JOINT RECOMMENDATIONS OF UK ANIMAL PROTECTION AND NON ANIMAL RESEARCH FUNDERS ON TRANSPOSITION OF DIRECTIVE 2010/63/EU

Introduction

We are not-for-profit organisations seeking to protect the welfare of animals while promoting effective biomedical research and safety testing.

We are pleased to offer advice to assist the Government in transposition of Directive 2010/63/EU. Thus, we submit the following proposals which aim at ensuring an efficient implementation of the Directive. In particular, we draw the Government's attention to the basic objective underpinning the Revised Directive:

The ultimate goal should be to replace the use of animal experiments all together. In addition to animal welfare benefits, alternative methods also have the potential to provide robust information through quality-controlled, state-of-the-art tests which could be faster and less cost-intensive than classical animal-based tests.[i]

This objective reflects the desirability of reducing and ultimately eliminating animal experimentation and is in line with the Government's most important pledge in this policy area: 'to work to reduce the use of animals in scientific research'.[ii] The transposition of Directive 2010/63/EU provides the opportunity to review the existing UK regulations and deliver the Government's commitment. We believe that the Government should follow these core principles for the transposition of the Directive:

Respecting the UK's cultural context: The Government should pursue animal welfare standards higher than the European threshold in order to take into account the British public's cultural and ethical interest in animal protection. Recital 7 of the Directive acknowledges that "*attitudes towards animals also depend on national perception*" and Article 2 allows for stricter national measures.

Democratic and open process: National legislation and guidance should recognise the importance of public opinion and democratic accountability in providing overall direction for policy and in weighing harms and benefits of proposed research projects. The UK Government should opt for a transposition of Directive 2010/63/EU through primary legislation, in order to ensure a process as transparent and democratic as possible and allow expert professional judgement from all perspectives and disciplines to inform decision-making. Expediting this important piece of legislation through regulation would simply leave the public out of the debate and deprive the Government of valuable input.

Importance of Recitals: In EU legislation, recitals are key to the interpretation of the provisions of the articles. Therefore, when transposing the Directive, the Government should ensure recitals are taken into account during any interpretation of a provision. According to current ECJ case law, recitals "*can expand an*

ambiguous provision's scope"[iii] and therefore be used to provide greater protection for the animals. This means that the Government can consider the following priorities during transposition:

- One of the tests of a civilised society is its treatment of animals
- Minimising animal suffering
- Supporting high quality science
- Replacing animal experiments

UK Objectives for Transposition of Directive 2010/63/EU into UK Law

The new European Directive offers significant scope for advancing laboratory animal protection in the UK. The following, listed in the order the relevant articles appear in the Directive, are the areas we believe must be priorities for Government action.

- **Maintaining the UK's Existing Stricter Animal Protection Provisions** (relates to Article 2)
- **Reducing the Use of Primates in UK Laboratories** (relates to Article 8)
- **Phasing-Out of the Use of Wild-Caught Primates by Suppliers** (relates to Article 10)
- **Limiting the Severity of Animal Suffering** (relates to Article 15)
- **Increasing Transparency** (relates to Article 43)
- **Increasing Data Sharing to prevent unnecessary experiments** (relates to Article 46 & Recital 47)
- **Creating a UK Laboratory for the Validation and implementation of Alternatives** (relates to Article 47)
- **Using thematic review to identify areas of research for replacement** (relates to Article 58)
- **Ensuring the effective implementation of non-animal methods**

These objectives are all within the grasp of the Government during this first major revision of UK animal experimentation regulation in over 25 years.

The Commission explains the need to revise Directive 86/609 by reference to its failure to reflect public attitudes to animal welfare.[iv] In the UK, permission to perform experiments on animals is a dispensation conditionally granted by the Government acting on behalf of the general public, rather than a right.[v]

We agree with the Home Office that ethical evaluation strengthens animal protection[vi] and observe that this and other processes that increase public accountability, such as transparency, are absolutely integral to mitigating suffering and improving animal welfare.

There is no evidence that tighter animal research regulation in one jurisdiction discourages investment in biomedical research and development.[vii] Indeed, given the scientific and ethical problems associated with animal research, such regulation can stimulate the development of new non-animal methods that offer medical, economic and social legitimacy benefits. We urge the Government to bear this in mind and learn the lessons from other policy areas such as banking regulation, when considering how to respond to special pleading to weaken UK standards, or resist a clear public desire for measures that strengthen animal protection.

The transposition of the new Directive provides the Government with the opportunity to become an objective and neutral arbiter, ensuring that measures are implemented to reflect public concern and effectively protect animals.

Keeping the UK's Stricter Animal Protection Provisions

Stricter measures: Where the UK has standards higher than those of the Directive, **the UK must not lower standards**. Article 2 is clear on the right of Member States to "*maintain provisions… aimed at ensuring more extensive protection of animals falling within the scope of that Directive*". A "stricter measure" means an existing law, regulations or unwritten rule such as the policy of the Home Office to never licence procedures involving Great Apes. In particular:

- **The UK should not transpose any of the safeguard clauses in Article 55 on the use of Great Apes and the upper-limit of pain, suffering and distress in experiments;**
- **The Home Office should maintain a tighter inspection regime than provided in Article 34;**
- **When creating the local 'Animal Welfare Bodies' required by Articles 26 and 27, the UK should maintain the harm-benefit considerations currently undertaken in local ERPs (ethical review processes) in order to ensure adequate scrutiny of animal research proposals;**
- **Article 42, the option of implementing a 'simplified administrative procedure' for some project authorisations should not be transposed;**
- **The UK should never allow any exemptions to bans on testing on stray or feral animals (Article 11), animals taken from the wild (Article 9) and animals belonging to an endangered species (Article 7);**
- **The UK should maintain current protection for embryonic forms of mammals, reptiles and birds from 50% of gestation (Article 1)**

Reducing the Use of Primates in UK Laboratories

As the No 1 user of primates in Europe[viii], the UK has a special responsibility to rapidly decrease the number of primates that it uses annually. Article 8 limits the use of primates to certain cases.

- **An exhaustive list of medical conditions for which primates can be used should be drafted:** Article 8 only allows applied research in debilitating and life-threatening conditions. This should be interpreted in light of recital 17, which describes a debilitating condition as having a "*substantial impact on a person's day-to-day functioning*".[ix] An exhaustive list of medical conditions should be drafted, in consultation with stakeholders and the public[x]. This should effectively reduce the number of primates used in the UK when transposed.

- **The use of non-endangered NHPs in basic research should not be allowed**: Although restrictions apply to the use of primates in applied research there are no restrictions at all to the use of most species of primates in basic research. This is entirely disproportionate, given that basic research does not aim at finding cures, and there is a strong risk that tests prohibited under paragraph 1 of the Directive might be allowed under the basic research category. **The Government should close this loophole and ensure that primate research unrelated to "areas essential for the benefit of human beings" (Recital 17) is not permitted.**

Phasing-Out of the Use of Wild-Caught Primates by Suppliers

More than 50% of all primates imported in the UK are born of (one or both) wild-caught parents (F1)[xi]. The capture of primates from the wild causes environmental degradation and great suffering to individuals and groups, which results in significant impacts on the conservation of primate species[xii].

Article 10 and Annex II of Directive 2010/63/EU set a timetable for the phase-out of the use of F1 monkeys, and their replacement with the young of captive-born animals (F2 animals). However, this timetable depends on the publication of a "feasibility study" (with the exception of marmosets); it is clear that industry suppliers obtained this measure in an attempt to delay the phase-out.

As a consequence, the deadline for phasing out the use of F1 macaques and other monkeys is between 5 and 12 years after the date of entry into force of the Directive (January 2013), "*provided that the study does not recommend an extended period*". The deadline for marmosets has been fixed to "*the third year following the date of entry into force of this Directive*".

However, a feasibility study has already been completed by the independent consultancy Prognos, on behalf of the European Commission, which concluded in its preliminary assessment that "*a transitional period of 5 years should allow most breeding facilities to raise their production and provide enough F2 animals to users*" and that "*additional costs should not be significantly high*". There is nothing to prevent the UK from complying with Article 10 of the Directive ahead of the targets provided in Annex II.

We therefore strongly urge the UK Government to end the use of F1 primates within 5 years after the date of entry into force of the Directive, regardless of the new feasibility study.

Limiting the Severity of Animal Suffering

Article 15 establishes an upper-limit of severity suffering: "*Member States shall ensure that a procedure is not performed if it involves severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.*" In order to transpose this provision efficiently, the **Home Office should create a sub-category in its "severe" band of suffering for prohibited experiments going beyond the upper-limit of pain.** We suggest that this category is called "severe and prolonged" and contains examples of experiments authorised in the past that are no longer licensed.

This should include, for example:

- **Conducting major surgeries without the use of anesthesia on control animals in assessing efficacy of analgesics; testing the efficacy of analgesics in animals with severe induced pain.**
- **Experiments that cause animals to die from poisoning by toxins in their diet; protracted and severe restrictions on water and/or feed intake.**
- **Deliberate exposure of conscious animals to lethal extremes of cold, heat or barometric pressure.**
- **Studies of the effects of infectious or toxic agents, which cause either a protracted death with marked distress or a rapid death with severe distress.**
- **Application of marked and repeated extremely noxious stimuli from which escape is impossible;**
- **Prolonged periods of close physical restraint.**

UK Laboratories for Development and Validation of Alternatives

The UK has a legal obligation under Article 47 of the Directive to "*contribute to the development and validation of alternative approaches*". Its paragraph 2 provides that "*Member States shall assist the Commission in identifying and nominating suitable specialised laboratories to carry out such validation studies.*"

The UK's National Centre for the Development of the 3Rs (NC3Rs) currently has too much focus on 'refinement' and 'reduction', and too little focus on 'replacement', which is where the major strides are being made in science and technology. The development of sophisticated non-animal methods is good for UK science and industry, and prevents the suffering of animals.

The signatory groups believe that, as the second largest user of laboratory animals in Europe, **the UK should make a substantial contribution towards both the development and validation of advanced, non-animal alternatives.** Several development and validation laboratories should be appointed, to work in coordination with ECVAM. This would put the UK at the forefront of innovation in this field and would accelerate the replacement of animals; it would keep UK science at the forefront internationally, and save money for businesses over time.

Greater Transparency, Public Accountability, Wider Scientific Scrutiny

Transparency increases public accountability and is absolutely integral to mitigating suffering and improving animal welfare. Wider scientific and public scrutiny is beneficial for science.

In accordance with Article 43, robust study summaries for all project applications must be published which provide more comprehensive and systematic information than current published abstracts. In particular, "*information on the objectives of the project, including the predicted harm and benefits and the number and types of animals to be used*" and "*a demonstration of compliance with the requirement of replacement, reduction and refinement*" are essential components, at present frequently either absent or inadequately described in abstracts. Retrospective assessment in accordance with Article 38 and 39, should be carried out for all projects and in order to increase public and scientific evaluation of procedures, the results of these assessments be published alongside abstracts, as provided for by Article 43.

Recital 41 of the Directive provides that "*to ensure that the public is informed, it is important that objective information concerning projects using live animals is made publicly available*". Section 24 of the ASPA currently prevents individuals possessing objective information about animal testing from making it publicly available and even threatens them with imprisonment. Therefore, **Section 24 should be repealed.**

Regular Thematic Reviews for Targeted Replacement of Animal Experiments

We support the Animal Procedures Committee's advice to the Government in 2005/6 that targets to end certain types of animal experiments should be explored because sincere concern for the suffering of animals requires '*a determination to work imaginatively and constructively to bring about the end of animal use. We noted that in relation to the obviously quite different area of environmental pollution, it had been the case that demanding targets have been identified as providing a goal even where these targets might require technological and other innovation if they were to be met.*'[xiii]

The Government should therefore work with all stakeholders to develop a road map for the replacement of animal experiments, implemented through thematic reviews of categories of animal research and testing.

Article 58 of the Directive provides for "*periodic thematic reviews of the replacement, reduction and refinement of the use of animals in procedures*". Member States will have an input in these thematic reviews, and we therefore **ask the UK to lead the EU agenda by conducting continuous national thematic reviews in consultation with all stakeholders in specific fields.** There are many areas where the use of animals can be quickly phased out. The Home Office has already announced the Government's intention to **ban the use of animals in household product testing**. We welcome this move and suggest that the Government review the use of animals in the following areas as soon as possible:

- **Education:** The use of animals in education represented just 1860 animals in 2009, and could be easily replaced by computer-based alternatives
- **Forensic studies:** 10 animals were used in 2008 in the category of forensic enquiries, and none in 2009. The signatory groups believe that the use of animals in this field is highly questionable, and the small number of animals used makes speedy replacement feasible.
- **Military:** the use of animals in weapons-related or war gear tests is highly unethical and strongly opposed by the British public. This should be ended immediately. Germany has already banned these types of tests. These have been in steady decrease in the UK, dropping from 21,118 in 2005 to 8,168 in 2009. However, the use of primates has increased[xiv].
- **Preservation of the species:** this justification for experiments exists in the new Directive, but not in UK law. We believe that few, if any, animals are used for this purpose in the UK, and therefore such tests should not be allowed in future. Conservation groups agree that the best way to protect species is by protecting them in their natural habitat.

Data Sharing

Recital 42 provides that "*It is necessary to introduce specific measures in order to increase the use of alternative approaches and to eliminate unnecessary duplication of regulatory testing. For that purpose Member States should recognise the validity of test data produced using test methods provided for under the legislation of the Union.*"

This requirement (Article 46) should be implemented with the strictest possible interpretation in the UK.

Ensuring the effective implementation of non-animal methods

The oft-repeated defence of animal experimentation legislation in the UK and elsewhere is that animals will only be used when there is no alternative available. Yet despite such reassurances, it has frequently been the case that animal experiments have taken place when non-animal methods are available.

A number of recitals and articles in the new Directive (e.g. Recitals 10; 11; 12; 42; 46 and 47 and Articles 4; 38 and 47), including the authorisation process, call for the implementation of non-animal methods. It is vital that the transposition of the new Directive is used as a driver to ensure that replacement methods are used. Where non-animal methods exist it is important that these are not regarded as being optional, or to be used when convenient; their use must be compulsory.

[i] Explanatory Memorandum to the *Proposal for a Directive of the European Parliament and of the Council on the protection of animals used for scientific purposes*: 3 (available from http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0543:FIN:EN:PDF)
[ii] *The Coalition: our programme for Government*: 18. (available from http://www.cabinetoffice.gov.uk/media/409088/pfg_coalition.pdf
[iii] 15 ILSA J. Int'l & Comp. L. 61 (2008-2009); Law of Recitals in European Community Legislation, The; Klimas, Tadas; Vaiciukaite,Jurate
[iv] See endnote ii
[v] 1876 Cruelty to Animals Act.
[vi] Home Office 'Consultation on EU proposals for a new directive on the protection of animals used for scientific purposes', paragraph 26, published May 2009.
[vii] Letter of 17 July 2009 from Lord Roper, Chairman of the Select Committee on the European Union of the House of Lords, to Admiral Lord West of Spithead, Parliamentary Under-Secretary of State, Home Office
[viii] See Sixth Statistical Report: http://ec.europa.eu/environment/chemicals/lab_animals/reports_en.htm
[ix] http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=P-2010-6294&language=EN
[x] Recital 17 states that "*the use of non-human primates is of the greatest concern to the public.*"
[xi] See Written Answer by Lynne Featherstone to Henry Smith MP, 4 November 2010: 1257 F1 primates and 1102 F2 primates were imported in the UK in 2009.
[xii] http://www.ad-international.org/admin/downloads/stpreporten.pdf
[xiii] Animal Procedures Committee, *Report of the Animal Procedures Committee for 2005*: 17 (see http://apc.homeoffice.gov.uk/reference/apc_ann_rep_2005.pdf)

[xiv] http://www.publications.parliament.uk/pa/cm200910/cmhansrd/cm100323/text/100323w0002.htm