









Home Office UK bioscience sector response

Consultation on EU proposals for a new directive on the protection of animals used for scientific purposes: Home Office 2009

3 July 2009

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These submissions represent the views of the following organisations:

Association of Medical Research Charities
BioIndustry Association
Biotechnology and Biological Sciences Research Council
Institute of Animal Technology
Laboratory Animals Breeders Association
Medical Research Council
Society of Biology (Biosciences Federation and Institute of Biology until 1 September 2009)
The Academy of Medical Sciences
The Association of the British Pharmaceutical Industry
Understanding Animal Research
Wellcome Trust

We consider the following to be the priority issues for our sector:

Competitiveness of the EU

The Directive should not undermine UK and European competitiveness. The Commission proposal would create in many areas a disproportionate workload, excessive cost-burden, and unnecessary restrictions to research, without proportionate benefit to animal welfare. It would make it increasingly difficult for international scientific collaborations with countries outside of the EU and for researchers wishing to work in Europe from other countries.

Restrictions on the use and supply of non-human primates

We disagree with attempts to impose sweeping restrictions or ban or set targets to reduce Non-Human Primate (NHP) use. This could have seriously negative impacts on fundamental and applied science, and on medical advances for patients across the world. Careful ethical evaluation and harm-benefit assessment is already required before primate use is authorised.

A blanket requirement for the use of second generation (F2) NHPs (ie offspring of animals that have been bred in captivity) would be problematic. Before time lines can be established this would require a feasibility study to assess the impact of such a policy both on animal welfare and on the availability of NHPs to EU researchers.

1 www.homeoffice.gov.uk/documents/cons-2009-animals-research/cons-2009-animals-research?view=Binary

Authorisation of decisions

The administrative implementation of the Directive must be clear and well-defined. It is currently confusing and unnecessarily bureaucratic, with potential for unnecessary delays and restrictions to research that would not promote animal welfare or the 3Rs. The Directive does not apply proportionality, in that the degree of control is not adjusted in relation to the potential harm to the animals.

Scope of the Directive

A number of the proposed extensions to the scope of the Directive are not based on scientific evidence , would significantly increase costs, and present an unworkable administrative burden with no benefit to the welfare of animals. These include the full regulation of all vertebrates humanely killed for their tissues, and the extension of species covered by the Directive to include embryonic and foetal forms of vertebrates, as well as certain additional classes of invertebrate, including their larval forms. Reliable evidence of sentience has not been scientifically established for most of the animals covered by these extensions.

Care and accommodation

We support the principle of minimum standards of care and accommodation across Europe (with derogations where necessary, eg for farm animal research). The Directive, as currently proposed, is overly prescriptive around cage sizing and environmental requirements. As well as greatly increasing costs for research, some proposals would be actively deleterious to welfare and may compromise the ability of the UK to maintain its animal breeding capabilities.

Alternative methods

The 3Rs are an intrinsic part of scientific research, not a separate activity. Much of the evidence contributing to the 3Rs has come from research that had other primary aims. 'Validation' of the 3Rs is best undertaken through normal scientific processes and not through separate national reference laboratories in every individual Member State. It is unlikely that these could ever contain all the necessary expertise and facilities, and they would be expensive and duplicative.

Sharing and disclosing data

There is no evidence of widespread duplication. Mandatory data-sharing proposals fail to recognise existing initiatives to avoid unnecessary duplication of animal research, the degree of success already achieved, and the technical and legal difficulties involved. They would have a detrimental impact on both industrial and academic research in a globally competitive marketplace, even though there is no evidence that significant welfare benefit would result.

Re-use

The excessive restrictions imposed by the Commission on the re-use of animals would make it extremely difficult to maintain many research programmes in the EU and, by hindering the application of the 3Rs, would have adverse effects on animal welfare.

Classification of severity levels

It is very important that severity levels of procedures are properly and precisely defined within the Directive, not least since this is relevant to important judgments elsewhere in the Directive. Bands must appropriately encompass all levels of regulated use, to encourage refinement from one band to a lower one.

Preface

We have some overarching concerns which pertain to the draft Directive as a whole, as listed below:

1. The Directive is overly-prescriptive and inflexible. In many areas it attempts to define specific details, rather than provide general provisions for the achievement of defined outcomes. This will potentially hinder the continued development of desired outcomes such as refinement of techniques and 3Rs technologies, for example around humane killing and accommodation requirements.

2. Clarification of mandatory provisions: The legal basis for how the mandatory provisions in the annexes are to be implemented and enforced needs to be made clear. The details in Annex IV, for example, were originally guidelines and not legally binding. The requirements are not clear and in some cases may be detrimental to animal welfare. There need to be provisions to make derogations from the annexes on the basis of scientific and animal welfare requirements. The ability of our sector to evaluate the potential impact of the annexes will depend on how and whether such derogations can be achieved.

3. Clarification of drafting: There are a number of places where the drafting needs to be tightened to avoid potential legal challenges over interpretation of the provisions. This should be a concern, not only for our sector, but for authorising bodies.

4. Over regulation: The UK has a tendency to implement EU legislation rigorously whilst other Member States do not do so consistently. This has led to tighter regulations being implemented in the UK. We are concerned that the ability of Member States to adopt stricter national measures seeking to improve the well-being and protection of animals used for scientific purposes runs counter to the aim of harmonisation, and may result in further disparities between Member States than what the Directive is currently trying to address. Our preference is that this should not interfere with key elements of beneficial harmonisation, such as mutual recognition of project authorisation between Member States, common training requirements etc. Some areas of the Animals (Scientific Procedures) Act 1986 (A(SP)A) are more restrictive than the current draft Directive. We consider the Home Office should consult on such areas, for scientific and welfare reasons.

In this response, all reference to "Amendments" refer to the respective numbered amendments passed by the European Parliament at the end of its first reading on 5 May 2009[2].

2 http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P6-TA-2009-0343

Chapter I: General Provisions

Article 2: Scope – 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?

This Directive should apply to the accommodation and husbandry of animals used or intended to be used in procedures or where they are bred specifically so that their organs or tissues may be used for scientific purposes. However, neither breeding (including of established genetically altered (GA) strains with no phenotypic deficit) nor humane killing (so long as it is carried out in accordance with Annex V or other methods subsequently endorsed) should constitute a procedure (with all the necessary requirements for ethical evaluation, approval and counting). This would cause a major increase in regulatory burden with no animal welfare benefit. Indeed it may adversely affect welfare in that raising the level of bureaucracy and cost around using isolated organs and tissue removes an incentive to use them instead of using living animals. It therefore runs counter to the 3Rs agenda.

An alternative approach could be to include animals killed for organs or tissues within the accommodation and husbandry requirements of the Directive, exclude them from all other requirements such as the need for project authorisation, but include them as a separate category in the Annual Statistics. This has two benefits in that it increases transparency around the total number of animals used (a regular criticism of animal research) and would bring the UK in line with a number of Member States that already do so. However, we would not wish to see included in these numbers animals culled during breeding. Simply counting them would be an additional unnecessary bureaucratic burden, for no welfare benefit.

We would prefer to see in the Directive an explicit exclusion ensuring that humane killing is not regulated as a procedure. In general, our sector supports the operation of the current UK system of the humane killing of protected animals under Schedule 1 of the A(SP)A, and would support a system which worked in an equivalent way with minimal bureaucracy.

Article 2: Scope – Q2: What are your views on the provisions regarding the protection of immature forms?

Including all embryonic and foetal forms of all the proposed protected species from the last third of their development is arbitrary, since sentience has not been established for all of them, notably invertebrates. Amendment 30 has thus helpfully restricted the “independently feeding larval forms and embryonic or foetal forms” to species of mammal as from the last third of their normal development. The wording, however, will need further clarification, since mammals do not have independently feeding larval forms. The European Parliament amendment would now exclude fish embryos, which are used as alternatives to higher animal species. We support this, since including them in the scope would subject them to administrative procedures listed in the Directive, and discourage further research on alternative methods using these immature non-sentient forms. However, there needs to be clarity on what constitutes “immature” for free living vertebrate forms (fish and amphibians).

Article 2: Scope – 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?

There is no clear scientific rationale as to why the scope should be extended to the range of invertebrates selected. The report of the Scientific Committee of the European Food Standards Agency (EFSA) does not provide robust scientific evidence to support such an extension. Extensive studies have not produced scientific evidence that decapods perceive pain and might "suffer" during scientific procedures. There may be a tentative case for extending EU regulation to certain adult form cephalopods, such as octopus (Superorder *Octopodiformes*), squid and cuttlefish (Superorder *Decapodiformes*). There is some evidence that these animals may experience pain as a result of having well developed senses and complex nervous systems.

Including other invertebrate species has no scientific basis. Similarly, including immature forms of any invertebrate species has no scientific justification and would result in regulation covering enormous numbers, given the density of immature planktonic forms in every sample of seawater.

Over the past 10 years, the BBSRC, MRC and Wellcome Trust have funded the following numbers of grants/programmes on these species (excluding any purely observational research). Numbers of animals are not available as they are not usually specified in applications.

Number of grants	BBSRC	MRC	WT
Cyclostomes	6	0	2
Cephalopods	5	0	11
Decapod crustaceans	2	0	0
Totals	13	0	13

Figures from other funders (including the private sector) are not available.

> **Article 2: Scope – Q4: Do you have any views on the proposed exemption affecting veterinary clinical trials?**

Legal clarity will be required in each Member State over the relationship between the Directive and veterinary and animal welfare legislation, so as to ensure that clinical trials are covered by one of them. A sensible dividing line could be to exclude tests on animal patients under veterinary care (including clinically normal animals such as in vaccine trials) but to include any tests on purpose-bred animals.

> **Article 2: Scope – 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?**

The generic wording of the Directive should be such that, of practicable methods to achieve the objective, those causing the least pain, suffering, distress, and lasting harm must be employed in all situations. Such generic wording ought to render unnecessary much specific cover such as that addressed here.

Whilst clearly the most appropriate humane methods should always be used, there are some situations in which it is difficult to be definitive about the most appropriate method and whether there is consistency between groups. Since judgments need to be made, the Directive should not be overly prescriptive.

Article 2: Scope – Q6: Do you have any comments on our approach to the proposed exemption of non-invasive practices?

The wording required here depends on clarity over other issues. Two definitions are of particular importance and need clarification:
i) 'lasting harm' – whether death is considered a lasting harm; and
ii) 'procedure' in Article 3.

There are potential difficulties over the use of "non-invasive" or "observation" for the exemption: for instance a non-interventional study of adult males fighting to the death would apparently be exempted. We prefer to retain wording based on not causing pain, suffering distress or lasting harm as in Amendment 33. In addition, we consider use of the word "may" in the definition of a procedure to be highly problematic, because there is always a remote possibility that anything done to an animal "may" cause pain, suffering, distress and lasting harm even when it is neither likely nor intended to do so. This has caused difficulties for the interpretation of the A(SP)A in the UK. We support the substitution of "is likely to" or "is expected to" instead of "may" throughout the text of the Directive.

Article 3: Definitions – Q7: Do you have any comments on any of the 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?

We support the Home Office seeking clarity on the definitions of key terms. We note a number of new definitions have appeared in the texts adopted by the European Parliament. These will require careful consideration, as some appear to define terms which do not appear in the proposal. As stated under Q6, the definition of "lasting harm" would be helpful. The Parliament's revised definition of procedure in Amendment 34, suggested to cover "may or may not cause pain etc" is all-embracing and would cause substantial difficulties.

Article 4: Replacement, reduction and refinement – Q8: Do you have any comments on the provisions of Article 4 relating to replacement, reduction and refinement?

We consider the first part of Amendment 170 to be an improvement on the Commission proposal. In addition, we support the Home Office view that the use of replacement alternatives should be limited to those which are reasonably and practicably available, and to those that have been appropriately validated for the relevant purpose.

We note that it is not within the remit of a Member State to "ensure that the alternative method is used". Rather, the Member State may only refuse to authorise the use of protected animals.

We recognise the difficulty of finding a reasonable balance across Europe between the use of human embryonic and foetal cells as alternatives, and the ethical concerns about that use. Where the use of human embryonic and foetal cells does constitute a viable alternative to the use of animals, this should only take place in those Member States where the legislation allows it.

Article 5: Purposes of procedures – Q9: Do you have any comments on the proposed permissible purposes?

We support the Home Office approach in the consultation document. In addition, we support Amendment 51.

In order to allow the development of medical devices, we support the addition of "or treatment (including development of medical devices) of disease" to point 2a.

Article 6: Humane methods of killing – 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?

We are satisfied with the provision that Member States should ensure that animals in an authorised establishment are killed by an authorised person and with a minimum of pain, suffering and distress, and in relation to the species included in Annex V, using an appropriate humane method of killing as set out in that Annex.

However, as well as addressing specific omissions and errors in the Annex, we wish to see the generic ability to use such other methods as are scientifically demonstrated to be at least as humane. Where an equally or more humane method of killing is possible and readily available, it could and/or should be used even if it is not included in Annex V. We therefore support Amendment 52. There is need for clarity over humane killing outside designated establishments, such that there is a generic requirement to use the best and most humane method in all situations, while allowing such practices to take place without requiring authorisation at national level.

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

Article 7: Endangered species other than non-human primates – 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?

We have no major concerns about the provisions relating to the use of endangered species, and support the position taken in the draft Directive. We support the helpful intention of the Home Office to clarify that evidence gathering by a veterinary surgeon relating to wildlife crime would be unaffected. It is, however, important that the provisions on release do not preclude the release of wild-caught animals (especially of endangered species) used in wildlife or other studies.

We believe it is widely recognised and agreed that none of the monkey species commonly used in research is endangered, and the Directive should acknowledge this.

Article 8: Non-human primates – Q12: What are your views on the provisions limiting the use of non-human primates?

We agree with the statement in the draft Directive that use of NHPs is of highest concern to the public. However, the UK public remains supportive of research, including the use of NHPs, when appropriate and proportionate controls are in place. The revised Directive should recognise the positive contribution that the use of NHP has made, directly and indirectly to treatments for humans and animals. It should also acknowledge the expert views of the Commission's own Scientific Committee on Health and Environmental Risks (SCHER) report, which cites internationally peer reviewed scientific evidence.

Limiting the use of NHPs to "life threatening or debilitating clinical conditions" as per Article 8 (1) (a), would: (i) substantially restrict fundamental research crucial to further development of therapeutics for human and animal health; (ii) limit R & D investment in health related-sectors; and (iii) slow innovation and vaccine and drug development and commercial collaboration.

However, nobody can predict in advance which areas of research are most likely to deliver scientific and medical benefit and in that light we are against arbitrary and artificial restrictions. The history of medical advance clearly shows it will not be possible for those administering the Directive to distinguish between projects whose object is better understanding and greater knowledge from those which might produce direct clinical or veterinary benefit.

The protections and controls for the use of NHPs are already very stringent, including ethical review, harm/benefit assessment, and explicit authorisation, as well as annual and retrospective reviews. They are sufficient for any foreseeable situation. Moreover, there is no evidence that NHPs are used for trivial purposes in Europe and the high costs of such research mean that funders are likely to be particularly selective and only fund work which has been deemed very important through peer review

We consider Amendments 56 and 57 to adequately address our concerns by lifting the restrictions on the use of NHPs, and believe they should be supported.

Article 8: Non-human primates – Q13: What are your views on the provisions relating to great apes?

Great apes have not been used in research in Europe since 2000. However, we strongly argue that the safeguard clause be retained. For example, vaccines for Hepatitis C are being developed in chimpanzees, as that is the only other species, aside from humans, which develops a Hepatitis C infection. It is essential that researchers are able to use great apes, should the need arise, especially as we are repeatedly seeing new disease variants and as global pandemic threats emerge. The policy on great apes need to reflect this.

Our organisations understand that the commitment of the UK government not to allow the use of great apes relates to the operation of cost-benefit assessments under ASPA. We support the contention of the Home Office that the exemptions allowed could only be invoked in genuinely exceptional circumstances, and consider therefore that this provision is close to a ban on the use of great apes consistent with current UK policy.

The right must be retained to use great apes for the preservation of great apes, such as for the development of a vaccine in the event of a new infectious disease, or the spread of an existing disease.

Article 9: Animals taken from the wild – 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?

In principle we support the implied intention of the draft Directive not to permit the use of wild-caught animals for medical research, although we consider this should be restricted to vertebrates. This is consistent with current practice in the UK and can be supported as long as there is exemption on the basis of scientific justification. An exemption on the basis of availability is supported so long as there are sufficient safeguards, for example to protect endangered species.

We would prefer to see an automatic exemption where wild animals are the subject of study under Article 5 paragraphs (4) and (5) written into the Directive. In light of environmental threats such as climate change, pollution and habitat destruction, it is vital that, for example, conservation studies can proceed without undue bureaucratic impediment.

It should be noted that some genetic strains of mouse lines used for experimental purposes were originally taken from the wild to develop mouse lines and so these are not purpose bred.

Article 10: Animals bred for use in procedures – 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?

The Directive should make allowance for the ability to use wild animals for agricultural, veterinary and wildlife research as appropriate. In addition, if invertebrates are included in the scope, then it might be acceptable to use animals taken from the wild.

A number of institutions or organisations that we are aware of are suggesting additional animals which need to be listed in Appendix II.

Article 10: Animals bred for use in procedures – Q16: What are your views on the proposed timetable(s) for the switch to the use of F2+ nonhuman primates? Do you agree that a feasibility study should be carried out to identify the best way forward?

It is unfortunate that the Directive was drafted before the publication of the SCHER report. We hope that the Commission will acknowledge and accept the findings of that report.

The provision for the switch to F2+ NHPs will compromise supplies of such animals for EU research programmes. Demand already exceeds supply and it is likely that breeders will favour other countries first which do not impose such restrictions, especially given the relatively small market share made up by EU research.

The requirement to use F2+ animals will necessitate a greater than 100% increase in the number of animals kept in captivity for breeding purposes. This has potential adverse animal welfare implications, contradictory to the intended aim.

The availability of first and second generation purpose-bred macaques is already such that breeders and suppliers can currently only just cope with the demand from the global scientific community. Macaques (cynomolgus and rhesus) are the more frequently used species of NHPs in toxicology tests to assess the safety of new drugs and in neurological disease models such as Parkinson's, infectious diseases, and in the production of vaccines.

There is inadequate information to fully evaluate the ability to achieve self-sustaining colonies of F2+ macaques. However, anecdotal evidence suggests significant problems with inbreeding and impact on fertility rates and other physiological parameters. These studies need to be properly completed to better assess the impact of an F2 requirement both on animal welfare and on research.

We therefore support Amendment 60 which provides that an animal welfare assessment and feasibility evaluation of implementation of the F2 requirements should take place five years after entry into force of the Directive.

The Commission suggests that its proposals are intended to encourage the move towards F2, whilst allowing flexibility in case the requirements are not achievable. We believe this approach is flawed because: (i) the welfare implications have not been adequately assessed (as outlined above and also in assessing breeding centres which provide F2s), (ii) this would make it difficult to operate research programmes which have uncertainty over the availability of NHPs hanging over them, and (iii) it would strongly deter major investment into Europe in the current internationally competitive climate.

Article 11: Stray and feral animals of domestic species – Q17: Do you have any comments on the proposed prohibition of the use of stray and feral domestic animals?

The welfare of these animals is regrettably poor at times. We would therefore suggest that research is allowed on these species under Article 5 point 5, as under Amendment 51, but not for other reasons.

Chapter III: Procedures

Article 12: Procedures – Q18: Do you have any comments on the provisions of Article 12 relating to the conduct of procedures?

We have concerns relating to the proportionality of the administrative systems of approval. There remains an important need for field studies / farm animal research, and extra administrative hurdles should not be put in their way, eg when they require exemption from generic restrictions. We would welcome a commitment from the Home Office to a mechanism of exemption that promotes the principles of better regulation, or appropriate amendments to the Directive to automatically exempt these studies (for example from the prohibition of using animals taken from the wild).

Article 13: Methods used in procedures – Q19: Do you have any comments on the proposed requirements regarding the selection of methods to be used in procedures?

We support the proposals in the draft Directive.

Article 13: Methods used in procedures – Q20: Do you have any comments on the proposed requirements regarding death as an endpoint?

We agree that death as an endpoint of a procedure is to be avoided unless strictly necessary – but this would be considered during the ethical review process in any event. We support the intention of the Home Office to seek confirmation that the killing of animals by humane methods, such as for their tissue and organs, will be considered to fall out with this restriction. (see also answer to Question 1).

Article 14: Anaesthesia – Q21: Do you have any comments on the proposed requirements regarding anaesthesia? Or our concerns about the inadequate provision made for post-operative animals?

We recognise that anaesthesia and analgesia must be used for surgical interventions. However, pain warranting anaesthesia affects only a minority of procedures. Its use should be for the benefit of the animals, where this is compatible with the objectives of the procedure, but this would be determined as part of the harm:benefit assessment during ethical review without requiring anaesthesia as the default position. Justifying an exemption should not be required for most cases, and in that light we are concerned that compliance with Article 14 may cause unforeseen legal problems.

We therefore support Amendments 65, 66 and 67. In addition, we consider that Article 14 – paragraph 5 should stipulate that where analgesic use is not possible, the animal shall be immediately killed by a humane method "unless the scientific justification and ethical review have resulted in authorisation to continue the procedure".

We accept the position of the Home Office that the majority of post-operative animals require appropriate analgesia even though they are not at risk of considerable pain. We note that Amendment 68 removes the word "considerable". We are concerned that this provision would cover any potential occurrence of any degree of pain, even if it might be no more than mild or transient discomfort. This could cause a significant increase in the unnecessary use of analgesics for rodents, even when the adverse effects of drug administration may exceed that of the procedure. It may be preferable to stipulate "significant" pain, or similar wording.

Article 15: Classification of severity of procedures – 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?

It is very important that severity levels of procedures are properly and precisely defined within the Directive. Clear bands must appropriately encompass all levels of regulated use, so as to encourage refinement from one band to a lower one.

We support clarification on whether the proposed categorisation will relate to the "likely or typical" or the "worst possible or maximum" outcome for the animals, and on whether the re-use requirements for individual animals relate to the prospective assessment or actual welfare outcomes of the re-use.

We believe it would be appropriate to adopt the UK terms of mild, moderate and substantial rather than those proposed in the Directive. The use of the term 'substantial' is preferable to the term 'severe'. Its use would leave the term "severe" open for use as a category that defines what types of harm to animals should not be authorised.

We welcome the setting up of a Commission working group on severity classification, and intend to input to this process.

Article 15: Classification of severity of procedures – 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?

We do not support the provisions of Article 15 which prohibits "severe" procedures if the pain, suffering or distress is prolonged (even if not severe). We share the Home Office view that this restriction could preclude research into the most debilitating or serious human and animal diseases. Instead the approach should be to ensure rigorous ethical review incorporating a harm:benefit analysis that ensures that serious adverse impact is only authorised when the likely benefit warrants it. A reference point in human clinical conditions could be appropriate here: the procedures to be undertaken would be no worse than those suffered by human patients and would almost always be far shorter-term (eg about two weeks for arthritis studies in rodents compared with decades for the disease in humans). We support the intention of the Home Office to permit the continuation of such research, subject to proper ethical review.

Article 16: Re-use – Q24: Do you have any comments on the provisions for re-use or the impact it would have on current UK practice?

The excessive restrictions imposed by the Commission on the re-use of animals would make it extremely difficult to maintain many research programmes in the EU – by increasing costs and the number of animals used. By hindering the application of the 3Rs, they would also adversely affect animal welfare.

These concerns were addressed in Amendments 72, 73, 74 and 75 which we support.

We support the Home Office in seeking drafting changes to permit the continued responsible re-use of animals. We wish to clarify that our sector is not seeking to increase the re-use of animals beyond what is currently allowable under UK legislation. We accept the need for restrictions, and that re-use should involve neither repeated severe suffering, nor prolonged and cumulative high

levels of suffering. We consider the best way of defining acceptable practice is through appropriate guidelines developed in consultation with stakeholders, together with ethical evaluation and veterinary determination for individual cases.

> **Article 17: End of the procedure** – **Q25: Do you have any comments on the provisions regarding the end of procedures?**

We agree with the presumed intent of these provisions but the wording is problematic. Clarification is required that: Article 17.2 applies only where there is a proposal to keep the animal alive, but does not require veterinary input prior to planned humane killing. Article 17.3 applies only after the procedure has finished, and is not a reason for terminating the procedure. Article 17.4 applies only during the transition to a post-procedure husbandry system, not for the rest of the animal's life, which would not be under the jurisdiction of the veterinary surgeon to control.

> **Article 18: Sharing of organs and tissues** – **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?**

We support the position outlined by the Home Office in the consultation document. We consider that Amendment 77, which stipulates encouragement of programmes for sharing animal organs and tissues, is an improvement on the Commission proposal.

> **Article 19: Setting free of animals and re-homing** – **Q27: Do you have any comments on the proposed requirement regarding the setting free and rehoming of animals?**

The current wording is restrictive; for instance it would apparently not permit release of farm animals that have been used in research back into a farming system. We therefore support Amendment 78 which provides greater clarity as well as the ability to release animals into their original habitat or return them to a husbandry system appropriate to the species.

Chapter IV: Authorisation

Article 20: Authorisation of persons – Q.28: What are your views on the proposed provisions for personal authorisation? And the specific issues highlighted in our analysis?

We support the position of the Home Office as outlined in this consultation document. In addition we support Amendments 81, 82 and 83.

We agree that harmonisation of authorisation of persons and projects is an important part of both the free movement of skilled labour and EU-wide research collaboration. While this is recognised in the Recitals, it is not reflected in the Articles.

Article 21: Authorisation of establishments – Q29: Do you have any comments on the proposed requirement for authorisation of establishments? Or our analysis of their impact?

We agree with the Home Office's concerns. The proposal to require authorisation of breeders and suppliers for all species needs to be re-considered (particularly if invertebrate species are to be included). The practicalities of ensuring supply of less commonly used animals from authorised breeding establishments would prove difficult, and the cost would be prohibitive. Given that appropriate welfare and quality controls should already be in place for farm livestock, the costs and limitations far outweigh any marginal welfare gains.

Article 22: Suspension and withdrawal of authorisation – Q.30: What are your views on the proposed provisions for the mandatory suspension and withdrawal of authorisation for non-compliance with the provisions of the directive and on our preference for a more proportionate approach?

We fully support the Home Office proposal for a more proportionate approach. In addition, we support Amendment 84, with its inclusion of a right of appeal. Unless this is clearly defined and more proportionate, it could have major consequences. For example the loss of a major study for a minor technical breach could significantly delay the delivery of medicinal therapeutics to patients.

Article 23: Requirements for installations and equipment – Q31: Do you have any comments on the proposed requirement for installations and equipment?

We agree with the intent, but the stipulation of "obtaining consistent results", while desirable, is scientifically impossible to predetermine and should therefore not be legislated.

Article 24: Requirements for personnel in establishments – Q32: Do you have any comments on the proposed requirement for personnel in establishments?

We support the position of the Home Office on this requirement. While we agree that skilled staff must be on call at all times, we are concerned about the interpretation of Amendment 86 which requires at least one trained person available at all times. It must be clarified that this is not necessarily on-site, let alone on every site within an establishment.

Article 24: Requirements for personnel in establishments – Q33: Do you have any comments on the roles proposed for the animal welfare and care person and designated veterinarian?

The wording of Article 24 should not be so detailed or prescriptive. It should identify clearly the outcomes which it is intending to achieve, and require Member States to set up systems to achieve the outcomes. It is potentially problematic in several respects.

Article 24.1.b places the legal onus of "ensuring" compliance on the care staff, which could potentially undermine relationships, particularly with the project licence holder. The A(SP)A does not require the Named Animal Care & Welfare Officer (NACWO) and Named Veterinary Surgeon (NVS) to identify and rectify non-compliance. However ASPA does require the Certificate Holder to "put in place systems that ensure compliance" with the possibility of notification of non-compliance to the Inspectorate "by the Certificate Holder or those acting on his or her behalf". In practice these systems and such notification may be managed daily by senior Named Persons and therefore the proposed role of stopping/preventing unauthorised procedures and studies where animal welfare is unduly compromised will likely be undertaken informally by the Named Persons. This informal role is best conducted in an advisory and collegiate manner and it is important that this beneficial working relationship can be maintained. This should be possible by maintaining a separate external Inspectorate.

Article 24.1.d requires that even trivial non-compliance (eg temporary temperature changes) would require cumbersome reporting – which is inappropriate. On the other hand, significant issues of non-compliance that adversely affect animal welfare should be reported to the national inspection body as well as the ethical review body.

The requirement of Article 24.2 for veterinary expertise in laboratory animals is not necessarily appropriate for studies on non-laboratory animals (eg farm or wild animals).

Article 25: Permanent ethical review body – 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?

We have had no objections to the way lay members join the ethical review process in the UK. It is difficult to define exactly the nature of the ideal "lay" member, and there can be problems recruiting them, particularly in certain institutions, for example those which are small or geographically isolated.

We would oppose any provisions for individuals or organisations which actively campaign against the use of animals in research to have a right to be involved in the ethical evaluation process or body. The right of appointment to the permanent ethical review bodies (PERBs) should rest with the institution. Experience in other countries is that where this is not the case serious disruption to research can ensue.

Article 26: Tasks of permanent ethical review body – Q35: What are your views on the proposed tasks of permanent ethical review bodies?

This article should be based on more general provisions, setting out the intended objectives which the PERB should achieve, rather than the detailed description of their operation and tasks.

We share the concern over the requirement to review projects annually and consider that compliance would add substantially to costs. We therefore support the limitation, in Amendment 89, of annual reviews to those projects of greatest welfare concern.

We remain concerned at the lack of clarity over the institutional vs competent authority roles in ethical review. For instance, although Article 26.1 a-c is about providing advice, paragraph 1 d-e is about implementing regulation, which elsewhere is stated to be the role of the competent authority, not the PERB. Such overlap and duplication should be avoided.

> **Article 27: Breeding strategy for non-human primates – 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?**

This is another aspect where the Directive runs counter to the SCHER report. We share the Home Office concerns that these provisions could reduce supply and/or increase costs. If it is true that this provision can only apply to breeders and suppliers located within the EU, then its impact is unclear.

> **Article 28: Re-homing scheme – Q37: What are your views on the requirement for re-homing schemes?**

The definition of 'rehoming' (here and in Article 19) needs to be tighter to distinguish (a) the release of cats and dogs etc to domestic homes (which is presumably what is intended), (b) the release of agricultural stock to commercial farming enterprises or the release of wild animals back to the wild, which should not be restricted, from (c) the release of GA animals, which should not be allowed.

This is an example of where having two separate Articles rather than one risks causing confusion rather than clarity.

> **Article 29: Records on animals – Q38: Do you have any comments on the requirements for records on animals?**

We support the principle of common, minimum information requirements for animal record-keeping by establishments. Such requirements should be proportionate to the welfare costs incurred. What is appropriate also depends on other provisions within the Directive, such as the extension of the scope to cover potentially large numbers of non-sentient animals.

We support Amendments 94, 95 and 96, although amendment 95 should stipulate "mammals" rather than "vertebrates", and should only take effect at weaning rather than at birth.

> **Article 30: Information on dogs, cats and non-human primates – Q39: Do you have any comments on the requirements for information on dogs, cats and nonhuman primates?**

We accept these requirements are broadly consistent with current UK requirements, and support Amendment 98. Where animals are imported or reared in semi-extensive conditions, it may not be possible to comply with all requirements eg establishing a file at birth.

> **Article 31: Marking – Q40 Do you have any comments on the requirements for marking?**

No.

Article 32: Care and accommodation – Q41: What are your views on the requirements for care and accommodation? Should the UK retain present standards where they exceed the recommendations in Annex IV?

We share the concerns of the Home Office over the provisions in this article.

We support the principle of minimum standards of care and accommodation across Europe (with derogations where necessary, eg for farm animal research in a commercial setting). The Directive, as currently proposed, is overly prescriptive around cage sizing and environmental requirements. As well as greatly increasing research costs, some proposals may compromise the UK's ability to maintain its animal breeding capabilities and some areas of research. Relying on imports would be bad for welfare (increased transport times, reduced controls over accommodation) and would threaten supply reliability (eg antivivisection groups pressurising carriers/ports).

A preferable solution would be for the recitals to refer to Appendix A as preferred guidelines. Minimum standards in Annex IV could then be based on established criteria, striking a balance between animal welfare and cost.

An alternative proposal is that Appendix A should be the formal basis on which national authorities inspect and implement, with the ability to apply discretion and derogations, as well as scientific judgment.

After the Directive has been agreed, the Home Office should consult specifically on those requirements for enclosure size and space allowances which fall below those set out in present UK codes of practice. It is impossible to say before seeing the final text of the Directive what the discrepancies will be.

Some in our sector have concerns over reverting more to the terms of ETS123, namely the controls over relative humidity. These have never been justified scientifically, and are enormously expensive in terms of both capital expenditure and energy consumption. Moreover they can be actively deleterious to welfare because of (a) the reduction in environmental enrichment that complete consistency generates and (b) the substantially enhanced risks that the highly complex control systems will fail with disastrous consequences for temperature control. We strongly recommend that relative humidity controls not be included in the Directive in terms other than the generic one of ensuring that animal welfare is safeguarded. Exceptions to daily observation of animals (Amendment 100) should be permitted when welfare could be compromised (eg rodent neonates or animals in isolators). The frequency of observation should be in line with good animal husbandry.

Article 33: National inspections – Q42: Do you have any comments on the requirements for national inspections?

We support the proposal and we recognise the value of inspections so long as their frequency and the power exercised are proportional to the welfare issues under inspection. We support a risk-based approach to inspections (and favour the wording in Amendment 103 for "adapting the frequency of inspection on the basis of a risk analysis for each establishment"). A greater frequency than twice a year (depending upon institutional size and the scope of work) with some proportion of visits unannounced could contribute to greater compliance. However, announced visits can also result in improved co-operation and information exchange between the inspectorate and the institution. Such co-operation is an important part of identifying ways to improve standards.

We would wish to see a minimum level of inspection maintained, so do not necessarily support the first part of Amendment 103, for which we are not aware of the rationale.

> **Article 34: Controls of national inspections – Q43: Do you have any comments on the provisions for audit of the operation of national inspections?**

Despite the risks of increased bureaucracy, we see potential benefits for harmonisation and the enforcement of standards if the Commission is required to carry out audits, in accordance with Amendment 186. We concur with the points made in paragraph 145 on biosecurity and confidentiality.

> **Article 35: Authorisation of projects – Q44: What are your views on the proposal for authorisation of projects and on possible provision for notification of projects?**

Our primary concern is for a system of approvals (whether authorisations or notifications) which is proportionate, flexible and risk-based. The Directive is currently confusing, complex and unnecessarily bureaucratic, with potential for unnecessary delays and restrictions that would not promote animal welfare or the 3Rs. Proportionality should operate in particular in relation to the degree of control against the severity level, and to some extent the species (and their stage of development) intended to be used.

The Directive should therefore seek to identify the outcomes it is intending to harmonise, rather than the mechanisms to achieve them. The Directive should set out as clearly and simply as possible the relationship between ethical evaluation and authorisation, and what elements need to be assembled and addressed at which stage. We consider that each aspect requiring review should be deliberated only once.

The main elements of proportionality which we would propose are as follows:

for projects where the harms to the animals are less, and/or species of lower neurophysiological sensitivity used, then considerably less detail should be needed in relation to information requirements (ie very short project licences), and the time limit on the whole approval process (including ethical evaluation) should be linked to the severity.

The comments in the consultation document appear to relate to projects as currently defined under ASPA. However, the scope of the Directive may become considerably broader and include aspects (such as humane killing for tissues, and microscopic invertebrate animals) that are currently not subject to licensing at all in the UK. Should licensing of such projects become required, then notification could be entirely appropriate. Until the scope of cover, the severity classification and the definition of 'procedure' are finalised, we wish to preserve the possibility of notification of those 'procedures' having the lowest welfare impact. However, in our view 'notification' must involve a delay before implementation, so that the competent authority has an opportunity to pick up on any concerns. We do not favour retrospective notification.

Even with projects as defined under ASPA, notifications would be appropriate in certain circumstances. For example, in the case of minor technical amendments to project licences which do not significantly change either the species, or the severity level, or the animal numbers, it is difficult to see why these should not be subject to advance notification, The same applies to renewal of licences involving routine mild or non-recovery procedures.

We therefore consider that it is entirely feasible for the UK to operate advance notifications for some categories of licencing. However, we recognise the Home Office concerns in relation to maintaining public confidence in a system which has long operated exclusively by a system of authorisation. We therefore reiterate that our primary concern is the proportionality of the system and the effective functioning of its administration.

> **Article 36: Application for project authorisation – Q45: Do you have any comments on the proposed content of applications for project authorisation?**

We agree that having a severity classification is a requisite for decisions on all stages of the licensing procedure. We consider that the information requirements for authorisation should have their wording and requirements harmonised with the information requirements for ethical evaluation, so that applicants do not have to re-assemble the same information in a slightly different way.

We support the intent of the proposal to allow applicants to submit a reduced project proposal for "mild" projects. However, we would wish to see a far less prescriptive approach to begin with, and more comprehensive and explicit methods for achieving proportionality.

It is difficult to comment on the requirement in Article 36 without knowledge of the final scope of the Directive (species, stages and procedures).

We consider that the use of the word "indispensable" in Amendment 110 and 111 is a translation error, and should read "necessary".

Persons involved in the project may change over time, and therefore authorisation is not an appropriate place to require demonstration of competence of persons.

> **Article 37: Ethical evaluation – Q46: Do you have any comments on the proposals for ethical evaluation of projects?**

We share the Home Office analysis that the information requirements are suitable, but are concerned about the confusing overlap and discrepancies in wording between the often similar requirements for authorisation and ethical evaluation. We would wish to see these harmonised.

While we are supportive of seeking the views of experts who are entirely independent of the research to be carried out, we share the concerns about the requirement in Article 37 para 4 for "integrating the opinion of independent parties". At the very least, the wording should be amended, either from "integrate" to "take account of" (as in the Home Office consultation); or by leaving the right of appointment of the independent parties with the institution. It would, for example, be impossible to properly integrate into ethical evaluation the views of individuals and organisations who completely oppose animal research.

> **Article 38: Retrospective assessment – Q47: Do you have any comments on the provisions for retrospective assessment of projects? Or our belief that further clarification is required?**

We agree that clarification is required. We also consider that the Commission has over-emphasised the potential benefits of retrospective assessment, and under-estimated the additional administrative burden. We support Amendment 120 to exempt projects with procedures rated "up to moderate" from retrospective assessment.

There is also the issue of how retrospective assessment relates to any annual review. Potentially at the end of the project there could be a requirement for both a final annual review and retrospective review, undertaken by different bodies. These two requirements must be considered together with the aim of the requirements being proportional and restricted to areas where welfare benefit is most likely to result.

Article 39: Records of ethical evaluation – Q48: Do you have any comments on the provisions relating to records of ethical evaluation?

This provision is acceptable as long as there is greater clarity about how ethical evaluation works in relation to authorisation. We understand that the cost-benefit assessment as operated under the A(SP)A constitutes advice from Government officials to the Minister, and therefore is not disclosed to establishments or the public. This needs to be considered.

The requirement for the institution to keep records provided by the competent authority for subsequent resubmission to the competent authority is not consistent with the better regulation agenda.

Article 40: Non-technical project summaries – Q49: Do you have any comments on the requirement for project summaries and its impact on current UK practice?

We support the proposal that the lay summary of work outlined in the project licence (generated by the applicant) should normally be made publicly available. Ideally we would wish to see more information rather than less in the public domain about animal research, including information relating to project licences.

However, the benefits of public disclosure of animal research data must be balanced against researchers' rights to privacy and the protection of confidential data. It is paramount to ensure both the safety of staff and premises, and the integrity of intellectual property. Enforced disclosure of some project summaries would immediately identify the institution and could put it at risk of illegal harassment.

The derogation for a reduced project application under Article 36(2) appears attractive in reducing administrative burden. However, we share Home Office concerns that this would significantly reduce the amount of information published. Furthermore, information which was published would be skewed towards projects and procedures of higher severity, potentially giving a misleading impression of the nature of animal research.

We therefore support the provision of non-technical summaries for all projects, subject to necessary derogations and exemptions.

Article 41: Granting of project authorisation – 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?

We strongly support the Home Office position that authorisations should be for five years, not least since many EU research grants are awarded for five years.

As for Article 39, it is inappropriate for establishments to be required to keep records on behalf of the competent authority.

Article 42: Amendment, renewal and withdrawal of a project authorisation – Q51: Do you have any comments on the provisions for the amendment, renewal and withdrawal of project authorisations?

At present it is not possible to know what detail will be required in licences and therefore how minor the issues will be that will require amendment. As noted earlier, we support the concept of advance notifications for amendments to project licences where there is no or minimal welfare impact of the proposed change. To this effect, we support the principle of Amendment 128, although we consider the wording will need to be clarified. Notifications should apply where the severity level is not increased (rather than when severity is not increased), and should be sent to the competent authority in advance of implementation, not in arrears.

Article 43: Authorisation decisions – Q52: Do you have any comments on the proposed provisions relating to authorisation decisions?

We welcome, in principle, deadlines for authorisations, but we believe such deadlines should also cover ethical evaluation. Currently this could apparently be open-ended (depending on how the competent authorities are designated) which could cause substantial delays. Deadlines would especially be of importance should the "independent parties" in ethical review be permitted to include individuals or groups opposed to the use of animals; default authorisation would limit blocking tactics by such parties. We certainly welcome Home Office acknowledgement that applications should be dealt with promptly and that applicants should know when to expect a decision.

We recognise the concerns that allowing authorisation by default risks undermining the credibility of the regulatory system, and hence public support. In addition, it potentially represents a way for Member States less interested in compliance with this Directive to evade their responsibilities. One option is that any instances where a Member State fails to take a decision would be required to be reported to the Commission. An alternative approach would be to adopt a system more like the UK which is based on targets rather than absolute deadlines. However, this may present problems for more diffuse systems of authorisation, such as regional ethics committees, and as intimated above, it could leave open the opportunity for some projects to be seriously delayed at ethical review.

This Article and the consultation document raise the issue of the link between ethical review and authorisation. It is not clear to us why authorisation should be delayed once ethical review is complete, although it is acknowledged that in some complex cases ethical evaluation may take some time.

Chapter V: Avoidance of duplication and alternative approaches

Article 44: Unnecessary duplication of procedures – 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?

We agree with the Home Office's concerns. We also agree there is no evidence of widespread unnecessary duplication.

The UK bioscience sector strongly supports the overall concept of sharing non-confidential data to avoid duplication of procedures. However, Commission and European Parliamentary proposals for mandatory data-sharing are likely to disproportionately increase costs with little animal welfare benefit, and would undoubtedly have a major adverse impact on the protection of intellectual property rights. This could threaten both the viability of pharmaceutical research in the EU and the competitiveness of academic institutions.

It would be administratively impossible to "ensure" that every item of data is shared. The word "ensure" should be amended to "encourage" in the original proposal.

Both industry and academia are already actively engaged in data-sharing initiatives, one of whose intentions is to reduce, refine and replace the use of animal toxicity tests. There are many successful initiatives already in operation, including those of the UK research funders, and we welcome more such plans where they are rationally conceived. We believe, however, that the Directive should encourage progress in this area, rather than mandate it - because of the immense difficulties of applying this practice across all areas.

Article 45: Alternative approaches – Q54: Do you have any comments on the provisions to encourage the development of alternative approaches?

While alternatives should be used where available and appropriate, they should not be mandated where there is no international acceptance, since animal studies would still be required outside the EU. This could result in an increase of animal use (if both isolated tissue and animal studies were required) and moreover the animal work might be undertaken to lower welfare standards.

We support the 3Rs initiative to develop alternative methods. However, it must continue to be recognised that new technologies which can replace, reduce or refine the use of animals are generally developed as an intrinsic part of the scientific process, not a separate activity. The UK bioscience sector funds and works closely with the National Centre for the 3Rs on programmes to support the 3Rs in research and embed them in daily practice. The NC3Rs in turn fund 3Rs research in the best research laboratories. This is a highly effective and efficient model that should be adopted across the EU.

Article 46: National reference laboratories – Q55: What are your views on the proposed requirements for the designation and functions of national reference laboratories?

The proposals for National Reference Laboratories are unnecessarily duplicative, are not feasible to implement, and for multiple reasons would not be an efficient way to develop alternative methods. They would divert funding away from the expert research groups that can promote the 3Rs alongside the high quality research they undertake.

We support the Home Office view that greater clarification about the potential future role of ECVAM is required.

We again suggest that the NC3Rs model of encouraging and facilitating the development and application of alternative approaches in academic and commercial institutions is a more effective and efficient means for achieving such ends. Moreover there is no justification for duplication of this costly provision in each member state; the benefits are achieved so long as there is a process available and applicable to each member state, but not necessarily housed within it.

> **Article 47: National animal welfare and ethics committee – 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?**

We consider the obvious solution would be to amend the remit of the Animal Procedures Committee. However, we see no reason why the Directive should be so prescriptive in the exact roles of the national animal welfare and ethics committees. We do not see that there is any "market" which needs harmonisation.

Chapter VI: Final provisions

Article 48: Adaptation of annexes to technical progress – Q57: What are your views on the proposed arrangements for updating the technical annexes?

We support the contention that detailed technical annexes need to be regularly updated to make the best provision for animal welfare and science. This process for updating such annexes should not be overly bureaucratic, and the process should be based on sound scientific evidence, and not simply the balance of opinion of a group of stakeholders. As a general point of principle, we consider it important that the wording of the Directive should be sufficiently general to permit the adoption of new information that promotes welfare without requiring legal updates. In particular, we support amendments that allow deviations from the annexes for scientific or animal welfare reasons.

Article 49: Reporting – Q58: Do you have any comments on the proposed reporting requirements?

We would support the establishment of a common format for reporting; without harmonisation across Member States the reporting will be meaningless.

Whilst the production of statistics is but one small part of the regulatory system, it does add to the administrative burden. We would wish to see efforts made to ensure the process is streamlined, and that good practice from Member States is identified and adopted throughout the EU.

Article 50: Safeguard clause – Q59: Do you have any views on the safeguard clause? And its likely impact on current practice in the UK?

We strongly argue that the safeguard clause be retained. We consider that it is unlikely to have any impact on current practice in the UK, except in very exceptional circumstances, for example in light of recent global pandemics.

Article 51: Committee – 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?

If there is to be a committee, we share the preference for greater clarity in its composition and remit. In particular, we are concerned that DG Environment will not always have the necessary expertise on scientific aspects of animal research. Therefore we would like to see this committee consisting of representatives from all relevant DGs, and any regular reviews of the Directive, or elements of it, could then be conducted or coordinated by this committee.

Article 52: Commission report – Q61: Do you have any views on the requirements for an implementation report?

We agree with the Home Office position. As well as concerns on the proposed timing and frequency of reports, we believe that the technical annexes if implemented as currently proposed may need frequent attention. However, we reiterate the point that the wording should be sufficiently flexible to permit welfare developments to be incorporated without the need for amendments to the Directive.

We would have no problem in principle with thematic reviews of the operation of specific elements of the Directive, as suggested in the consultation. However, we would wish to see that these are based on sound scientific evidence, and are not simply the balance of opinion of a group of stakeholders. Moreover they should be proportional in addressing primarily those issues of greatest welfare impact or regulatory burden. We would not support a mandatory provision to "set targets for the implementation of validated replacement methods" if this was not scientifically achievable. The reviews would need to take into account the legitimate interests of science and medical advancement, as much as animal welfare and the 3Rs.

The purpose of undertaking a thematic review and how the outputs will be used in the future development of regulatory policy in this area should also be made clear.

Article 53: Review – Q62: Do you have any views on the proposal for review of the directive?

We are strongly against the multiple reviews that are proposed across these several Articles. First, the wording should allow developments without review. Second, one review process should cover all aspects, otherwise the overlap between reviews will be bureaucratically very pedantic and expensive. We would wish to see this and other reviews conducted by a committee encompassing all the relevant Commission DGs (see also Q60).

Whilst every 10 years may be acceptable for review (although the current Directive and ASPA have served tolerably for over twice as long), we have concerns with proposed shorter periods in other cases. For example, Amendment 59 calls for review of non-human primate use every two years. This would mean an almost continuous process of revision, which is unrealistic. There appears to be an assumption behind this and other similar amendments that many new alternatives will have been discovered within such short time periods; we would not wish to support these unrealistic expectations. Moreover we again emphasise that the terms of the Directive should ensure that advances in the 3Rs are incorporated as they become available, without requiring review of the legislation.

Article 54: Competent authorities – Q63: What are your views on the provisions for competent authorities and the best option for the UK?

We support this article, but reiterate our concerns that in places the draft Directive is overly prescriptive. For example, in the confusing information requirements between ethical evaluation and authorisation, and in the arrangements for record-keeping between competent authorities and user establishments, the wording in many places could be improved.

We strongly welcome the recognition from the Home Office that this article could provide an opportunity to review options within the UK, but in view of the remaining uncertainties over the content of the Directive, we cannot yet have a firm view on which options would be best. We urge government to take the opportunity to think broadly and creatively in the interests of serving both animal welfare and better regulation agendas.

Article 55: penalties – Q64: Do you have any views on the provisions for penalties?

This is an area where some degree of harmonisation is essential. Some Member States could in effect bypass some or all of the controls by imposing minimal penalties for non-compliance.

If penalties are substantially different between member states, then that may generate pressure for work to be transferred from those States with stronger penalties to those with weaker ones, undermining the intended benefit of harmonisation.

The proposal that penalties must be effective, proportionate and dissuasive is right, providing that a range of penalty options are genuinely available and used, to ensure that penalties do reflect the potential wide variation in scale of non-compliance. It is important that the threat of penalties does not result in the loss of the UK culture of self reporting non-compliance.

Q65: Do you have any views on Articles 56 Transposition, 57 Repeal, 58 Transitional provisions, 59 Entry into force or 60 Addressees?

No.

Annexes

Annex I: Invertebrate species referred to in Article 2(2) – Q66: Do you have any views on Annex I (invertebrate species)?

This Annex (if these invertebrates remain covered) should read as follows:

Agnatha chordates
Cephalopods

Inclusion of adult forms of some cephalopods may be justified on scientific grounds, but the free-feeding immature planktonic forms should definitely be excluded – as covered in our response to Question 3.

Annex II: List of animals referred to in Article 10 – Q67: Do you have any views on Annex II (list of animals referred to in Art. 10)?

No.

Annex III: List of non-human primates referred to in Article 10(1) – Q68: Do you have any views on Annex III (list of non-human primates referred to in Art, 10(1))?

This Annex should be revised or become redundant if a feasibility study is carried out (see Question 16).

Annex IV: Care and accommodation standards referred to in Article 32 – Q69: Do you have any comments on the accommodation and care standards set out in Annex IV ?

We share the Home Office concerns that the way Appendix A of ETS 123 has been appended into this Annex could actively impair welfare. This is partly because of discrepancies in the wording, and partly because of the lack of supporting text to interpret the standards.

We support Amendment 157 which stipulates that the care and accommodation conditions shall be tailored to the scientific objective.

Annex V: Humane methods of killing animals – Q70: Do you have any comments on the humane killing methods set out in Annex V?

We have not commented specifically on the content of this Annex. We have instead tried to ensure that Parliamentary amendments permit derogations to better techniques (see response to Question 10). We hope that such derogation is legally permissible (and the Commission has confirmed in writing that derogations are possible), but if it is not then much closer attention would be required to the details of this Annex.

We agree that the common methods for humane killing should be listed and further that the use of these techniques should not require license authority beyond the demonstration of competence by those using them. Techniques that are not listed should be permissible subject to ethical evaluation and project licensing, as is currently the case under A(SP)A. We therefore support Amendment 53.

The techniques listed in the Annex should be limited to those that have been scientifically validated, those that are generally applicable without highly specialised equipment, and those that are relatively easy to use with reliably humane results.

Simplification of the list would remove some of the current problem areas (which we agree are significant). It is however important to seek stakeholder input to help ensure that commonly used techniques are not missed (a problem both in the current Annex and in A(SP)A). It would be important to ensure that changes could be made rapidly by comitology.

> **Annex VI: List of elements referred to in Article 20(4) – Q71: Do you have any comments on Annex VI (education and training)?**

Annex VI is inadequate as a core curriculum sufficient to ensure harmonisation of training standards across member states. Published curricula are available (including in EU documents) and could be referred to in the Recitals. The Commission should, with stakeholder input and based on such published curricula, develop a core curriculum in time for inclusion in the Directive. Without that, a core Commission aim of the revision, namely to promote mobility of research workers, will fail.

> **Annex VII: List of elements referred to in point 3 of Article 36 – Q72: Do you have any comments on Annex VII (project authorisation)?**

Our views on the duplicative and confusing requirements for authorisation are addressed in the consultation questions relating to the relevant articles.