UK Bioscience Sector Coalition

Executive Summary

We consider the major priorities for the transposition of European Directive 2010/63/EU to be ensuring high animal welfare standards and the application of the 3Rs (Reduction, Refinement and Replacement of Animals in Research); harmonisation of European Union (EU) regulatory requirements and the promotion of public confidence in humane animal research which enables high-quality science and leads to patient benefits.

Our sector considers that the implementation of the Directive provides an opportunity to transform the UK's regulatory system into one which consistently, effectively and efficiently promotes these priorities in complying with the obligations of the Directive. We believe that this will promote public confidence in humane animal research.

There is a need to harmonise across Europe. The bioscience sector works across Europe and free movement of both knowledge and people should be encouraged so as to facilitate research and minimise competitive disadvantage. Experts from the bioscience sector, animal welfare groups and other stakeholders across Europe contributed for many years to develop the accommodation standards in ETS 123 which have been incorporated into the new Directive 2010/63/EU. This was agreed by the European Commission, Parliament and Council after much deliberation, so any proposals to deviate from the Directive should only be considered if based on good evidence. We would expect the Home Office to work with its counterparts across Europe to ensure that training standards are harmonised to facilitate free movement between Member states.

Transposition of the Directive provides an important opportunity to increase flexibility by basing the regulatory systems on optimising welfare outcomes rather than on controlling processes. Regulatory systems need to take account of the variation in both the size of establishments and the type of procedures being undertaken. This is particularly an issue in the project licensing system and the requirement for retrospective reviews.

We support the need for additional clear, robust and unambiguous guidance documents and Codes of Practice. These should be written so as to provide clarification of the regulations and encouragement towards good practice, rather than imposing additional requirements not specified in the Directive. We look forward to working with the Home Office in the development of this guidance.

We support the view that the restriction on the use of NHPs was intended to prohibit trivial uses but not research that would currently be allowed under UK regulations. We support the development of breeding strategies designed to minimise the wild-capture of NHPs. However, it is essential to await the outcomes of the Commission feasibility study before enforcing restrictions on the use of non-F2 NHPs.

The UK bioscience sector is rightly proud of its leading position in global bioscience research and its reputation for high animal welfare standards. We wish to ensure that the UK retains its position in both respects.

UK Bioscience Sector Coalition

Submission to Home Office

A Submission From The UK Bioscience Sector Coalition In Response To The Home Office Consultation On Options For The Transposition Of European Directive 2010/63/EU On The Protection Of Animals Used For Scientific Purposes.

1: GENERAL INFORMATION

The UK bioscience sector coalition (henceforth "we" or "the Coalition"), consisting of the organisations listed below, offer their comments in response to this consultation.

We are the UK's key bioscience organisations involved with the use of animals in scientific and medical research. We represent the perspective of academia, industry, small and medium enterprises, charities and other research funders, as well as patient and medical groups.

Association of Medical Research Charities
Association of the British Pharmaceutical Industry
BioIndustry Association
Biotechnology and Biological Sciences Research Council
Institute of Animal Technology
Laboratory Animal Breeders Association
Laboratory Animal Science Association
Medical Research Council
Society of Biology
The Academy of Medical Sciences
Understanding Animal Research
Wellcome Trust

We welcome this consultation. Our response has been assembled through a process of seeking comments from the members of the Coalition to draft responses, through a number of iterations. We have also held a series of meetings and discussions, including with Home Office officials. Our submission has been signed off at a senior level in each organisation.

We circulated our response widely in the bioscience sector prior to submitting it to the Home Office and have received a lot of support for it from within the sector. The following organisations have also formally endorsed the response.

Biochemical Society
Bioscientific Events Ltd
British Association for Lung Research
British Neuroscience Association
British Pharmacological Society
British Society of Animal Science
British Society for Immunology
British Association for Psychopharmacology
Nutrition Society
Queen's University, Belfast
Sequani Ltd
Society for General Microbiology
Society for Experimental Biology
The Physiological Society
UCB Pharma Ltd
Wellcome Trust Sanger Institute
Wickham Laboratories Ltd

2: INTRODUCTION

Members of the Coalition welcomed the adoption of the revised European Directive 2010/63/EU on the protection of animals used for scientific purposes (the Directive).

We agree that many of the provisions of the Directive are similar to current UK legislation and practice. The Coalition submitted to the UK Government in June 2010 our views on the principles by which this Directive should be transposed into UK legislation, and those principles still stand.[1]

We consider the major priorities to be:

- Promoting high-quality science and patient benefits
- Ensuring high animal welfare standards and the application of the 3Rs (reduction, refinement and replacement)
- Harmonisation of EU regulatory requirements
- Promotion of public confidence in humane animal research.

Our sector considers that the implementation of the Directive provides an opportunity to transform the regulatory system into one which consistently, effectively and efficiently promotes the objectives outlined above, whilst complying with the obligations of the Directive.

The Coalition fully supports the "additional" transposition objectives outlined on page 8 of the consultation, namely "*adopting measures which are proportionate; provide for efficient and effective regulation and appropriate standards of animal welfare and protection; promote the use of alternatives to animal use; avoid unnecessary administrative and regulatory burdens; and support the success, sustainability and competitiveness of the UK research and science base.*"

Options for transposition

The Coalition agrees that Option 1: No change in current legal and administrative arrangements is not viable.

The Coalition agrees that Option 2: Transpose the minimum requirements of the Directive is unlikely to be satisfactory for every article. Nonetheless, we consider that for individual articles the principle of "copying out the text" will often be a reasonable

[1] 25 June 2010. A submission from the UK bioscience sector coalition advocating principles for the implementation and transposition of the proposed Directive EU 8869/10 on the protection of animals used for scientific purposes.
http://www.understandinganimalresearch.org.uk/page/download_document/?document_id=75

starting point for consideration of transposition. This will facilitate consistency across Europe and create a level playing field for the UK bioscience sector. Since we strongly support harmonisation of regulations across Europe, we consider it is important that the Government seeks to transpose and implement the new Directive, rather than simply make adjustments in ASPA to bring it into line with the obligations of the Directive.

We also consider it important that the greater flexibility allowed within the Directive should in general be preserved, since it facilitates research in an internationally competitive environment that can change quite rapidly. The consultation indicates the importance of harmonisation and we agree fully that the UK should not be put in a position of being under different rules than those operating in the rest of Europe other than where there is sound evidence that there would be benefits to animal welfare.

Option 3: Retain current higher UK standards and requirements.

We believe that the default should be Option 2, with the only exceptions being where there is credible evidence that existing UK specifications would enhance welfare standards above the level provided for in the Directive.

An evidence based approach was followed in the drafting of the Directive. We are conscious that considerable work was undertaken in the development of the Council of Europe ETS 123 specifications that were signed off by all the parties involved, including animal welfare bodies, scientists, animal technologists and the UK government. The incorporation into the Directive of these specifications will, in several respects, further enhance the welfare standards currently operating in the UK.

Where existing UK specifications exceed those of the Directive, there should be an assessment of the potential welfare benefits rather than an automatic assumption that stricter specifications equate to improved welfare standards. Some members of the Coalition believe that an animal welfare impact assessment should be undertaken before any decision is made to change current UK specifications.
The UK bioscience sector is rightly proud of its leading position in global bioscience research and its reputation for high animal welfare standards. While we wish to ensure that the UK retains its position in both respects, in the process of transposition we must be careful not to lose the benefits of harmonised, evidence based legislation.

Impact on establishments

We will encourage both members of the Coalition and other organisations in the UK bioscience community to provide information to assist the Home Office in its impact assessment, and in particular to provide any data which would enable the impact on UK competitiveness to be assessed more fully. The Impact Assessment issued with the Consultation suggested that Option 3 would be essentially cost-neutral for the bioscience sector. We do not believe that this is true and we will seek to provide more detail to the Home Office following this consultation.

3: SUBJECT MATTER AND SCOPE

Limit on protection of foetal forms of mammals to the last third of the gestation period

Question: Is our analysis of the impact of this provision correct? Is there scientific evidence that suggests that the UK should continue to protect mammals from half way through gestation using Article 2 to the Directive?

Under article 2, the revised Directive covers foetal forms of mammals as from the last third of their normal development. This differs from the current UK requirement to cover the second half of normal development. In this case our sector considers that there is no evidence of a welfare benefit from current UK standards, and would support harmonisation with the Directive.

Exclusion of foetal forms of birds and reptiles from protection

Question: Is there scientific evidence to support the continued protection of foetal forms of birds and egg laying reptiles using Article 2 to the Directive?

Under Article 2, the revised Directive does not cover foetal forms of birds or reptiles (i.e. eggs). ASPD should investigate evidence for welfare benefit and, if coverage of these forms is thought necessary, consider moving the time limit towards that designated for mammals.

Inclusion of cephalopods

Question: Are our assumptions correct? Do you have any further information of the current use of cephalopods?

The Coalition broadly agrees with the assumptions set out in the consultation. We supported the inclusion of cephalopods in the Directive on the basis of a balance of evidence suggesting sentience. The criterion for inclusion currently applied to amphibians and fish, i.e. independent feeding, would be objective and, while precautionary, might be appropriate and workable.

A significant concern would be to ensure that (often inadvertent) “use” of possibly microscopic forms of cephalopods (for example in a bucket of seawater) is excluded from legal controls. In addition, we recommend that immature cephalopods are excluded from the statistics. The burden of counting, even if using a method of estimation, is not justified and the process risks stress and physical damage, especially to the young of these fragile animals, rather than providing any tangible benefit to animal welfare.

Inclusion of animals specifically bred for organs and tissues

Question: Are our assumptions correct? Do you have any further relevant information of the current breeding and use of animals bred for organs and tissues?

The Coalition agrees with the assumptions in the consultation. Animals killed for organs and tissues come from a variety of sources. It must remain clear that the breeding of such animals will not be a regulated procedure requiring either authorisation or statistical reporting. Care should be taken not to bring in additional regulations which inadvertently affect the supply of organs and tissues from animals killed for other purposes e.g. from abattoirs.

Absence of special protection for cats, dogs and equidae

Question: Is loss of special protection likely to lead to increased use of cats, dogs and equids? Should the UK retain its current special protection for dogs, cats and equids using Article 2 to the Directive?

The Coalition recognises public sensitivities around research involving cats, dogs and equids. We believe that the requirements of the Directive to use an animal with the least capacity for pain, suffering or distress, along with the project evaluation and authorisation (ethical review), provide a better mechanism for ensuring the minimisation of animal use and application of the 3Rs concept to **all** animals, including cats, dogs and equids. However, we see no problem with maintaining the special protection for dogs, cats and equids as provided under current UK law.

We do not believe that the loss of "special protection" would lead to an increased use of cats, dogs or equids. It is already a requirement in the Directive to use an animal with the least capacity for pain, suffering or distress. In addition, project evaluation and authorisation (ethical review) is an appropriate mechanism for ensuring the minimisation of animal use, and application of the 3Rs concept.

There has been a consistent decline in the use of cats, dogs and equidae in the UK in recent years. The Home Office statistics show that:
Usage decreased in 2009: cats -24%, dogs -3%, and equidae -7%.

Usage decreased again in 2010: cats -32%, dogs -2% and equidae -5%.
We believe that the decline is primarily a consequence of the emphasis on the 3Rs.

Practices to which the Directive does not apply

Question: Is our assessment of the impact of this omission correct? Should we retain our current requirements exempting only those methods of marking (used for scientific purposes) which cause no more than momentary pain or distress, and no lasting harm?

While we agree with the assessment of the impact of this omission, we consider that there are adequate safeguards under the Animal Welfare Act to protect animals in this situation. The current UK requirements therefore do not need to remain in place.

We consider that practices undertaken for the primary purpose of identifying an animal should not count as regulated scientific procedures, where the same practices are not regulated outside the arena of scientific research.

The introduction of the Directive provides an important opportunity for simplification in recognising that 'identification' covers both physical and genetic identification. Since genetic identification is a requirement for every animal within a genetically modified strain, we consider it routine husbandry rather than a procedure that is separate from physical identification. This would involve a change in policy since, under ASPA; identification has been taken to mean only physical identification, not genetic identification. The current policy creates an unhelpful regulatory anomaly in which it is the intent rather than the practice that determines the degree of regulation; this impedes good science without any welfare benefit. [A related example is the insertion of a microchip, which has the same welfare impact whether or not it is used (additionally to identification) for making scientific measurements].

There should be no adverse welfare or 3Rs implications in deregulating genetic identification since under Articles 1.2 and 4.3 there remain 3Rs obligations in breeding any animal for research purposes. Therefore there is already an obligation to use the identification techniques, whether physical or genetic, that have the least welfare impact.

4. PROVISIONS ON THE USE OF CERTAIN ANIMALS IN PROCEDURES

Article 7: Endangered species

Question: Should the UK retain its current restrictions on the use of endangered species using Article 2? What implications would adoption of the provisions of Article 7 of the Directive have for the use of endangered species in the UK?

Article 8: Non-human primates

Question: Do you agree with our analysis of the likely impact of Article 8 on work involving non-human primates? Are there any further issues we should consider when transposing these provisions relating to the use of non-human primates?

We agree that your analysis is the most likely scenario, and we accept the necessity to transpose these provisions. It is widely agreed that the intention of this restriction was to prohibit trivial uses of NHPs and not to prohibit research using NHPs which would currently be allowed under UK regulations.

Question: Are there any further issues we should consider when transposing these provisions relating to the use of endangered species of non-human primate?

Great apes

Question: Do you agree that the UK should continue to operate a policy ban on the use of great apes? Are there any further issues we should consider relating to the use of great apes?

Our sector agrees that there are no circumstances in which we could currently envisage a requirement to use great apes in medical research.

However, we are aware, for example, of recent deaths in wild gorillas due to human viruses, and so can envisage a need to test vaccines on such species. It is therefore important that there is no absolute ban that would preclude UK scientists from contributing to such tests.

We believe that the wording of the Directive's safeguard clause prohibiting the use of great apes, except in "research aimed at the preservation of those species or where action is warranted in relation to a life-threatening or debilitating condition endangering human beings where no other species or alternative method would suffice" is a sufficiently high barrier to the future use of great apes in research in the UK.

We, therefore, do not see that the continuance of the UK policy ban adds to the wording of the Directive.

Article 9: Animals taken from the wild

Question: Are there any issues we should consider relating to the prohibition on the use of animals taken from the wild? What impact will the more limited derogation provided in Article 9 have on the conduct of research in the UK?

We agree that the provisions of the Directive are more restrictive than ASPA. We therefore urge the Home Office to transpose them in a way which minimises the administrative burden, especially when the use of animals taken from the wild is self-evident, for example, the study of wild animals themselves. There should be an automatic exemption for wild-caught fish and we suggest that this should be included in the project authorisation rather than requiring a separate method of authorisation. We hope this would minimise the impact on research in the UK.

New requirements relating to trapping and capture

Question: What criteria should be applied to ensure the competence of persons capturing animals in the wild?

We consider the response to this question requires specialist expertise and input which goes beyond this Coalition's ability to advise on. Nonetheless, the variability of requirements likely to be involved across species indicates that the general principle should be for regulation to place limits on the harms caused by those involved, rather than controlling or restricting specific procedures. We believe that the important feature here is the outcome for the animal – i.e. that the animal after trapping should be placed in an appropriate and secure environment with access to food and water as soon as possible. Persons involved in capturing animals should be aware of the importance of these outcomes. Given the variable requirements, a bureaucratic system of demonstrating competence is unlikely to be either practicable or of clear benefit.

Article 10: Animals bred for use in procedures

Question: Are our assumptions regarding the impact of Article 10 correct? Is there a case for retaining the current UK requirement that common quail and ferrets should be purpose bred, as permitted by Article 2?

It is entirely appropriate that purpose breeding should be required where there are proven welfare benefits that apply to significant numbers of animals and/or where the numbers required justify commercial operations. However where very small numbers of animals are required for study, purpose breeding can cause both excessive cost and wastage of breeding stock. There should therefore be some flexibility in the accepted sources of animals for small scale use, and this could be incorporated where the UK chooses to invoke Article 2.

There is arguably a case for retaining the current UK requirement that ferrets should be purpose bred.

However, in the case of quails, where commercial breeding takes place for agricultural reasons, the requirement for purpose breeding of the small numbers used in research is excessive.

Wild caught fish are used routinely to maintain breeding stocks and an exemption is required.

We anticipate specialist responses to this question from the scientific community.

Question: What impact will this have on UK breeders, suppliers and users? Will opening up the ability to supply animals have any animal welfare impact?

The Coalition does not take a view on the commercial implications on the supply of laboratory animals across Europe. However, in order to promote good science and maintain animal welfare, it is important that researchers can have access to supplies of the animals that they need (including the most scientifically relevant animal models) from reliable sources with a minimum of bureaucracy, including the ability to import from both within and outside the EU, and transfer between institutions.

It will be important not to impose additional controls on UK compared with other EU breeders such as to increase costs relative to other EU countries. Market pressures, plus current activist activities, may cause breeders to consolidate breeding centres and with additional requirements in the UK it would be more likely that these would be based elsewhere. There are clear implications for welfare in longer transportation times. Activist pressure might then apply more pressure on transporters of animals, making it difficult for users in the UK to get supplies. We urge the Government to think through these implications and ensure the support of UK-based breeders.

Non-human primates

Question: What impact will these requirements have on UK breeders, suppliers and users? What impact, if any, is there likely to be on animal welfare?

The Coalition supports in principle the long-term objective of ending the use of animals captured from the wild for breeding purposes where this is feasible. However, we caution that considerable care should be taken in the transposition of article 10, since it is not clear that the welfare benefits are as universal as assumed.

We retain significant concerns about the desirability and feasibility of adopting the timetable set out in the Directive for using only animals that are the offspring of animals bred in captivity (F2), or those sourced from self-sustaining colonies.

It must therefore be clear that the timetable adopted in the transposition process is to be amended in the light of the feasibility study which is to be carried out by the European Commission. We consider it vital that the study is a properly constituted scientific investigation incorporating the best international expertise, and that all relevant decisions should be deferred until it has reported. The study must take proper account of breeding timescales to produce F2 colonies, and self-sustaining colonies, and ensure that supply of F2s can meet demand.

Article 11: Stray and feral animals of domestic species

Question: Is there a case on animal welfare grounds for retaining the current UK prohibition on the use of stray and feral animals, as permitted by Article 2?

Stray or feral animals of domestic species should not be used as a substitute for purpose bred animals. The use of stray or feral animals of domestic species in medical research would be a potential risk to the quality of the biomedical research output..

We consider that the wording of the Directive would prevent the use of such animals as a substitute for purpose bred animals but would permit essential studies of, for example, the welfare of these animals. A total ban would prevent studies which could improve the welfare of stray and feral animals of domestic species.

The Coalition, therefore, considers that the exceptions in the Directive are sensible and should be transposed. This should be further clarified in the guidance being developed by the Home Office.

5. PROCEDURES

Article 3: Definition of 'procedure'

Question: Do you have any proposals as to how this might be achieved?

The Coalition suggests that the rules for seeking exemption need to be clear and fair with an emphasis placed on ensuring a simple system is put in place to monitor and ensure competence. This could be managed at an institutional level. In terms of exemptions from Annex IV, the relevant sections of a standard project licence application form could be used to apply for that exemption. The Competent Authority could then decide on the basis of 3Rs considerations whether the exemption should be applied nationally or whether its use was project specific, in which case a project licence would be required. [See also under Section 6 below].

We note that the Directive is variable throughout the document in its use of “may” or “is likely to” in causing adverse effects. The Coalition cautions against the use of the word “may” which encompasses the remotest possibility; in contrast “is likely to” permits a risk-based approach that can prevent predictable harms without unnecessary constraint over procedures that are most unlikely to cause significant harms.

Article 5: Purposes of procedures

Question: Are there any further issues we should consider in relation to the ‘permissible purposes’ set out in Article 5?

We support a proposal to copy out the provisions of article 5 as they stand.

We believe that “education and training” should be interpreted as permitting practical training to gain competence under supervision and thereby promote the 3Rs. [See also under Section 12 below].

Article 12: Procedures

Question: Are there any further issues we should consider in relation to the provisions on procedures set out in Article 12?

We support the proposal to transpose these provisions as they stand. However, we caution against duplication of rules for wild-caught animals (given Article 9).

Article 14: Anaesthesia (and the use of neuromuscular blocking agents)

Question: We propose to transpose these provisions relating to the use of anaesthesia as they stand. Are there any further issues we should consider relating to the use of anaesthesia?

We support transposition of these provisions as they stand, subject to the proviso below on neuromuscular blocking agents.

We consider it important that ASPD provides guidance on the applicability of Article 14.2(b), such as for studies on pain mechanisms and treatments.

Neuromuscular blocking agents

Question: Should current UK provisions relating to the use of neuromuscular blocking agents in mammals be retained? Should we continue to apply the same provisions to other animals?

We agree that current UK provisions of reducing awareness as well as pain should be retained for postnatal mammals.

We are cautious about the case in other animals, and agree with the consultation that non-pain distress is not likely to be significant in immature forms including larval fish and amphibians and embryonic birds (although the latter are not covered by the Directive).However, the same rationale applies to non-breathing foetal mammals.

Article 16: Re-use

Question: We propose to transpose the provisions of Article 16 relating to re-use as they stand. Are there any further issues relating to re-use we should consider?

We recognise public sensitivities about the re-use of animals, but consider that when done appropriately this can contribute materially to the 3Rs. We consider the provisions in the Directive on re-use to be a good solution for both science and animal welfare. We therefore support a proposal to transpose the provisions as they stand. Additional guidance is needed for the rare exceptional circumstances when it may be appropriate for re-use following a severe procedure. This would have to be justified on a case by case basis.

Although not a requirement under the Directive, we would welcome ASPD guidance on the extent to which reuse should be defined and justified in project licence applications and the roles and responsibilities of veterinarians and licence holders in determining this from clinical and ethical perspectives.

It is also important that the guidance from the Home Office facilitates the ability of large farm animals to be housed under natural conditions in between studies, as well as at the end of procedures.

Article 17: End of the procedure

Question: Should we retain current stricter UK requirements relating to the welfare of animals at the end of a regulated procedure? What issues may arise if animals suffering mild effects are released?

We consider the UK's current requirements relating to the welfare of animals at the end of a regulated procedure to be more stringent than the Directive in four areas:

1. Under ASPA, animals must be humanely killed when they are suffering or likely to suffer adverse effects as a result of the procedures applied; under the Directive animals must be killed by a humane method only when they are likely to experience moderate or severe pain.

We support the retention of the current stricter UK requirements relating to any animals with impaired welfare at the end of a regulated procedure. Under ASPA, if there is any pain, suffering or distress after the procedure, then the animal is invariably killed. If the provision to release animals suffering mild adverse effects is retained, it would be helpful to have examples provided for animals which fall under this category.

2. Under ASPA, an animal can be kept alive with the agreement of a veterinary surgeon or suitably qualified person, where appropriate provision has been made on the project license. There is no requirement for such project license provision in the Directive.

3. Under ASPA, Home Office and Veterinary authorisation is required for any animal to be discharged from the controls of ASPA, moved from the designated establishment, or released into the wild. The Directive requires that, at the end of a procedure, an animal should receive care and accommodation appropriate to its health.

We consider it is satisfactory for the designated veterinarian or other suitably qualified person to provide consent for an animal to be moved to another designated establishment, released to the wild or otherwise discharged from the controls of the revised Act.

4. GM animals and their progeny are also retained under the controls of ASPA, even if they are not suffering or unlikely to suffer adverse effects. (There is provision for their discharge from the controls of ASPA, but this has not been used to date). Under the Directive, the progeny of GM animals no longer expected to experience pain or suffering are considered to be 'at the end of the regulated procedure'.

We believe that the breeding of established colonies of GM animals (beyond 2 generations) with 'non- harmful phenotypes' should be treated as any other breeding colony and discharged from the controls of the new Act. This would make the regulation of GM animals consistent with that of other naturally occurring 'mutant' animal strains used in research. We would welcome guidance from the Home Office regarding how this could be achieved and what constitutes a non-harmful phenotype.

An associated issue is whether breeding of GM animals should be included in Home Office statistics. These animals could be included in a separate category, or entirely removed from Home Office returns.

An additional specific issue relates to the export of GM stock, which must be made administratively simple.

Article 18: Sharing organs and tissues

Question: How should we facilitate the sharing of organs and tissues? Are there any further issues relating to the sharing of organs and tissues we should consider?

We consider it to be a good principle that the sharing of experimental animals is maximised between authorised projects. In that light the wording required in project licences should be sufficiently broad to promote rather than hinder this. This is another reason for shifting the emphasis of the project licence from purpose to welfare impact.

In particular, greater effort should be put into the sharing of organs/tissue from non-human primates, other higher animals and specialist tissue samples (e.g. those from aged animals) across different centres. For non-specialist tissue, sharing should primarily be at a local level and the new Animal Welfare Body would be best placed to promote this.

Specialist input will be required in relation to the setting up and effective operation of tissue/organ banks and other specific mechanisms for sharing.

6. METHODS OF KILLING

Article 6 and Annex IV: Methods of killing

Question: Do you agree with our analysis of Article 6 and Annex IV? Should the UK retain some methods listed in ASPA Schedule 1 using Article 2? Which methods should be retained?

We agree with the Home Office analysis that the principles of these provisions are broadly consistent with current UK policy and practice, but share the concern about the omission or provision of specific methods of killing.

The Home Office needs to set out a mechanism by which scientific evidence can be assessed, without unnecessary delay, where another method comes to light which is considered at least as humane as a method in Annex IV. Ideally this new method would subsequently be specified as an acceptable method of killing on a national basis to take immediate effect across all institutions. We hope that other groups will provide specialist input to the consultation on specific techniques and situations.

7. CHOICE OF METHODS

Article 4: Principle of replacement, reduction and refinement

Question: We propose to transpose the requirements of Article 4 as they stand. Are there any further issues relating to replacement, reduction and refinement we should consider?

We agree that the provisions of the Directive are broadly similar to those of ASPA, and we welcome a proposal to transpose these requirements as they stand.

Article 13: Choice of methods

Question: Is our analysis of the impact of Article 13 correct? Are there any further issues relating to the choice of methods we should consider? Are there any currently permitted testing methods which will be prohibited?

We consider that the analysis of the impact of Article 13 is correct. We anticipate that institutions within the scientific community will be able to identify the likely impact, including any currently permitted testing methods which may be prohibited.

This Article raises significant concerns over the need to conduct studies for non-EU regulators. It will impact on pharmaceutical companies and their Clinical Research Organisation partners that are required to carry out studies in order to meet national requirements. We urge regulators to increase efforts to promote international harmonisation of the acceptance of alternative methods.

Question: We propose to transpose the provisions of Article 13 as they stand. Are there any further issues we should consider relating to the use of death as an endpoint?

These provisions are consistent with current practice and we agree with direct transposition.

8. AVOIDANCE OF DUPLICATION OF PROCEDURES AND ALTERNATIVE APPROACHES

Article 46: Avoidance of duplication of procedures

Question: We propose to transpose the provisions of Article 46 as they stand. Are there any further issues we should consider relating to avoidance of duplication of procedures?

We consider the provisions of Article 46 to be desirable and support a proposal to transpose them as they stand.

Article 47: Alternative approaches

Question: Are there any further issues we should consider in relation to the provisions for alternative approaches set out in Article 47?

Article 47 lays out sensible ways for the scientific development of alternatives to animal experimentation and will build on the work already being done. We do not believe that new institutions need to be set up to achieve this. We suggest that the NC3Rs be the UK single point of contact referenced in 47.5. We recognise and endorse the government's continued support for the UK NC3Rs in helping to promote the 3Rs.

Article 48 and Annex VII: Union reference laboratory

Question: Are there any further issues we should consider in relation to the Union reference laboratory?

The Coalition supports the European Centre for the Validation of Alternative Methods (ECVAM) as the basis for the new Union reference laboratory. However, we note that ECVAM will need adequate resourcing for this remit which is an expansion of its current role.

9. SEVERITY OF PROCEDURES

Article 15 and Annex VIII: Classification of severity of procedures

Questions: Are there any areas in which the Annex VIII severity classification is unclear? Are there any additional examples of severity that might be included in guidance on the application of the proposed severity classification system? [See also questions relating to Article 55 below.]

The Coalition can envisage no circumstances in which procedures that under current rules would be considered to involve "severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated" would be required and hence that the use of the safeguard clause in Article 52(3) would be requested.

We support the transposition of article 15 as it stands, however, we note these concerns:

The annex on severity classification was put together in haste and was subject to relatively little scrutiny or amendment. Most importantly, the paucity of examples, especially towards the upper limits of acceptability, could mean significant variations in interpretation across Europe. A particular area of concern is over studies utilising pain models and neurophysiological models in non-human primates, where the Annex provides no guidance, and so interpretations could vary significantly. In this light, the only situation in which we can envisage using the safeguard clause provision would be if procedures currently considered acceptable were reclassified as a result of variations between Member States.

Additional examples of procedures below the threshold would be beneficial. General guidance is also needed on how to apply a prospective estimate of severity considering outcomes as well as procedures. The foot-notes developed at the Commission's Expert Working Group should be included.

Application of severity classification is inevitably a matter of judgement, and application of this Annex should, after a transition period, be no more difficult than before, so long as significant variations between Member States do not develop.

We emphasise again the importance of harmonisation across EU in applying the severity classification. FELASA/ESLAV/ECLAM is undertaking a study of this important topic and we strongly recommend that the outcome from this be taken into account. We also urge that the guidance recognises all the potential sources of suffering; encourages their effective and comprehensive prediction and recognition; and promotes consideration of severity as an important tool to assist with refinement.

10. BREEDERS, SUPPLIERS AND USERS

Article 3: Definition of establishment
Article 3: Definition of 'breeder', 'supplier' and 'user'
Article 20: Authorisation of breeders, suppliers and users

Question: Are the changes to the requirements for authorisation of breeders, suppliers and users and the need to notify changes likely to raise any problems? Are there any further issues we should consider in relation to the requirements set out in Article 20?

We agree that the requirements of the Directive are less prescriptive in relation to the authorisation procedure currently carried out through certificates of designation. We welcome the opportunity to focus the regulation on welfare outcomes rather than on following administrative procedures. We believe this to be a good opportunity for better regulation, whereby a risk-based approach is taken to minimise the administrative burdens while safeguarding animal welfare.

We appreciate the intention to minimise the administrative costs of moving to a new system.

Article 21: Suspension and withdrawal of authorisation

Question: We propose to transpose the provisions of Article 21 as they stand. Are there any further issues we should consider relating to the suspension and withdrawal of authorisations?

We support transposing the provisions of Article 21 as they stand. However, the Directive lacks any overt right of appeal. Both that right and the process for doing so should be clarified in the new system.

Article 22: Requirements for installations and equipment

Question: Are there any further issues we should consider in relation to the requirements for installations and equipment set out in Article 22?

We agree that these provisions are consistent with UK requirements, and we are not aware of any further issues.

Article 28: Breeding strategy for non-human primates

Question: Are our assumptions relating to Article 28 correct? Are there any further issues we should consider in relation to the requirements for a breeding strategy for non-human primates set out in Article 28?

We agree that UK-based *breeding* establishments already supply only F2 animals (but not necessarily non-breeding establishments which may be holding centres for imported non-F2 animals). Nonetheless, the requirement for a breeding strategy should still hold, not least since the supply of F2 animals from UK breeding establishments is by no means free of problems. See also our response to Article 10 concerning the need for the feasibility study.

Article 19: Setting free of animals and re-homing

Question: We propose to transpose the provisions of Article 19 as they stand. Are there any further issues relating to the setting free and re-homing of animals we should consider?

Article 29: Scheme for re-homing or setting free of animals

Question: We propose to transpose the provisions of Articles 28 and 29 as they stand. Are there any further issues we should consider relating to these issues?

Article 30: Animal records
Article 31: Information on dogs, cats and non-human primates
Article 32: Marking

Question: We propose to transpose the provisions of Article 30, 31 and 32 as they stand. Are there any further issues we should consider relating to these issues?

We support the proposal to transpose these provisions as they stand. One potential issue concerns the release of the record to a new owner of the animal. There will need to be the ability to redact confidential information from the record before any such transfer.

11. CARE AND ACCOMMODATION

Article 33: Care and accommodation

Question: We propose to transpose the provisions of Article 33 as they stand. Are there any further issues we should consider relating to the issues covered by Article 33?

We agree.

Annex III: Care and accommodation standards referred to in Article 33

Question: Are there any specific issues we should consider when preparing guidance and codes of practice on accommodation and care?

Questions: Please see Appendix II for detailed questions on Annex III.

We support the approach set out in the consultation. We note that the majority of standards for accommodation and care in Annex III are similar to existing UK Code of Practice standards.

Since harmonisation to internationally agreed standards is highly desirable, we agree that Annex III should be transposed unchanged, unless there is specific evidence that it would have a demonstrably negative impact on animal welfare.

In that light, we view with concern the statements under Section 22 of the Consultation, which implies that the current Guide and Codes could remain largely unaltered. We consider it imperative that any supplementary Code on accommodation should adhere to the principles of ETS123 and be soundly evidence-based. One specific example would be the current limits of accepted temperature and humidity. In particular there would need to be explicit and accepted welfare benefits to justify any continuation of the major costs and risks that are currently imposed in satisfying the relative humidity requirements. The revised

guides and codes of practice should also take into account modern technology e.g. IVC and Scantainer® housing.

We strongly endorse the Consultation's support for harmonisation across the EU.

12. COMPETENCE AND AUTHORISATION OF PERSONNEL

Article 23 and Annex V: Competence of personnel

Impact on the UK personal licensing system
Questions: Should the UK: (a) retain its current system of personal licensing using Article 2, as necessary; or (b) adopt a simplified version of that system with greater local accountability? What might be the features of a system involving greater local accountability? What risks might be associated with such a system and how might these be mitigated? What will be the cost to individual breeders, suppliers and users of implementing such a system?

The Coalition suggests that the rules need to be clear and fair with an emphasis placed on ensuring that a simple system is put in place to monitor and ensure competence.

In view of the emphasis of the Directive on education, training, supervision and competence, we consider that such a system will invariably involve greater local accountability. We also believe that the UK should adopt a simpler system. We consider that the level of administrative controls in the personal licensing system as currently operated is disproportionate. We recognise that a system of authorisation of persons will still be required, and we do not take a view on the naming of such a system (for example, it could be through registration, or it could still be through licensing). We concur with the Consultation that the opportunity to simplify the system should be taken, and that the need for amendments should be reduced or eliminated by removing the detail of procedures currently included.

We would therefore favour option (b), of a simplified version of the current system and draw attention to the LASA 2007 Guiding Principles on the supervision requirements for Personal Licence Holders, which would be helpful in this context.

The key features of such a system are that both the individual and the establishment have clear responsibilities for compliance. The establishment is responsible for ensuring that the systems for training, monitoring and assessment are established and operated. The individual will be registered or licensed by the Home Office and will be responsible for compliance with the licence requirements.

The establishment will identify a person who is responsible for ensuring that the training takes place and that the individuals being trained are assessed by a competent person. A detailed record will be kept of all training and outcomes down to technique and species level. This will also record any instances of non-compliance. Individuals undergoing training will be supervised until competence has been established.

Education and training

Questions: What specific features would you like to see in a UK or European training system? What elements of current UK training could be omitted whilst still complying with Annex V? How should the quality of individual training and supervision be assured so that new employers are confident about training and competence and to facilitate the transfer of individuals within the UK and across Europe? Would such a system result in any additional costs? If so, please specify. How might the requirement for continuous professional development best be met?

We agree that it is essential that the system of authorisation includes (a) mutual recognition of training and competence across Europe, and thereby facilitates the free movement of personnel; and (b) training options tailored to the needs of the individual. Ideally, such a system would be based on mutually agreed requirements, such as those we hope will come out of the current deliberations by FELASA/EFAT and subsequently by the Commission, in time for consideration for transposition in all Member States.

Currently, both the IAT and FELASA provide accredited education and training courses in the UK. We note that the current QCF accredited qualifications, with syllabuses based on learning outcomes, provide a valuable framework which offers the opportunity for those in Europe and beyond to understand the science and technology of laboratory animal care, their legal responsibilities, the ethological and physical needs of the animals in their care, and society's wish for animal research to be performed ethically and humanely.

Institutions should be held responsible for demonstrating that appropriate attempts have been made to train and where necessary retrain individuals so as to minimise adverse effects and promote the 3Rs. The same strategy would be appropriate for continuous professional development.

The Directive, unlike ASPA, permits the use of animals in training. The Coalition welcomes the flexibility this offers to maximise the 3Rs by formally permitting practical training under expert supervision. We suggest that any new system needs to take care to allow on-the-job training as a legitimate method to develop competence.

Article 24: Specific requirements for personnel

Question: Are there any further issues we need to consider regarding the requirements for personnel?

We support the approach that the certificate holder is responsible (and accountable) for overall compliance, while allowing the day-to-day work of ensuring competence to be delegated. This allows flexibility whilst not being overly-prescriptive.

We agree that the majority of the roles required in the Directive are broadly consistent with ASPA.

See also the response above to Article 23.

Article 25: Designated veterinarian

Question: Are there any further issues we need to consider regarding the requirement for a designated veterinarian or other suitably qualified person?

We agree with maintaining flexibility over the most appropriate skills set for the institution concerned.

13. PROJECTS

Article 3.2: Definition of 'project'

Article 36: Project authorisation

Article 37 and Annex VI: Application for project authorisation

Article 38: Project evaluation

Question: We propose to transpose the provisions of Article 36, 37 and 38 as they stand. What type of information should be placed in the public domain about the project evaluation process to ensure transparency of the process? Under what circumstances would you expect project applications to be referred to external experts and/or the new national committee required under Article 49? Are there any further issues we should consider relating to project authorisation and evaluation?

We support the proposal to transpose these provisions as they stand.

The Home Office should publish a description of the project evaluation process on its website, which should include a link to the place(s) where non-technical summaries are available. Guidance on the project evaluation process should exemplify

Hampton principles [2]to clarify with examples (a) the detail that is expected in applications (especially on adverse effects); and (b) the level of flexibility that inspectors have to vary those requirements, and thereby potentially introduce inconsistency in the way some aspects of the regulations are applied across the UK. The current lack of consistent guidance is the cause of much confusion, even for experienced applicants. The aim must be for the guidance to ensure that first time applicants are able to submit successful applications without needing multiple iterations of the form.

Neither Articles 36-38 nor Annex VI stipulate the level of detail of procedures that is currently required by ASPI under ASPA; instead the emphasis is on the harms caused balanced against the intended benefits. We strongly agree with the Directive in this regard, and cannot agree with the consultation document that the requirements for detail in Directive and ASPA are 'similar'. Indeed, this difference provides an opportunity for the UK to move towards a more flexible and risk-based licensing system in which the expected benefits and welfare impact of a procedure (and the associated 3Rs policy) is the basis for the authorisation, rather than the details of procedures to be undertaken. This would (a) simplify applications; (b) provide much needed flexibility over research protocols and thereby (c) reduce the need for amendments; (d) reduce the number of technical infringements; and (e) reduce the requirement for advice and frequent iterations of project licence drafts between inspectors and applicants.

The procedure description should be sufficiently generic to enable flexibility in experimental design on a day to day basis whilst still adhering to principles of 3Rs and minimising pain and distress. It should contain enough information to enable any adverse effects on animals to be assessed e.g. by description of expected effects on animal well-being, methods by which any pain and distress will be minimised, and description of humane endpoints. In other words, the focus should shift towards a greater concentration on animal welfare and 3Rs.

In this regard, the current application form is generally seen as a significant improvement on its predecessor in complying with ASPA. However, its implementation still focuses on procedures rather than on minimising adverse effects. The headings in Annex VI are in several ways more intuitive and could well form the basis of further simplification of the form. The degree of detail required should be related to the severity of procedures and the promotion of animal welfare.

[2] http://www.bis.gov.uk/policies/better-regulation/improving-regulatory-delivery/assessing-our-regulatory-system

We believe that such a shift of emphasis would simplify the role of inspectors and would thereby give them more time to promote good science and animal welfare/3Rs. Indeed, the Coalition welcomes the input that inspectors can have on the 3Rs, and is keen to ensure that this aspect is promoted by both parties by freeing time currently spent on form filling.

We consider that, as at present with the APC, very few project applications should require referral to the national committee. Any application to invoke the safeguard clauses in the Directive, and severe procedures on non-human primates, should require this additional scrutiny. We would strongly encourage a process that permits the national committee to report rapidly on such cases so that there is no serious delay to the decision on the proposed research, and a reporting structure that ensures confidentiality.

Article 39: Retrospective assessment

Question: Should we extend the requirement for retrospective assessment to some or all projects involving procedures classified as "mild" or "non-recovery"? What should be the process for retrospective review and should this involve the animal welfare body?

We consider that retrospective review of the operation and outcomes of projects should be a routine part of the scientific process, and that the Animal Welfare Body (AWB) should be tasked with ensuring that this happens locally. The requirement for a formal retrospective assessment external to the research team, and submitted to the national Competent Authority, is somewhat different. The requirements of the Directive are satisfactory for setting out which projects should require mandatory retrospective assessments. Institutions may wish at any time to additionally undertake more detailed retrospective reviews as part of their internal practices – and this can be done individually for project licences as part of the AWB function of "follow the development and outcome of projects" (Art 27 (d)) .

Formal retrospective assessments are most effectively undertaken by those who know the history of the project and the local environment (facilities, skills, personnel). We consider that members of the Animal Welfare Body will be best placed to undertake them, and that the AWB should therefore be designated as the Competent Authority for this purpose. The results of these could, for the record, be submitted to the central Competent Authority.

The emphasis of formal retrospective assessment should be on learning lessons which can in the future help to improve science, welfare and the application of the 3Rs (rather than being a tick-box exercise seen as a bureaucratic intrusion).

Development of guidance would be beneficial. The administrative processes should be kept simple.

While any renewal of a project licence will inevitably require review of past operation, there is no suggestion in the Directive that completion of a formal retrospective assessment is a requirement for approval of a renewal. Given that the formal assessment cannot be undertaken until after the end of the project, whereas continued research requires renewal to be complete before the end of the previous licence period, linking the two must not be allowed to happen either by intent or by default. However, if the retrospective assessment does highlight areas that need addressing, the AWB should ensure incorporation of these into future work as well as encouraging the sharing of any experience or knowledge gained.

We see no benefit to extending the requirement for formal retrospective assessment to 'non-recovery' or 'mild' procedures. The situation regarding 'moderate' procedures is not clear from the Directive. We suggest that only those 'moderate' projects involving procedures new to the UK be subjected to this requirement.

Article 40: Granting of project authorisation

Multiple generic projects

Question: Are there any other categories of project that should be covered by these provisions?

Article 41: Authorisation decisions

Question: How should 'complex and multidisciplinary projects' be defined for the purposes of Article 41?

Multiple generic project licences should not be granted for any project involving non-human primates, unless for standard toxicological studies.

Wherever possible, project assessment and authorisation should be completed within the stipulated time period. Extended timelines due to classification as "complex or multidisciplinary" should only occur in exceptional circumstances e.g. for procedures that are both severe and new to the UK.

Article 42: Simplified administrative procedure

Questions: Should the UK adopt a simplified administrative procedure for relevant categories of project? What form should the simplified administrative procedure take?

The scope for simplifying administrative procedures set out in the Directive is rather limited and thus far we can see relatively little benefit in adopting them. If used,

sufficient information should still be included to permit NACWOs to discharge their responsibilities on the welfare of the animals.

Article 43: Non-technical project summaries

Questions: Should we waive the requirement for non-technical summaries for some projects involving only mild or moderate procedures? Or, should we continue to aim to publish non-technical summaries for all authorised projects? What details should be included in non-technical summaries?

Our sector considers that considerable improvements could be made to the current project licence abstracts, and we welcome the requirement for non-technical summaries on the terms specified, in particular the reduced emphasis on the procedures to be carried out. We are supportive of the principle of issuing guidance from the competent authority on the content of these summaries. Although this should not be overly-prescriptive or bureaucratic, we consider that the non-technical summaries should have a consistent structure as set out in that guidance; this would also help to avoid a local 'house style' identifying institutions.

A central aspect of the non-technical summaries is to provide the public with a sense of the body of research undertaken across the EU. It is therefore important that that view is not distorted by exempting the least severe procedures and including only those causing more harms. The principle should therefore be that all projects provide a non-technical summary.

Article 44: Amendment, renewal and withdrawal of a project authorisation

Questions: Are there any risks involved in limiting the requirement to amend or renew project authorisations to changes that may have a negative impact on animal welfare? If so, how might the risks be mitigated?

There is a risk that there is a difference of opinion between the holder of a project authorisation and the competent authority on whether a change to a project might have a negative impact on animal welfare. However, such judgements are inevitable in a more risk-based regime, and institutions should continuously strive to maintain the competence, professionalism and systems of oversight to be able to make such judgements. The risk could be mitigated by ensuring that the AWB has oversight of this. It should at all times be incumbent on project licence holders to respond promptly and openly to any unexpected incidence of adverse effects, which should terminate any inappropriately-amended protocol.

The review and authorisation of amendments should be conducted in an efficient manner and take less time than that required for consideration of a new project application.

We suggest that guidelines be produced containing examples of what warrants re-submission for approval. We expect that amendments should be considered by the AWB.

14. ANIMAL WELFARE BODIES

Article 26 and Article 27: Animal Welfare Body and Tasks of the Animal Welfare Body

Questions: Is there a case for animal welfare bodies to have more extensive membership and functions than the minimum requirement set out in Articles 26 and 27? If so, what additional members and functions should be required or recommended in guidance? Might animal welfare bodies play a role in advising on training and competence? How might 'small' establishments be defined and how might they meet the requirements for animal welfare bodies 'by other means'?

We agree that most of the functions of the animal welfare bodies are similar to those of the current ERPs. We also agree with the consultation that many establishments will model their AWB on their existing ERP. As indicated above under Article 39, we believe that the AWB is the body best placed to oversee the process of formal retrospective assessment, and that it should therefore be appointed as the Competent Authority for that purpose.

We do not agree with the impact assessment conclusion that writing the current ERP arrangements into law is cost neutral. This will solidify those requirements, decreasing flexibility to adapt to differences in size and nature of institutions and increasing bureaucratic load, particularly for small establishments and those carrying out a very narrow range of procedures.

The current arrangements offer significant flexibility as they are bound by guidance not regulatory requirements, allowing establishments to implement them in a way which suits their needs.

The Directive sets out the minimum requirement for membership of the AWB. We consider it appropriate to encourage in guidance that the membership is wider than this and includes the named animal care and welfare officer (NACWO); the named veterinarian (or suitably qualified other) and a lay member who is entirely independent of the research team. In addition, we would expect the Certificate Holder to ensure a wide involvement of relevant establishment staff.

The animal welfare body should be responsible for ensuring that advice from relevant staff, including NACWOs and NVS, is channelled into the development of project licence applications, as part of the requirement to "follow the development and outcomes of projects". We understand this to mean providing advice to those developing and working under projects on specifically local aspects of welfare and the 3Rs (such as the suitability of accommodation at an establishment for a particular project).

We see no need for there to be additional instructions for institutions; so, for instance, institutions (including small ones) should be permitted simply to inform the competent authority how they comply with Articles 26 and 27. Inspectors would determine whether any of the tasks in Article 27 were not being addressed and could respond appropriately to ensure the promotion of welfare and the 3Rs.

We consider it likely that the new AWBs will have a role in the oversight of training requirements within establishments as is the case currently. However, how this is managed differs widely between organisations (large commercial organisations, for example, have internal processes to manage this) and a mandated structure would lead to duplication of effort.

15. NATIONAL COMMITTEE FOR THE PROTECTION OF ANIMALS USED IN SCIENTIFIC PROCEDURES

Article 49: National committees for the protection of animals used for scientific purposes

Questions: Should the Animal Procedures Committee form the basis for the new National Committee? Are there any models other than the APC on which the National Committee might be based? What should be its membership and what range of expertise will the National Committee require to enable it to meet the requirements set out in Article 49? How might this expertise be accessed?

In implementing Directive 2010/63/EU, the UK is required to establish a national committee for the protection of animals used for scientific purposes ('new National Committee'). We anticipate this body will succeed the current Animal Procedures Committee (APC) in the UK.

The Coalition believes that the purpose and remit of the new National Committee should be fully clarified. In light of the recommendations of the Directive and the

Omand Review of the APC (2009-10)[3], the new National Committee's activities should expand on those of the present APC by, among other functions to:

- Ensure sharing of best practices relating to the acquisition, breeding, accommodation, care and use of animals in procedures.
- Advise on matters dealing with acquisition, breeding, accommodation, care and use of animals in procedures
- Exchange information on the operation of AWBs and project evaluation, sharing best practice with the European Commission.

The Coalition believes the finalised new remit should then drive the membership (fixed or flexible) and *modus operandi* of the new National Committee.

The Coalition believes that the first two of the above additional functions would be best served by establishing a strong link between the National Committee and AWBs, such as that provided for by the Certificate Holders Forum and access to existing initiatives such as those from LASA. The third additional function could be done similarly and perhaps include an exchange of members between National Committees and the Commission.

This remit may turn out to be similar to the current APC. However, in establishing the new National Committee in this way there is an opportunity to refresh composition and operation to accommodate this expanded purpose:

The Coalition believes the new National Committee should be:

- Multidisciplinary, involving people with knowledge of ethics, the humanities, social sciences, law and the biological sciences as well as people without specific expertise in these fields, and be able to co-opt additional expertise when relevant.
- Transparent, making its proceedings, deliberations, reasoning, conclusions and recommendations available for public scrutiny.
- Outward facing so that interested persons are aware of its function and feel able to input into its work programme.
- Actively involved in public engagement and consultation; and maintain regular forward-looking dialogue with the scientific community. A major strength of this approach would be the ability to ensure that scientific work in this area proceeds with reasonable public understanding and support, and is not unduly influenced by extreme views.
- Empowered to develop guidelines to promote consistency and transparency in the regulatory process.

[3] Report of the 2009/10 NDPB Review of the Animal Procedures Committee. Sir David Ormand 2010 http://www.homeoffice.gov.uk/publications/agencies-public-bodies/apc/publications-2010/review-apc-0910?view=Binary

Much of the work of the National Committee could be carried out through either permanent or *ad-hoc* sub-committees, drawing their membership from within wider organisations. This would allow that where the representative of a particular organisation does not have the necessary expertise for committee work, another individual can be co-opted.
We consider that the new National Committee should be open and transparent in its operation. It will also be important that its structure and operation permit timely responses, whether to individual applications submitted to it for review or generic issues requiring dissemination.

16. INSPECTIONS

Article 34: Inspections by the Member State

Questions: What system of inspection would best meet UK needs? What impact would adoption of a detailed and more formal, but less frequent audit-style approach to inspection have on (a) establishments; (b) public confidence? What aspects of the current UK inspection system should be retained? How might it be improved?

There is evidence from the Hampton review [4]that UK establishments value the advisory role of the Inspectorate, which can give more emphasis to promoting good science, animal welfare and the 3Rs, as well as seeking to prevent problems occurring – rather than identifying problems which are happening. We agree and would wish the Inspectorate to keep this function, which does depend on more inspector visits than the Directive minimum.

The sector is however in a position of extreme cost consciousness, and needs to reduce both direct ASPI fees and the costs of the associated bureaucracy. It is therefore important that there is a cost-benefit review of ASPI time input before final decisions on inspections are formulated.

In that light we believe that inspector time should focus on a more 3Rs-oriented advisory capacity and be shifted away from an unnecessarily complex regulatory system. An integrated and functional IT system would help in this regard.

We support the currently stated policy intention of the Inspectorate to work in a way which is more open and more risk-based. We look forward to dialogue and

[4] Animals (Scientific Procedures) Division and Inspectorate - A Hampton Implementation Review Report. Better Regulation Executive, London 2010
http://www.bis.gov.uk/assets/biscore/better-regulation/docs/10-610-animals-scientific-procedures-division-inspectorate-hampton-implementation-review.pdf

discussion between Inspectors and establishments about the risk-evaluation. We believe there is room for substantially greater openness to aid understanding of authorisation process.

In particular we see no rationale for the lack of openness surrounding inspectors' discussions and policy documents; for example feedback from the Consistency Working Group has not been disseminated and this area of consideration remains obscure. We are also concerned that no open mechanism is in place to communicate APC advice given to the Secretary of State to the applicant concerned.

We see no benefit to administratively heavy audits, but do not understand the bipolar alternatives presented in the consultation document. The competent authority is required to perform audit functions, and inspectors already do so. If the bureaucratic load on licence processing can be substantially reduced, as we believe is both possible and desirable, then the audit and advisory functions of the Inspectorate can be achieved with fewer visits than under ASPA and no loss of quality, albeit with more than the minimum visits under the Directive. This combination should permit a substantial reduction in costs to institutions.

We would like to see that inspectors produce visit reports similar to those provided by other regulatory body auditors. This would ensure that inspector requests are clearly documented both for the facility and for other inspectors to review.

We support an option where the best of the current inspection regimen is retained with a greater focus on risk assessment and transparency on how those risk assessments are carried out.

17. REPORTING

Article 54: Reporting

Questions: Should the UK continue to publish a full range of statistics as in the current annual statistics report? Is there scope for streamlining UK statistics? Are there additional statistics it would be useful to publish?

The Coalition supports openness and transparency and believes that the public should have access to useful, comparable information. A system of reporting which informs the public and facilitates international comparisons will support public confidence.

From our understanding so far, the European Commission is likely to mandate the collection of a more limited set of statistics than those the UK currently produces. This would mean that there is an opportunity to streamline statistical reporting and

some of the associated costs, although the development and operation of recording actual severity levels will counterbalance such savings. Work in the area is being co-ordinated by the EU coalition of EFPIA/FELASA/ESLAV/ECLAM/FELABA/ESF and we urge the Home Office to take note of their report.

This report suggests the following: -
Information published should be relevant to both the public and the animal research community and should be meaningful and useful information.

- Only information on regulated procedures should be collected – procedures below the threshold should be excluded
- The new tables should be representative of the permitted uses stated in Article 5, which now encompasses fundamental research, education and training and forensic inquiries
- The current regulatory toxicology tables should be reduced in number to reflect the proportion of animals used (11% of total) and allow a better balance with fundamental research. Additional regulatory data could be presented as thematic reviews
- All data should be collected retrospectively when the fate of animal is known to enable severity information to be introduced
- Counting should only be performed once for each animal i.e. not annually
- Opportunities to reflect progress with the 3Rs should be considered by use of thematic tables and narrative information
- Specialised information should be presented in ad hoc tables e.g. NHP source and generation of genetically altered animals
- Hyperlinks should enable cross-referencing of data including narrative information e.g. non-technical project summaries
- Statistical information should not be used as enforcement tools

We suggest that immature larval fish incapable of independent feeding be excluded from the reporting.

We doubt that the full range of information currently collected contributes to animal welfare. We consider that there is no reason why the UK should operate a regime of statistical reporting which is more onerous than other European countries, and we would therefore wish to see harmonisation in this area so as to enable international comparisons.

18. SAFEGUARD CLAUSES

Article 55: Safeguard clauses

Questions: Is our analysis of the likely need to invoke the provisions of Article 55 correct? Are there any areas of work currently authorised that you believe may require reference to the Commission under Article 55?

We agree with the analysis in the consultation. We cannot see that there will be a necessity to invoke the safeguard clauses so long as the regulatory system maintains its position with respect to these issues. We agree, however, that interpretations of derogations may be different in other EU countries, or may be subject to rulings by the European Court. For these reasons, we support the transposition of the safeguard clauses.

Article 58: Review

183A. Article 58 requires the Commission to review the Directive by 10 November 2017 taking account of developments in the 3Rs and to propose amendments, where appropriate.

183B. Article 58 also requires the Commission to conduct periodic thematic reviews of the application of the 3Rs, paying specific attention to non-human primates, technological developments, and new scientific and animal welfare knowledge. The Commission is to conduct these periodic thematic reviews in consultation with Member States and other stakeholders.

Question 58A: We strongly support the requirement for periodic thematic reviews. What structure would you like to see to the thematic review process? Are there any further issues we should consider in relation to Article 58?

The Coalition supports the need for thematic reviews which would be beneficial in dissemination and developing best practice and harmonisation across the EU. The thematic reviews should be evidence based and involve appropriate UK experts in their design and implementation. The UK has significant expertise in conducting independent evidence based reviews. The thematic reviews should be structured to include evidence based work conducted by independent experts and expert bodies.

19. PENALTIES

Article 60: Penalties

The following sanctions are currently available to the Secretary of State: Questions: Should the UK incorporate the penalties from Part 3 of RESA into transposing legislation? Should they include provision for monetary penalties?

Our sector considers that ASPD/I should have regard to harmonisation across Europe when setting penalties. There will be little by way of a level-playing field if the Directive is rigidly enforced with more stringent penalties in the UK than in other European countries.

Penalties and the procedures for imposing them should be transparent, consistent and proportionate. Our sector commends ASPD/I for its recent clarification of procedures for dealing with infringements under ASPA, but would wish the basis of infringements to alter to reflect the emphasis of the Directive on welfare rather than procedures. In that light we recommend that penalties should focus on any unauthorised and/or unnecessary infliction of adverse impacts on welfare, and most especially on any failure to address such unexpected or unauthorised adverse effects.

A weakness of the Directive is the lack of any overt process for appeal against penalties. This should be clarified during transposition.

20. OTHER PROVISIONS

Article 50: Adaptation of annexes to technical progress

Article 56: Committee

Article 59: Competent authorities

Article 63: Amendment of Regulation (EC) No 1069/2009

Article 64: Transitional provisions

Question: Are there any issues we should consider in relation to Articles 50, 56, 59, 63 and 64?

As indicated above, we suggest that AWBs be designated the competent authority for the purposes of retrospective review.

21. CONFIDENTIALITY (ASPA SECTION 24)

Background to ASPA section 24

Question: How might ASPA 24 be amended to provide greater flexibility regarding disclosure of information while protecting proprietary rights and intellectual property?

We support greater general openness and transparency in relation to the use of animals in scientific research. We agree that ASPA s24 is no longer fit for purpose, especially given that recent Freedom of Information (FOI) decisions do not protect information held by public institutions.

We recognise that there are exemptions in the Freedom of Information Act which apply to some components of animal licences. We agree that some information provided to the competent authority will continue to require protection from disclosure. Whilst it is easier to see how overtly personal information can be

separated and protected, it is much harder to see how, within the current licensing system under ASPA, information containing IP can be protected; or how the identity of individuals can be protected from exposure by 'triangulation'. Moreover there are certain types of information which could have a serious impact on animal research if they entered into the public domain, such as those relating to the transport of animals. It is also not acceptable that there is a major distinction in the level of scientific confidentiality available between public institutions and private ones. In making changes it is important to ensure that neither the names and addresses of individuals conducting animal studies nor the institution that they are working at are required to be released under FOI requests.

We consider that the current level of detail, especially in project authorizations, would make determining what should or should not be released complex, time-consuming, liable to legal challenge, and hence costly. There is therefore a direct link between the information requirements demanded for project licensing and the need for a formal system to maintain confidentiality. Reducing the detail required in project authorisations and focusing the information requested will enhance the ability of organisations to be open. On multiple grounds (see above) including this one, we consider it more satisfactory to operate a system in which the information provided on procedures is curtailed in favour of that on adverse events. That would permit much more openness over licence 'details', which would avoid the need for an updated equivalent of s24.

We note that the current system of word limits appears not to be universally accepted by Inspectors, which does not help when seeking to reduce unnecessary detail.

22: ASPA PROVISIONS NOT COVERED BY THE DIRECTIVE

Definition of 'death'

Questions: Should ASPA section 1(4) be retained? What would be the effect if it were not retained?

The definition works but we are not aware of any welfare problems that are likely were it to be removed in the interests of harmonisation.

Fees

Licence conditions

Appeal against licensing decisions

Use of animals in public exhibitions

The sector understands that the competent authority will (as is current practice) need to recoup many of its costs rather than impose them on the taxpayer, especially in the current financial climate. By the same token, however, industry and the academic sector will increasingly need to limit their costs. It is therefore vital that bureaucracy is minimized to that actively serving both animal welfare and scientific progress; and that it is as efficient and cost-effective as possible. In that light, the sector would anticipate seeing a reduction in the current level of fees, rather than an increase. Comments above about Article 34 illustrate how this could be achieved.

The proposal "to retain this power to apply conditions" is potentially a major concern, since it is not clear on what basis additional conditions might be imposed.

We recommend the provision of revised and updated 'standard conditions' equivalent in function to those currently used by ASPI.

Question: Should restriction on public exhibition be retained?

We support a continuation of the ban on use of animals in public exhibitions. However, it is important to prioritise harmonisation and to encourage a consistent voluntary code of practice across the EU. EU wide agreement would avoid scenarios untenable with current communications technology (for example akin to the recent 'injunctions' debate where television broadcasts were available across the EU but not in the UK).

The Inspectorate

We consider that it would be appropriate to review the appointment criteria to assess what mix of skills would be best suited to inspect under the Directive.

Publication of guidance and codes of practice

We strongly endorse the production of guidance on how to promote the 3Rs and on how ASPD and ASPI will operate under the Directive. We do not favour restrictions beyond those required by the Directive, as occurred with ASPA. Legislation should therefore define the terms under which additional codes and guidance are produced, their status, and operation.

Comments on the Impact Assessment

Concerns have been raised by the Coalition about the validity of the figures used in the Impact Assessment.

For example, in the Impact Assessment, Option 2 appears to be significantly more expensive than Option 3. This is almost entirely due to the additional costs for establishments associated with a system of local control of personnel in Option 2.

However, the Coalition believes that the current UK training does not meet the requirements of the Directive. The costs of implementing the required training under Option 3 are, therefore, likely to be the same as the costs of implementing Option 2. This significantly changes the impact on establishments and results in the difference in costs between Option 2 and Option 3 being relatively minor.

Even these preliminary observations are speculative, since the current Impact Assessment provides no information on the proposed future charging structure under the new Directive. For example, Personal Licences (which currently incur a significant annual charge) may be substantially modified or even disappear. On the other hand, Project Licences, which remain a fundamental component under the new Directive, are currently 'free of charge'.

As a result the Coalition has not sought to provide a detailed review of the Impact Analysis at this stage. Nonetheless cost and competitiveness are key aspects, particularly for commercial organisations. The Coalition looks forward to engaging in further discussion on these matters with the Home Office during the second phase of consultation, once other aspects of how the Directive will be transposed become clearer.