

Response to the Home Office consultation on EU proposals for a new directive on the protection of animals used for scientific purposes.

From: *[Please insert your name and address here]*. I am responding to the consultation as an individual.

Chapter 1: General Provisions

Q1. Animals bred for their tissues and organs should be protected within the scope of the directive.

Q2. The proposals on immature forms do not go far enough: protection of vertebrate animals should begin from the point at which larval forms hatch and foetal forms reach half way through their natural gestation period. The immature forms of invertebrates listed below should be protected from the point at which they feed independently, as proposed by the European Commission.

Q3. Cyclostomes, cephalopods and crustacean decapods should be protected within the scope of the directive.

Q9. The list of proposed permissible purposes should be more detailed, so that the purposes are broken down into more precise categories, and those purposes for which certain species of animal should not be used (eg non-human primates) can be more clearly defined.

Chapter II: Provisions on the use of certain animals in procedures

Q11. Endangered species should not be used in procedures as defined in Article 3 of the Commission's proposal.

Q12. I support provisions limiting the use of non-human primates. It is necessary to eliminate the use of primates in procedures, and prohibiting their use in experiments that have no direct medical application (as proposed by the European Commission) is a useful first step towards this goal.

Q13 (and Q59). I believe the use of great apes in procedures should be prohibited, and I do not support inclusion of the so-called 'safeguard clause'; the ban should be complete and unconditional.

Q14. Animals taken from the wild should not be used in procedures.

Q16. The use of 'F1' generation primates (the offspring born to wild-caught primates) should be prohibited earlier than the timeframes proposed by the European Commission.

Q17. Stray and feral domestic animals should not be used in procedures.

Chapter III: Procedures

Q18. I agree with the provisions of Article 12.1 (subparagraph 1) and 12.2 but do not agree that exemptions should allow procedures to be conducted outside user establishments.

Q19. The compulsory application of the 3Rs is extremely important, and I fully support the proposed requirements relating to selection of methods.

Q20. Death as an endpoint should be prohibited without exception.

Q21. Drugs and methods of restraint that prevent or restrict animals from showing pain should be prohibited without exception. If post-operative analgesics or other pain relief are 'not compatible' with the purpose of the procedure, the procedure should not be authorised.

Q22. I agree that EU-wide severity classifications should be adopted, including a clearly defined 'upper limit' of severity beyond which procedures will not be authorised. I do not believe that establishing three categories of severity is adequate, and would like to see at least six categories adopted so that more precise information on the levels of pain distress and suffering can be made available to the public.

Q24. Animals used in experiments classified as 'moderate' or above should not be re-used in another experiment, without exception.

Chapter IV Authorisation

Q28. The system of authorisation proposed, whereby persons, establishments and projects should be authorised, evaluated and monitored, is appropriate and necessary in order to ensure full application of the 3Rs during all life-stages of all protected animals.

Q30. Where the authorisation requirements are not met, the 3Rs should be applied including through immediate termination of projects and euthanasia of animals in order to prevent further pain, suffering or distress.

Q34. It is necessary to involve external lay-members and experts in alternative methods in permanent ethical review bodies.

Q42. National inspections should be unannounced and carried out at least twice each year, with additional inspections being carried out where persons, establishments or projects merit greater attention.

Q44. All projects should be authorised individually by the Competent Authority (CA), and should be subject to ethical review carried out by the CA rather than at institution-level.

Q47. All projects should be subject to retrospective assessment.

Q48. Project applications, ethical evaluation reports and retrospect assessment reports should be made publically available.

Chapter V

Q53. Data sharing should be facilitated through increased transparency and publication of project applications and retrospective assessment reports. Regulatory tests on animals should not be carried out unless the applicant can provide evidence that existing data have been searched for. Once an application to carry out a test has been made, the application should be subject to a comment period during which existing data could be brought forward by other data-holders.

Q54. Use of all existing alternative techniques that replace, reduce or refine animal procedures should be compulsory in all cases, and both the EU and member states should increase funding provided for the development of new alternative methods. An EU Centre for Alternative Methods should be established to create strategies to replace the use of animals in procedures

(including those undertaken for the purpose of basic research, applied veterinary and medical research, diagnosis, and education as well as regulatory testing), conduct and coordinate research, coordinate validation studies and provide training in use of alternative techniques.

Q55. National Centres for Alternative Methods should be created and tasked with carrying out research identified as necessary in order to further replacement strategies identified, to carry out validation studies and to promote the use of alternatives to animal procedures/3Rs approaches.

Q56. I support the proposal to create a national animal welfare and ethics committee.

Chapter VI Final provisions

Q57. I support the proposed method for updating the technical annexes, but would also like to see Annex I updated regularly in response to increasing scientific knowledge.

Q58. The reporting requirements should be extended to include regular reporting on progress made towards developing and implementing strategies to replace the use of animals in procedures. Reporting on the number of animals used, the severity classification of projects, and the purposes for which animals have been used (in more detail than is currently required) should take place annually.

Q62. Establishment of biannual thematic reviews of experiments to set targets for replacing animal use must be added to the Commission proposal. I want to see practical measures that will end unnecessary experiments rapidly.

Annexes

- I support inclusion of the Annexes currently proposed by the Commission, but would like to see the housing and care standards expanded upon to require by law the full provisions set out in Recommendation 2007/526/EC (Appendix A of Council of Europe Guideline ETS 123).
-