NATIONAL ANTI-VIVISECTION SOCIETY

Parliamentary Briefing

Transposition into UK law of EU Directive 2010/63 on the use of animals for scientific purposes:

Summary of Key Areas of Concern

March 2012

Key Areas of Concern for Parliamentary Scrutiny of Government Proposals

Summary

The National Anti-Vivisection Society, together with the Lord Dowding Fund for Humane Research and Animal Defenders International, are highlighting some key concerns and opportunities for progress for parliamentarians when the Government submits its proposals for approval under secondary legislation.

Top among these issues is that of parliamentary scrutiny. Animal experimentation is a matter of enormous public disquiet and concern. Yet rather than primary legislation and full parliamentary debate, we understand that the Government plans to lay statutory instrument proposals, under the European Communities Act. This means that the need for parliamentarians to speak for the public and properly scrutinise the proposals when they are laid before the statutory instruments committees is absolutely essential.

Key issues for attention during scrutiny should be:

1. There should be no downgrading of UK animal protection measures
2. Accountability and wider scientific scrutiny of proposals to use animals, allowing suggestions for alternatives
3. Thematic Review – biennial reviews of specific animal procedures, involving all stakeholders, with a view to examining the specific procedure and setting a deadline for replacement.
4. Alternatives – creation of a network of centres of excellence; ensuring that alternatives are used; even when this means outsourcing
5. Limiting Severity – upper limits on severe and prolonged pain; in modern science, death endpoints cannot be justified.
6. Primates – limiting their use in procedures and phasing out the use of wild-caught primates to boost supplies in breeding colonies

1. No downgrading – maintain the UK's higher standards (Directive, Art.2)

In many respects, the Animals (Scientific Procedures) Act 1986, (ASPA) provides higher standards of animal protection and laboratory practice than provided for in Directive 2010/63/EU (the Directive). The UK's higher standards must be maintained. It is well established that stress in laboratory animals affects scientific outcomes, therefore good science, well managed and controlled, protects both animals and scientific standards.

Retention of UK standards would include for example, keeping special provisions on use of cats, dogs and horses under the ASPA, in contrast with the Directive (which only affords special protection to non-human primates, under Article 8). However, Article 2 of the Directive allows Member States to retain higher standards[1].

Although the Home Office notes that Article 13(2)(b) of the Directive requires that animals of the lowest sentience be used[2], there is concern that if the UK Government chooses to remove the special protection for cats, dogs and horses, this would likely counter the downward trend in their use for the past two years[3]. The loss of special protection for these species would have a detrimental effect on public confidence as the use of these animals is of particular concern to many people.

A number of other Articles in the Directive would *compromise* provisions set out in the ASPA and *should not be implemented*. These include:

Great ape safeguard clause (Art.55): The use of great apes in scientific procedures has not been permitted in the UK since 1987[4]. This safeguard clause should not be transposed.

Simplified administrative procedure (Art.42): The UK should not adopt simplified administrative procedures for any categories of project. Any use of animals for scientific purposes should be fully scrutinised. Any proposal that reduces the requirements for project application also reduces the transparency of the process.

Exemption on stray animals and animals taken from wild (Arts. 11 & 9): Relaxation of the prohibition on the use of stray or feral animals in the UK would be a major step backwards for animal welfare, would have a detrimental effect on public perception and carries scientific implications.

Creation of 'Animal Welfare Bodies' (Arts. 26 & 27): The NAVS believes that the current UK Ethical Review Process has had a limited impact due to inadequacies including lack of centralised information, access to outside expert opinion and limited animal protection representation. If the Animal Welfare Body were to replace the current ethical review process in the UK, it must not reduce the expertise available otherwise it is likely to negatively impact animal welfare. Indeed the body would lose its fundamental role of reviewing the ethics of a project. What is needed is more independent scientific and ethical review, not less.

Protection of embryonic and foetal forms (Art. 1): As there is evidence that some foetal forms of animals have the ability to feel pain[5], their use in experiments must be regulated in line with their potential for feeling and sensory level consciousness. The current level of protection afforded to foetal forms in the UK from midway through gestation should be retained as a humane, considerate, and precautionary approach towards the sentience of unborn animals.

Restrictions on methods of killing (Directive Annex IV & Art. 6): It is of concern that methods of killing other than those specified in Annex IV are permitted. Similarly, exemptions in Article 6.5 would allow animals to be killed by non-competent individuals, by any method in given circumstances. This could result in serious welfare issues. It is imperative that current UK restrictions (i.e. size/weight) relating to the use of methods currently listed in Schedule 1 of ASPA are retained, and that any methods currently not permitted under Schedule 1 are not transposed.

Use of endangered species (Article 7): ASPA section 10(3)(c), does not permit a vertebrate of an endangered species to be used, except for research aimed at the *"preservation of the species in question"* or for *"essential biomedical purposes"*[6]. Article 7 of the Directive however, significantly widens the scope for research using endangered species to include *"the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs and other substances or products"*[7]. To permit the use of CITES Appendix I species, which are by definition, *"species threatened with extinction which are or may be affected by trade"*[8], with a view to the development of foodstuffs and feed-stuffs would be unacceptable. Under no circumstances should the use of endangered species be authorised for such purposes. Any relaxation of the ASPA restrictions on use of endangered species would be a major retrograde step for UK conservation goals and species protection.

2. Transparency, Public Accountability, Wider Scientific Scrutiny

Remove the Secrecy Clause, S.24: In order to increase public confidence in the Government's regulation of animal experiments, it is vital that the blanket secrecy clause, Section 24 of the ASPA be repealed. With the introduction of the Freedom of Information Act 2000, which carries safeguards for personal information, health and safety and intellectual property, blanket secrecy on the use of animals in research is unjustified and unsustainable. To repeal S24 would comply with the Directive's objectives for transparency and public accountability.

Wider scientific scrutiny and mechanisms to replace animal use with advanced alternatives:
The Directive's aims include transparency and public accountability, with mechanisms to challenge animal use and promotion of alternatives (Articles 34, 36, 37, 38, 39, 42, 43). The UK should adopt these provisions to allow for:

- Wider scrutiny of project licences. In order to provide more independent and scientific scrutiny before project licences are granted, all applications should be placed online, with a time limit for response. This would allow stakeholders to identify trends in animal testing, avoid unnecessary duplication and monitor the replacement, reduction and refinement of the use of animals in research. Applications must also include more detail with a critical and meaningful assessment of the proposed work.
- Retrospective Assessment by the Home Office of all animal experiments to determine whether a project has achieved its objectives and the actual level of suffering experienced by the animals. This will provide invaluable feedback into the cost-benefit assessment for future projects. Similar schemes are working successfully in other European countries.
- Improve Inspections. A number of failings in the existing inspection system have been identified. The number of inspections must be maintained, or increased, including an increase in unannounced inspections. We propose a system of CCTV monitoring in order to identify deficits in laboratory practice and welfare; this would enable the Animals Scientific Procedures Inspectorate to monitor at any time.

3. Thematic Review of specific animal tests to set targets for replacement (Art 58)

Article 58 of the Directive provides: *"The Commission shall, where appropriate, and in consultation with the Member States and stakeholders, conduct periodic thematic reviews of the replacement, reduction and refinement of the use of animals in procedures, paying specific attention to non-human primates, technological developments, and new scientific and animal-welfare knowledge".*

The concept of thematic review allows for all stakeholders to be invited to submit candidate animal procedures for review to a joint panel. The procedure would be examined on the basis of the quality of the science, outcomes, availability (or necessity) of alternatives and a timetable would be set for replacement. The Directive allows for the European Commission to co-ordinate Europe-wide activity, but each Member State is free to initiate thematic reviews.

The NAVS and Lord Dowding Fund proposed the concept of thematic review to the Home Office; this concept has received widespread support. The UK can move forward quickly on replacement of animal procedures, as well as reduction and refinement. Calls for submissions to the thematic review process would be every two years, in order to maintain support and show a reasonable level of progress. It will be important that this is seen to be a workable, meaningful process where opportunities for replacement of animals are driven forward, rather than it becoming a 'talking shop'. More details are provided in the separate 'Thematic Review' briefing.

4. Implementation of Alternatives – centres of excellence (Art 47)

Advanced, cutting edge technologies are currently in use or have the potential for use as alternatives to animal methods: Microdosing and Accelerator Mass Spectrometry (AMS), QSARs (Quantitative Structure-Activity Relationships) computer modelling, human cell lines, scaffolds and 3-Dimensional (3D) cultures, high throughput screening (HTS) techniques, biochips, toxicogenomics. All of these methods avoid the problem of species differences and are directly relevant to humans.

Wherever possible, a scientifically satisfactory non-animal testing method or strategy should be used, but this has often been set aside when alternatives have not been readily available for use, or convenient. There remains little incentive (or drive from governments) for researchers to use non-animal methods in fundamental research. By implementing compulsory outsourcing, where if a non-animal alternative exists in another establishment, it must be used, the UK would remain at the forefront of advanced technologies.

Directive 2010/63 EU provides for each Member State to establish a centre of excellence for the development and validation of advanced non-animal methods. The UK must adopt measures to increase the access to advanced alternative methods and this can be achieved by creating centres of excellence for the development of alternatives and with the European Commission, establishing a network of similar centres throughout Europe.

5. Limiting Severity

An upper limit of pain and suffering must be set, for both scientific and ethical reasons. In modern scientific practice, there can be no justification for allowing animals to suffer severe and prolonged pain, and neither should death be viewed as an acceptable end-point.

In order to establish more accurately the level and duration of suffering, we suggest a further sub-category within the 'severe' pain band be created, which would establish a clear upper limit to the level and duration of suffering. This "severe and prolonged" category would describe those procedures that are prohibited and which cannot be authorised by invoking the 'safeguard' clause (Article 55 of the Directive).

In order for pain and suffering to be quantified, classified and minimised, it is essential that it be quickly and correctly recognised. Recognising suffering in different species of laboratory animals can be problematic, as many species have evolved to conceal signs of pain or distress, so it is vital that staff receive appropriate training in order for suffering, pain and distress to be effectively reduced in practice[9].

6. Primates: restrictions on their use and ending of wild capture

The Directive provides tighter restrictions the use of non human primates in research and sets out objectives for ending the wild capture of primates to replenish laboratory breeding colonies (Articles 8 and 10).

Use of non human primates in procedures:

Use of non human primates is restricted to basic research and *"potentially life-threatening conditions in humans or in relation to cases having a substantial impact on a person's day-today functioning, i.e. debilitating conditions"* with proscribed uses. However, in order to make this workable, a clear definition of *"life threatening"* and *"debilitating"* is needed. A list of medical conditions should be drafted, in consultation with stakeholders, to establish the diseases, illnesses and conditions to be placed in this category.

EU statistics on primate use in Europe show that the UK is the largest user of primates among the Member States[10]. In view of this, and that the 2009 report of the House of Lords Select Committee on the use of animals in research as well as the revision of the Directive noted that there is overwhelming public support for greater protection of primates used in research and testing, the UK has the responsibility to take the lead on restriction of primate use.

Currently, under the ASPA, proposals for experiments expected to inflict suffering of substantial severity on non human primates, or for use of wild-caught primates, are placed before the Animal Procedures Committee. We suggest that all proposals for the use of primates should be put forward to wider scientific consultation and/or referral to the new national committee provided for in the Directive.

Ending the capture of primates from the wild:

Article 10 of the Directive provides for implementation of the phase out of use of F1 primates (born of one or both wild-caught parents). This is to follow a feasibility study to be published no later than 10th November 2017, with certain species being phased out 5 years after this date, *"provided the study does not recommend an extended period"*.

The use of wild-caught primates for research is permitted only in exceptional circumstances, but primate breeding establishments based abroad that supply European laboratories, including the UK, are known to capture significant numbers of wild macaques to replenish their breeding stock[11].

Concern about the capture and use of wild-caught primates includes both the **damage to wild populations** and the **suffering caused to intelligent and sensitive primates**. Studies have revealed the high levels of suffering and mortality associated with capture, handling and housing of wild animals. Welfare problems include violence, stress and fear during capture, sudden confinement and tearing apart of family groups[12]. Methods of trapping are indiscriminate, with little regard to the demographic status of the wild populations[13]. This can be especially damaging, when the IUCN/SSC Primate Specialist Group has advised that 48% of all primate species are threatened globally[14], and it has been noted that a significant threat to cynomolgus macaques exists as a result of trapping for pharmaceutical testing, research and development, especially throughout the Indochinese region[15].

The International Primatological Society (IPS) has recommended that *"the establishment of self-sustaining captive breeding colonies is strongly encouraged in order to decrease or eliminate the demand on wild primate populations"*[16].

Following an investigation of the treatment of primates at Nafovanny in Thailand, the NAVS pressed the Home Office for the information retained on overseas suppliers. The UK Home Office has said that it is unable to set standards for overseas suppliers. We disagree. The UK should set standards of welfare for overseas primate suppliers, who wish to sell their animals to UK users. In order for UK standards to be meaningful, dealers must only be permitted to supply the UK, if they meet UK standards.

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Parliamentarians are urged to closely scrutinise the UK Government's proposals for transposition of Directive 2010/63EU into UK law and the overhaul of the Animals (Scientific Procedures) Act, with particular emphasis on the above key issues of concern.

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