

Animals in Science Committee

Minutes of the 20th Meeting: 17th September 2018

1.0 Welcome, Introductions and Conflicts of Interest

- 1.1 The Chair welcomed attendees to the 20th meeting of the Animals in Science Committee (ASC).
- 1.2 Dr Gerlinda Stoddart and Dr Sally Robinson joined the meeting via teleconference. Apologies were received from Dr Joanne Wallace. A full list of attendees is provided at Annex A.

2.0 Chairs Update

2.1 Minutes and Actions from the last ASC Meeting

- 2.1.1 Minutes of the last meeting had been agreed and published on the ASC website.
- 2.1.2 Actions were complete with the following exceptions which were in progress:

'Action 6: Non-Human Primate Welfare Assessment subgroup Chairs to finalise co-optee letters and send to recipients.;

'Action 12: ASRU to circulate data on processing times for personal project licences to ASC members'

'Action 14: ASRU to share the updated Animals in Scientific Procedures Act A(SP)A (reflecting the United Kingdom's exit from the EU) with ASC, once drafting has been complete.'

2.2 Research Excellence Framework 2021

- 2.2.1 The Chair thanked the Subgroup Chairs for providing an initial assessment of the Research Excellence Framework 2021 consultation. The committee agreed that the ASC would form a Task and Finish subgroup to submit a full response.
- 2.2.2 Members of the Subgroup offered to be co-optees on the subgroup.

Action 1: ASC to form a Task and Finish Group to prepare and submit a full response to the REF 2021.

2.3 Annual Meeting with the Royal Society of Biology Animals Science Group

2.3.1 The Chair informed members that the Royal Society of Biology Animals in Science Group (ASG) had extended an invitation for the annual meeting between the Chair of the ASC and the Chair of the ASG. The Chair invited members to send him any topics or issues they wished raised in the meeting.

2.4 Statutory Instrument (The Animals (Scientific Procedures) Act 1986 (A(SP)A, EU Exit)

2.4.1 The Chair updated the Committee on discussions with ASRU regarding wording in the Statutory Instrument which will remove references to the EU in A(SP)A.

2.5 Harm Benefit Analysis (HBA)

2.5.1 It was noted that a formal response to the ASC's '*Review of Harm-Benefit Analysis in the use of animals in research*' report had yet to be received following the ASC having written to the Secretary of State¹ on 24 May 2018 setting out those recommendations for ASRU to action. ASRU agreed to send a formal response to the ASC.

Action 2: ASRU to send a formal response to the ASC in respect of the recommendations set out in the ASC's letter to the Secretary of State (24 May 2018).

3.0 Animals in Science Regulation Unit (ASRU) Updates

3.1 Recruitment

3.1.1 ASRU informed the ASC that both the Head of Unit role and Chief Inspector role would shortly be advertised as Senior Civil Servant roles.

3.2 EU Exit

3.2.1 ASRU informed the ASC that the unit had been preparing for the exit from the EU by considering the legislative changes to A(SP)A. When completed, this would be shared with Committee members.

3.3 Meeting with Dutch counterparts

3.3.1 ASRU's policy team had met their equivalent Dutch policy officials to exchange information on promoting the 3Rs.

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3.3.2 The Dutch championed and promoted non-animal alternative technologies and were working towards a future with no animal testing through the use of animal-free innovations.

3.3.3 Dutch officials reported similar issues to those in the UK, regarding timings of the project licence evaluation system. ASRU would continue to review the project evaluation process.

Action 3: ASRU to put CSR Subgroup chair in contact with Dutch policy officials for input re comparative regulation.

3.4 Memorandum of Understanding – NC3Rs

3.4.1 ASRU and the NC3Rs had developed and signed a Memorandum of Understanding (MOU) with a mandate to improve collaboration between both parties. The MOU formalised the relationship between ASRU and the NC3Rs and set out high level principles to ensure end-users were informed of the latest 3Rs developments.

3.4.2 The MOU allowed for feedback on 3R's techniques, including those in use and in development.

3.4.3 In fulfilment of the MoU ASRU reported that:

- NC3Rs funded scientists would begin to attend ASRU conferences to share information directly with Inspectors;
- NC3Rs would identify 3Rs advances, opportunities and priorities, and communicate these to ASRU;
- The NC3Rs and ASRU's Chief Inspector would assess current priorities for Inspector training.

3.4.3 ASRU reported that they had applied for resource to work directly on the 3Rs.

3.5 Non-Technical Summaries (NTS)

3.5.1 ASRU had bid for funding from the Regulators' Pioneer Fund to build a searchable NTS database which would be an addition to the new Animal Scientific Procedures E-Licensing (ASPeL) system.

3.5.2 Members noted the potential for automatic integration of the NTS database to allow for data mining and agreed to share references regarding this system with ASRU. Members agreed to be points of contact for the developers regarding the searchable NTS database should ASRU be successful in gaining the funding.

Action 4: ASC members to share references on automatic integration with ASRU.

Action 5: ASC members to provide advice to ASRU during the development of the searchable NTS database.

3.6 Update on Freedom of Information Requests (Fols) and Parliamentary Questions (PQs)

3.6.1 Members were provided with a list of Fols and PQs received by ASRU since the ASC's last plenary meeting.

4.0 Project Licence Application subgroup

4.1 Feedback was provided by members on two project licence applications that had been reviewed since the last ASC plenary meeting.

5.0 AWERB Subgroup Update

5.1 ASC AWERB Road Shows

5.1.1 The AWERB subgroup had organised two ASC AWERB Road Shows, one to be held in the South and one in the North of the UK. All AWERB members had been invited to attend one of the Road Shows.

5.1.2 Committee members discussed additional ways of promoting the ASC AWERB Road Show workshops. Members attending the forthcoming RSPCA Scottish lay members workshop agreed to circulate the ASC AWERB Road Show agenda. Members also agreed that the Road Show agenda should be added to the ASC website.

Action 6: Members agreed to promote the ASC AWERB Road Show at the RSPCA lay members workshop.

5.2 Knowledge Hub

5.2.1 At the March 2018 AWERB Hub workshop, attendees raised the importance of facilitating wider communication between AWERBs, beyond the regional AWERB Network, so that those with similar foci and needs could discuss and share ideas. Consequently, the AWERB subgroup had developed an online platform called the AWERB Knowledge Hub Group, which all AWERB members would be invited to join. This community would allow members of AWERBs to effectively talk to each other on forums, share ideas, collaborate on shared documents, upload relevant materials to the library and promote upcoming events.

5.2.2 The ASC had undertaken a soft launch of the AWERB Knowledge Hub Group and had gathered feedback to make improvements to the Group ahead of the full launch at the ASC AWERB Road Shows.

Action 7: Secretariat to forward joining details for the AWERB Knowledge Hub Group to all ASC members.

5.3 Hub Restructure

- 5.3.1 The March 2018 AWERB Hub workshop had also raised the possibility of a limited restructure of the AWERB Regional Hub Network. The AWERB subgroup would discuss the Hub restructure at their next meeting.

6.0 Task and Finish Subgroup Update

6.1 Non-Human Primate Welfare Assessment (NHPWA) subgroup

- 6.1.1. The Subgroup Chairs reported that the subgroup terms of references had been agreed with ASRU. The next steps would be to send letters to co-optees.

Action 8: NHPWA subgroup Chairs to send out co-optee letters.

6.2 Comparative Study of Regulation (CSR) subgroup

6.2.1 Directive 2010/63 EU Survey

- I. The CSR subgroup had drafted a response to Section 2 of the EU Directive survey on the questions that related directly to the role of EU member states' national committees. Members' comments from the previous ASC meeting had been incorporated into the draft. The Chair of the CSR subgroup discussed the final comments with the full Committee ahead of submission.

Action 9: CSR Chair to send full ASC EU survey response to ASRU.

Action 10: Secretariat to explore whether diagrams can be included in the EU survey response.

- II. Members noted that the ASC's responses to both recent REF consultations should be included in the 'key achievements' section of the survey. The ASC's earlier contribution resulted in the inclusion of animal research as a topic of assessment for the REF. The ASC's contribution to the REF 2021 will build on this. In addition, members agreed that, once published, the Nuffield Bioethics Consultation response should also be added as a key achievement.

Action 11: CSR Chair to include the response to REF consultation and Nuffield Bioethics consultation in the 'key achievements' section of the EU survey.

- III. The ASC agreed that, following these agreed final actions, the draft for Section 2 could be submitted to ASRU for incorporation in the full survey response.

6.2.2 Update on Scope of CSR Work Stream

- I. The Subgroup Chair reported that the remit of the project had been focussed down into two areas: i) exploring the processes in which project licence applications are evaluated in both EU and non-EU countries, and ii) considering how regulatory systems operate in different contexts within the UK, and if good practice in these could usefully be applied to the regulation of animal-use in science.
- II. The CSR Chair reported on a useful teleconference with ASRU's Chief Inspector, where they explored other appropriate regulatory systems that could be considered as part of the study, given ASRU's unique role. It was concluded that it could be useful to investigate the role of 'ratings' in these regulatory systems, why they are used and what they achieve.
- III. Members discussed the wider use of incentive schemes by other UK regulatory systems and how these motivate good behaviour while also providing accountability for bad behaviour. It was felt that an exploration of the use of incentives would be more useful than a review of official ratings schemes.
- IV. The Subgroup Chair asked whether members would agree to her taking on a Masters student or an intern to aid in the evidence gathering for the subgroup. Members agreed that a student or intern could be co-opted onto the subgroup provided they were aware of confidentiality protocols.

6.3 **Licence Review subgroup**

- 6.3.1 The Subgroup Chair reported that the subgroup had received the licences from ASRU and could begin the review. Members agreed that the licences selected included an appropriate range and number of protocols with different classifications.
- 6.3.2 It was also noted the review would benefit from the inclusion of a general regulatory toxicology licence. The Subgroup Chair agreed and would seek such a licence from ASRU.

Action 12: Secretariat to contact ASRU to request an additional licence in toxicology.

- 6.3.3 An additional member agreed to be co-opted onto the subgroup to help with the assessment of non-technical summaries.

Action 13: Secretariat to send project licences to Subgroup for review.

6.3.4 The Committee also suggested reviewing whether there was any evidence that the benefits identified in the licences were being scaled according to the severity of the licence, i.e. the higher the severity of the protocol the more benefits claimed. The subgroup agreed to consider whether as severity increased, benefits also increased in scale but noted that these judgements would be difficult to (semi) quantify in practice.

6.4 Nuffield Consultation on Bioethics in Global Emergencies

6.4.1 The Subgroup Chair reported that the response to the Nuffield call for evidence on Bioethics in Global Emergencies had been submitted. She noted that she had found no references in the consultation regarding the application of ethics to, or consideration of the welfare of, animals used as part of the research response to global emergencies. Therefore, it was imperative to highlight the importance of animal welfare in scientific research.

6.4.2 She also noted that there were uncertainties surrounding the harm-benefit analysis applied to the use of animals in research in the context of a global health emergency. Therefore, the ASC response outlined the importance of the harm-benefit analysis to mitigate harms and ensure meaningful benefits. The subgroup had also included a discussion on accelerated practice in drug development during global health emergencies and reflected on the implications for animal use, for example the potential for increased use in primates when moving directly from pre-clinical research to application in humans.

6.4.3 The Chair thanked the subgroup for their work in responding to the consultation in a short time frame.

7.0 Chairs Update

7.1 Members noted the commissioning letter from the Minister outlining the commission of work for the ASC for the next 18 months.

8.0 AOB

8.1 The Committee was reminded that the date of the next meeting was the 11th December 2018.

Annex 1

Animals in Science Committee (ASC)

Dr John Landers (Chair)

Mrs Wendy Jarrett

Dr Donald Bruce

Dr Hannah Clarke

Prof Gail Davies

Dr Sally Robinson

Mrs Anna Rowland

Prof Clare Stanford

Dr Aurelie Thomas

Mr Ken Applebee

Dr Gilly Stoddart

Mr Barney Reed

Prof Malcolm Macleod

Observers

Will Reynolds (Head of Unit, ASRU)

Dr Kate Chandler (Head of Policy, ASRU)

Victoria Wheeler (Policy Development Officer, ASRU)

ASC Science Secretariat

Caroline Wheeler (ASC Secretary)

Laura Zagarella (ASC Secretariat)

Annex B

Action Table

ASC 20 1	ASC to form a Task and Finish Group to prepare and submit a full response to the REF 2021.
ASC 20 2	ASRU to send a formal response to the ASC in respect of the recommendations set out in the ASC's letter to the Secretary of State (24 May 2018).
ASC 20 3	ASRU to put CSR Subgroup chair in contact with Dutch policy officials for input re comparative regulation.
ASC 20 4	ASC members to share references on automatic integration with ASRU.
ASC 20 5	ASC members to provide advice to ASRU during the development of the searchable NTS database.
ASC 20 6	Members agreed to promote the ASC AWERB Road Show at the RSPCA lay members workshop.
ASC 20 7	Secretariat to forward joining details for the AWERB Knowledge Hub Group to all ASC members.
ASC 20 8	NHPWA subgroup Chairs to send out co-optee letters.
ASC 20 9	CSR Chair to send full ASC EU survey response to ASRU.
ASC 20 10	Secretariat to explore whether diagrams can be included into the EU survey response.
ASC 20 11	CSR Chair to include the response to REF consultation and Nuffield Bioethics consultation in the 'key achievements' section of the EU survey.
ASC 20 12	Secretariat to contact ASRU to request an additional licence in toxicology.
ASC 20 13	Secretariat to send project licences to Subgroup for review.