

Animals in Science Committee

Minutes of the 29th Meeting: 07th December 2020

1. Welcome, Introductions and Conflicts of Interest

- 1.1. The Chair welcomed attendees to the 29th meeting of the Animals in Science Committee (ASC), which took place via teleconference.
- 1.2. No apologies were received. No conflicts of interest noted. The list of attendees is attached at Annex A.

2. Minutes and Actions from the previous ASC meeting

- 2.1. Minutes from the previous meeting (14 September 2020) were with ASRU to review their contributions and would be circulated to members for comments as soon as possible.
- 2.2. Actions were complete with the following exceptions:
 - 2.2.1. ASRU's response to the ASC's question regarding the European Chemical Agency (ECHA) Board of Appeal decision on substances used exclusively in cosmetics products. ASRU confirmed they were consulting with another Government Department and would send a response.
 - 2.2.2. The HBA Summary of Recommendations for AWERBs would be published, pending accessibility checks.
 - 2.2.3. An ad hoc meeting of ASC members to discuss Human Ethics. This action was pending, following a meeting arranged between the ASC Secretariat and a representative of the Human Ethics Research Council's training.

3. Chair's Update

3.1. Meeting with the Minister

- 3.1.1. The Chair updated the Committee on his meeting with Home Office Minister, Baroness Williams of Trafford. Topics covered including current work of the ASC, the Ministerial Commission for 2020/21 and 'who, within government, had ownership of the broader strategic interest of animals in science policy beyond regulation' (see para 3.2).

3.2. Update on ASC/ NC3Rs Workshop

- 3.2.1. The Chair advised Committee members that he had been working closely with NC3Rs to develop the planned workshop on the broader strategic interests of animals in science policy (beyond regulation). Before finalising the arrangements, he would meet with the new Home Office CSA, Professor Jennifer Rubin, to provide her with a comprehensive briefing on the project and opportunity to be involved in the workshop, planned for Spring 2021.

3.3. Invitation to ASG meeting

- 3.3.1. The Chair reminded the Committee of the opportunity to attend the Animals in Science Group's annual workshop, held on 10 and 11 December. The ASC Chair would not be attending due to other commitments.

3.4. Letter of Support for Gail Davies and the HBA

- 3.4.1. The Chair informed the Committee that the University of Exeter would be writing an impact case study on Professor Gail Davies' work on the Harm- Benefit Analysis. The Chair had agreed to write to the University, informing them of what Professor Davies' role had been in this body of work. These case studies were published to recognise what a researcher's work had achieved and the Chair felt that the work on the HBA would make a good case study.

3.5. Annual meeting with Chair of Animals in Science Group

- 3.5.1. The Chair advised the ASC that he had an upcoming meeting with Professor Dominic Wells Chair of the Animal Science Group at the Royal Society of Biology. This meeting was held annually to keep the scientific community updated on the work of the ASC. Topics that would be covered included:

- i New areas of work from the Ministerial Commission
- ii The ongoing work of the ASC
- iii Governance of animals in science, beyond regulation
- iv EU Statements on Cosmetics and non-animal derived antibodies

The Chair also informed the committee that he had a meeting planned for the beginning of 2021 with Helmut Ehall (ELF).

4. Update from the Animals in Science Regulation Unit (ASRU)

- 4.1. ASRU Head of Unit (HoU) and Head of Policy (HoP) provided the committee with an update on several workstreams.

4.2. ASRU Operational Update

- 4.2.1. ASRU Head of Policy (HoP) provided the ASC with a short operational update.
 - i HoP advised that ASRU has legislation in place for the Brexit transition period and they do not anticipate there would be any changes as a direct result of the transition. The HoP did highlight one key area relating to import and export of animals. DEFRA was responsible for the transportation of animals and ASRU were liaising with organisations involved; directing them to DEFRA for latest information.
 - ii On-site inspections of research establishments had resumed on 7th September with ASRU liaising with establishments to ensure all local Covid rules had been followed. ASRU continue to supplement physical inspections with remote inspections. One key issue that had been resolved, was establishment concern over a potential break in continuity of staffing as a result of staff

- having to self-isolate. Most establishments had successfully managed this risk by creating teams within their staff.
- iii HoP advised that ASPeL was in continued development with two changes due to be made in early 2021. First would be the inclusion of 'returns of procedures' function within ASPeL. The 2020 returns would continue through the current system. By moving this function to ASPeL ASRU hope to improve the quality of the data collection. Another feature to be added would be a Non-technical Summary Database; this was planned for delivery in 2021.
 - iv ASRU HoP advised that the planned 200 PPL review was due to begin in early 2021 and that ASRU would inform the Committee once a date had been set.

4.3. Quality Management System Update

- 4.3.1. The ASC received an update presentation on the ASRU quality management system (QMS). This included themes identified following one-to-one interviews with ASC Members.
- 4.3.2. The other topics covered by the presentation included
 - i The purpose of the QMS
 - ii 'Critical to quality' features
 - iii Next steps for QMS Project, ASRU Strategy and ASC Involvement.
- 4.3.3. Members were invited to comment on the content of the presentation as well as participate in a Q&A.

4.4. ASRU response to ASC question regarding the recommendations of EURL ECVAM report on alternatives to animal derived antibodies

- 4.4.1. Committee members thanked ASRU for their written response but felt that the response was rather generic in nature, aimed at an audience unfamiliar with ASPA rather than the ASC who already had an understanding of how ASPA works.

4.5. Role of the ASRU Observer on Subgroups

- 4.5.1. Ahead of the meeting, ASRU provided ASC members with draft text outlining the role of ASRU observer members in ASC Subgroups. Once agreed, the text would be included in all ASC SG Terms of Reference. The aim of this text was to provide clarity to the Committee on the role of the ASRU Observer and to the ASRU attendee on the scope of their responsibility.
- 4.5.2. The ASC advised ASRU they value the working relationships with ASRU observers that participate in the Subgroups.
- 4.5.3. The Committee agreed to some editorial changes to the draft text to improve the readability, "ASRU to provide an Observer who will" would be changed to "ASRU to provide an observer who may"; underlined text was superfluous and would be removed. The ASC also requested a clause be added, indicating that there may be closed sessions in meetings when only Subgroup members would attend.

Action: Secretariat to amend text for ASRU Observer role for inclusion to ToRs of ASC Subgroups.

4.6. Animal Husbandry and ASPA Compliance

- 4.6.1. In response to a request by the ASC about the regulation of Animal Husbandry and where it could intersect with ASPA, the ASC had been provided a written response by ASRU ahead of the meeting.
- 4.6.2. ASRU provided information on:
 - i The regulatory requirements under ASPA of the application of agricultural practices to animals otherwise being used under the controls of ASPA; and
 - ii How ASRU provides assurance that academic institutions that do not hold ASPA establishment licences do not undertake regulated procedures, including animal husbandry techniques that may need to be regulated under ASPA.
- 4.6.3. ASC Members noted that the issue of Animal Husbandry was broader than agricultural practices alone, for instance horse racing, and that there was a risk that this wider community might, potentially, not realise that the animal husbandry procedures they were carrying out may need to be regulated.
- 4.6.4. One member also noted that new bioinformatics procedures were being introduced to animal husbandry and agriculture. The application of these in a farm-based setting could possibly be considered an experiment and therefore require regulating.
- 4.6.5. The Chair considered the ASC may need to assist in disseminating this information.

4.7. HBA – Progress on the implementation of recommendations

- 4.7.1. Ahead of the meeting, ASRU provided a written update to the ASC on ASRU's implementation of the recommendations set out in the ASC's 2017 Review of Harm-benefit analysis in the use of animals in research. This paper provided an update on the progress made by ASRU.

4.8. PQs and FOIs

- 4.8.1. ASRU provided an information paper ahead of the meeting, detailing the Parliamentary Questions and Freedom of Information requests received by ASRU since the last Plenary meeting.

5. Project Licence Application Subgroup – Revised Terms of Reference

- 5.1. The 2020/21 Ministerial Commission sets out a requirement for the ASC to review the Terms of Reference (ToRs) for the Project Licence Application Subgroup to ensure the advice provided was strategic and widely applicable across relevant licences.
- 5.2. In discussion, Committee members agreed to maintain the PLA subgroup in its current format to enable the ASC to continue its legislatively required role to review licences referred to it by ASRU. Delivery of the Ministerial requirement would be through the formation of a new subgroup whose

role would be to assess the strategic application of advice provided by the ASC. This would include advice as provided by the PLA subgroup, but also other topics or issues as identified by the ASC or referred to it by ASRU. To assist the exchange of views between ASC subgroups, members agreed that the Chairs of the Futures Capability Working Group and Brain Organoids, Reanimation and Sentience Subgroup should also report to the new subgroup.

- 5.3. The ToRs for the new subgroup would be discussed further at the March 2021 Plenary meeting.

Action: Revised ToRs to be presented at March 2021 Plenary for further discussion.

Action: An updated proposal for the structure and function of the Project Licence Strategic Review Subgroup to be submitted for the next ASC Plenary.

Action: ASC to submit membership suggestions to the Secretariat for the new Project Licence Strategic Review Group.

6. ASC Strategic Positioning

- 6.1. At the September ASC plenary, members discussed the recent EU announcements regarding requirements for animal testing of chemicals used exclusively in cosmetics, and the recommendations of EURL ECVAM on the potential for replacing animal-derived antibodies.
- 6.2. Following this, ASC Members discussed their strategic advisory role, beyond the legislative requirement to advise the Minister and policy, and how that could be used to influence the animals in science community more widely.
- 6.3. ASC members agreed there was an influencing role for the Committee, however care would be needed to find the correct balance in providing views on topics verses co-badging a statement. Also, it would be essential to take ASPA regulation and the role of ASRU into account.
- 6.4. Given the range of issues that could be involved, members did not feel the ASC had the breadth of expertise needed to lead individual discussions, and instead suggesting they could encourage appropriate collaborations between relevant bodies to stimulate the necessary conversations.
- 6.5. The Chair advised that he form a small Task and Finish Group of ASC members to discuss this further and report back at the next ASC meeting.

Action: ASC Chair to meet with ASC members for a discussion on Strategic positioning.

7. AWERB Subgroup Update

7.1. Hub Chair Workshop

- 7.1.1. The Subgroup Chair updated the ASC on the Hub Chair Workshop which took place via a virtual platform on the 21st October. The workshop attendance was high and there was a

good level of interaction from the attendees. The Chair advised the Committee of the SG's next steps following the workshop:

- i Presentations and participant contributions from the day had been circulated to the attendees and would be uploaded to the AWERB Knowledge Hub.
- ii A report of outcome from the event would be written by the Secretariat
- iii A feedback questionnaire would be circulated to the attendees
- iv The SG would be considering how best to use the feedback collected from the attendees during the workshop.

7.2. ASC members were also provided with a written update on the AWERB workstreams.

7.3. Support Note

- 7.3.1. The Subgroup was reviewing the AWERB Hub Support note to reflect the revised Hub Network structure and changing working practises. The first draft of the updated support note was circulated to Subgroup members at the end of August. SG members were working a second draft.

7.4. NTS Guidance

- 7.4.1. AWERB SG Member, would prepare NTS guidance for AWERBs. Based around the new ASPeL system NTSs, it will be encouraging engagement between Lay members and applicants and provide tools for AWERBs to assess the quality of NTSs.

7.5. HBA Recommendations for AWERBs

- 7.5.1. This report had now been ratified and would be published on the ASC website and the AWERB Knowledge Hub.

7.6. Newsletter

- 7.6.1. The AWERB SG would be publish a newsletter in the first quarter for 2021. Topics would include:
 - i Key findings from the Hub Chair's Workshop
 - ii AWERBS - Lessons learned from Covid-19
 - iii Update to the Support Note
 - iv Updated links to recent publications including the Licence Analysis Report and the HBA Recommendations for AWERBs report.

7.7. Non-animal alternatives (NAA)

- 7.7.1. The AWERB Subgroup had been tasked with raising awareness of NAA and the 3Rs via the AWERB Hub Network as part of the 2018/19 Ministerial Commission. The work of the AWERB SG had primarily focused on sharing 3Rs good practice among AWERBs. The SG had discussed sharing advice on NAA however, they agreed this went beyond the remit of the SG, specifically on the grounds of providing assurances of scientific validity of NAAs. Therefore, the AWERB SG had referred this workstream back to

the ASC to potentially be incorporated into the broader policy question on Animals in Science.

8. Task and Finish Groups

8.1. Futures Capability Working Group (FWG)

- 8.1.1. The FWG Chair thanked ASC members for their further contributions of horizon scans, which would be added to the 'futures' evidence base, as well as their suggestions of organisations and entities to contact to enable wider participation in the horizon scan/7 question exercise.
- 8.1.2. The Chair would shortly begin writing out to these organisations; contributions received would be included in evidence base for analysis by FWG members and the Home Office Futures team to help identify 'futures' issues and trends. The next stage would be a workshop, to which contributors would be invited to further analyse the trends identified. The outputs of the work would be summarised in a report for the ASC.

Action: ASC to send in any additional suggestions for organisation or entities (and contact details) to contact for the Futures Capability evidence gathering to the ASC Secretariat.

8.2. Brain Organoids, Reanimation and Sentience Group (BORSG)

- 8.2.1. The BORSG SG Chair provided the ASC with an update on the progress made by the Subgroup since the last ASC Plenary. Members were notified of the following decisions regarding the BORSG workshop.
 - i Due to the interdisciplinary nature of the work and potential for confusion in the use of definitions, the SG had agreed to include 'working definitions' for the purpose of the project.
 - ii The workshop would be split into two separate events. The first would consider Brain Organoids and Reanimation of post-mortem brains, with the second focusing on Sentience. The first workshop would be organised for the first quarter of 2021, with the second workshop occurring later in the year.
 - iii The format of the first workshop had been agreed as:
 - a. Overview of the current status of the work and likely future advances.
 - b. Discussion of the likelihood of sentience, consciousness or suffering arising in such studies
 - c. Ethical discussion and current regulation.
 - iv The SG had agreed on a preliminary list of invitees, with one attendee being invited from each relevant specialisation. The SG would also ask an attendee to Chair each of the topics.
 - v The outputs from this workshop would be:
 - a. Guidance for ASRU on issues or question to ask applicants to help make an assessment on the justification of proposed projects.

- b. A report for a wider stakeholder group.

9. AOB

9.1. Laboratory of Pharmacology and Technology (Germany)

- 9.1.1. An ASC Member updated the Committee on the German Laboratory that was closed by the competent authority last year due to serious issues relating to non-compliance and serious animal welfare breaches. The establishment had since been reopened, apparently under different management.

Annex A

Animals in Science Committee Members

Dr David Main (Chair)

Mrs Wendy Jarrett

Professor Stephen May

Dr Donald Bruce

Dr Virginia Warren

Professor Christine Watson

Dr Sally Robinson

Mr Barney Reed

Professor Clare Stanford

Mrs Susan Sparrow

Professor Andrew Jackson

Professor Johanna Gibson

ASRU

Mr William Reynolds (Head of Unit, ASRU)

Dr Giles Paiba (Head of Policy, ASRU)

Dr Finn Lonsdale (Inspector, ASRU)

Science Secretariat

Mrs Caroline Wheeler (ASC Secretary)

Ms Jessica Daly (ASC Secretariat)