Home Office Consultation 2011

on new legislation on animal experiments

A new European Directive (2010/63/EU) is to become law in the United Kingdom – this is your opportunity to take part – deadline 5th September

National Anti-Vivisection Society (NAVS), Millbank Tower, Millbank, London SW1P 4QP.
Tel. 020 7630 3340 www.navs.org.uk

YOU CAN HELP

use this guide to save lab animals:

The UK Government is about to introduce a new law on animal experiments. This new law will follow what has been agreed in a new EU Directive on animal experiments (*Directive 2010/63/EU on the protection of animals used for scientific purposes*).

For the new law, the Government is conducting a public consultation, where they are asking people to tell them what they think is important.

The National Anti-Vivisection Society, the Lord Dowding Fund for Humane Research and Animal Defenders International are working together to improve research and protect animals from suffering.

Key objectives we are pressing for the UK Government to introduce in any new law are:

- A ban on household product testing.
- No downgrading of existing UK animal protection measures.
- Commit to replacing experiments on monkeys in UK laboratories.
- End the capture of monkeys from the wild, by laboratory dealers.
- Set limits on the pain laboratory animals are allowed to suffer.
- Increase public transparency on animal experiments – before animals are used.
- Increase compulsory data sharing to prevent unnecessary experiments
- Establish a UK co-ordinating body for the development and validation of replacement techniques – include specialist groups like NAVS.
- Ensure the effective implementation of non-animal methods – where there's an alternative it *must* be used.
- The UK should lead in regular 'thematic reviews' to identify and agree replacement methods for specific animal experiments and specific uses of animals.

Take part in the consultation online, by following the NAVS answer guide at: *www.navs.org.uk/consultation*

or

you can use the NAVS postcard, and send it to the Home Office – call us or order online at *www.navs.org.uk/consultation*

The deadline for responses to the consultation is: 5th September 2011

The National Anti-Vivisection Society (NAVS) is pressing the UK Government to maintain the requirements and standards under our Animals (Scientific Procedures) Act 1986 (ASPA), that are actually more stringent than the requirements under the new European Directive.

The Directive allows governments of individual Member States to retain requirements and standards that are higher than the Directive. However, in our view the UK Government is leaning too much towards just using the text of the Directive for our new law, which would mean lowering of standards in UK laboratories, lowering of controls over licensing, less information on the annual statistics.

We must retain the advances the UK has made under our current law, and also, ensure the parts of the Directive that can actually end animal experiments, such as 'thematic reviews', are taken up.

Our proposal to the European Parliament for thematic review was included in the Directive. The idea is that all stakeholders, including animal protection groups and non-animal research groups, propose a review of certain animal experiments or uses of specific species and binding targets are set for those experiments to be replaced with non-animal methods. This would mean that step-by-step, we can end the use of animals in research – this benefits people, because it makes the government policy favour advanced scientific method; it benefits animals, because they will no longer suffer in experiments that are unreliable, unethical and unnecessary.

We've selected below some key questions from the Home Office Public Consultation, and we've provided guidance on the answers to the questions that we would like our supporters to include if you decide to take part in the consultation.

The key HO Consultation Questions:
(please send these answers to the Home Office)

Question 1: Should the UK continue to protect mammals from half way through gestation?

Suggested answer: Yes

NAVS reasoning: The UK currently protects foetal mammals from half way through their gestation period, this compares to Directive 201063/EU which protects these same animals for the last third of their gestation. It is acknowledged that all animals develop at different rates. To treat all mammals the same, and to err on the side of less protection is to underestimate the differences between species. The different degrees of sentience and cognition for the multitude of different species means that it is difficult to protect all animals with one time point - for this reason, and also to give animals the benefit of the doubt in the absence of clear scientific evidence to the contrary – as well as uphold the stricter measures in the UK's Animals (Scientific Procedures) Act 1986 (ASPA), the UK should continue to protect foetal mammals from halfway through their gestation period.

Question 5: Should the UK retain its current special protection for dogs, cats and equids?

Suggested answer: Yes

NAVS reasoning: The current UK Animals (Scientific Procedures) Act 1986 (ASPA) goes beyond the European Directive on the scope of protection for certain animals such as birds, foetal forms of mammals or reptiles from halfway through the gestation or incubation period (section 1.2), vertebrates of endangered species (section 10.3), dogs and cats and equines (section 5.6) and feral and stray animals (section 10.3). The Home Office also publishes detailed annual statistics of animal use under the ASPA, which contributes to public access to information about animal experiments. The EU Directive (Article 2) allows EU Member States to go beyond the provisions of the Directive, therefore the UK must maintain these higher standards.

The special protection which is afforded to these animals, alongside primates, is a reflection of the public concern about their use. There must be special clearance to use these animals. To revoke the special protection which is extended to these animals is a retrograde step and should be resisted.

Question 8: Are there any further issues to consider regarding the use of non-human primates?

Suggested answer: Yes

NAVS reasoning: The probability that Article 8 of the Directive will affect research which is currently being conducted using non-human primates depends very heavily upon the exact definition of "debilitating condition". If this definition is taken in its strictest sense, then the number of primates and the research which can be conducted with them, will be minimised, which is in the spirit of the Directive. If almost any condition can be considered to be "debilitating", then the number of permissible procedures and protocols will increase. For this reason, it is imperative that a comprehensive, exclusive list of conditions and diseases considered to be debilitating is drafted and then strictly adhered to, without the use of any safeguard clauses

Question 13: Is there a case for retaining the current UK requirement that quail and ferrets should be purpose bred?

Suggested answer: Yes

NAVS reasoning: the ASPA (schedule 2) lists the animals which must be obtained from designated breeding or supplying establishments. This means that the animals are bred under codes of practice and government guidance and that the establishments where they are bred can be inspected by the UK's Animals Scientific Procedures Inspectorate (ASPI). Whilst this system is far from perfect, buying animals only from designated establishments does confer a degree of protection to these animals, and allows the public to check that inspections are being carried out. Article 2 of the Directive allows Member States to maintain higher standards, and this is an instance where this should happen.

Question 20: Should UK restrictions on neuromuscular blocking agents in mammals be retained?

Suggested answer: Yes

NAVS reasoning: The ASPA does not allow the use of neuromuscular blocking agents (NMBAs) without an anaesthetic (ASPA section 17) whereas the Directive would allow its use, with analgesics. This would be to the serious detriment of animal welfare given that NAVS research clearly shows that their use will induce fear and distress. NMBAs stop the ability to move, but do not affect consciousness – a terrifying prospect for an animal which has been given an NMBA without anaesthesia as it would not prevent it feeling pain, but it would be in a helpless state of paralysis.

Question 21: Are there any further issues relating to re-use we should consider?

Suggested answer: None. Animals should not be re-used.

NAVS reasoning: Historically, the re-use of laboratory animals has been responsible for considerable suffering. Allowing the re-use of animals may increase animal suffering. For example an animal being allowed to recover from anaesthetic following a procedure in order to be used again, when otherwise the animal would have been euthanised while unconscious. There are also scientific concerns about the impacts of multiple procedures – it is acknowledged that the animal's welfare has an impact on the outcome of the experiment, and re-use adds an additional factor. It is misleading to assume that re-use reduces the amount of suffering because fewer animals may be involved, since a single animal simply endures twice as much suffering. The current provision of the Directive would allow animals, in exceptional circumstances, to be re-used after a severe procedure has taken place and does not explicitly require prior authorisation for re-use. The UK should maintain its stricter standards and not take up the same position as the Directive.

Question 28: Are there any further issues relating to avoidance of duplication of procedures?

Suggested answer: Create a UK database of experiments being conducted to share information

NAVS reasoning: Laboratories must be held accountable, and sharing of data is part of this. Data sharing and detailed and regular statistical reporting are essential to avoid duplication of experiments and assess progress made in the promotion of alternatives. According to the data of the European Commission, "approximately 160,000 animals are subject to duplication in regulatory testing each year". These could be avoided by creating a UK database collecting information on animal experiments and sharing, data, as with the European chemicals regulations. Compulsory data sharing is vital for the reduction of animal testing. This will also contribute to transparency of animal testing and accountability of licence holders.

Question 29: Are there any issues we should consider for alternatives?

Suggested answer: More emphasis is needed on replacement techniques. These are advanced scientific methods to replace animal use. Establish a UK co-ordinating body for the development and validation of non-animal methods and ensure their implementation. This needs to be wider than the scope of the present National Centre for the 3Rs, and needs to include participation of specialist organisations.

NAVS reasoning: Advanced scientific techniques that replace animals are at the forefront of scientific developments, but these are not being implemented quickly enough. There is a lack of coordination on specifically, replacements. The National Centre for the 3Rs (Reduction, Refinement, Replacement) is still focussed on animal research techniques, rather than advanced replacements.

Question 31: Are there any additional examples of severity that might be included in guidance?

Suggested answer: Yes. A "severe and prolonged" category must be created which has a list of procedures which are prohibited. This must be compiled and adhered to without safeguard clauses.

NAVS reasoning: To function effectively and meet its objectives, severity classification needs to have clarity, consistency, and be easily understood by researchers and those processing and authorising applications. The system needs to clearly link common procedures and practices to categories of pain and suffering which are readily understood by the public. Grouping procedures which cause both severe and prolonged suffering within a single "severe" category should be eliminated. ***Such ambiguities mislead the public, are detrimental to standards of accountability and they represent poor scientific planning.***

An upper limit of pain and suffering must be set, for scientific and ethical reasons. In modern scientific procedures, animals should not suffer severe and prolonged pain, neither should death be an acceptable end-point. Without this category to report non-authorised prolonged suffering, the "severe" category has the potential to be open-ended and the suffering animals endure without limits. This would be reprehensible.

Question 41: Should the UK retain its current system of personal licensing or adopt a simplified version of the licensing system?

Suggested answer: The UK should retain its full licensing system to maintain animal welfare standards.

NAVS reasoning: The UK should retain a strict three tier licensing system (for establishments, personnel and projects) administered by the Home Office. Even competent handling will cause stress in laboratory animals. Therefore it is fundamental that, throughout their entire lifetime, animals are handled by competent personnel. Numerous investigations have shown that mishandling animals can lead to severe suffering, especially during and after scientific procedures. This has been shown to happen under the current licensing regime, and was clearly demonstrated in our expose of work at Huntingdon Life Sciences only recently. Therefore, all personnel carrying out experiments on animals should hold a personal licence issued by the UK authorities. This system should not be simplified as it would compromise animal welfare.

Question 45: Should information be placed in the public domain about the project evaluation process to ensure transparency of the process?

Suggested answer: All information about the project evaluations should be made public to ensure accountability and public confidence. This can be achieved with online access.

NAVS reasoning: Publication of technical details of project licence applications (with private information excluded) would allow wider scientific scrutiny of proposals to use animals and consideration of non-animal alternatives or other sources of the information required. Ethical evaluation reports and retrospective reviews should also be made available to the public.

Question 46: Should the UK extend the requirement for retrospective assessment to some or all projects involving procedures classified as "mild" or "non-recovery"?

Suggested answer: All projects must be retrospectively assessed.

NAVS reasoning: NAVS strongly supports the implementation of retrospective reviews of all projects, where a review is conducted to see what actually happened to the animals, as opposed to what the researchers predicted might happen when they applied for permission to use animals. These can be very useful to establish whether animal procedures have been conducted within the terms of the project licence and they are useful to inform future cost-benefit assessments and define priorities for replacement techniques. Animals suffer in all experiments and this suffering should be acknowledged and quantified at all times.

Question 49: Should the UK adopt a simplified administrative procedure for relevant categories of project?

Suggested answer: The UK should not simplify the current administrative procedures

NAVS reasoning: There should not be a simplification of the current administrative procedures. To fast track or in any way speed up or simplify the scrutiny to which these projects are subjected would give researchers the impression that the procedures are less serious. All procedures that are undertaken on animals, with the animals bearing the cost of the procedure, should undergo a rigorous and robust assessment. This is important not only to maintain scientific robustness, but also to ensure that public transparency and accountability is ensured for each and every aspect of procedures involving animals.

Question 50: Should the UK aim to publish non-technical summaries for all authorised projects?

Suggested answer: Yes

NAVS reasoning: Waiving requirements for non-technical summaries for mild or moderate procedures, not only implies to the public and researchers that these procedures are of less concern, but also that less information is required – this is incorrect on both counts. All non-technical summaries must be published in order to ensure the highest level of public confidence, transparency and accountability. In addition, if there are different rules for different severities of procedure, this may lead researchers to categorise their work into the categories which undergo the least amount of scrutiny – this is unacceptable.

Question 54: Should all aspects of the current UK inspection system be retained? How might it be improved?

Suggested answer: Yes, all aspects should be retained, and the proportion of unannounced visits and the frequency of visits should increase.

NAVS reasoning: The system of inspections which is currently in place, although it is far from perfect, is much stronger than what is proposed under the Directive. Two ways to increase the strength of the current inspection system would be to increase both the frequency of visits and the proportion of these which are unannounced.

A detailed, more formal approach would not (a) be favoured by the establishments as they are able, under the current process to see inspectors frequently and to gain information and feedback from them. In addition,

the frequency of visits will enable an inspector to spot if things have changed over a shorter period of time. And (b), public confidence would, quite rightly, be seriously undermined by less frequent inspections, irrespective of how "detailed" these are intended to be, compared to the current process. The Home Office has suggested that there may be periods of between 3 to 5 years between inspections for some establishments. This is far too long between inspections and would allow controls, procedures and facilities at establishments to deteriorate without regular inspections and guidance. In addition, generation of animals may live, be used and die in between inspections of this frequency – this is unacceptable.

Question 55: Should the UK continue to publish a full range of statistics as in the current annual statistics report?

Suggested answer: Yes

NAVS reasoning: The current UK (ASPA) goes beyond the European Directive on the scope of protection for certain animals such as birds, foetal forms of mammals or reptiles from halfway through the gestation or incubation period (section 1.2), vertebrates of endangered species (section 10.3), dogs and cats and equines (section 5.6) and feral and stray animals (section 10.3). The Home Office also publishes detailed annual statistics of animal use under the ASPA, which contributes to public access to information about animal experiments. The EU Directive (Article 2) allows EU Member States to go beyond the provisions of the Directive, therefore the UK must maintain these higher standards.

Question 58A: The UK will introduce thematic review – would you like to see thematic review include all stakeholders and allow them to submit at least five animal experiments a year for review?

Suggested answer: Yes

NAVS reasoning: We have lobbied for 'thematic reviews'; a system where groups of experiments are reviewed and scheduled for replacement with non-animal methods is essential to ensure progress on this issue. The thematic review process must involve all stakeholders (including NAVS, Lord Dowding Fund and Animal Defenders International). The weight of importance placed on certain experiments will be of more or less concern or value to different stakeholders.

Consideration by the stakeholders and then the submission of five specific procedures for review is a manageable number for an annual review. The thematic review process, allowing the gradual removal of the procedures of most concern, is essential to the spirit of the Directive, as outlined in its Recital 10 – *"this Directive represents an important step towards achieving the final goal of full replacement of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible to do so".*

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Millbank Tower
Millbank
London SW1P 4QP.
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