. Supporting development
 - b. Enabling validation
 - c. Driving uptake
 - d. International co-operation
 - e. Improving training
 - f. Governance
- 23. The Committee asked whether DSIT could give an indication of the overall aim and breadth of the strategy, recognising how broad the field of non-animal methodologies was. DSIT responded that the strategy itself would set the aim out in detail, but the overall focus would be on alternatives to animal research with an emphasis on replacement whilst recognising the value of refinement and reduction. The strategy would also cover both the research and the regulatory aspects of animals in science.
- 24. The Committee asked about the publication process for the strategy, and whether it would need to go to public consultation. DSIT advised that, as the strategy would not be changing policy, a public consultation would not be necessary. Instead, DSIT were engaging directly with relevant stakeholders for their input, including the ASC. On the publication process, DSIT explained that, once the document had been agreed by the responsible DSIT Minister, it would be circulated via write-round to the relevant government departments. The strategy would be published once all relevant departments had agreed.

Department for Environment, Food and Rural Affairs Update

- 25. The Chair welcomed a representative from DEFRA, who joined the meeting to provide an update on their workstreams arising from the passage of the Genetic Technology (Precision Breeding) Act 2023.
- 26. DEFRA began by thanking the Committee for their input on the expertise and experience required by a welfare advisory body to enable its effective reporting on applications for precision bred animal marketing authorisations.
- 27. DEFRA then provided an update on their progress with the precision breeding workstream.
- 28. The Genetic Technology (Precision Breeding Act) 2023 introduced four key safeguards for animal welfare:
 - a. Marketing authorisation

- b. Animal welfare declaration
- c. Welfare advisory body
- d. Post-market reporting system
- 29. To put this system into place, over the next couple of years, DEFRA would be seeking Ministerial opinion on implementing statutory instruments, statutory guidance, an application form, a post-market questionnaire and general guidance for developers.
- 30. DEFRA drew the Committee's attention to a report that had previously been commissioned with Scotland's Rural College to determine the potential impacts of precision breeding on animal welfare⁸. DEFRA has recently commissioned a second project⁹ to explore links between the Animals (Scientific Procedures) Act 1986 (ASPA) and the Genetic Technology (Precision Breeding) Act 2023, assess animal health and welfare for marketing authorisations and assess post-market reporting on precision bred animals and their progeny.
- 31. The Chair reminded the Committee that they had previously responded to a consultation from DEFRA on the regulation of genetic technologies.
- 32. The Chair asked DEFRA whether there were any specific areas that DEFRA would be seeking ASC input on. DEFRA confirmed that there was nothing specific at this stage, but DEFRA are keen to seek ASC's input following the completion of the research.
- 33. The Committee then opened up to discussion, where the following points were raised:
 - a. There were not many establishments that currently had the capability to do CRISPR in farm animals, which these safeguards seemed to be aimed at, but regulations would also impact commercial breeders of small animals. ASRPU highlighted that there were still some discussions to be had on permissible purposes, and the definition of "scientific purpose" in relation to the use of animals to avoid these unintended consequences where possible.
 - b. The absence of information in the legislation and document on the housing, management and care of animals in commercial units was noted.
 - c. The changes made should not compromise the welfare standards for precision-bred animals by focusing exclusively on commercial production.
 - d. The public communications plan for this workstream, including roles and responsibilities, would need to be considered carefully to promote public acceptance.
 - e. The remit of the ASC is to provide advice on licence applications for scientific projects of societal concern that use animals, so it should be considered

⁸ Determining potential impacts of Precision Breeding on Animal Welfare - AW0521 (defra.gov.uk)

⁹ Developing further evidence requirements for precision bred animals – AW0523

whether processes should be implemented for the ASC to scrutinise these licences.

- f. There needed to be some consideration within the DEFRA policy on what level of harm is considered to be acceptable, and the public should be consulted on this.
- 34. One Member suggested whether the Committee might consider selfcommissioning a piece of work on this topic. The Chair responded that the scope would need to be carefully considered with a specific focus on ASPA.
- 35. The Committee agreed to come back to this topic once the election outcome had been finalised.

Action: Committee to reconsider the precision breeding workstream following election outcome.

Animals in Science Regulation Policy Unit Update

36. ASRPU provided the Committee with an update on the key areas of the policy programme, regulatory reform programme, and ASRU operations. The Committee were reminded that, due to the announcement of the general election, much of the policy activity had been paused.

Decapods

- 37. On the inclusion of decapods in the Animal Welfare (Sentience) Act 2022, ASRPU updated the Committee that an internal draft of the commission had been completed following feedback received from call for evidence.
- 38. The Committee asked about the next steps for the decapods commission. ASRPU advised that they were in conversation with DEFRA concerning next steps.
- 39. The Committee queried whether the inclusion of decapods in the Animal Welfare (Sentience) Act 2022 would have significant impacts, recalling that the recognition of cephalopods as sentient had not caused significant issues. ASRPU reminded the Committee that cephalopods had been introduced via a different mechanism, the EU Directive 2010/63/EU, which had different implications.

Section 24

40. The Committee queried whether the decision by the Minister not to review Section 24, as notified at the previous plenary, would potentially be reconsidered by the responsible Minister following the general election. ASRPU confirmed that this was possible.

Non-Human Primates bred for use in scientific purposes report

41. Following the advice¹⁰ from the ASC on this matter, the policy approach to reinstating Article 10 of the EU Directive 2010/63/EU had been largely developed. ASRPU were in the process of seeking input from ASRU and other key

¹⁰ Non-human primates bred for use in scientific purposes - GOV.UK (www.gov.uk)

stakeholders in preparation to seek advice from Ministers following the election outcome.

Forced Swim Test report

- 42. ASRU were continuing to review all licences to implement the recommendations from the ASC in their Forced Swim Test (FST) report¹¹.
- 43. Since 1 March 2024, three project licences had been amended to remove authorisation of the FST, one project licence that authorised the FST had expired, and two project licences that authorised that FST had been revoked. For the remaining three licences, ASRU was engaging with licence holders to ensure that recommendations of the report were being implemented in full.

Licence duration review

44. Following the commitment made by the Minister for Science, Research and Innovation at the animal testing debate in Westminster Hall on 19 February 2024, ASRPU would consult with the new Minister for the review of project licence duration.

Retained EU legislation

45. ASRPU intended to lay a statutory instrument for a consolidated code of practice by the end of 2024. This would not make substantive changes to requirements.

Regulatory reform programme

- 46. ASRPU updated the Committee on the progress and next steps of the regulatory reform programme. They advised that the two main focus areas for the regulatory reform programme were on validating the work that had been done by PwC during their contract, and implementing some initial changes to increase clarity and efficiency.
- 47. ASRPU provided an update on the recommendations to enhance governance of ASRU. Plans had been informally agreed internally but further internal clearances were required before plans could be implemented. ASRPU would continue to develop the required documentation, with the view to set up strengthened arrangements, subject to clearances, in 2025.
- 48. The Committee sought to clarify how they would interact with any new governance arrangements of ASRU. In particular, they asked whether any new governance arrangements would overlap with the ASC's advisory function. The Committee additionally highlighted the importance of clearly outlining the distinct responsibilities of the ASC, which are centred on advising the Minister, and do not include oversight of the Regulator.

Action: ASRPU to share documentation for enhanced governance of ASRU with ASC once developed.

¹¹ Advice on the use of the forced swim test - GOV.UK (www.gov.uk)

Operational update

- 49. ASRPU provided an update on the operations of ASRU, including business performance, stakeholder engagement, recruitment and publications. ASRPU then gave an overview of the licensing and compliance data for the previous quarter.
- 50. The Committee requested clarification on why the number of tasks completed during May was significantly lower than those completed in March and April. ASRPU highlighted that this metric did not give any indication of the type and number of tasks that needed to be completed, and that they were looking into how to improve metrics to give more meaningful information. The Committee suggested that RAG ratings and trends would be particularly useful. An additional suggestion was to measure "number of days in the system" to provide more useful data on timeframes and delays.

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. The key points were:
 - a. Relating to the additional funding for non-animal methodologies announced by DSIT, NC3Rs had been allocated £5 million to spend within the 2024/25 financial year. With this funding, the NC3Rs had announced £4 million for grants for infrastructure to accelerate the use of approaches that replace the use of animals in research and testing. The remaining £1 million would be used for grants for validating and characterising non-animal derived products and reagents.
 - b. An additional funding announcement had been made for £1 million (which includes co-funding from the British Heart Foundation and Cancer Research UK) for partnership and impact projects which aim to de-risk and accelerate the adoption of existing 3Rs models, tools and technologies into routine practice.
 - c. The NC3Rs had been providing input to the cross-government non-animal methods strategy.
 - d. The NC3Rs funding for the next five years would shortly be reviewed by its core funders, for which its initial submission was due in November 2024.
- 52. The Chief Executive of the NC3Rs also raised that it would be beneficial if the ASC agreed a definition for the NAMs acronym that they would use to improve consistency with the public, academia and industry. The two most common uses of NAMs were to refer to "non-animal methods" and "new approach methodologies". "New approach methodologies" was the most widely accepted definition of NAMs, but as this primarily had applications in safety testing, it was

rarely used in academia. The NC3Rs had already published information on this issue¹² but would encourage the ASC to promote a consistent definition as well.

- 53. The Committee discussed the alternative terms that might be used in place of non-animal methods, to avoid the abbreviation of NAMs and confusion with new approach methodologies. The term "replacement" was discussed, but as this included animals outside of the scope of ASPA, it was not necessarily synonymous. The terms "full replacement" and "partial replacement" distinguished between removing animals entirely and using animals outside of the scope of ASPA.
- 54. The Chair concluded that this issue warranted further consideration, especially in the context of the DSIT non-animal methods plan. The Chair agreed to write to DSIT on this issue and suggest an appropriate alternative term.

Action: Chair to write to DSIT on NAMs terminology and suggesting an alternative name for the proposed strategy.

Animal Welfare Ethical Review Body Subgroup

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

Subgroup Membership

- 56. The Subgroup Chair updated the Committee on new finalised Membership of the Subgroup. This would be updated on the ASC website in due course.
- 57. Each Member had additionally been paired with an AWERB Hub to facilitate communication between AWERBs and the ASC.

Hub workshops

- 58. Whilst there would typically be an AWERB Hub workshop hosted in April, this was cancelled whilst new ASC Members were being inducted and allocated to Subgroups.
- 59. The next workshop date had been agreed as 16 October 2024. The suggested agenda was:
 - a. Update on ASC work
 - b. Skills and training needed by an AWERB
 - c. Benefits of an active AWERB Hub

Newsletter

60. A newsletter providing these updates to the AWERB Chairs would be sent on behalf of the Subgroup before the end of June.

Grant funding bodies

¹² <u>Replacement – it's all in the NAMe | NC3Rs</u>

- 61. The Subgroup had recently discussed the issue that many AWERBs face with challenging 3Rs aspects of licence applications that had already received grant funding, as changing the detail of funded applications could cause difficulties with the funding.
- 62. The Subgroup proposed that the ASC directly engaged with grant funding bodies on this issue, in collaboration with the NC3Rs, to explore options for ensuring that ethical considerations were made at or before the grant funding stage of applications.
- 63. The Chief Executive of the NC3Rs raised that the Rawle report¹³ would be a useful resource for raising this with grant funders, and that the NC3Rs had been in conversation with UKRI funding councils about this issue. She suggested that the Committee invite a representative from the funding councils to a plenary meeting to speak about their activity in this space.
- 64. There was a discussion on whether applicants should be required to send their consideration of ethical issues to AWERBs before grant funding was awarded, but a view was expressed that this would be too much of a burden on AWERBs as there are many grant applications that then do not get approved for funding. Another option might be that there should be some consideration of flexibility within project proposals to enable changes to be made by the AWERB.

Action: Committee to consider whether a representative from the funding councils should be invited for a discussion item at a future plenary.

Project Licence Strategic Review Subgroup

- 65. 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. This was nearing finalisation, and the Subgroup Chair requested feedback from the Committee. The Subgroup Chair also welcomed Dr Sally Robinson, who had been co-opted to the Subgroup until the finalisation of the report for her toxicology expertise, and who had joined the meeting to contribute to discussion on the report.
- 66. One Member notified a conflict of interest due to their involvement in a related PPL, and therefore withdrew from the discussion.
- 67. Generally, the Committee considered the draft to be strong and particularly appreciated the focus on service licences. There was some discussion on the phrasing of the recommendations and whether these could be strengthened. The Subgroup Chair agreed that this wording should be updated.

¹³ The role of review and regulatory approvals processes for animal research in supporting implementation of the 3Rs (2023) | NC3Rs

68. The Subgroup Chair advised the Committee that there was one outstanding section to be finalised following a meeting between the relevant Subgroup Members and ASRU, and that this would be shared with the Committee.

Action: Chair of the Project Licence Strategic Review Subgroup to update the Non-Human Primates used in service licences report and share the finalised version with the Committee via email.

Committee Matters and AOB

Animal Sentience Committee

69. The Chair updated the Committee on his intention to set up a meeting with Animal Sentience Committee to share and receive updates on respective workstreams.

Action: Secretariat to set up a meeting between ASC Chair and Animal Sentience Committee Chair.

Committee name

- 70. The Chair raised the possibility for the Animals in Science Committee to revert their name to the one proposed in ASPA, the Committee for the Protection of Animals Used for Scientific Procedures, to avoid confusion with the Animal Sentience Committee.
- 71. The Committee agreed that the ASC had been established for too long to change its name, as it would be confusing for stakeholders.

Annex A – List of Attendees

Committee Members

Professor David Main (ASC Chair) Professor Jonathan Birch Mrs Caroline Chadwick Professor Johanna Gibson Professor Andrew Jackson Mrs Wendy Jarrett Professor Martin Knight Professor Martin Knight Professor Stephen May Mrs Tina O'Mahony Professor Hazel Screen Professor Christine J Watson Dr Carl Westmoreland Dr Lucy Whitfield

Secretariat

Caroline Wheeler Jessica Stone Emily Townley

Animals in Science Policy Regulation Unit

William Reynolds Chloe Jenkins Mamataj Begum Lucy Duncan Alice Whiteman Nicholas Were

Department of Health, Northern Ireland (NI)

Christine Henderson Karen Somerville

National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3Rs)

Dr Vicky Robinson

Co-optees

Dr Sally Robinson

Apologies

Dr Stuart Greenhill Dr Dharaminder Singh