
Home Office: Consultation on options for the transposition of European Directive 2010/63/EU on the protection of animals used for scientific procedures**Response by the Wellcome Trust**

August 2011

Introduction

1. The Wellcome Trust endorses the response of the UK Bioscience Sector Coalition¹ and would like to provide further comments in the following areas:
 - Article 8: Non-human primates
 - Article 14: Anaesthesia
 - Article 16: Re-use
 - Article 6 and Annex IV: Methods of killing
 - Article 33: Care and accommodation
 - Article 26: Animal Welfare Body
 - Article 34: Inspections by the Member States
 - Genetically modified animals
2. We welcome the revised Directive and believe that transposition into UK legislation provides an important opportunity to ensure high animal welfare standards in the UK and harmony in practice across Europe. We are therefore pleased to respond to this consultation.
3. The Wellcome Trust Sanger Institute (WTSI) is a world class research centre focused on understanding the role of genetics in health and disease. WTSI has provided considerable input into this response and we support their separate response.
4. The Wellcome Trust part funded the Academy of Medical Sciences inquiry into 'Animals containing human material'² and support the report's recommendations on the role of the National Committee, as reiterated in the Academies response to this consultation.

Article 8: Non-human primates

5. We agree that transposing this article should not prevent research using non-human primates (NHPs) that would currently be acceptable under ASPA. The recent review of research using NHPs by an independent panel chaired by Sir Patrick Bateson confirmed that a vast majority of this type of research is valuable for human and animal health³. The review recommended that

¹ http://www.understandinganimalresearch.org.uk/page/download_document/?document_id=96

² <http://www.acmedsci.ac.uk/download.php?file=/images/project/Animalsc.pdf>

³ http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/wtvm052279.pdf

NHP research should continue with appropriate regulations and where there are no alternatives to NHP use. We support the conclusions of this review.

Article 14: Anaesthesia

6. We agree with transposing these provisions as detailed in the Directive. However, we would like to reiterate the call for further information in guidance on what constitutes enacting 14.2 (b) “whether anaesthesia is incompatible with the purpose of the procedure”. This is especially important for research such as pain studies where anaesthesia would be detrimental to the outcome of the experiment. This may also be the case for some other areas of research and so guidance must be clear on what is appropriate, taking into account the welfare of the animals and the experimental outcomes.

Article 16: Re-use

7. As stated in the Bioscience Sector response, re-use where appropriate can contribute to the 3Rs, and we support the proposal to transpose the article as it stands. We would like to reiterate the need for guidance on applying for re-use in a project license application. We believe the current system of seeking pre-approval for re-use in project license applications enhances animal welfare, as it requires researchers to plan for using animals in multiple experiments, taking their welfare into consideration at early stages of research. It also allows the NACWO and named vet (or appropriate person) to be informed of the proposal to re-use animals and plan their involvement in the assessment of animal welfare throughout the project.

Article 6 and Annex IV: Methods of killing

8. We share the concern regarding the list of permissible methods in Annex IV and reiterate the call for a mechanism that allows the swift introduction of new more humane methods based on scientific evidence. Additionally, the Home Office should take into account these points:

- Cervical dislocation of rodents, undertaken by an appropriately skilled person, is more humane than sedation prior to dislocation. Cervical dislocation of adult rodents should therefore not require prior anaesthesia as this can cause more distress. The need for appropriate skills to undertake this are therefore of utmost importance.
- Further, it is very important that decapitation of rodent pups (up to one week old) is not done under anaesthesia. Again, subjecting these animals to anaesthetic injections or inhalations will produce more stress than skilled cervical dislocation.
- We do not believe there is sufficient evidence that inert gassing of rodents is humane and propose that scientific justification for this should be required.
- The cooling of mice foetuses, used widely under ASPA Schedule 1, should be maintained in its current state and be allowed without authorisation.

Article 33: Care and accommodation

9. We would like to see a mechanism in place that will enable the introduction of more humane stocking densities of animals based on robust evidence of animal welfare. Such studies are being undertaken at the Jackson Laboratory⁴, to be published over the next two years. We urge the Home Office take this evidence into account when it becomes available and ensure they have the ability to amend the stocking density requirements according to this evidence.

⁴ <http://www.jax.org/>

Article 26: Animal Welfare Body

10. In addition to comments in the Bioscience Sector response, we would like to highlight the requirements on institutions should they be seeking funding from outside Europe, for example from the NIH. The NIH require specific representation on the committee responsible for animal welfare assurance at the institution level, for instance the Animal Welfare Body, that may not be stipulated in UK legislation⁵. Although this is not a major concern of the Home Office, institutions should be aware of these criteria and the inspectorate should be able to give advice and guidance to institutions wishing to seek funds from these sources.

Article 34: Inspections by the member states

11. The WTSI highly values the advisory role and close communications with the inspectorate, and would like to see a similar system remain in place. Their interactions with inspectors allow them to develop their science in close partnership with the inspectorate, and therefore in line with regulations. This close partnership also enhances public confidence in the work undertaken at the WTSI and provides the inspectorate with opportunities to interact with the fast developing science taking place.

Genetically modified animals

12. We concur with the Bioscience Sector in relation to discharging established genetically modified (GM) animals with 'non-harmful phenotypes' from the controls of the new Act. As proposed, these could then either be returned in a separate category or removed from statistical reporting. Guidance on what would constitute a 'non-harmful phenotype' would be required.

13. We believe a possible solution would be that GM colonies with 'non-harmful phenotypes' be registered at a local level, e.g. under the certificate of designation, recording the explicit full genetic make-up of the animal (for comparison with wildtypes from the same background). These lines could then be audited by the competent authority to ensure the lines comply with guidance.

14. This solution would allow institutions and research facilities to breed natural and engineered mutants in exactly the same way. It would also allow the return of GM animals with 'non-harmful phenotypes' as a separate category in the statistics, if they are to be included. If they are not included in the statistics, a record of the numbers being bred would still exist for auditing purposes. Agreement will be needed from the Animal Welfare Bodies, the competent authority and animal welfare groups to ensure that this is not seen as avoiding returning animal numbers. Rather, it could allow institutions to inform groups that these animals do not experience any pain, suffering, harm or long-lasting distress beyond that of a normal wildtype mouse of the same background.

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⁵<http://grants.nih.gov/grants/olaw/references/phspol.htm#FunctionsoftheInstitutionalAnimalCareandUseCommittee>