

Animals in Science Committee

Minutes of the 34th Meeting: 7th March 2022

Welcome, Introductions and Conflicts of Interest

1. Professor David Main, Chair of the Animals in Science Committee (ASC), welcomed members to the first plenary meeting of 2022. Apologies were received from Stephen May. No conflicts of interest were declared.
2. The Chair welcomed officials from the Home Office's Animals in Science Regulation unit. The Chair explained that minutes from the previous meetings were in the process of being ratified by the ASC.

Chair's Update

Decapods

3. The Chair updated the committee on the current status of a proposed letter to the Minister, from the ASC supporting the LSE review recommendation to widen the scope of ASPA to include the decapod crustaceans.
4. The Chair noted that because any future changes to ASPA would be led by the new policy unit, it would be more effective in terms of timing to revisit sending the letter once the formation of the policy unit was completed.
5. Members also discussed the breadth of work that would need to be carried out by the new policy unit in order to understand the implications of the legislation change; This would include identifying the UK institutions that use decapods in order to bring them under ASPA for the first time as well as having a clear understanding of decapod characteristics (including larval stages) in order to ensure they are properly regulated.
6. Members suggested a consultation process should take place in order to better understand the scope and range of these issues.

Meeting with UK Bio Science Coalition

7. The Chair briefed the committee on his meeting with the UK Bio Science Coalition held on the 20th of January; the meeting attendees included Professor Dominic Wells and Joanna Storey, BSC Co-Chairs. Topics discussed included:
 - a. General update on ASC activities including work programmes, engagement with the EU, and 2022-member recruitment.
 - b. General update on Animal Science policy events including animal rights activism, Animal Sentience Bill, and DEFRA Genetic Technologies consultation.

- c. ASRU Change Programme – timeline, concerns by the sector, including members of the ASC, such as lack of transparency, speed of change, and slowness in response to those concerns.
- d. Developing relationships between the animal research sector and the ASC in light of the change programme.
- e. Brexit and animal transport – DEFRA consultation on welfare of animals in transport.

Testing on animals of pre-approved compounds when for other purposes

- 8. The Chair informed the committee that he had responded to Professor David Heal regarding the FSA regulatory requirements in relation to toxicity testing for cannabidiol as a novel food stuff.
- 9. The response sent noted the regulatory requirement to ensure only necessary testing was carried out in animals used in science and that the Chair would raise the issue with the Home Office with a view to reviewing interactions between departments to ensure that all proper processes have been followed and the required regulatory testing is appropriate and complies with 3Rs principles as defined in legislation.

NC3Rs project – Licence review processes supporting 3Rs advances.

- 10. The Chair updated members on his meeting with Francis Rawle, who was leading a project for NC3Rs looking at review processes for animal research. The key aims of the project were:
 - a. To map in detail what the various different regulatory and review processes and bodies currently do to ensure compliance with 3Rs principles and to promote adoption of 3Rs advances
 - b. To identify any current variations in review processes, any gaps (or overlaps) in coverage and any lessons to be learned from examples of particularly effective practice.
 - c. To explore opportunities for adjusting current processes and responsibilities so as to cover any gaps, remove unnecessary duplication and more effectively promote adoption of 3Rs advances.
- 11. This discussion mostly centred on processes around regulation and the ethics review of potential funding applications and how this supports implementation of the 3Rs.

Animals in Science Regulation Unit

- 12. Ahead of the update from ASRU, the Chair noted that members were aware of and had briefly discussed concerns expressed by some stakeholders about the Change Programme.
- 13. The Chair commented that, although several members of the Committee had an association with the stakeholder institutions which had written to the Minister, he

wished the minutes to note that members of the ASC participate in committee meetings in an individual capacity, and not as representatives of any organisation.

14. ASRU HoU advised that stakeholder correspondence about the Change Programme was being considered by the department.
15. ASRU HoU provided an update via a presentation with two aims:
 - a. To update on the Animals in Science Policy and Coordination Function
 - b. To update on the progress of the Change Programme

Animals in Science Policy and Co-ordination Function

16. The committee was aware that No 10 and the Cabinet office had decided to implement an Animals in Science Policy and Co-ordination function. In the interim this would be established in the Home Office but independent from the regulator.
17. Members heard that the recruitment process for the interim function had begun and that it would lead a Task and Finish group across Whitehall and the devolved administrations to determine the best permanent way for the function to operate.
18. Members received an overview of how the policy unit structure would look when all roles had been filled.
19. Following a question relating to public accountability, the Head of ASRU advised the committee that as the function would be a Home Office structure, it would report to the Director General and therefore the Permanent Secretary and overseen by the Minister.
20. Members asked several questions relating to the governance of the interim policy unit. It was explained that a governance framework was being finalised, but the current outlook suggested mid-April for the formation of the unit to be completed. It would then require further time to fill the staffing positions.
21. The interim policy unit would also need to establish the protocol between itself and ASRU to establish the regulator according to arms-length body principles.
22. It was noted that there would likely be a requirement for a new terms of reference for the Animals in Science Committee and how it would work going forward with the new policy unit.
23. The Chair reminded ASRU that the ASC expects to be involved in the conversation regarding how the committee provides advice. ASRU HoU agreed with this point and informed the committee that work on the Terms of Reference would be carried out jointly between committee members and the new Policy Unit.
24. Several members of the committee commented that the structure of ASRU's updates were not as beneficial as they could be, resulting in limited opportunity for discussion. The Head of ASRU took these comments on board and informed the committee that the intention was to keep the committee as informed as possible.
25. A member raised a question, and a brief discussion followed, relating to how the use of animals in regulatory testing to satisfy the requirements of legislation such as REACH are considered within the context of Home Office policy development and

implementation. The Head of ASRU advised that REACH is a permissible purpose for animals in science work to be conducted under ASPA i.e. if it is to fulfil a regulatory requirement.

Change Programme

26. The Head of ASRU informed the committee that the Change Programme had been created due to the recognition that improvement was needed in the frameworks that underpinned ASRU's work. In order to achieve this a re-design of the operating model and organisational structure of ASRU was necessary.
27. The Chair noted the critique received by ASRU regarding the Change Programme. The Head of ASRU acknowledged that concern had been expressed by some organisations in the animals in science sector and these would be discussed by the ASRU leadership team in a forthcoming meeting.
28. The committee was informed that the Home Office was committed to the strategic direction and the changes in the operating model for ASRU. However, until the organisational re-design was implemented it would be necessary to prioritise work and implement quality control processes. This was to ensure that ASRU would match its regulatory requirements to its existing capacity and capability.
29. The Chair noted that the ASC wanted to be of use in the Change Programme process and would like to be informed how the regulator was reassuring the research community and addressing their concerns.
30. An AWERB member raised a concern regarding information which had been provided to ASRU under Section 24 but which had subsequently been released under the Freedom of Information Act. Those providing the information had believed it to be confidential and protected by Section 24.
31. HoU advised that the only case where information has been released was in FOI's related to MBR Acres. The decision to release that information was due to the requirements of the FOIA.

AWERB Subgroup Update

32. The AWERB subgroup Chair, provided the committee with an update.
33. The committee was informed that, subject to any ongoing restrictions, the subgroup had discussed arranging a Roadshow in 2022 as it would be beneficial to the community. This would hopefully assist with reinvigorating the AWERB Hubs following the pandemic.
34. The subgroup had published the report from workshop held in October 2021 on the ASC Gov.uk website. The report had also been circulated to the AWERB Hub mailing list.
35. Following discussion at the December 2021 Plenary, the subgroup would contact the interim Animals in Science Policy Unit, once formed, to discuss a co-designing approach for the NTS document. The aim would be to help ensure synergistic messaging from the ASC and Home Office.

36. The SG note the impact on the work of AWERB subgroup following the clarification as a result of the Change Programme that the committee and its subgroups to not include work or advice on operational matters. Given the majority of the work carried out by AWERBs concerned operational issues, the subgroup was unsure on what items of work to proceed on.

Action: AWERB SG to review the NTS document at the next AWERB SG meeting.

NC3Rs Presentation

37. The committee welcomed Mark Prescott, Director of Policy and Outreach at the NC3Rs. Mark had attended the plenary meeting in person to provide the committee with a presentation.
38. This presentation covered the following topics:
- a. Overview of NC3R activities
 - b. New projects
 - c. Stakeholder relations
39. Mark gave the committee an update on the most recent funding headlines, grants that have reported 3Rs impacts with examples of successes. The committee heard how the NC3Rs had successfully attracted co-funding for several of their schemes, investing in areas that they have identified as strategically important for the 3Rs.
40. The presentation gave the committee an overview of the current work of the NC3Rs, acknowledging their scientific approach to furthering the 3Rs which they believed was essential for sustained progress. Collaborating extensively across the Biosciences sector, the NC3Rs looks to influence at all stakeholder levels, aiming to deliver 3Rs impact across the board.
41. The presentation was followed with a short question and answer session, with all committee members given the opportunity to ask further questions relating to the presentation including:
- a. Peer reviews
 - b. Funding
 - c. How the NC3Rs board is constituted
42. An ASC member informed Mark that the ASC were working on strategic licence reviews which might be of interest to the NC3Rs once reports were published.
43. The Chair thanked Mark for joining them and acknowledged the importance of the work carried out by the NC3Rs.

Project Licence Strategic Review (PLSR) Subgroup

44. The Chair of the PLSR subgroup provided the committee with an update on their programme of work and findings from their review of the antibody licences. The subgroup had submitted their draft report to the ASC ahead of the meeting.
45. The members had carried out a review of a set of licences, the criteria used had previously been agreed by the subgroup in consultation with two independent immunology and antibody experts.
46. The Subgroup had identified general themes and summarised initial findings and produced 2-3 recommendations for each theme. These were then collated by the subgroup Chair and included in the draft report.
47. The subgroup Chair welcomed comments from the committee to be sent to the ASC Secretariat for the group to further review at their next meeting.
48. An ASC Member highlighted for information that a sub-group of the Network of National Committees was continuing its review of the potential use of non-animal methods for antibody production.

Action: ASC Members to submit comments on the PLSR draft report to the ASC Secretariat.

Task and Finish Groups

Futures Capability Working Group (FWG)

49. The Chair of the FWG provided the ASC with an update on the work of the group.
50. The subgroup Chair informed the committee that the report had been revised with a new structure and a more narrative approach, as previously agreed. The Chair informed the committee of the process that was followed by the FWG and their reasoning behind the changes in the report structure.
51. The subgroup invited the rest of the committee to comment on the revised report and send any feedback or suggestions to the ASC Secretariat. Following this the FWG would produce a final draft for the ASC to consider at the next plenary meeting.

Action: ASC Members to submit comments on the FWG draft report to the ASC Secretariat.

Brain Organoids, Reanimation and Sentience Group (BORSG)

52. The subgroup Chair updated the committee on the changes to the work of the BORSG. The SG met at the end of 2021 to discuss adjusting the methods by which the group would gather evidence. It was decided that the best approach to move the work forward would be for:
 - a. The SG to undertake a review of the documentation and research already completed on sentience and reanimation

- b. The SG to circulate a set of focused questions to representative individuals within the animals in science sector community either for discussion as part of an 'interview' style meeting or for written reply only.
53. The draft list of questions had been circulated to the ASC ahead of the meeting and the subgroup welcomed comments from the wider committee.
54. Following the circulation of the questions the subgroup intended to produce a set of recommendations around the ethical implications for ASRU to consider. It was noted that it would be beneficial to inform the DEFRA Sentience Committee of this piece of work once the report was ready for publication.
55. The ASC discussed how to best approach the task to ensure a robust set of recommendations could be made and it was agreed to focus on Organoids work.

Committee Matters and AOB

56. Members were informed by the Chair that it would be likely for the committee's appointments would be extended. Due to the significant organisational and governance changes currently in progress, it would be inefficient to recruit new committee members at this stage.
57. ASC members noted recent publicity relating to an investigation alleging the illegal importation into the USA of wild caught nonhuman primates falsely labelled as captive bred.
58. However, there did not seem to be any immediate implications for the UK related to this topic.

Annex A

Committee Members

Dr 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 Virginia Warren

Linda Horan

Dr Hannah Clarke

Prof Christine Watson

Secretariat

Caroline Wheeler

Jessica Daly

Animals in Science Regulation Unit

William Reynolds

Apologies:

Professor Stephen May