EUK0004

Written evidence submitted by the European Animal Research Association

Thank you for the opportunity to contribute to the call for evidence in the inquiry into the government's progress in managing its borders post-Brexit. We are submitting this evidence on behalf of the European Animal Research Association (EARA) and its members. EARA is a not-for-profit association with over 120 members drawn from public and private scientific research that operate in twenty-four European countries, including the UK.

Overview of animal research

In the UK, animals are used in biomedical and veterinary research to advance scientific understanding, to develop solutions to medical problems, to protect the safety of people, animals and the environment, and as models to study disease. The use of animals is tightly regulated (The Animals (Scientific Procedures) Act 1986 (ASPA) and limited to those cases where alternatives are not available, in line with the 3Rs (Reduction, Replacement, Refinement). It is very difficult, and in most cases simply not yet possible, to develop non-animal methods to replace the use of living animals completely.

The selection of species for study depends on the type, aim and method of the research. Critical to the continuing success of the life science sector is the timely and efficient transport, import and export to and from the UK, of purpose-bred research animals, biological samples from research animals (blood, tissues, organs, embryos), medical and pharmaceutical supplies, plus supplies of specialised animal feed and research diets.

Safe and reliable transportation of research animals and biological samples by air, rail, road or sea is an essential element of medical and scientific advancements across the globe. Without the ability to move research models from one country or continent, to another, or from a breeder to a research institution, crucial scientific research seeking new treatments will stall. The main reasons for transportation are:

- Both biomedical and veterinary research and development of new treatments relies on the supply of animals and animal-derived products for use across the academic, public and private sectors of life sciences.
- The animals required possess specialised anatomical, genetic and psychological conditions that differ from other members of the same species.
- Animals may often be sourced from purpose-bred colonies, which maintain certain attributes within the breeding group.
- Transportation enables researchers to share genetically unique strains and to enhance collaboration. It also reduces the potential overbreeding of commonly-used strains.

EARA has previously contributed to the *2025 UK Government Border Strategy Public Consultation*, we would like therefore to take the opportunity here to reinforce our previous comments and outline our concerns on the current operation of the UK Border and its impact on our sector.

2025 UK Border Strategy

EARA noted that the 2025 UK Border Strategy proposal was for an 'ambitious' strategy: The UK Government proposes to create a 'world-class', 'world-leading', and even 'the world's most effective border' by 2025. EARA agreed with the UK Government when it stated that the indicated strategic objectives and related outcomes 'if achieved' would deliver the greatest benefits to the UK. For EARA the question continues to be, whether the envisioned system can be achieved as planned.

EARA is concerned that delivering 'the world's best' border system by 2025 is not realistically possible for the biomedical sector and the experience of EARA member organisations (outlined below) reveals significant dissatisfaction with the current operation of UK border management. While the UK may achieve a bespoke system over a longer period of time, significant and potentially irreversible damage is currently being done in the interim. In our view, an overly ambitious plan risks ignoring current concerns, the resolution of which would offer immediate relief to research institutes and businesses already under pressure, due to Brexit and the Covid-19 pandemic. We have outlined some suggestions that will help resolve the current problems.

The importance of efficient border management for UK life sciences

Biomedical research depends on the timely movement of live animals and biological samples from research animals, including CITES-listed non-human primates. Delays in the movement of biological samples from research animals can result in the deterioration of the samples, prevent compliance with regulatory timelines, have knock-on effects on other areas of research, and result in increased animal use. Delay in the movement of live animal models for biomedical research can also severely impact the welfare of the research animals and consequently have a detrimental effect on the biomedical research projects concerned. In both cases, delays not only bring extra costs for public research and business, but slow down the speedy development of and access to human and veterinary medicines, diagnostics and treatments for patients.

Shipments which suffer delays due to long waits to obtain the required permits and clearance procedures, therefore have direct costs when time-sensitive (such as fragile biological samples or age-sensitive live animal consignments) are compromised and therefore are no longer fit for purpose. The experience of EARA member organisations is that inefficiencies in issuing permits, certificates, licenses, approvals, and pre-and post-notifications, creates impactful costs both in terms of finances and delay. Costs also increase where there is a lack of clear information about the specific requirements applicable to a given transaction, such as with the issue of Export Health Certificates; where forms are mandated, but not readily available; where certain additional formalities are imposed without a proper evaluation of need or benefit; and where information services provide inadequate, or even conflicting advice.

EARA requested actions:

- For the last two years EARA has informed the UK Government of the need to enact a general license to import biological samples from laboratory minipigs. These licenses exist for other species of animals involved in biomedical research and avoid the time and costs to both researchers and Government of obtaining individual licenses for each import. We have had no information available about whether this long-standing request is being dealt with, or if it is even under consideration.

Electronic CITES permitting

For more than two years EARA members have been requesting improvements to the permitting system for CITES, including the specific request to move to an electronic permitting system to handle applications for permits and certificates. In addition to significant delays in obtaining CITES permits, an unacceptable level of error exists in the issuing of Government permits, resulting in researchers returning permits and waiting for new ones, leading to further costs and delay. Many of these problems stem from the lack of an electronic system for permitting, which means among other things, duplication of data entry and human error.

In its Border Operating Model, the UK Government stated that traders should allow three weeks to obtain CITES permits, however, our evidence is that the current average for many in the biomedical research sector is a delay of four weeks or more. The introduction of an electronic CITES permitting system in Switzerland reduced the processing time for CITES permits from 10-20 days to between only five hours or three days at most. Traders choose between different guaranteed permit processing times (same day, next day and three days), paying higher fees for expedited permit processing. The system has led to increased revenue for the [Swiss] Management Authority and reduction of resources required for processing. The investments into the Swiss CITES permitting system have been recovered in less than one year.

Like Switzerland, Canada used the e-CITES system to improve its electronic permitting. France has its own i-CITES permitting system, which provides another model to be considered by the UK. It should also be noted that the German CITES system delivers permits within four to five days; a dialogue to explore the key elements that lead to such efficiency should therefore be undertaken without delay.

The movement of research samples

The movement of biological samples between test facilities is a crucial element of UK biomedical research and a pre-requisite for the international collaboration set out in the UK Government's recently published *Life Sciences Vision.* However, some of our members are currently facing significant challenges, related to the export of animal research samples to the EU, which may impact on their future UK operations,

The movement of samples between test facilities is a common need in scientific research, with specialist techniques and bespoke methods available only in certain locations with the necessary technical expertise or equipment to support them. One of EARA member in the UK alone has more than 500 shipments to the EU per year.

Samples of animal origin (e.g. tissues, blood samples) constitute the majority of these shipments, and Brexit brought with it a requirement for accompanying permits and paperwork that was previously unnecessary. Primary examples include the need for Export Health Certificates (EHC) and CITES permits (specifically for samples of primate origin).

In the absence of a common agreed standard for such documentation, the need for this UK entity to deal individually with regulators in each EU country, differing requirements within individual countries (at different ports of entry), and different requirements for individual species, has led to significant challenges and delays. In many cases these requirements were not known until 2021. This has led some of their EU-based clients to consider the placement of their studies with EU-based competitors, in order to avoid these avoidable challenges.

Each EU member country determines the specific requirements for the accompanying paperwork necessary for their import of animal samples from the UK. As standards were unable to be agreed/negotiated prior to the end of the Brexit transition period, there has been a great deal of confusion in relation to individual country requirements since the start of 2021, and consequently a lot of demand on UK agency staff (DEFRA and APHA) for support, which they have clearly struggled to cope with. The resolution of enquiries by those agencies is often slow, we believe, due to the limited resources available. Furthermore, as there is no dedicated point of contact, effort is often duplicated when enquiries are passed between agency officials and departments.

The delays resulting from the above have significant implications. Time is critical in drug development, with even relatively short delays having the potential to cost millions. In addition, the nature of the samples being shipped means they have a finite lifespan. Failure to analyse the samples within that period may well invalidate data and necessitate study repeats – again a costly matter, but more significantly this may trigger a need for additional animal usage. It is not surprising therefore that issues such as those we are seeing will lead this company's clients to look at ways to minimise the risk, by opting to place studies with research facilities within the EU.

The lack of standardisation in export paperwork requirements inevitably results in a need for DEFRA staff to engage with their individual EU state counterparts, with requests to approve even relatively simple documentation changes stalled due to the slow pace of inter-agency discussions. It is clear DEFRA is working to address these issues, and we are aware that some DEFRA requests to EU Member State ministries have met with no response. However, there is a growing perception within the sector that this is a poor reflection in terms of UK legislation and business efficiency.

Export Health Certificates

In addition to the need for digital solutions for CITES permitting, despite repeated queries and requests, the biomedical research sector still lacks clear information from Government regarding any requirements for specific Export Health Certificates (EHC) to export live animals to each and all of the 27 EU Member States.

Example 1: ***Shipment of primate blood samples from a UK entity to a client in Germany.***

The client in Germany needs to conduct the analysis of primate blood samples from a

study conducted in a UK facility. The analysis uses a proprietary method that cannot be set up to be conducted in the UK within the timelines necessary for sample stability. Officials at the German port of entry specified on the client's import permit (Frankfurt) have informed the UK exporting entity that an official EHC, signed by DEFRA, must be provided for the samples to be imported by the client. Such documentation can only be provided using standard agreed document templates, but the receiving regulator is insisting on numerous additional declarations, and specific formatting requirements. With little scope for the UK entity to negotiate with the receiving regulator, there is a need for DEFRA to liaise with German federal agency counterparts to resolve this issue. After more than six months of continued dialogue they remain unable to ship. The German client involved, places significant volumes of business with entities in the UK, and they have informed the UK entity that failure to resolve the shipping issues will result in them placing studies within the EU in future. The client simply sees this issue as a general issue of doing business with the UK post-Brexit.

Example 2: Delays in the processing of Export Health Certificates for a non EU country.

An urgent request was made to DEFRA on the 24 August, 2021, for an EHC to be amended to allow the export of primate samples to South Korea:

- *21 September: After several chasing emails from the customer, DEFRA eventually asked what the samples were.*
- *12 October: After more chasing emails from the customer, APHA say they have forwarded the request to their policy colleagues.*
- *28 October: After further chasing emails to APHA a response from DEFRA Carlisle states the need to contact the British Embassy in South Korea.*
- *9 November: APHA provides a draft EHC to the customer, while awaiting Korean agreement to the draft. Once confirmed, the EHC has to be built into a useable format. Once this is available the customer will be notified.*
- *12 November: At the time of writing there has been no response from APHA regarding this urgent scientific and business critical request.*

EARA requested actions:

- A simplified process for the export of animal research samples, with clearly defined and agreed document templates, between the UK and those EU countries that will require Export Health Certificates for such samples.
- The necessary resources, including dedicated staff linked to those UK entities reliant on the export of samples, within DEFRA to answer queries swiftly and definitively.
- DEFRA to urgently intercede on behalf of our sector to determine what certification is required by the individual EU 27 member states and if the DEFRA EHCs currently on the DEFRA website are still required by certain EU 27 members
- A proactive effort to communicate with/educate EU import officials on UK legislation and procedures.
- The BALAI Directive is now revoked and EU Law 2016/429 has been instigated. We have been told that this will ensure that the EU27 will subscribe to one certificate for the movement of both live animals and biological products/samples, but that these have not yet been produced. We would urgently ask that DEFRA intercede on behalf of our industry to determine what certification is actually required by the EU27.

The movement of live research animals through UK borders

The UK biomedical sector is limited by the nature of its consignments to particular ports. In particular, limited options exist for the importation of live animals (and CITES). In addition, the choice of ports is dictated by the ongoing and wholly damaging embargo, by many carriers and transporters, of live animals for biomedical research. Groups opposed to the use of animals in scientific research have targeted airlines and the wider transport sector in a concerted effort to harass, intimidate and extort companies to hinder the research process. They have successfully forced all but a few transport providers to stop transporting research animals. Refusals by airlines, such as British Airways, and ferry companies, to carry research models also means circuitous routing, additional controls, and multi-stage transport via other countries (i.e. for non-human primates, air transport to France is followed by road transport and then followed by cargo air transport). There are also issues with transporting research animals to and from mainland UK to Northern Ireland for similar reasons.

The ongoing embargo seriously threatens the future of drug development and research in the UK and also raises animal welfare concerns through increased journey times and delays caused by multiple clearance processes and the need to transfer consignments via a chain of transporters. Given the time sensitive nature of most consignments and elements specific to the transport of live animals, the sector is largely limited to air transport and has few options available to it should major disruption arise at one or more key entry borders.

EARA requested action:

- The UK Government should initiate immediate discussions with air carriers maintaining an embargo on the transport of live animals for biomedical research to reach compromises allowing transport of animals needed for biomedical research by the UK life sciences sector, until such a time as alternative non-animal methods are developed and validated.
- The UK Government should also should facilitate sector specific discussions with the biomedical research community, carriers and ground process operators to promote information sharing and understanding of requirements and to identify areas for improvement through further co-operation. Government also should expand port capabilities, adding more options for clearance of time sensitive consignments and live animals.

Future areas of concern

As noted above, the issues now being experienced began shortly after the conclusion of the Brexit transition period. However, whilst it was to some degree expected that there might have been some initial teething troubles, worryingly these issues appear if anything to be increasing in frequency as this year has progressed. Individual EU countries continue to communicate new or revised expectations that suggest there is no immediate end to these challenges in sight.

Without quick and resolute action by the UK Government this situation will continue to incur significant business challenges in terms of efficiency, competitiveness, and potentially, animal welfare. The long-term concern is that this will impact the ability of significant players in the UK biomedical sector to do business, and consequently investment in UK-based facilities may well suffer.

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