

CONSULTATION ON EU PROPOSALS FOR A NEW DIRECTIVE ON THE PROTECTION

Completed consultation response forms should be sent no later than

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REPORT ON ANIMALS USED FOR SCIENTIFIC PURPOSES

from 3 July 2009 to the following address:

www.gov.uk

Division

<p>EU PROPOSALS FOR A NEW DIRECTIVE ON THE PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES</p>	
<p>Q1: What are your views on the proposed inclusion of animals bred for their tissues and organs within the scope of the proposal and our estimate of its impact?</p>	<p>There must be full protection, within the scope of Directive for animals bred and killed so that their tissues and organs can be used in experiments. This must also include appropriate reporting and publishing of data relating to use. There should additionally be reporting on and protection of animals bred for 'procedures' but who are ultimately regarded as surplus to needs. Their fate, typically, is to be killed.</p>
<p>Q2: What are your views on the provisions regarding the protection of immature forms and our estimate of their impact?</p>	<p>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. The scope of the Directive should be broadened to include immature forms of both mammalian and non-mammalian species, because there is sound scientific evidence of their potential to feel pain and be harmed.</p>
<p>Q3: What are your views on the inclusion of cyclostomes, cephalopods and crustacean decapods within the scope of the proposal? Can you provide any information on their current use in the UK for experimental or other scientific purposes?</p>	<p>The scope of the Directive should be broadened to include cyclostomes, cephalopods and crustacean decapods.</p>
<p>Q4: Do you have any views on the proposed exemption affecting veterinary clinical trials?</p>	
<p>Q5: Do you have any views on the proposed "marking" exemption? Do you support the proposition that the most appropriate humane methods should be used?</p>	
<p>Q6: Do you have any comments on our approach to the proposed exemption of non-invasive practices?</p>	

Q7: Do you have any comments on any of proposed definitions set out in Article 3 and their implications? Are there any other terms used in the proposal that should be defined in this article? How would you define those terms?	
Q8: Do you have any comments on the provisions of Article 4 relating to replacement, reduction and refinement?	There needs to be a well-funded, well-coordinated and executed EU-wide programme directed at simplifying the replacement of animal tests with non-animal methods.
Q9: Do you have any comments on the proposed permissible purposes?	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.
Q10: What are your views on the implications of the requirements relating to humane killing? Is there evidence-based alternative provision you believe should be considered?	
Q11: What are your views on the provisions protecting endangered species? Are you aware of any current classes of animal use in the UK that would be affected?	Endangered species should not be used in procedures as defined in Article 3 of the Commission's proposal. In other words, the use of endangered species should be prohibited without exemptions.
Q12: What are your views on the provisions limiting the use of non-human primates?	An amendment passed by the European Parliament (Amendment 56) acknowledges that non-human primates have a 'particularly high level of neurophysiological sensitivity and cognitive development'. Additionally, according to a recent opinion poll, 81 per cent of the public across Europe believes 'that the new law should prohibit all experiments causing pain or suffering to primates'. There is thus a need for 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: What are your views on the provisions relating to Great apes?	The use of Great Apes in procedures must be prohibited across the whole of the EU with no exemptions. The so called safeguard clause must not be included.

Q14: What are your views on the provisions limiting the use of animals taken from the wild? Would there ever be justification for the use of such animals on the grounds that suitable purpose-bred animals were not available?	The use of all species taken from the wild should be opposed without exception.
Q15: Do you have any comments on the proposed requirements regarding the use of purpose-bred animals? Are you aware of any potential problems with the likely availability of sufficient, suitable, purpose-bred animals?	
Q16: What are your views on the proposed timetable(s) for the switch to the use of F2+ non-human primates? Do you agree that a feasibility study should be carried out to identify the best way forward?	The use of F1 generation primates (the offspring born to wild caught primates) should be prohibited earlier than the time frames suggested by the European Commission.
Q17: Do you have any comments on proposed prohibition of the use of stray and feral domestic animals?	Stray and feral domestic animals should not be used in procedures
Q18: Do you have any comments on the provisions of Article 12 relating to the conduct of procedures?	No procedures should be permitted to take place outside user establishments.
Q19: Do you have any comments on the proposed requirements regarding the selection of methods to be used in procedures?	The compulsory application of the 3Rs is extremely important and the Green Party supports the proposed requirements relating to selection of methods.
Q20: Do you have any comments on the proposed requirements regarding death as an endpoint?	Death as an end point should be prohibited. There should be no exceptions to this prohibition.
Q21: Do you have any comments on the proposed requirements regarding anaesthesia? Or our concerns about the inadequate provision made for post-operative animals?	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.

<p>Q22: Do you have any comments on the proposed severity classification requirements? Or our belief that fuller details must be agreed before a new directive is adopted?</p>	<p>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. 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.</p>
<p>Q23: Do you have any comments on the proposed limitation on the performance of "severe" procedures? Or our belief that it may prohibit important areas of research?</p>	<p>There can be no scientific or ethical justification for an animal being deliberately subjected to prolonged, severe pain. Monitoring such suffering, as suggested by the Parliament, cannot make it justifiable nor can reference to research into various chronic human conditions such as arthritis. Other, non-animal, research methods can and must be adopted.</p>
<p>Q24: Do you have any comments on the provisions for re-use or the impact it would have on current UK practice?</p>	<p>Animals used in experiments classified as 'moderate' or above should not be re-used in another experiment, without exception.</p>
<p>Q25: Do you have any comments on the provisions regarding the end of procedures? Or the reservations set out above?</p>	
<p>Q26: Do you have any comments on the proposed requirement regarding the sharing of organs and tissues and how it might be implemented in practice?</p>	<p>Sharing of organs and tissues can play an important role in achieving a reduction in the total number of animals used. Driving down the numbers of animals used is a principal objective at the heart of the draft Directive. Aside from questions of ethics, the sharing of organs and tissues, if coordinated and managed strategically, will produce cost savings. In fact, donated tissues of human origin should be used instead of animal tissues. It is a more ethical material and would give better results.</p>
<p>Q27: Do you have any comments on the proposed requirement regarding the setting free and re-homing of animals?</p>	<p>The proposal to rehome or set free animals should be supported. The draft Directive at present is specific only about cats and dogs. It is important that less favoured species such as rats and rabbits are given a chance of a new beginning. The Home Office, in its consultation commentary, is suggesting rehoming is difficult because sanctuaries are full but the authorities should provide funding and other resources so that proper provision is made for victims of animal research.</p>

Q.28: What are your views on the proposed provisions for personal authorisation? And the specific issues highlighted in our analysis?	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.
Q29: Do you have any comments on the proposed requirement for authorisation of establishments? Or our analysis of their impact?	
Q.30: What are your views on the proposed provisions for the mandatory suspension and withdrawal of authorisation of establishments for non-compliance with the provisions of the directive and on our preference for a more proportionate approach?	Any breach, which results in the suffering, neglect or harm of animals, should lead to mandatory automatic suspension.
Q31: Do you have any comments on the proposed requirement for installations and equipment?	
Q32: Do you have any comments on the proposed requirement for personnel in establishments?	
Q33: Do you have any comments on the roles proposed for the animal welfare and care person and designated veterinarian?	
Q34: Do you have any comments on the proposed requirement for permanent ethical review bodies (PERBs)? What are your views on their proposed membership? Is there a need to involve lay or external members?	Permanent Ethical Review Bodies (PERBs) in reality have little power to refuse or significantly change proposed research. Their inclination to attempt to do so will be much reduced without a genuinely independent component, with members unconnected with the establishment concerned. PERBs should have as members external lay members and experts in alternative methods.
Q35: What are your views on the proposed tasks of permanent ethical review bodies?	

Q36: What are your views on the proposed requirement that establishments breeding and supplying non-human primates shall have a strategy for increasing the supply of F2 animals?	
Q37: What are your views on the requirement for re-homing schemes?	
Q38: Do you have any comments on the recording requirements?	
Q39: Do you have any comments on the information on dogs, cats and non-human primates requirements?	
Q40: Do you have any comments on the requirements for marking?	
Q41: Do you have any comments on the requirements for care and accommodation? Should the UK retain present standards where they exceed the recommendations in Annex IV?	
Q42: Do you have any comments on the requirements for national inspections?	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.
Q43: Do you have any comments on the provisions for audit of the operation of national inspections?	
Q44: What are your views on the proposal for authorisation of projects and on possible provision for notification of projects?	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 through 'notification' at institution-level.
Q45: Do you have any comments on the proposed content of applications for project authorisation?	

Q46: Do you have any comments on the proposals for ethical evaluation of projects?	
Q47: Do you have any comments on the provisions for retrospective assessment of projects? Or our belief that further clarification is required?	Retrospective reviews should be carried out for all experiments because they would contribute important information that would drive down the total number of experiments and reduce the harm inflicted.
Q48: Do you have any comments on the provisions relating to records of ethical evaluation?	Project applications, ethical evaluation reports and retrospect assessment reports should be made publically available.
Q49: Do you have any comments on the requirement for project summaries and its impact on current UK practice?	
Q50: Do you have any comments on the provisions for granting of project authorisations? Or our preference for retaining a five-year maximum duration for project authorisations?	All projects should be licensed on an individual basis. Providing multiple authorisations reduces scrutiny and potentially damages animal welfare. Conducting lethal experiments on animals is an extremely serious matter. In each and every case, 'justification' should be offered and permission sought.
Q51: Do you have any comments on the provisions for the amendment, renewal and withdrawal of project authorisations?	
Q52: Do you have any comments on the proposed provisions relating to authorisation decisions?	
Q53: Do you have any comments on the provisions relating to the sharing of data and any practical suggestions how data sharing might be implemented in practice?	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.

<p>Q54: Do you have any comments on the provisions to encourage the development of alternative approaches?</p>	<p>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.</p>
<p>Q55: What are your views on the proposed requirements for the designation and functions of national reference laboratories?</p>	<p>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.</p>
<p>Q56: What are your views on the proposed requirement for a national animal welfare and ethics committee and how it might be staffed and resourced?</p>	<p>The proposal to create a national animal welfare and ethics committee is a good one.</p>
<p>Q57: What are your views on the proposed arrangements for updating the technical annexes?</p>	<p>The Green Party 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.</p>
<p>Q58: Do you have any comments on the proposed reporting requirements?</p>	<p>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.</p>
<p>Q59: Do you have any views on the safeguard clause? And its likely impact on current practice in the UK?</p>	<p>There must be an outright ban on the use of Great Apes across the whole of the EU with no exemptions.</p>
<p>Q60: Do you have any views on the proposal for the Commission to be assisted by a committee and of the need for the directive to contain more information on its terms of reference and composition?</p>	

Q61: Do you have any views on Article 52?	
Q62: Do you have any views on the proposal for review of the directive?	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.
Q63: Do you have any views on the provisions for competent authorities?	Whichever body(ies) is (are) assigned the role of competent authority, it is vital that it operates in a transparent and accountable manner. There is a far better chance of accomplishing this outcome if the body concerned is a public entity that has a minister at its head who is directly answerable to Parliament and the electorate. A deregulated or self-regulating competent authority could not provide such accountability.
Q64: Do you have any views on the provisions for penalties?	
Q65: Do you have any views on Articles 56, 57, 58, 59 or 60?	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).
Q66: Do you have any views on Annex I?	
Q67: Do you have any views on Annex II?	
Q68: Do you have any views on Annex III?	
Q69: Do you have any comments on Annex IV?	
Q70: Do you have any comments on Annex V?	
Q71: Do you have any comments on Annex VI?	
Q72: Do you have any comments on Annex VII?	
IMPACT ASSESSMENT	

Q. Do you agree that the retention of Directive 86/609/EEC and current UK legislation (Option 1) is not a viable option? If you disagree, please explain your reasons.	
Q. Do you have any comments on the functional headings and grouping of articles used for this impact assessment?	
Q. Can you suggest any additional sources of evidence to supplement those used in developing this impact assessment?	
Q. Can you suggest how we might estimate the monetary value of increased transparency, improved animal welfare, or increased development and use of alternative methods? Can you suggest any sources of evidence to enable such an estimate to be made?	
Q. Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the extended scope of the proposed new directive?	
Q. Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the extended scope? Can you suggest any sources of evidence to enable such an estimate to be made?	
Q. Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the authorisation, enforcement and information requirements under the proposed new directive?	

<p>Q. Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of those authorisation, enforcement and information requirements? Can you suggest any sources of evidence to enable such an estimate to be made?</p>	
<p>Q. Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the provisions in the proposed new directive relating to animal welfare and alternatives?</p>	
<p>Q. Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the provisions relating to animal welfare and alternatives? Can you suggest any sources of evidence to enable such an estimate to be made?</p>	
<p>Q. Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the provisions in the proposed new directive relating to non-human primates?</p>	
<p>Q. Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the provisions relating to non-human primates? Can you suggest any sources of evidence to enable such an estimate to be made?</p>	
<p>Q. Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the provisions in the proposed new directive relating to procedures?</p>	

<p>Q. Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the provisions relating to procedures? Can you suggest any sources of evidence to enable such an estimate to be made?</p>	
<p>Q. Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the provisions in the proposed new directive relating to personnel and training?</p>	
<p>Q. Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the provisions relating to personnel and training? Can you suggest any sources of evidence to enable such an estimate to be made?</p>	
<p>Q. Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the provisions in the proposed new directive relating to places?</p>	
<p>Q. Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the provisions relating to places? Can you suggest any sources of evidence to enable such an estimate to be made?</p>	
<p>Q. Can you suggest any additional sources of evidence to supplement those used in estimating the costs of the provisions in the proposed new directive relating to compliance?</p>	
<p>Q. Can you suggest how we might estimate the monetary value of the potential benefits to science, welfare, transparency and harmonisation of the provisions relating to compliance? Can you suggest any sources of evidence to enable such an estimate to be made?</p>	

Q. Do you have any comments on the assumptions we have made about the timing of transitional costs and benefits?	
Q. Do you have any comments on the small impact test?	