

# **Animals in Science Committee**

## **Minutes of the 30th meeting: 1 March 2021**

### **1. Welcome, introductions and conflicts of interest**

- 1.1. The Chair welcomed attendees to the thirtieth meeting of the Animals in Science Committee (ASC), which took place via video conference.
- 1.2. Apologies were received from Hannah Clarke. The list of attendees is attached at Annex A.

### **2. Minutes and actions from the previous ASC meeting**

- 2.1. Minutes from the previous 2 meetings were with the Animals in Science Regulation Unit (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. An ad hoc meeting of ASC members to discuss and compare how some of the ethical and practical issues associated with the use of animals in research are considered within the regulatory system overseeing research involving humans. This action was postponed until late spring.
  - 2.2.2. An ad hoc meeting relating to recent developments in non-animal alternative approaches and methods. This topic had been added to the Project Licence Strategic Review work programme.
  - 2.2.3. ASC Chair to lead a Task and Finish Group to discuss ASC wider strategic advisory role.

### **3. Chair's update**

#### **3.1. Welcome to Linda Horan**

- 3.1.1. The Chair welcomed Linda Horan as a co-opted member to the ASC.

#### **3.2. Introductory meeting with the new Chief Scientific Advisor (CSA) Professor Jennifer Rubin**

- 3.2.1. The Chair advised the committee that he had met with Professor Rubin on 5 February to discuss the work of the ASC, ASRU's Change programme and the initiative 'Leadership in animals in science beyond regulation'.
- 3.2.2. Following this the Chair had written to Professor Rubin to provide further details outlining the issues surrounding the 'Leadership in animals in science' work. This and Professor Rubin's response had been circulated to ASC members.

#### **3.3. Leadership in animals in science beyond regulation**

- 3.3.1. The Chair advised the ASC that following the discussion with the CSA and further engagement with ASRU, it had been agreed that

more work to better understand the issues underpinning the 'Leadership in animals in science' initiative was required.

- 3.3.2. The ASC were informed that ASRU had agreed to specify, in the scope of their Change programme, the need to clarify the understanding of oversight/co-ordination of animals in science policy beyond compliance with regulation - both within ASRU and also other government departments.
- 3.3.3. The Chair confirmed he would discuss this with NC3Rs due to the potential affects this could have on the planning of the future joint ASC/NC3Rs workshop.
- 3.3.4. The Committee discussed the issues involved in developing the programme of work and agreed that although complex, this is important to pursue as there is currently no co-ordinated strategy or overall policy lead amongst the different government departments that all have their own responsibilities relating to Animals in Science.

**Action: ASRU to provide ASC with a paper summarising the responsibilities of the regulator within the animals in science policy area, which the ASC can use to help identify policy gaps.**

#### **3.4. Annual meeting with the Royal Society of Biology**

- 3.4.1. The Chair informed the committee that he met with Professor Dominic Wells from Royal Society of Biology (RSB). This meeting was held annually to enable sharing of information between the RSB Animal Science Group (ASG), which Professor Wells chairs, and the ASC. Topics discussed included:
  - i ASC and ASG priorities
  - ii COVID-19 impact.
  - iii Brexit and future UK/EU.
  - iv Horizon Scanning and futures 'emerging themes'.

#### **3.5. Meeting with Helmut Ehall (Chair, Establishment Licence Holders Committee)**

- 3.5.1. The Chair advised the ASC that he and Professor Robinson had met with Helmut Ehall in advance of the Chair attending an Establishment Licence Holders (ELH) meeting. Topics discussed included the issue of 'Leadership in animals in science beyond regulation'.

#### **3.6. Northern Ireland**

- 3.6.1. The Chair invited ASRU to update members on issues around the administration of the Animals (Scientific Procedures) Act 1986 (ASPA) in Northern Ireland (NI) and potential implications for the role of the ASC.
- 3.6.2. ASPA is regulated in mainland GB by ASRU but ASRU does not regulate ASPA in NI. Regulation in NI is via the Department of Health in the Devolved Administration. NI is also not part of ASPeL system, and instead maintains a separate licencing system.

- 3.6.3. ASPA is a UK Act and the ASC had been constituted under that UK Act. There is presently not clarity in guidance on the implementation of ASPA and the role and responsibility of the ASC to advise the NI Executive.
- 3.6.4. ASRU advised they would provide further information to the ASC on the position.

**Action: ASRU to provide further information on the framework in relation to extent/responsibility of the ASC to provide advice to the Northern Ireland Devolved Administration.**

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

### **4.1. ASRU Presentation on Change programme and ASC metric commission**

- 4.1.1. ASRU have used 'critical to quality' feedback to further clarify their purpose and strategic intent. ASRU advised the committee on the process they are using to decide on the metrics that will be used.
- 4.1.2. ASRU will be focusing on developing outcome metrics based on compliance. It had been agreed with the minister that the ASC should have input with regards to which outcome metrics should be included.
- 4.1.3. Committee members were concerned that by focussing on compliance metrics it would miss some important performance metrics, including measuring the overall experience of the animals.
- 4.1.4. The Chair and ASRU had agreed to establish a working group to develop a set of metrics as outputs for the ASRU metrics commission. However, the Chair required that ahead of this all ASC members should have an opportunity to provide views on the metrics commission.
- 4.1.5. ASRU provided the committee with an update on revisions made to their Change programme and the benefits they expect from this direction of change.
- 4.1.6. The committee discussed with ASRU the new processes for the development of policy and whether the ASC would be involved, or have sight of, draft policy. ASRU advised that this would likely be on a case-by-case basis, dependent on the degree of substantive changes involved.

**Action: Chair and ASRU to agree a mechanism to collate views from ASC members to feed into the ASC metrics commission.**

**Action: ASC /ASRU to form a working group to develop a set of metrics as outputs for the ASC metrics commission.**

### **4.2. ASRU advised they would provide written updates on:**

- i Brexit – border disruption (impact on movement of animals and equipment)

- ii Brexit – regulation of chemicals following UK departure from REACH (use of animals in testing). With the focus being on access and use of the [Comply with UK REACH](#) webpages.
- iii Implications of the European Chemicals Agency (ECHA) policy relating to testing using animals under REACH legislation of substances which, at the time of testing, were expected to be used solely in cosmetics products; and of ECVAM's recommendations relating to the use of animals (or non-animal approaches) in the development and production of antibodies.

**Action: ASRU to provide an update to the ASC on: Brexit – border disruption (impact on movement of animals and equipment), Brexit – regulation of chemicals following UK departure from REACH (use of animals in testing).**

**Action: ASRU to provide an update to the ASC on ECHA Cosmetics and NAA Antibodies following their review within the context of the ASRU change programme.**

#### **4.3. Animal Husbandry – definition of scientific purpose**

- 4.3.1. The ASC previously discussed developing a definition of scientific purpose to assess the use of recognised animal husbandry and where this may intersect with ASPA to ensure institutions are in compliance with ASPA. The recent DEFRA consultation on regulation of genetic editing had further highlighted the need for a definition.
- 4.3.2. ASRU agreed to incorporate this into their Change programme with priority consideration.

**Action: ASRU to provide a definition of scientific purpose as part of the Change programme as one of the initial outputs.**

### **5. Department for Environment, Food & Rural Affairs (DEFRA) Consultation on the regulation of genetic technologies**

**5.1.** ASC members attended an ad hoc meeting in February to discuss drafting a response from the ASC to the DEFRA consultation on 'The Regulation of Genetic Technologies'. The first draft of the response had been circulated to the Committee ahead of the plenary.

**5.2.** Members noted the following points:

- i The Defra document was missing a key definition/scope of what constitutes 'traditional breeding', and neither did it set out a clear definition of gene editing (GE).
- ii That it would have been advisable not to have covered plant organisms and animal organisms in the same consultation.
- iii That the ASC response should restrict itself to issues directly relevant to regulation.
- iv That despite the statement 'These questions do not apply to the use of genetic technologies in contained conditions i.e. laboratories' – all gene editing of animals is initially experimental by its nature, and as

such must be regulated by ASPA. If, following the consultation, it became government policy to allow a wider application of gene editing technologies using animals, ASRU would need clarity from DEFRA on how to implement appropriate regulation of this.

- v The consultation referred only to the current regulations on genetically modified organism (GMO) and did not refer to any new regulatory structures relating to gene editing.

**5.3.** In the absence in the consultation of proposals for a framework of regulation specific to genetic editing, and whilst noting that the membership of the ASC was not expert in this scientific field, the majority of the committee were of the opinion they should respond to the consultation question “Currently, organisms developed using genetic technologies such as GE are regulated as GMOs even if their genetic change(s) could have been produced through traditional breeding. Do you agree with this?” with ‘Yes – they should continue to be regulated as a GMO’.

**5.4.** ASC member Dr Donald Bruce did not agree with this response and requested that this be formally noted in the ASC minutes.

**5.5.** Otherwise all ASC members were in agreement with the remaining responses to the consultation questions and were content for the response to be recirculated via email for final ratification following the addition of the changes discussed.

**Action: Secretariat to include a sentence in the ASC response to the DEFRA consultation on the regulation of genetic editing to note that a single member of the ASC disagreed with responding ‘Yes – they should continue to be regulated as a GMO’. To also note that all Committee members agreed with the supporting text accompanying that answer.**

**Action: Secretariat to circulate draft ASC response to the DEFRA consultation on the regulation of genetic editing to ASC members for comment/views. ASC members to send comments to Secretariat.**

## **6. AWERB subgroup update**

### **6.1. Hub Chair workshop**

6.1.1. The AWERB SG Chair welcomed Linda Horan to the subgroup and updated the committee on the Hub Chair workshop report. The Hub Chairs workshop took place on the 21 October and the report had now been finalised, ASC members were invited to review, comment and if content, to ratify the report.

6.1.2. Once ratified the report would be circulated to attendees, published on the ASC GOV.UK website and posted on the AWERB knowledge hub. The presentations from the day would also be added to the knowledge hub.

6.1.3. A feedback questionnaire had been circulated to all the attendees with a response deadline of 28 February.

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

### 6.3. Support note

- 6.3.1. The subgroup had reviewed and updated the Hub Chair support note. This included an updated Hub Map. ASC members were invited to review, comment and if content to ratify.
- 6.3.2. Once ratified the support note would be circulated to AWERB Hub Chairs, published on the ASC website and posted on the AWERB knowledge hub.

**Action: Secretariat to prepare the ASC AWERB SG support note and Hub Chair workshop report for publication.**

### 6.4. Non-technical summary guidance

- 6.4.1. Following the publication of the ASC Licence Analysis Review report, members of the subgroup had produced guidance for AWERBs on improving the quality of NTSs.
- 6.4.2. The Chair requested a further draft of the guidance be ready and circulated ahead of the next plenary meeting in May.

**Action: Secretariat to collate comments on the NTS draft and send to subgroup.**

**Action: Subgroup to prepare a further draft of the NTS guidance for AWERBs for the next ASC meeting.**

### 6.5. Newsletter

- 6.5.1. The AWERB SG would publish the Hub newsletter in the first quarter of 2021. Topics would include:
  - i A summary of the Hub Chair's workshop
  - ii A short summary of the AWERB relevant recommendations contained in the ASC's report on the Harm Benefit Analysis
  - iii Updates on current work in progress
  - iv Links to recent publications such as the Licence Analysis report

## 7. Project Licence Strategic Review standing subgroup

- 7.1. The Project Licence Strategic Review (PLSR) subgroup has been created in response to the ministerial commission of work for 2020/21. A paper detailing the terms of reference and the intended initial work programme were circulated ahead of the plenary meeting.

### 7.2. Terms of reference (TOR)

- 7.2.1. Following discussion at the December plenary, the TORs for the PLSR have been amended to reflect the standalone nature of the SG. The committee ratified the amendments and agreed they could now be published to the GOV.UK website.

**Action: Secretariat to amend Subgroups' TORs for publication on the ASC website**

### 7.3. Work programme

- 7.3.1. SG members had their initial meeting on 16 February, with the following topics being proposed for their initial work programme, with the group looking for observations relating to authorised licences involving:
  - i Non-human primate (NHP) use in regulatory testing.
  - ii The use of animals in antibody development and production.
  - iii Use of the forced swim test.
- 7.3.2. The PLSR SG Chair welcomed views from the committee on the appropriateness/relevance of these topics, as well as views from ASRU on the prioritisation that would be of most use to ASRU's work priorities.
- 7.3.3. ASRU requested the SG write to them to request their views on the prioritisation of the above topics. The SG Chair also identified the need for a mechanism to access relevant project licences.
- 7.3.4. The SG Chair advised that following completion of the first topic, the SG would undertake an exercise to assess the review processes used with outputs informing the next review.

**Action: Project Licence Strategic Review group to write to ASRU to invite their views on the prioritisation of the three initial topics for review.**

**Action: ASRU and Secretariat to discuss methods to provide access to the required project licences for review as part of the Project Licence Strategic Review group's work programme.**

## 8. Task and finish groups

### 8.1. Futures Capability Working Group (FWG)

- 8.1.1. The ASC were provided with a written update ahead of the meeting which was then summarised by the SG Chair.
- 8.1.2. During December 2020, the Chair wrote to 48 organisations inviting them to contribute to the 'Futures' evidence base by submitting one or more horizon scans on a topic/s of their choice which they thought could have "potential to have an impact upon, or be affected by, the use of animals in research", additionally recipients were also invited to nominate a colleague to participate in a 7-questions exercise.
- 8.1.3. By the end of February, the Secretariat had received positive responses from 25 organisations who had submitted over 40 scans, with 11 interviews carried out and several yet to be arranged.
- 8.1.4. Next steps would include summarising the key points raised in the horizon scans and, separately, preparation of an issues paper summarising the key points emerging from the 7-questions interviews. These summaries would inform the FWG plan for the workshop.
- 8.1.5. The FWG workshop had been scheduled for the second half of July 2021. The workshop would invite attendees to analyse the issues

and trends emerging from the horizon scans and interviews forming the evidence base. The outputs of the workshop would be used to aid the FWG in preparing a report with advice/recommendations to ASRU and identify the next stages of the work programme.

## **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 also provided with a written update ahead of the meeting.
- 8.2.2. The BORSG SG met in February to finalise the workshop arrangements. The workshop will be held virtually on 20 or 22 April and formal invitations had been sent out, including a request for the attendee's preferred date.
- 8.2.3. Speakers and attendees had also been invited to outline their considered description/definition of sentience and consciousness with responses being collaged for discussion at the workshop and outputs used to assist in developing a working definition for the report.
- 8.2.4. The SG Chair invited ASC members to join the workshop as observers and welcomed any further suggestions.

**Action: Secretariat to send an invite to ASC members to join and observe the BORSG and Futures workshops.**

## **9. AOB**

### **9.1. Maintaining ongoing contact between ASC and EU National Committees**

- 9.1.1. The ASC had had no contact with the EU commission since April 2020, as the National Committees meeting had been cancelled due to COVID-19.
- 9.1.2. ASC members felt that it was important to continue with a global outlook including, where possible and appropriate, maintaining relevant European contacts.



## **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

Ms Linda Horan (co-optee)

### ASRU

Mr William Reynolds (Head of Unit, ASRU)

Dr Giles Paiba (Head of Policy, ASRU)

Dr Finnuala Lonsdale

### Science Secretariat

Mrs Caroline Wheeler (ASC Secretary)

Ms Jessica Daly (ASC Secretariat)