Animals in Science Committee Minutes of the 40th Meeting: 11th September 2023 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 2023. Apologies were received from Dr Donald Bruce, Professor Andrew Jackson and Mr Barney Reed. 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 representatives from the Department of Health, Northern Ireland (NI) who joined the meeting online. The Chair also welcomed 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 explained that minutes from the previous meetings were in the process of being completed and would be circulated as soon as possible.
- 4. The Chair provided the Committee with an update on actions. The Chair highlighted three key points:
 - a. Flagging potential improvements to the Animals (Scientific Procedures) Act 1986 (ASPA) should be included in an updated ASC Terms of Reference.
 - b. The ASC would write to the Department for Science, Innovation and Technology (DSIT) regarding the reintroduction of the public attitudes to animal research survey.
 - c. The ASC Code of Practice and Ways of Working documents would be amalgamated into one comprehensive document.

Chair's Update

Letter to Ministers – strategic direction for animals in science

5. The Chair updated the Committee on the letter that had been sent to Lord Sharpe, Minister George Freeman, and Minister Rebecca Pow in relation to the strategic direction for animals in science¹. The Chair advised that this had been generally well-received and had been quoted on the day of publication by MPs in the Westminster Hall debate on Human-Specific Medical Research.

¹ Strategic direction: use of animals in science - GOV.UK (www.gov.uk)

6. Supportive comments had also been received from FRAME, Animal Free Research UK, and PETA.

Meeting with Home Office Minister and stakeholders

7. The Chair met with Lord Sharpe and senior sector stakeholders on 27 July 2023 to discuss the 'Continuous improvement of the Animals in Science Regulation Unit'. The Chair advised that it had been a productive conversation with positive discussion about the ongoing Animals in Science Regulation Unit (ASRU) regulatory reform programme and potentially moving policy responsibility away from the Home Office.

Recruitment campaign update

- 8. The Chair advised the Committee that the recruitment campaign for new ASC Members had progressed, with interviews now completed.
- 9. The campaign had attracted an excellent variety of candidates to fill all of the specialisms sought and the campaign remained on target to have new Members in post by the end of the year.

Response to Review of Antibody Licences report

10. The Chair drew Members' attention to the Home Office's response² to the Review of Antibody Licences report³, thanking Committee Members for their work on this. The response outlined how the department intended to implement the recommendations set out in the report. The response set out the short-term, long-term, and continuing actions, some of which would be addressed by the ongoing regulatory reform programme.

Animals in Science Regulation Policy Unit update

11. ASRPU provided the Committee with an update on key aspects of the policy programme, operations and the regulatory reform programme.

Decapods

12. A call for evidence on decapods⁴ had been published in early June, for a period of three months, with the window for responses closing on 13 October 2023. Next steps would be considered in the autumn following review of the evidence received.

Non-Human Primates bred for use in scientific purposes report

13. ASRPU recognised the frustration felt by the Committee regarding the delay in response to the Non-Human Primates bred for use in scientific purposes report⁵.

² Review of antibody licences: letter from Lord Sharpe - GOV.UK (www.gov.uk)

³ Review of antibody licences: report by the Animals in Science Committee - GOV.UK (www.gov.uk)

⁴ Decapods: call for evidence - GOV.UK (www.gov.uk)

⁵ Non-human primates bred for use in scientific purposes - GOV.UK (www.gov.uk)

ASRPU advised the Committee that this had been due to conflicting resourcing priorities and that they hoped to respond to this work in the autumn.

Cosmetics regulatory testing

14. Progress had been made on reviewing legacy licences and the crossdepartmental discussion to ensure a unified position and approach.

Training and continuous professional development guidance

- 15. The training and continuous professional development (CPD) guidance (and supporting explanatory memorandum) was laid before Parliament on 12 July 2023 and, in accordance with Parliamentary procedure, following the 40 sitting days negative resolution procedure, would come into force on 24 October 2023. ASRPU would continue to work with stakeholders to implement the guidance and take on considerations for future iterations.
- 16. Following a question from the Committee, ASRPU confirmed that they were aware of concerns from some stakeholders who felt that they had not been adequately represented on the 'training stakeholder group'. ASRPU had met with the stakeholders to hear their concerns. Further discussions were planned to discuss the scope of the guidance and future work.

ASRU operational update

- 17. The Committee were provided with an update on ASRU operations and invited to comment or ask questions. This update covered:
 - a. Business performance
 - b. Process and standards
 - c. Stakeholder engagement
 - d. Recruitment and resourcing
 - e. Publications
 - f. Licensing data
 - g. Compliance assurance
- 18. The Committee queried the delays in responses to Standard Condition 18 reports, highlighting their concern for the anxiety this may cause those waiting to receive a response. ASRPU advised that these reports were triaged so any immediate animal welfare concerns would be addressed promptly. ASRPU would request that ASRU confirm this in future updates to the Committee.
- 19. Members felt that ASRPU's workforce requirements were not clear and that establishing those requirements would be essential to any improvements. ASRPU noted their comments and advised that phase three of their regulatory reform programme would look at capability and capacity.

Regulatory reform programme

20. The Chair welcomed representatives from PricewaterhouseCoopers (PwC) who joined the meeting to provide an update on the regulatory reform programme and to receive feedback from the Committee.

21. Key points of the update were:

- a. An overview of the high-level milestones achieved to date.
- b. The reform programme was currently in its 'design phase', with consultants working with ASRPU to review ASRU's current operations and plan improvements.
- c. Following the design phase, a business case would be submitted recommending changes to ASRU and plans for how those could be effectively implemented. If approved by the Minister, the implementation phase would begin in 2024.
- d. Strategic priorities for ASRU had been outlined and feedback from various stakeholders had been mostly positive, with comments mainly relating to the descriptions of priorities rather than large revisions.
- e. An overview of the work carried out by PwC which included initial assessments, operating model design, organisational design, process improvements, change management and culture change planning, planning for implementation, and project management.
- f. ASRPU provided some examples of expected benefits of the reform work such as:
 - i. Improved licensing process
 - ii. Improved compliance process
 - iii. Increased use of leading practice for animal protections in the regulated sector
 - iv. Improved transparency on outcomes and ability to measure ASRU's impact.
 - v. Prevention of non-compliance through increased emphasis on assuring establishment's systems
 - vi. Increased clarity and access to online guidance for stakeholders through improved ASRU website.
- g. The Committee voiced support of the inclusion of incentives to encourage compliance.
- 22. The Chair thanked PwC for the overview and noted that it would be beneficial to look at the language used in their reporting as terms such as 'customer' and 'market' were not clearly applicable to a regulated community. PwC advised that there were no clear equivalents in the private or commercial sector to parallel the remodelling of ASRU. PwC had to look at other types of regulators such as Ofsted and MHRA for examples of procedures used.
- 23. One Member commented that inspections should also be seen as an opportunity for an establishment to feedback to ASRU and as an opportunity for ASRU to use such feedback for information gathering exercise and providing establishments with an opportunity to discuss important topics with an inspector face to face.

Leading practice

- 24. ASRPU presented an exploratory piece of work to the Committee, which looked at leading practice in the sector.
- 25. Publication on leading practice by the Home Office was currently limited to the Code of Practice. ASRU is also responsible for publishing non-technical summaries (NTS) and retrospective assessments which can detail methodological advances or lessons learnt from past studies.
- 26. ASRU did not have a formal or consistent way of recognising establishments that were going beyond the statutory minimum standards for animal care through adopting leading practice.
- 27. ASRPU invited the Committee to discuss the potential of producing a framework outlining roles and responsibilities for leading practice of those working with animals in science, with the following comments being noted:
 - a. Feedback should not just be focused on failures but also successes, with processes and behaviour being assessed. There may be some instances where a certain standard or good practice cannot be achieved in a particular area of research, but if it has been well discussed, critiqued and justified then that should be acceptable.
 - b. Inspections should also play a vital role in the sharing of leading practice. Without visiting establishments, it would not be possible to see what the actual leading practices achieved 'on the ground'.
 - c. It was highlighted that one an ideal route would be to focus on continuous improvement of behaviour, with excellent governance and communication through awards and other processes.
 - d. The NC3Rs representative was in agreement with comments made by the Committee and supportive of the suggestions and areas for improvement highlighted by ASRPU when introducing the topic.
- 28. The Chair noted that it would be important to have cross-sector ownership of this in order to capitalise on the wealth of good practice already taking place within organisations and establishments. Therefore, it would be important to establish good communication links between the regulated community, the animal welfare community, charity groups, and scientists etc.

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

- 29. The Chief Executive of the NC3Rs provided the Committee with an update on the work of the NC3Rs, specifically noting the following items:
 - a. The NC3Rs would have a new Chair starting at the beginning of January 2024.
 - b. The NC3Rs announced their latest project grants of £3 million, split across seven grants mainly focused on replacement. This was part of their

- commitment to focus 75% of their research and innovation budget on non-animal technologies.
- c. They had just launched their CRACK IT Challenges innovation competition for the year.
- d. The NC3Rs had launched an e-learning resource on mouse handling, in collaboration with the US-based '3Rs collaborative'.

Animal Welfare Ethical Review Body Subgroup

- 30. The Chair of the Animal Welfare Ethical Review Body (AWERB) Subgroup provided the Committee with an update on their ongoing workstreams.
- 31. The final draft of the workshop report from the Subgroup's April 2023 AWERB Hub workshop had been completed and had been sent for publication. The next workshop would be held on 11 October 2023 with the following topics:
 - a. A presentation by Dr Frances Rawle on 'The role of review and regulatory approvals processes for animal research in supporting implementation of the 3Rs'.
 - b. The role of AWERBs
 - c. An overview of the ASC review of the Forced Swim Test
 - d. A presentation on the current NTS template guidance questions and prompts
- 32. The Subgroup had planned to review a batch of published NTSs to make some general observations to use as evidence for their draft report on NTSs. However, due to several Members of the Subgroup demitting at the end of the year, this would not be possible to complete within the time frame. An alternative had been suggested by way of having the NTS as a topic at the next workshop and circulating a set of questions to attendees for them to discuss in groups. This would provide the Subgroup with additional evidence and feedback to inform the report.

Project Licence Strategic Review Subgroup

- 33. The Chair of the Project Licence Strategic Review (PLSR) Subgroup updated the Committee on the status of their work programme.
- 34. The Forced Swim Test report⁶ had been sent to the Minister and published on the ASC website.
- 35. The Minister had written to the Committee in response to the report on the Review of Antibody Licences, accepting the report's recommendations and setting out an implementation plan. The Minister also commented that the responsibility for the development and promotion of new scientific methodologies that replace the use of animals in the development and production of antibodies, rests with DSIT.
- 36. The Subgroup was working on a report on Non-Human Primates in service licences. Members had reviewed the licences forwarded by ASRU.

⁶ Advice on the use of the forced swim test - GOV.UK (www.gov.uk)

- 37. The Subgroup had also prepared questionnaires to be sent out to individual project licence holders and would hold a public call for evidence to receive input from a wider range of stakeholders.
- 38. The next steps would be to assess all the evidence gathered from which Subgroup Members would begin drafting the report to review at their next meeting.

Committee Matters and AOB

39. Committee Members discussed a revised approach to the draft Ways of Working document, agreeing its amalgamation with the ASC Code of Practice into one comprehensive document.

Annex A - List of Attendees

Committee Members

Professor David Main (ASC Chair)
Mrs Wendy Jarrett
Dr Sally Robinson
Professor Clare Stanford
Professor Johanna Gibson
Professor Stephen May
Professor Christine Watson

Dr Hannah Clarke

Secretariat

Caroline Wheeler Jessica Stone

Animals in Science Policy Regulation Unit

William Reynolds Gideon Winward Chloe Jenkins Mamataj Begum

Department of Health, Northern Ireland (NI)

Lynsey Armstrong

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

Dr Vicky Robinson

<u>PricewaterhouseCoopers</u>

Annie Dalton Catherine D'Souza George Bainbridge

Apologies

Professor Andrew Jackson Dr Donald Bruce Mr Barney Reed