Royal Society of Biology response to the DEFRA consultation on improvements to animal welfare in transport

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The Royal Society of Biology welcomes this consultation and the opportunity to provide evidence informed by our membership of individuals and organisations with expert interests across the biosciences (please see page 17 for a list of our member organisations). Much of this expertise is represented in the Animal Science Group[1], a special interest group of the Royal Society of Biology.

Preamble

The RSB response to this consultation does not attempt to address the policy proposal of ending live animal export for slaughter and fattening but to consider Defra's broader question about improvements to the welfare of animals during transport, and to discuss the specific requirements for the import/export of laboratory animals for research.

Animal research plays a pivotal role within the UK bioscience research sector and it remains necessary, where no alternatives are available, to support improved scientific and medical knowledge and health and welfare outcomes for people and animals[2,3,4,5,6].

In the UK, scientific procedures involving animals can be only performed under licence by the Home Office and according to legal requirements set in the Animals (Scientific Procedures) Act. In 2019, 3.4 million procedures were carried out in Great Britain as part of studies that range from fundamental biological research to the development of drugs and treatments for human and animal health[7].

A collaborative approach to international research efforts is crucial for maintaining UK scientific excellence and a leading role in the global science and innovation community. These collaborations often require the sharing of resources, including for example certain animal

[1] For further information about the Animal Science Group, a special interest group of the Royal Society of Biology, see: https://www.rsb.org.uk/policy/groups-and-committees/asg
[2] For the fundamental contribution of animal research to biomedical and veterinary progress and an overview of how these studies are highly regulated in the UK please see https://www.rsb.org.uk/policy/policy-issues/biomedical-sciences/animal-research
[3] UK Research and Innovation: The use of animals in research. https://www.ukri.org/about-us/policies-standards-and-data/good-research-resource-hub/use-of-animals-in-research/
[4] The Wellcome Trust: Research involving animals. https://wellcome.org/what-we-do/our-work/our-policy-work-animal-research
[5] The Association of the British Pharmaceutical Industry: Research using animals. https://www.abpi.org.uk/medicine-discovery/new-medicines-data/research-using-animals/#ab19d050
[6] The Concordat on openness on animal research in the UK. http://concordatopenness.org.uk/
[7] Home Office, National Statistics Team (2019). Statistics of scientific procedures on living animals, Great Britain: 2019. https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2019

strains and biological samples. Undue restrictions on the movement of laboratory animals could therefore disrupt ongoing and upcoming collaborative international projects - thereby impacting the UK biosciences sector and medical progress, and animal health and welfare.

The RSB supports the approach to achieve current best practice and standards of animal health and welfare at all points in animal care and husbandry, including in transport between and within this and other nations. We consider the highest standards of animal welfare and research conduct as essential and interdependent components that ensure research quality, and the public benefit that derives from it.

Recommendations

1. We welcome DEFRA commitment to improve the welfare of animals transported not just in the food supply chain but for other purposes too. As far as research animals are concerned, high standards of transport are required and this should remain the case for the benefit of animal welfare and the quality of research.
2. Any proposed review of transport regulation that will impact research animals should consider their specific welfare requirements and modes of transport (import and export). We offer some examples of these requirements in our answers to a subset of the consultation questions.
3. A review of the regulations for research animal transportation will be best achieved outside of the scope of this consultation, which focuses almost exclusively on livestock species, as part of regulatory and policy developments specifically suited to research animals, to ensure that their transport continues following best practice and in a manner that is fit for purpose.
4. In addition to EU Council Regulation No 1/2005 (transposed into UK law), the Laboratory Animal Breeders Association of Great Britain (LABA) and the Laboratory Animal Science Association (LASA) have published guidelines for the care of laboratory animals in transit, which supplements that of the International Air Transport Association (IATA). Alongside these regulations and guidelines, the 3Rs principles for Replacement, Reduction and Refinement should be taken into consideration when developing research animal specific policies in this area.
5. When establishing new rules for research animal transportation, the species-specific welfare needs and the most welfare considerate transport route must be determined and considered. The need for further research on the impact of transport on the welfare of species commonly used in research was suggested in the Farm Animal Welfare Committee's expert opinion to DEFRA and we would support their view. Effective policy making in this area will require broad engagement with stakeholders in the animal research sector.
6. We also recommend that a transport authorisation and monitoring system is put in place that achieves the right level of biosecurity and animal welfare without hampering scientific collaboration. A system that works effectively and in an accessible, transparent and timely manner.

7. The RSB has a wide ranging community of contacts across impacted sectors and we offer to engage with the consultation team at DEFRA, colleagues at BEIS, and at the Home Office, to convene discussions on the best way forward.

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QUESTIONS ON LIVE ANIMAL EXPORTS (Q1-5)

Q3: Do you agree that the only exceptions to prohibiting live export journeys should be for poultry live exports, and animals going for breeding or production that will not be slaughtered within 6 months of arrival? Please explain your views.

3.1. As specified in the Farm Animal Welfare Committee (FAWC) opinion to DEFRA[8] and the RSB response to the 2018 DEFRA consultation[9], the transport of animals in relation to any commercial activity, including between research facilities, has been covered so far by the EU Regulation, Council Regulation (EC) No 1/2005 and related UK legislation.[10]

3.2. As detailed further in our answer to question 28 of the consultation guidance document, we would recommend that high standard transport (import and export) of animals necessary for scientific use (predominantly breeding and research) should be separately considered as part of any regulatory development, to ensure it continues. Experimental animals are exported and imported for either: a) breeding and production of specific strains or breeds and/or b) for specific experimental use (which can take place within a short time after transport).

3.3. Any review of the regulations governing live animal transport must take due care to avoid unintended consequences for the regulated transport of live animals for the purposes of scientific use.

3.4. UK breeders or research centres may export laboratory animals as part of research programmes that are based on international collaboration across borders. These research collaborations are vital for the success of the UK bioscience sector and the objective of increasing scientific knowledge and supporting biomedical innovation for the benefit of human and animal health.

QUESTIONS ON MAXIMUM JOURNEY TIMES (Q6-Q12):

[8] The Farm Animal Welfare Committee (2019). Opinion on the welfare of animals during transport. https://consult.defra.gov.uk/transforming-farm-animal-health-and-welfare-team/improvements-to-animal-welfare-in-transport/supporting_documents/fawcopinionontheWelfareofanimalsduringtransport.pdf

[9] The Royal Society of Biology (2018). Response to the Defra call for evidence on controlling live exports for slaughter and to improve animal welfare during transport after the UK leaves the EU. URL: https://www.rsb.org.uk/images/article/policy/RSB_response_to_the_Defra_call_for_evidence_on_controlling_live_exports_for_slaughter_for_submission.pdf

[10] EU "Council Regulation No 1/2005 on the protection of animals during transport and related operations" is the main legislation governing the transport of animals, it states that: "No person shall transport animals or cause animals to be transported in a way likely to cause injury or undue suffering to them"; URL: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32005R0001&from=EN . The Welfare of Animals (Transport) (England) Order 2006 and parallel national legislation in Scotland, Wales and Northern Ireland is the UK statutory instrument that transposes this into UK legislation; URL: https://www.gov.uk/government/publications/welfare-of-animals-during-transport.

Q6: Do you agree with the proposed maximum journey times as outlined in Table 1? Please explain your views and highlight any potential regional impacts that your business or organisation might experience.

6.1. In response to the 2018 DEFRA call for evidence on controlling live exports for slaughter and to improve animal welfare during transport after the UK leaves the EU, the Laboratory Animal Breeder Association (LABA) provided a list of journey parameters and their common value ranges, including journey times, applicable to laboratory animals transported within the UK, to other European countries and to non-European countries.

6.2. We would like to refer the DEFRA consultation team to the LABA submission as an initial source of information about the potential impacts of policy changes to journey parameters.

6.3. However, we would also like to stress that whilst maximum journey times listed in this consultation,[11] and the inclusion of rest periods, are an important element in maintaining welfare standards, especially to larger animals (e.g. non-human primates and agricultural research animals), for smaller species (rodents) the inclusion of a mandatory rest period could have a negative impact on welfare. The majority of these animals (e.g. rodents) are shipped in filtered boxes with their own micro environment, food and moisture. Opening the filtered shipping containers at a border inspection post, for example, would compromise biosecurity and risks the contamination of the animals with unwanted pathogens. Therefore, the most important objective to preserve health and welfare of the animals in this case is to get the transport boxes safely and quickly to destination and a period of rest in this instance would not be beneficial. At destination the animals are routinely checked by either a Veterinary Surgeon or a competent person (the Named Animal Care and Welfare Officer, NACWO).

Q7: Do you see a need for any exceptions to the maximum journey times and, if so, why? Please provide evidence.

7.1. We would encourage DEFRA to engage with LABA, the Laboratory Animal Veterinary Association (LAVA), the Institute of Animal Technology (IAT), named people at research establishments (e.g. via the establishment licence holder forum and the Home Office Liaison, Training and Information Forum or HOLTIF group), and representatives from the animal research sector (e.g. via the UK Bioscience Sector Coalition[12]) to determine the necessary exceptions to this and the following policy proposals in order to avoid unintended impacts on scientific research programmes and to best preserve the health and welfare of research animals in transport.

Q8: In the case of such exceptions, what requirements should be put in place to ensure animal welfare is protected?

8.1. In establishing exceptions, the species-specific welfare needs of research animals[13] and the most welfare considerate transport route must be determined and considered.

[11] The maximum journey time proposed by FAWC for species other than those listed in table 1, which includes species used in research, is 21 hours (this is an absolute maximum). Beyond 21 hours, APHA should receive and review a written consent regarding the consignment.

[12] https://www.rsb.org.uk/policy/groups-and-committees/uk-bioscience-sector-coalition

[13] FAWC acknowledges that not all of the species have been covered in their opinion paper and recommend that other species should be considered in a follow up opinion on the transport of animals that are not covered i.e.

If specific exemptions are required, then an efficient, timely and agile approval and animal movement monitoring system, managed by the APHA and consisting of species-specific health certificates for import and export, is of paramount importance and should be put in place as a matter of priority, with due community consultation from the outset. Monitoring of animal movements between approved sending and receiving institutions could therefore be managed without compromising scientific efforts and biosecurity.

QUESTION ON THERMAL CONDITIONS AND VENTILATION:

Q15: Do you agree that we should prohibit both short and long livestock and horse journeys when the external temperature is outside of a temperature range of 5-30 ºC, unless the vehicle is able to regulate the internal temperature within this range for the duration of the journey by means of a thermo-regulation system, and that this temperature range should be 5-30 ºC? Please explain your views.

15.1. We have been advised that both the upper and lower temperature limits should be more carefully considered in light of scientific evidence on livestock responses to their thermal environments and the animals' ability to thermoregulate. The adoption of the same defined external temperature range for transport regulation of all species is likely to have unintended consequences, related to both animal welfare and the upstream UK animal production and transport chain.

15.2. There are well defined differences in thermoregulatory mechanisms between different species of homeotherms. For example, cattle, sheep and horses have a wider thermoneutral zone than pigs and poultry. This is, however, dependent on many factors relating to both the characteristics of the individual animals (e.g. age, size, coat length, hydration level, genotype), the environment inside the transporter (e.g. stocking density, temperature, humidity, air velocity, bedding) and other variables (e.g. whether the vehicle is moving or stationary, how long the journey lasts for, or the adequacy of water provision – which should be provided at the frequency required by legislation). These nuances were recognised in the FAWC recommendations (on page 39 of their opinion)[14] but we fear that these nuances, and their clear importance for the correct implementation of a system fit for purpose to

fish, cats and other animals. Please see point 30 (limitations of this report) on page 15 of the 2019 'Opinion on the welfare of animals during transport' by the Farm Animal Welfare Committee (Op.cit.).

[14] "*FAWC recommends that more research and evidence is required to determine the acceptable temperature ranges for the different species and classes of livestock, horses and companion animals i.e. age, breed, sex, shorn/ unshorn that are transported. Until this time, FAWC have suggested temperature ranges for cattle, sheep, pigs and poultry (Appendix C). These temperature ranges should only be used as a guide and only when outside temperatures are exceeded i.e. outside 5 ºC to 30 ºC. Where temperature ranges are not defined in Appendix C, then the current 1/2005 Regulation should be applied to all other animals. FAWC recommended that a maximum and minimum temperature should also be devised for all animals (farm, equine and companion animals) where they are not permitted to be transported outside of these extreme temperatures ranges. This should be a research priority due to the increased levels of extreme temperature ranges that are being experienced, and are likely to experienced, in future. Vehicle design should also be considered when considering the thermal requirements of animals*." The Farm Animal Welfare Committee (2019). Opinion on the welfare of animals during transport. Page 39, available at https://consult.defra.gov.uk/transforming-farm-animal-health-and-welfare-team/improvements-to-animal-welfare-in-transport/supporting_documents/fawcopinionontheWelfareofanimalsduringtransport.pdf

protect animal health and welfare during transportation, might be in danger of being overlooked during policy making, in the interests of simplicity[15].

15.3. For example, mature animals of more cold temperature-resilient livestock species, such as cattle, sheep and horses, given the appropriate management, are generally adapted to cope with lower temperatures than 5ºC[16] (dependant on the individual animal and environmental characteristics, and other variables at play, as described above, and below). At the high temperature end of the spectrum, poultry and adult pigs can become heat stressed at temperatures below 30ºC (range values can be found, for example, in Wathes and Charles, 1994, op. cit.).

15.4. We fully support the tightening of regulations on temperature range for animals that are poorly able to withstand temperature extremes[5,6]. Therefore, we would recommend that the policy proposals determining legally-binding temperature ranges for animal transport take consideration of other important factors, such as the characteristics of the animals for transport, and atmospheric and transport environment parameters beside temperature, and are made species specific.

15.5. Since temperature alone cannot represent all the possible combinations of environmental factors interacting with the animal, if practically implementable on the ground by farmers and animal transport carriers through available technology (e.g. on smartphones), we would recommend developing an index that combines a wider set of atmospheric parameters in a suitable model that can estimate the effect of the heat load on the animals. Resultant index values represent effects produced by the heat exchange process between the animal and the environment[17].

15.6. Numerous such models and indices exist and we were suggested two potential ones by members of our community: the Comprehensive Climate Index[18] (CCI, which includes temperature, humidity, wind speed and solar radiation) and the Adjusted Temperature Humidity Index (THI_{adj}), which was developed on the basis of the impact on panting score[19]. The CCI has the advantage that it can be used in either cold or hot conditions. The adjusted THI_{adj} also includes solar radiation and wind speed in

[15] "*In the light of this, we are proposing that no livestock or horse journeys will be allowed to take place if the forecast external temperature for the journey is outside of a temperature range of 5-30ºC, unless the vehicle is able to regulate the internal temperature within a 5-30ºC temperature range for the duration of the journey by means of a thermo-regulation system. This will apply to both short and long journeys*." DEFRA (2020). Consultation on improvements to animal welfare in transport. Page 11, available at https://consult.defra.gov.uk/transforming-farm-animal-health-and-welfare-team/improvements-to-animal-welfare-in-transport/supporting_documents/consultationonimprovementstoanimalwelfareintransport.pdf

[16] Wathes, C.M. and Charles, D.R. (ed.) (1994). Livestock housing. Wallingford (UK): CAB International, p. 52, illus. 3.2

[17] Hahn, G.L., et al. (2009). Chapter 5: Thermal Indices and Their Applications for Livestock Environments. In J. A. DeShazer, ed., *Livestock Energetics and Thermal Environmental Management*, St. Joseph, Michigan: American Society of Agricultural and Biological Engineers, pp. 113-130. ISBN 1-892769-74-3.

[18] Mader, T.L. et al., (2010). A comprehensive index for assessing environmental stress in animals. *J. Anim. Sci.*, 88(6), pp.2153-65. DOI: 10.2527/jas.2009-2586

[19] Davis, S. and Mader, T. L., (2003). Adjustments for Wind Speed and Solar Radiation to the Temperature-Humidity Index. Nebraska Beef Cattle Reports. 224. https://digitalcommons.unl.edu/animalscinbcr/224

addition to the typical temperature and humidity normally used for the THI. Several corrections to the THI have been proposed, particularly for use with feedlot cattle[20,21].

15.7. Figure 1 in Appendix 3 shows daily variations in these two indices computed on data collected by the North Wyke Farm Data Platform[22], part of Rothamsted Research's National Capability Network, during the summer of 2018. The results of this analysis have been personally communicated to us, with the permission of researchers working at North Wyke research centre.

15.8. Researchers have used the value of these indices to define thresholds of stress risk for the animals involved (e.g. the categories mild to severe in the image shown), which are considered "arbitrary and capable of being shifted based on many factors including age, adaptation effects, genetic composition, body insulation and fat content, size and shape (e.g., surface area exposure), and food and feed intake"[23].

15.9. Based on this result, it would appear that during certain times of the day, when the air temperature is slightly above 20°C, animals can already incur severe stress. Moreover, it is important to consider the specific heat stress risk not just on the day of transport but also in the preceding days because of potential cumulative effects of stress affecting the animal's resilience to the stressor (i.e., if the day of transport is the first day on a series of high-risk days, the effect would be less when compared with an animal that is transported after suffering several days of stress).

15.10. As such, requirements to monitor the condition of the animals during transport, using modern sensor technology, should also be considered and encouraged where possible. Those responsible for the transport of animals must also have a duty of care and proven competency to ensure that animals are not placed at risk of heat or cold stress during transport.

15.11. We have been advised that there is an additional and large body of literature available on the nuanced and context-specific effects of temperature and ventilation on livestock species, which could be systematically reviewed to inform an evidence based policy and associated guidance, for examples see[24,25,26]. There may also be significant benefits to, and we would recommend, Defra consulting with international researchers and regulators who assess and manage animal transport through extremes of temperature, such as in Australia or Canada – not least since UK regulations will need to be resilient and agile in the face of current and predicted climate change, where the UK may experience these extremes more frequently. We would be more than happy to assist Defra further in consideration of this point, and

[20] Mader, T.L. et al., (2014). Environmental factors influencing heat stress in feedlot cattle. *J. Anim. Sci.*, 84(3), pp.712-9. DOI: 10.2527/2006.843712x

[21] Eigenberg, R.A. et al., (2005). Dynamic Response Indicators of Heat Stress in Shaded and Non-shaded Feedlot Cattle, Part 2: Predictive Relationships. *Biosystems Engineering*, 91 (1), pp.111–118. DOI:10.1016/j.biosystemseng.2005.02.001

[22] https://www.rothamsted.ac.uk/north-wyke-farm-platform

[23] Mader, T.L. et al., (2010). Op.cit.

[24] EFSA Panel on Animal Health and Welfare (AHAW), (2011). Scientific Opinion Concerning the Welfare of Animals during Transport. EFSA Journal, 9(1), 1966. https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.1966

[25] Bracke, M.B.M, et al., (2020). Review of climate control and space allowance during transport of pigs. EURCAW-Pigs – version 1.0. https://edepot.wur.nl/515292

[26] Kettlewell, P., et al. Guide to the ventilation of livestock during transport. Available online at http://www.jmrt.co.uk/pdf/Ventilation%20guide.pdf

to facilitate further discussion with our national and international community of experts.

QUESTIONS ON EXEMPTIONS TO THE PROPOSED REGULATIONS ON TRANSPORT:

Q28: Do you think that there should be any exceptions to the previously mentioned proposals alongside the specific exceptions already outlined, excluding the proposal to prohibit live exports for slaughter and fattening? Please provide evidence.

28.1. We would recommend that DEFRA consider the requirements and processes involved in the transportation of animals for research separately from those of other commercial activities while keeping in line with the best available scientific evidence and best practice for animal welfare in transport.[27]

28.2. The regulated use of laboratory animals in research remains necessary, where no alternatives are available, to support improved scientific and medical knowledge and health and welfare outcomes for people and animals.

28.3. National and international legislation and regulations on the use of animals in scientific procedures incorporate a set of principles, called the 3Rs for Replacement, Reduction and Refinement[28], which provide a framework for performing humane animal research and endorsing appropriate methods of experimentation on animals[29]; these should be taken into consideration when implementing current best practice for transportation of animals for research purposes.

28.4. We are pleased to see that FAWC included the 3Rs in the list of welfare principles to be applied to the transport of animals[30]. The justification for transporting live animals for research should be considered in light of these important principles. A decision to transport live individuals of certain species, relative to embryos and/or germplasm, should be reached as the result of a balanced assessment of the total number of animals and severity of procedures involved in the research project for which the animals are transported. Such assessment enables the identification of many instances in which the transport of live animals results in fewer animals used for a scientific project, with less harm caused to them, making live animal transport the higher welfare approach, overall, in these circumstances.

28.5. The vast majority of animals used for research in the UK in 2019 were bred in the UK (which amounts to more than 98% of animals from all species excluding non-human primates (NHPs), see appendix 1). For the case of NHPs, the proportions are different and the majority of them are bred in either Asia or Africa – with only 10% of them born

[27] In their recent opinion FAWC highlighted that: "The SRUC systematic review, the Call for Evidence, and FAWC's own review highlighted a lack of objective scientific evidence in many areas pertinent to animal welfare during transport. [..] The lack of a strong evidence base is concerning, considering the large numbers of animals that are transported and the considerable number of journeys being taken by animals at the direction of man. [..] Not all of the species have been covered in this FAWC opinion and recommend that other species should be considered in a follow up opinion on the transport of animals that are not covered i.e. fish, cats and other animals". Executive summary of FAWC opinion (pages 8-9)

[28] 'What are the 3Rs?' on the National Centre for Replacement, Refinement & Reduction of animals in research; URL: https://www.nc3rs.org.uk/the-3rs

[29] About government's commitment to the principle of the 3Rs please see https://www.gov.uk/guidance/research-and-testing-using-animals#replacement-reduction-and-refinement

[30] FAWC opinion (page 53)

at a licensed establishment in the UK. The use of NHPs in research is permitted but undergoes additional scrutiny by the regulator (ASRU). Expert committees of the European Commission have recently reviewed the need for research on NHPs particularly in areas such as: safety testing for medical devices and pharmaceuticals, treatment and prevention of infectious diseases, neuroscience, ophthalmology and xenotransplantation[31].

28.6. Many research programmes are based on international collaboration across borders. In certain cases, the animals' breeding and rearing may rely on specific techniques only available at a research institution overseas, with subsequent transport to the UK when the necessary research facilities and expertise are here. Furthermore, UK animal breeders export research animals to research facilities globally. Undue restrictions on the movement of laboratory animals could therefore disrupt ongoing and upcoming collaborative international projects - thereby impacting the UK biosciences sector and medical progress, and animal health and welfare.

28.7. There is general consensus that the transport of cryopreserved germplasm (frozen embryos and gametes) for use in research is preferable to the transport of live animals, however, transport of germplasm is very difficult in some cases and for some species and strains; thus, the transport of live animals is currently necessary in these cases. A few examples of exemptions to the preferential movement of cryopreserved germplasm are listed here[32]:

- "Reliable cryopreservation techniques are not widely available for all species and strains (e.g. non-human primates, *Mus castaneus* and specific strains of pigs and sheep). The protocols available for freezing germplasm are very inefficient for a number of species, using a significant number of animals to generate gametes for freezing and to perform the subsequent revival. If exports/imports of live laboratory animals were limited to frozen germ plasm, there may be a significant increase in the number of animals used overall, in these procedures".
- "UK laboratories are currently contributing significant numbers of genetically-altered (GA) animals to international research efforts. Genome editing technologies are, for the first time, providing the opportunity to alter the genome of every species attempted so far. In addition to GA rodents, genetically altered pigs, sheep and non-human primates are increasingly likely to be essential resources in the future for research into complex human diseases such as cancer, cardiovascular disorders and dementia (e.g. importation of mature genetically altered sheep from Australia for Huntington's disease research in the UK)".
- "For some species, sufficient numbers of animals cannot be produced in the UK (e.g. non-human primates). Although providing a critical step in research, the absolute numbers of individual animals required for certain species is

[31] The need for non-human primates in biomedical research, production and testing of products and devices (update 2017); URL: https://ec.europa.eu/health/scientific_committees/non-human-primates-testing-3-current-use_en#fragment0

[32] Examples are described in the Laboratory Animal Science Association (LASA) response to the 2018 DEFRA consultation on animal welfare during transport.

relatively low. For example, in 2016, 3,600 research procedures were undertaken in the UK on non-human primates, predominantly in studies legally required for the safety of medicinal products. Supplying the small and fluctuating numbers required by UK laboratories, without being able to import animals to cover short falls or conversely export animals bred but not required in the UK, would lead to significant delays in scientific programmes and animal wastage."

- "For some scientific studies it is still necessary to transport animals that are undergoing procedures. For example, animals which have undergone complex surgery such as hypophysectomy or adrenalectomy at a specialist centre are supplied to other scientific institutions for studies which may include the use of specialist equipment, such as imaging modalities, only available at a limited number of institutes. Safeguards for the welfare of such animals are written into the research project authorisations."

28.8. New regulations and policies for research animal transport must take into consideration the species-specific welfare needs of the animals and the most welfare considerate transport route through consultation with UK breeders, representatives of the animal research sector (e.g. UKBSC, LABA, LASA and IAT) and with the Animals in Science Regulation Unit (ASRU) at the Home Office.

Q29: What conditions should be met in order to ensure animal welfare is protected in the case of other exceptions?

29.1. As mentioned in previous answers, when establishing exceptions for research animals, their species-specific welfare needs and the most welfare considerate transport route must be determined and considered. If specific exemptions are required, then an efficient, timely and agile approval and animal movement monitoring system, managed by the APHA and based on permits and health certificates for import and export, is of paramount importance and should be put in place as a matter of priority, with due community consultation from the outset. We advise that a timely, clear and accessible dissemination of the required paperwork to all stakeholders should be carried out to avoid legal infringements and to support animal welfare and scientific efforts.

29.2. The transport of research animal must always be planned meticulously and carried out at the best possible standards, using trusted carriers and with the animals transported in a controlled environment. For the benefit of animal health and welfare and research needs, animals should be moved across the border without additional friction or delay. Research animal movements between approved sending and receiving institutions could be managed effectively without compromising scientific efforts and biosecurity, if the right monitoring management system is put in place.

29.3. In addition to EU Council Regulation No 1/2005 (transposed into UK law) and national implementations, the Laboratory Animal Breeders Association of Great Britain (LABA) and the Laboratory Animal Science Association (LASA) have published guidelines for

the care of laboratory animals in transit[33], which supplements that of the International Air Transport Association (IATA)[34].

29.4. At present, transport of live animals for research is possible, in carefully controlled conditions, and is regulated under the authority of licences issued under ASPA[35] as a result of a balanced consideration of harm and benefits and the application of the 3Rs principles. Conditions applied to the transportation of research animals according to best practice include, for example: minimal time in transport, sufficient food and hydration sources and the maintenance of optimum temperature and airflow – all of which can be assisted by efficient export/ import process on the ground, and access to the most appropriate transport routes and means, including by sea and air[36].

29.5. The GA sheep model for human Huntington's disease, which we described in our 2018 response to DEFRA consultation on this subject, provides an example of the different regulations applying to the transport of animals for use in research. In summary, in addition to the requirements of The Welfare of Animals (Transport) (England) Order 2006, the required license to conduct research is obtained from the Home Office under the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 (ASPA)[37] and the Health and Safety Executive is responsible for regulation of Genetically Modified Organisms (GMO)[38].

29.6. Conditions in animal research licences and permits for animal transport require the competence of licence holders and of the named people responsible for checking the animals before travel. We would recommend that DEFRA ensure that competencies

[33] LABA and LASA, (1993). Laboratory Animal Breeders Association of Great Britain and Laboratory Animal Science Association. Guidelines for the care of laboratory animals in transit. Laboratory Animals, 27: 93-107

[34] IATA, (2002). International Air Transport Association. Live Animal Regulations Montreal.

[35] "Conditions applied to the export of GA rodents, fish and frogs are written into application for project licences authorised under the Animals (Scientific Procedures) Act (see Appendix 2). For all other species, authority has to be sought from the Secretary of State on a case by case basis. When live animals are exported to the EU they must be deemed fit for transport prior to export by either the Named Animal Care and Welfare Officer or the Named Veterinary Surgeon. For exports to countries outside the EU, animals must be determined fit to travel by a Named Veterinary Surgeon" from the Laboratory Animal Science Association response to the 2018 DEFRA consultation on animal welfare in transport.

[36] "This relates to all animals but especially dogs and Non-Human Primates (NHPs). Currently there is limited breeding of NHPs in the UK to meet the current needs of establishments. Therefore, there is an on-going need to import NHPs from outside the EU. There is an extremely efficient system of transporting these animals set up to ensure the highest standards of welfare during transit and during any stopovers. For the smaller species, the animals travel in dedicated shipping containers with their own supply of food and moisture. Sufficient provided for minimum twice the expected journey time. For the larger species then arrangements are made during stops to provide food and moisture as required". Communication from LABA to the RSB as part of the evidence gathering in 2018.

[37] Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012.
Available at: https://www.legislation.gov.uk/ukdsi/2012/9780111530313/pdfs/ukdsi_9780111530313_en.pdf.
ASPA requires that consideration of potential pain and suffering plays a central role within the framework of the harm-benefit analysis that is used to grant licences to carry out experiments on animals. Schedule 2C: Conditions in Licences, Section 10(1), Part 1: Conditions in Section 2C Licences, point 11 (1) b) states: "a section 2C licence must include such conditions relating to the general care and accommodation of protected animals kept at the place specified in the licence as the Secretary of State considers appropriate to ensure that the conditions under which any such animal is transported are appropriate for the animal's health and well-being".

[38] The UK competent authority (CA) for the Genetically Modified Organisms (Contained Use) Regulations (GMO(CU)) (2014 URL: https://www.legislation.gov.uk/uksi/2014/1663/pdfs/uksi_20141663_en.pdf) comprises representatives of the four responsible authorities for GMO(CU) in the UK. The GMO(CU) 2014 regulations apply to England, Scotland and Wales. The GMO(CU) (Northern Ireland) 2015 Regulations apply to Northern Ireland; URL: http://www.hse.gov.uk/biosafety/gmo/whos-responsible.htm

based on European qualifications and experience are aligned with UK standards and therefore acceptable.

29.7. Regulatory requirements for transport should marry-up with other forms of national and international legislation and regulation related to human interaction with animals, where there may be points of intersection, such as in the case of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). In this case, special consideration should be given to endangered species which might be transported for research purposes - and the appropriate regulatory frameworks that determine their protection status. Research project licences specifically invoke CITES, but there are other important regulations that assign protection to species, for example the EU Habitats Directive[39], which may need to be considered. We were informed about ongoing research work with amphibian species (e.g. *Discoglossus sardus*), which are classified as 'Least Concern (LC)' by the International Union for Conservation of Nature (IUCN)[40] and therefore would not be listed as endangered on a project license (if endangerment is based solely on IUCN status), but which are included in Annex IV of the Habitats Directive[41], which requires the application of a strict protection regime across the entire natural range of the species within the EU, both within and outside Natura 2000 sites. Similarly, several widely distributed amphibian species, including the common frog, are listed on Annex V, which states that EU Member States must ensure that their exploitation and collection from the wild is compatible with maintaining them in a favourable conservation status. All four of the amphibian species listed on Annex V are IUCN LC and would not be listed as endangered on a research project license. These points pertain more closely to authorisation of collection for research purposes but at least, as far as Annex V of the Habit Directive is concerned, the legal text adopts 'exploitation' as terminology, which arguably covers collection, transportation and eventual use in any licensed procedures. Cross-department policy making, involving the Animals in Science Regulation Unit and DEFRA, is needed to ensure that collection and transport of wild animals for research is carried out in a controlled manner and by persons with standards of competency; all in full accordance with UK, international and European regulations, depending upon the regions involved in collaboration, and according to animal welfare and scientific best practice.

29.8. We would recommend that DEFRA carefully evaluate that new legislation does not introduce loopholes that could be exploited to illegally smuggle animals into the UK (for the exotic pet trade, for example) under exemptions specifically designed for research animals. An efficient and agile process of verification that would include both sending and receiving laboratories and personnel, and verify authorities granted under the Animals (Scientific Procedures) Act, should be put in place to avert unwarranted policy outcomes.

29.9. Currently there are no sea transport providers operating out of the UK that will carry research animals. Furthermore, many airlines now refuse to carry live animals for research; sometimes charter of private aircraft is required for efficient transport. To enable vital research - of importance to human and animal health - to continue, we must ensure that, when necessary, animals can be transported using the most

[39] https://ec.europa.eu/environment/nature/legislation/habitatsdirective/index_en.htm
[40] https://www.iucn.org/
[41] https://ec.europa.eu/environment/nature/legislation/habitatsdirective/index_en.htm

appropriate mode. This should resonate with FAWC's opinion that when animal transport is necessary 'the most welfare considerate route is chosen which is a combination of journey quality, including they type of transport, duration and suitability'. Responsible decision making relating to the transportation of animals should take into account the cumulative suffering and carefully consider species-specific needs of the individual animals transported.[42] We would recommend that DEFRA engage with the animal research and transport sectors to expand the availability of the high standard routes and modes of transportation in the future.

Q30: Do you think that it should be possible to obtain permission to use an exception on an ongoing basis to avoid the need for transporters to apply before every applicable journey? Please explain your views.

30.1. We were made aware of current regulatory uncertainty and bureaucratic difficulties in determining and obtaining the right health certificate (including CITES permits) to export research animals to the EU. Long waiting times, lack of clarity over requirements, and bureaucratic delays in the transport of research animals can have significant impacts on ongoing scientific programmes and the standing of the UK as a scientific partner in collaborations with EU partners, which should not be underestimated. It is of the upmost importance that DEFRA delineate and operate a transport authorisation and monitoring system that achieves the right level of biosecurity and animal welfare without hampering scientific collaboration; a system that works effectively and in an accessible, transparent and timely manner. It has been suggested to us that it may be effective, for example, to negotiate continuing permissions for export to individual EU Member States where the export is for similar purposes, under similar transport conditions and for the same or similar species. Any such agreement should first be consulted on at the earliest stage with sector stakeholders (for example those involved in running breeding and conservation programmes for zoological collections, among others); and of course delivered in accordance with international legal obligation, and in a timely fashion. The RSB has a wide ranging community of contacts across impacted sectors and we offer to engage with the consultation team at DEFRA, colleagues at BEIS, and at the Home Office, to convene discussions on the best way forward.

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[42] For example, the *Suncus murinus* (house musk shrew) is highly susceptible to motion sickness. Nausea is not only unpleasant, but can also lead to dehydration and sometimes death of an animal. In these cases, the method of transport and the monitoring of animals must be very carefully considered. As an additional example, Council Regulation (EC) No. 1/2005 (in particular Annex 1, Technical Rules, Chapter 1: Fitness for Transport, point 2. c)) requires certain restrictions on moving pregnant animals and dams and their offspring – a similar restriction should not be omitted from UK legislation;
URL:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/218747/council-reg1-2005.pdf

Appendix 1: Extract from the Statistics of scientific procedures on living animals, Great Britain 2019. (the full report can be found at: https://www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2019)

Excluding non-human primates (covered below), of the 1.657 million animals used in experimental procedures for the first time in 2019 (including species listed and not listed in Schedule 2):

- 98.28% (1.628 million animals) were born in the UK (1.548 million of these animals were born at a licensed establishment)
- 1.06% (17,486 animals) were born in the EU (15,087 of these animals were born at a registered breeder)
- 0.02% (257 animals) were born in the rest of Europe
- 0.65% (10,827 animals) were born in the rest of the world

All 2,156 primates used for the first time in experimental procedures in 2019 were purpose bred. Of those 2,156 primates:

- 54% (1,154 primates) were born in Africa
- 36% (782 primates) were born in Asia
- 10% (220 primates) were born in the UK at a licensed establishment

Also, of the 2,156 primates used for the first time in experimental procedures in 2019:

- 80.8% (1,741 primates) originated from self-sustaining colonies
- 13.7% (295 primates) were first generation primate (i.e. the parent was wild-caught)
- 5.6% (120 primates) were from a second generation, or greater, primate (i.e. grandparent or earlier generation were wild-caught)

Appendix 2 - Home Office standard authority for the export of animals which appears in every granted Project Licence.

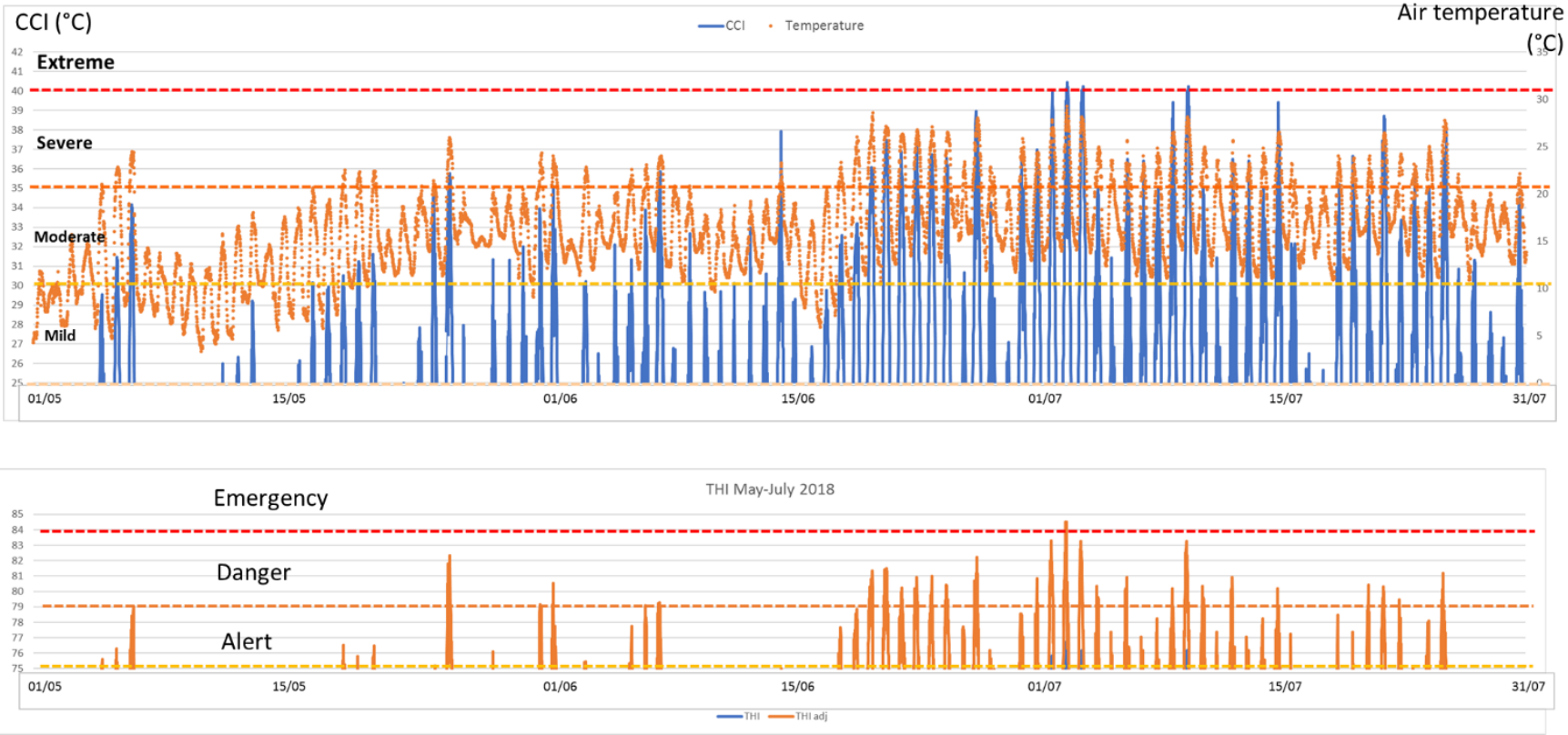
The following gives authority to transfer animals from a previous project to this project, and/or to export genetically altered rodents, genetically altered zebra fish or genetically altered Xenopus spp.

Authority is hereby given to transfer animals undergoing regulated procedures under the licence(s) specified above to this project for continued use in the relevant protocols. Genetically altered rodents, genetically altered zebra fish and genetically altered Xenopus sp. bred and/or maintained under the authority of this project may be transferred to scientific establishments outside the United Kingdom only if:

1. The transfer will be made to a recognised scientific research establishment with a scientific requirement for genetically altered animals (or their controls) of that type; and where appropriate veterinary care can be provided as necessary; and
2. Sending tissue, gametes or embryos is not practicable or carries a higher potential welfare cost than moving live animals; and
3. Animals will be transported in accordance with all relevant regulations regarding welfare of animals in transit or the import or export of animals; and

4. Animals will be inspected by a competent person before transfer; and
5. A veterinary surgeon will confirm that he/she is not aware of any reason why these animals might suffer by virtue of the fact of being moved to another recognised scientific establishment.
6. Any transport related problems with the welfare of the animals will be notified to the Home Office promptly.

Appendix 3: Figure 1 - example of daily variations in thermal indices for the assessment of environmental stress in animals (data acquired at the North Wyke Research Farm, part of Rothamsted Research's National Capability Network, during successive days in the summer of 2018)



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