

## Gene Editing Working Group

25<sup>th</sup> January 2024, 3pm on MS Teams

### Attendees:

Madeleine Campbell, Chair  
Rose Jackson, BCVA  
Dominic Wells, Professor of Translational Medicine, RVC  
Emily Craven, AWC  
Justine Shotton, Vet Sustain Board  
Fran Fletcher, Breeding and Genetic Technologies, Animal Welfare Team, Defra  
Gideon Winward, Head of Policy, Animals in Science Regulation Policy Unit, Home Office

### BVA:

Anna Judson BVA JVP  
Amelia Findon – Director of Policy and Governance  
Ali Ramsay – Head of Policy and Public Affairs  
Hannah Killeen – Policy and Public Affairs Officer

### Apologies:

Richard Piercy, Professor of Comparative Neuromuscular Disease, RVC  
Polly Compston, BVA Policy Committee  
Fritha Langford, BVA EWAP

## Minutes and Matters Arising

1. The minutes of the October meeting were agreed without amendment.

## Update from Defra and the Home Office

2. Fran Fletcher from the Defra Animal Welfare Team updated the group on the proposals for authorising and regulating gene edited animals for commercial use. The detail is covered in the slide pack which has been circulated to the working group.
3. She noted that the team is currently reviewing the recommendations from a study commissioned by DEFRA from SRUC on welfare assessment methodology. They are also due to publish an evidence review carried out by Queen's Belfast this spring. The next steps are to work out the detail of the welfare advisory body, which will review all applications for marketing authorisations, and to consider mechanisms for post-market reporting on welfare.
4. In response to a question, she clarified that marketing authorisations would have to be approved before the animal was released from ASPA – or prior to import if it had been developed overseas.
5. Gideon Winward, from the Home Office Animals in Science Regulation Policy Unit, spoke about the link between ASPA and the new legislation, and how animals developed in labs would be transferred from the scientific regulatory regime to the new commercial one. He noted that there has previously been no mechanism for “releasing” an animal from ASPA. He said the three big questions are:
  - Permissible purposes – ASPA will be a constraint on using gene editing to create “designer pets” for example.
  - The mechanism for releasing an animal from ASPA to market.
  - The point at which you have confidence in long-term welfare, and no longer need to consider it an experimental scientific procedure.

6. He was clear that the process between the two sets of legislation needed to be joined up, and to follow a logical flow at the point of transfer.
7. On current timeframes, proposals for guidance and secondary legislation are due to be worked up later this year.

### **Regulatory Issues**

8. The Precision Breeding Act applies only to England, which raises multiple questions relating to the devolved nations. Once gene edited animals are released into the market, how can they be traced, and kept out of Wales, Scotland, and Northern Ireland where gene-editing is not legal. This poses potential issues for cross-border holdings, movements to abattoirs in devolved nations, and preventing the sale of gene-edited meat outside England. The Livestock Information Service would be one possible means of marking animals as precision bred. A genetic marker is not an option as this would introduce foreign DNA, which is expressly forbidden by the Precision Breeding Act. Concerns were also raised about the lack of labelling requirements, making traceability more difficult.
9. Another element of traceability is for how many generations an animal's progeny should be considered gene-edited. Defra are considering this issue as part of their research. This becomes yet more complicated when considering imported animals, and animals that are cross-bred with conventionally-bred animals. The group agreed to invite an FSA representative to the next meeting to discuss some of these questions.
10. Traceability will also be important for reporting of adverse outcomes for health and welfare after the animal has come to market, and potentially in subsequent generations. It was suggested that the regulations for the reporting of adverse effects of medications may provide some sort of precedent. Vets will be a key source on information in this process, as well as in the health and welfare assessment during the application for a marketing authorisation.
11. Questions were raised about animals developed overseas and then imported as commercial stock. Other countries may have less rigorous standards than ours, leading to a commercial incentive to develop the animals in lower welfare systems and then import them to the UK. Defra have considered this, and will require evidence for the marketing authorisation to be equal to that required from UK laboratories.

### **Review of Workplan and Themes Document**

12. Following the questions raised about traceability, it was agreed to invite an FSA representative to the next meeting to hear their thinking.
13. In line with the work plan, it was agreed that the next meeting should also look more closely into issues relating to the gene editing of fish.
14. It may also be helpful to speak to a plant geneticist, and also a virologist to find out how the process is developing in those fields.
15. It was agreed to plan a further meeting towards the end of March.

### **Any Other Business**

16. None raised.