UK Bioscience Sector
Submission to Home Office

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.

The organisations listed at the end of the document offer their views on the general approach and principles which should be adopted during the transposition and implementation of the new Directive.

The UK bioscience sector supported the high-level policy objectives of the revision of the existing Directive (86/609), as outlined in the Home Office consultation of May 2009. These included (in our own wording):

- Promotion of 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 8869/10 provides an opportunity to transform the regulatory system into one which consistently, effectively and efficiently promotes the objectives outlined above. We are reassured by indications that the Animals Scientific Procedures Division and Inspectorate (ASPD&I) officials share that view, and have been pleased to work with them to identify key areas of the new legislation requiring attention. We will continue to offer support during transposition and implementation.

We would like to stress the following as key principles to be considered during implementation (with the most important principles at the beginning).

1. Implementation should focus on outcomes, in particular those which promote good science as well as animal welfare and the 3Rs.

2. There should be continued efforts to harmonise implementation across Europe. It remains important to gain the benefits of harmonisation, and this should not be "lost" because implementation will be in the hands of member states. The need to harmonise should not, however, undermine standards which clearly contribute to animal welfare. Where UK "standards" are currently higher than those in the Directive, a view should be taken on the genuine welfare impact of maintaining or harmonising those standards.

3. The approach to all aspects of implementation should be mindful of the need for better regulation. Our sector has welcomed moves by ASPD&I towards a risk-based approach. However, we consider such an approach should be increasingly explicit and transparent, as recommended in the Hampton review publication of early 2010.

4. As advocated in the Davidson review of 2006, there should be minimal or no embellishment or 'gold plating' of the Directive. ASPD&I officials should be open to the possibility that the UK could learn lessons from how other countries interpret and implement particular articles.

5. Officials responsible for making recommendations on implementation should recognise the opportunity for taking new approaches and reconsidering current requirements. Implementation should not be unnecessarily constrained by historical practices.

6. Requirements for information in submissions for authorisations should balance the acknowledged benefits of greater openness with legitimate concerns about confidentiality (in particular commercial confidentiality and the protection of individuals). The current situation whereby an excessive level of detail is provided, for example in some authorisations, works against greater openness, and is not sustainable.

7. New national legislation and guidance should recognise the importance of expert professional judgement in matters of science, welfare and the 3Rs, so that new regulations are not unduly prescriptive in terms of processes.

8. The Home Office should anticipate that there will be future changes in practices in both science and welfare. The new regulatory system should both permit flexibility and allow simple procedures for amending guidance documents (these procedures should not be unnecessarily constrained by a future need to gain access to a crowded parliamentary timetable).

9. The revised Directive has not always achieved clarity or consistency in its drafting. In situations of uncertainty, the emphasis should be on achieving the outcomes of good science, animal welfare and the 3Rs rather than on defining regulatory processes.

10. There should be proper consultation with all those who will be directly affected by the legislation, or their representatives. We recognise that there are organisations with a range of views about what is acceptable for the use of animals in research. However, this Directive will impact directly on users, suppliers and breeders (and their establishments), and proper account must be taken of that impact in terms of costs incurred, delays experienced, and competitive advantage eroded.

Organisations supporting this briefing:

Association of Medical Research Charities
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
The Association of the British Pharmaceutical Industry
Understanding Animal Research
Wellcome Trust