



Rt Hon Sir George Howarth MP
House of Commons
London
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31 March 2022

Dear Sir George,

Thank you for your email of 28 March to the Home Secretary on behalf of a number of your constituents regarding the Animals in Science Regulation Unit (the Regulator) change programme. I am replying as the Minister with responsibility for this area of policy.

In February 2021 we launched the change programme with the objective of modernising and transforming the Regulator in alignment with its purpose of protecting animals in science by maintaining compliance with the Animals (Scientific Procedures) Act (ASPA) by ensuring continuous improvement of the governance of the Regulator and the regulated community following feedback from a wide range of perspectives.

The most effective way for the Regulator to assure compliance with ASPA is to systematically assess the robustness of governance systems within establishments and projects. Our approach, which is objective and evidence based, ensures fair and transparent standards are used and applied across all establishments and projects in Great Britain which assures delivery of ASPA.

Under ASPA, Establishment Licence Holders are required to have governance systems in place to ensure all Personal and Project Licence Holders work in compliance with procedures in place and to maintain compliance with the conditions on their own establishment licence. The governance requirements for Licence Holders under ASPA are provided by the Standard Conditions of licences found on the Regulator's website at:

www.gov.uk/guidance/research-and-testing-using-animals.

Specifically, the responsibility for individual animal care and welfare is primarily with Personal Licence Holders. The responsibility for conducting programmes of work in the most refined way and in accordance with the 3Rs principles (Replacement, Reduction, Refinement) is with Project Licence Holders who are also required to have governance systems in place to ensure the compliance of all Personal Licence Holders working under their project licence. More broadly, ASPA requires an effective framework within an establishment, including an Animal Welfare and Ethical Review Body (AWERB) and named persons that advise the Establishment Licence Holder on the 3Rs and animal welfare.

It is the responsibility of the Regulator to be assured, through the process of audit, of systematic processes where the legal benchmarks for compliance with ASPA are assessed against verifiable evidence; including cage side checks, evaluation of documented systems and records, interviews with licence holders and named persons.

I can assure you that this is not a 'tick box' exercise. An audit is a systematic, independent and documented process of objectively obtaining and evaluating audit evidence to determine whether specified criteria/standards are being met. The Regulator has published its process of full system audits at:

www.gov.uk/guidance/animal-research-technical-advice#process-and-standards-for-establishment-full-system-audits.

The Regulator's audit process is therefore a strengthening of the regulatory system to ensure a consistent and robust approach that assures compliance with the legal requirements. I would like to assure you that high quality regulation and animal welfare remains a priority.

The Regulator will continue to conduct, where required, unannounced audit visits to assure compliance in licensed establishments. The Regulator will continue to prioritise activities that increase the strength of governance at establishments and therefore compliance with ASPA that protects animals in science.

Thank you again for taking the time to write. I can assure you that the Department continues to listen to the valuable feedback from stakeholders. I hope you will find this information useful in responding to your constituents.

A handwritten signature in black ink, appearing to read 'Susan', is centered on the page.

Baroness Williams of Trafford