Member state: United Kingdom

1. Project evaluation before Directive 2010/63/EU

The project evaluation process was undertaken by veterinary or medically qualified Inspectors at the Home Department of the Government of the United Kingdom (the Home Office). Inspectors advised the Secretary of State whether to grant or refuse an application. Before formal applications were submitted to the Home Office, they were assessed by the local ethical review process (ERP) at the local establishment at which the project was to be done. The aim of the ERP was to provide independent ethical advice to the "certificate holder" at the establishment, who held the "certificate of designation" (the licence held at the establishment authorising animal work to be undertaken there) and had overall responsibility for compliance. ERPs had specific membership requirements, including the named veterinary surgeons (NVS) and named animal care and welfare officers (NACWO), who had specific roles under UK legislation (Animals (Scientific Procedures) Act 1986; ASPA). Licence holders were also represented and it was recommended that a lay member, independent of the establishment, was also included. Once approved by the ERP and supported by the certificate holder of the establishment, projects were submitted to the Home Office. Inspectors evaluated projects to determine whether the legal requirements of ASPA were met, and whether the work was undertaken with due consideration to the 3Rs whilst achieving the scientific objectives.

2. Implementation of Directive 2010/63/EU

The directive has been transposed into the national law through the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 - No. 3039 (ASPA, from 18th December 2012). The amended legislation is available at: https://www.gov.uk/government/publications/animals-scientific-procedures-act-1986-amendment-regulations. ASPA is implemented by the Home Office in England, Scotland and Wales and by the Department for Health, Social Security and Public Safety in Northern Ireland.

3. Regulation and authorisation process: main actors

3.1. Ministry: Home Department of the UK Government

3.2. Competent authority: Animals in Science Regulation Unit (ASRU), Home Office

3.3. Entity responsible for the project authorisation: Animals in Science Regulation Unit (ASRU), Home Office

4. Project evaluation according to Article 38 of Directive 2010/63/EU

4.1. Geographical organization of the project evaluation process

From 1 January 2013, the local establishment ERPs were replaced by animal welfare and ethical review bodies (AWERBs). All applications, whether for a new project licence, or amendments to an existing licence, must be reviewed by the AWERB at the establishment where the work is going to take place (if the work will occur in more than one establishment, the researcher needs to arrange the review at each establishment). The AWERB advises the establishment licence holder whether to support the project proposal. Project applications are sent, once endorsed by the establishment licence holder (PELh or PEL holder) (previously known as the certificate holder), to the Animals in Science Regulation Unit (ASRU), at the Home Office. A central licensing team deal with administration of the application and it is sent to the assigned Inspector for that specific establishment. Project evaluation is then undertaken by the Inspectors who may also refer to other Inspectors, the Animals in Science Committee or to independent assessors. The requirement for referral depends on the severity of the work in the application, species to be used, and whether or not the work is contentious e.g. the public or Ministers may have particular concern. Advice from the Inspector(s) and the other sources if relevant, is provided to the Secretary of State. Her officials then grant or refuse the licence based on the advice. After review/evaluation by the AWERBs, both the evaluation and authorisation is undertaken at a national level by Home Office officials.

4.2. Evaluators

The evaluation is firstly conducted by the AWERBS and then by the Animals in Science Regulation Unit Inspectors, who give advice to Officials responsible for the authorisation, acting on behalf of the Secretary of State.

4.2.1. Evaluators' characterization

Considering the user establishments, ASPA specifies that the AWERBs must have, as full members, at least one of the establishment's Named Animal Care and Welfare Officers (NACWO), at least one of the Named Veterinary Surgeons (NVS) and also include a scientific member. They are also expected to take into account the views of people who do not have responsibilities under ASPA, as well as one or more persons who are independent of the establishment. Inspectors may also attend meetings of the AWERB from time to time as part of their responsibilities for monitoring compliance with the legislation.

There are approximately 22 Inspectors operating in the UK. They are required to have medical or veterinary qualifications. Inspectors often have both clinical and research experience and frequently have postgraduate qualifications such as PhDs and specialist diplomas. All Inspectors are required to have medical or veterinary degrees. They frequently have additional certificates, diplomas and PhDs and come from diverse clinical and research backgrounds.

4.3. Project submission

Evaluation by AWERBs is a local process which is administered in various ways at establishments, and occurs before the project is evaluated at the Home Office. The project licence application forms are available at https://www.gov.uk/research-and-testing-using-animals. Projects are programmes of work which address a specific aim and objectives, using 1 or more protocols to achieve those objectives. It should be noted that projects are not authorised by individual experiment, rather a 5 year programme (or shorter) is authorised, which could consist of several protocols. An online application process is being developed by the Home Office, but currently applications are submitted in hard copy and are granted as licences in hard copy.

4.4. Fees

There are no fees for project authorisation but there are charges for other parts of the licensing process.

4.5. Guidelines for project evaluation

There are guidelines regarding the role of the AWERB issued by the competent authority, in the Guidance on the Operation of the Animals (Scientific Procedures) act 1986 (see Appendix A). Also, "A resource book for lay members of Ethical Review Processes, 2nd edition, July 2009" [RSPCA] and the "Guiding principles on good practice for ethical review processes, 2nd edition, July 2010" (developed with LASA) were published to advise ERPs before transposition. Inspectors evaluate the projects in accordance with requirements of the legislation. The cornerstone of the evaluation is the harm-benefit analysis which is described in Appendix I of the Guidance to ASPA.

4.6. Follow-up of projects' authorisation (I.e. inspections, retrospective review, etc.)

Inspectors are responsible for inspecting the establishments and determining whether the work is compliant with ASPA. Retrospective assessment is undertaken by the AWERBs who then submit to the Inspectorate. The Inspectorate makes a final evaluation of the retrospective assessment.

5. Changes expected to occur in 2015

The competent authorities are currently writing a new paper describing their current harm-benefit analysis and it is possible that minor changes could arise from this review.