Questions and Answers

Who is the UK Bioscience Sector Coalition?

The Coalition comprises the UK's key bioscience organisations involved with the use of animals in scientific and medical research. It represents the perspectives of academia, industry, small and medium enterprises, charities and other research funders, as well as patient and medical groups.

The following organisations are all members of the Coalition. In addition, a diverse group of organisations have signalled their support for the Coalition response.[1]

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

Why are animals used in research?

Animals are used in scientific and medical research:

- To advance scientific understanding
- As models to study disease
- To develop and test new medical and veterinary treatments
- To protect the safety of people, animals and the environment

Animals are needed to find out what happens in the whole living body, which is far more complex than the sum of its parts. Research involving animals has been key in the development of most major medical advances.

[1] See page 4 of the "UK Bioscience Sector Coalition response to the Home Office Consultation on the Transposition of European Directive 2010/63/EU"

See http://www.understandinganimalresearch.org.uk/about_research for further details.

The Home Office consulted on a number of options for transposition. Which option does the Coalition support?

We believe that the majority of the provisions of the Directive should be copied into revised UK legislation, except 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 underpinned the drafting of the Directive. For example, considerable work was undertaken in the development of the Council of Europe ETS 123 guidelines for accommodation and care of animals. These were signed off by all the parties involved, including animal welfare groups, scientists, animal technologists and the UK government.

Do you support retaining the UKs current special protection for cats, dogs and horses?

The Coalition recognises public concerns around research involving cats, dogs and equids (horses and donkeys) and agrees with maintaining the special protection for dogs, cats and equids as provided under current UK law. There has been a consistent decline in the use of these animals in the UK in recent years.[2] Objectively speaking, we believe that the requirements of the Directive to use an animal with the least capacity for pain, suffering or distress, along with project evaluation and authorisation (ethical review), actually provides a better mechanism for ensuring the minimisation of animal use and application of the 3Rs concept to **all** animals, including cats, dogs and equids.

Will the Directive result in the use of stray or feral cats and dogs in medical research?

No. For many reasons, stray or feral animals of 'domestic' species should never be used as a substitute for purpose-bred animals. We feel that the wording of the Directive would prevent the use of such animals as a substitute for purpose-bred animals.

What effect will the restrictions in the Directive on the use of non-human primates have on research undertaken in the UK?

We recognise public concerns around research involving non-human primates. It is widely agreed that the intention of the Directive was to prohibit trivial uses of non-

[2] 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%.

human primates, not to prohibit research using non-human primates that addresses important unmet clinical needs which would be allowed under current UK regulations. The Directive actually introduces an additional restriction, limiting research to life-threatening and debilitating conditions.

Non-human primates are currently used in research into infectious diseases such as HIV, TB and malaria which cause millions of deaths each year, and the study of brain disorders such as Parkinson's and Alzheimer's that constitute one third of the burden of disease across Europe. They would never be used in research into minor or trivial conditions.

Are the methods of killing in the Directive as humane as the current UK methods?

We urge the government to retain the existing UK humane killing methods, which we believe are of a better standard than those proposed by the Directive.

Should the safeguard clause allowing long-lasting severe pain, suffering or distress be transposed?

There is no intention to increase the level of severity beyond what is currently permitted in the UK. As there is little guidance in Annex VIII, the safeguard clause is needed in case the severity classification of procedures is not interpreted and implemented uniformly across Europe. For example this could lead to a situation where procedures are no longer permitted in the UK simply through variation of classification in other member states.

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. So we do not envisage that the use of the safeguard clause in Article 52(3) would be requested.

Should the UK adopt the care and accommodation standards in the Directive?

The majority of standards for accommodation and care in the Directive are similar to existing UK standards.

We agree that the standards should be transposed unchanged, unless there is evidence that they would have a demonstrably negative impact on animal welfare.

Should personal licences be retained in the UK?

Yes. There should be some form of authorisation of persons (whether called registration or licensing) but not as it exists, as the system needs to be simplified. We suggest 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.

Do you think that the project licensing system should be changed?

The Directive provides an opportunity for the UK to move towards a more flexible and risk-based licensing system which would be more beneficial for animal welfare. This should be based on the expected benefits and welfare impact of a procedure, rather than the details of procedures to be undertaken. In other words, the focus should shift towards a greater concentration on animal welfare and 3Rs, and encouraging this culture within all aspects of work.

Should the role of the Inspectorate change?

We want the Inspectorate to keep its advisory function and believe that this requires more inspector visits than the Directive minimum. UK establishments value the advisory role of the Inspectorate, ie emphasis on promoting good science, animal welfare and the 3Rs, as well as seeking to prevent problems.

Inspector time should focus on providing advice about the 3Rs and shift away from an unnecessarily complex regulatory system. We support an option where the best of the current Inspection regimen is retained with an increased focus on risk assessment.

Do you agree that Animal Welfare Bodies (AWB) should replace the current Ethical Review Processes?

We would like to see the current flexibility of the Ethical Review Processes (ERPs) maintained in AWBs and not hindered by a prescriptive legislative approach. Most of the functions of the animal welfare bodies are similar to those of the current ERPs. We believe that many establishments will model their AWB on their existing ERP.

The Directive sets out the minimum requirement for membership of the AWB. We believe that the membership should be wider than this and include 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.

We urge the government to produce guidance on AWBs so that they reflect current best practice. This would allow the development of flexible ways of working appropriate to the size of the establishment.