European Animal Research Association

European Animal Research Association Brexit Taskforce

Potential implications for animal science in the UK and EU stemming from Brexit

This briefing raises areas of concern on the potential impact of Brexit on animal science and drug innovation for the development of human and veterinary medicines. We highlight issues in the UK/EU connected to:

- The import and export of live purpose-bred research animals, biological materials derived from research animals and other equipment and supplies essential for animal science
- The regulatory framework governing animal research
- The ability to attract research talent and safeguard R&D investment

TRANSPORTATION. Much attention has focused on the unresolved consequences for UK-based research and development of human and veterinary medicines in the UK following the UK's exit from the EU. Critical to the continuing success of this sector will be the timely and efficient transport, to and from the UK, of purpose-bred research animals (including frozen embryos and sperm), biological samples from research animals, medical and pharmaceutical supplies, plus supplies of specialized animal feed and research diets.

1. Live Research Animals. Without the ability to move research animals from one country or continent to another, or from a breeder to a research institution, crucial scientific research seeking new treatments may be disrupted. Purpose-bred animals (including fish and amphibians) sourced from unique breeding facilities, and which are exported from and imported into the UK, often possess specialised anatomical, genetic and physiological features. Such global partnerships enable researchers in the UK to share genetically unique strains and species and to enhance scientific collaboration. They also reduce the potential risk of over-breeding commonly used strains.

Under the current policy restrictions of airlines, handling agents and airports in the UK on the transportation and handling of specific research animals (dogs, NHPs and mini-pigs) for biomedical research, the sector is unable to use scheduled passenger or cargo airlines to bring those species into the UK. Consequently, imports into the UK have first to land at an EU international airport. Here, they are processed by the EU Border Inspection Post (BIP). Once cleared by the BIP and customs checks, they are accepted into the EU customs union and are able to be shipped into the UK without the need to pass through a BIP in the UK. Post Brexit, the BIPs in the EU would no longer have the responsibility to carry out the current checks to ensure that EU import conditions have been met, since the animals are only 'transiting' the EU airport. However, such animals will still need to pass through the EU BIPs – but remain in a 'bonded area' pending their transhipment to the UK. Any increase to transport times would in addition have a negative effect on animal welfare. Handling costs for this process will still apply.

Therefore, we wish to see:

- UK airports permit the landing of research animals, so that the necessary checks on health and compliance with UK import regulations can be performed. We require a timely decision over the future position and operation of BIPs in the UK to determine if suitable DEFRA-approved BIPs can be found and that they will handle our imports.
- The feasibility of live research animals, if transiting into and out of Europe through Paris, being 'bonded' - potentially at CDG Paris – be explored. It is imperative that such imports from EU states into the UK, as well as UK exports of these animals to EU member states, can be entered into the TRACES online system. Should the UK lose access to TRACES then the smooth transit of laboratory animals and related products into and across the EU will be seriously impaired.
- Continuing recognition and acceptance by the UK of Council Directive 92/65/EEC (Balai Directive) to support imports to the UK from the EU27; registration of the UK on the existing EU approved third countries list under the Balai Directive, thus reducing the potential imposition of damaging licence costs and customs duties.
- The movement of products and items required for drug development should be ensured via comprehensive regulatory co-operation and/or mutual recognition agreements with the EU.
- Governmental support to encourage service providers to transport live research animals directly to and from the UK to reduce transport time and thus improve animal welfare.
- Special requirements and consideration of the valuable contribution of non-human primates (NHPs), dogs and minipigs to science are also needed to ensure speedy transit into the UK. These movements should be facilitated and not subject to any additional bureaucracy.
- Elimination of the EU's stricter measures for implementing CITES so that only an export permit is required in the post-Brexit period for the import of CITES Appendix II species such as NHPs and NHP samples into the UK for biomedical research in compliance with CITES Article IV.

2. Biological Samples: Currently, there are no restrictions on the movement of biological samples (i.e. tissues, blood samples and other histopathological samples) from NHPs and other animals within the EU. Neither are there any regulatory approvals that must be obtained. At the point when the UK becomes a third country vis-à-vis the outside EU, and in the absence of any transitional or co-operation arrangement, movements of samples would require compliance with customs formalities and export health certificates (EHCs) for each individual shipment for all animal species, and the issuance of several CITES permits for samples from NHPs.

We seek:

- A system to be established for simplified procedures for the import and export of biological samples from research animals.
- Governmental support to ensure the options to transport samples to and from the UK to reduce transport time.
- Action taken by the UK to reduce the regulatory burden, including the use of simplified procedures and electronic permitting for CITES and possible facilitations for Authorised Economic Operators (AEOs).

REGULATION. A future relationship between the UK and the EU must be built on mutual recognition acknowledgement, as access to medicines and the safety and well-being of human and veterinary

patients across Europe are in the interests of all parties. If this is to be achieved, continued collaboration in research and development, regulatory co-operation, and information sharing is essential. In addition, EU Directive 2010/63 provides important and internationally regarded safeguards for animal welfare in research. The Directive also provides a level regulatory playing field for trade across the EU.

Continuity and certainty is critical for the present period and harmonization with the EU remains important. Consideration of any potential amendments to the UK Animals (Scientific Procedures) Act 1986 (ASPA) should be delayed at least until such time as further information on the success of the implementation of the Directive is received and evaluated by the European Commission in 2019. Maintaining UK law in its current form has encouraged further development of alternatives, under the 3Rs, to the use of animals in research. We wish to see:

- A Government commitment to maintain the Animals (Scientific Procedures) Act 1986 in its current form (other than for adjustments for major scientific developments) to maintain consistency with EU Directive 2010/63 and provide certainty for the biomedical research sector.

TALENT. Keeping and attracting skilled healthcare professionals to the UK is critical for maintaining high quality research and drug development innovation. We wish to see:

- Mutual UK/EU recognition of professional qualifications of animal science staff
- Rapid creation of online platforms for research staff to apply for settled status
- The immigration system reviewed with an eye toward facilitating access to talent
- Government efforts made to attract global research talent to the UK

Horizon 2020/Innovative Medicines Initiative (IMI). Leaving the EU potentially means the loss of access to important opportunities for research and development in alternative models for animal research. We seek:

- Clear and early agreement that ongoing participation will be permitted for any project underway, within Horizon 2020/IMI, before the end of the transition period
- Serious thought given to strengthening UK tax incentives to support and attract R&D

May 2018