NATIONAL ANTI-VIVISECTION SOCIETY

Legislative Briefing

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

A mechanism for replacement of animal use with advanced scientific methods through Thematic Review

March 2012

Thematic Review of Animal Experiments

Background

Article 58 of Directive 2010/63 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"*[1].

The concept of thematic review discussed and envisaged by the European Parliament, the Commission and the Council of Ministers provided a clear mechanism to move forward, primarily, on the replacement of the use of animals in specific experiments, as well as establishing the scope for refinement and reduction of animal used in specific protocols. It is vital that this be a workable, meaningful process where opportunities for replacement of animals are driven forward, rather than it becoming a 'talking shop'.

A clear focus will be critical to the success of thematic reviews. The European Commission should coordinate Europe-wide activity, with Member States initiating projects. The first stage would be a call for submissions (from all stakeholders) on the first group (a), candidate animal tests or uses of animals that could be replaced, with the aim that 3-5 candidate protocols or uses would be established for investigation each year. The primary candidates for thematic review need to be those where replacement is either established or emerging, or where there is clear evidence that the experiments are not necessary. The second group, (b) would be protocols/areas of animal use where there are opportunities for a reduction in the number of animals used, or suffering reduced.

Frequency will be vital to ensuring focus. Thematic review needs to become part of the daily administration of the regulations, i.e., calls for submissions at least every two years, regular reporting, management of numbers and progress of projects.

Calling for submissions less frequently would likely result in an overwhelming number of projects for assessment, and puts the whole system at risk of failure. Furthermore less frequent calls for submissions could mean that opportunities are missed, where replacement might be straightforward.

During the Committee stage of the Directive in the European Parliament, thematic review was discussed at length and adopted with a call for the reviews to take place every two years[2]. It was noted that thematic review allows "a more focussed approach to the use of animals in specific areas of research and testing"[3]. It was acknowledged that a ten year review of the whole Directive would not keep pace with advances in technological and scientific progress.

When the wording of the Directive was streamlined by the Council of Ministers the requirement for a review every two years was removed, leaving Member States to determine frequency. There is a case to be made that the countries performing the highest numbers of animal experiments, such as the UK, Germany and France, should be undertaking thematic review far more frequently than, say, Malta. Nevertheless the intent remains that this will be a regular, proactive process.

The support provided by the European Commission has provided the Member States with the flexibility to take unilateral action and commence their own thematic reviews, drawing in collaborations with the European Commission and other Member States once their own system is under way.

The UK unilaterally banned cosmetics testing on animals in 1998, with an EU ban following in 2004.

Whereas In the case of thematic review, a foundation has been provided to enable the UK to lead Europe in the development of its own thematic review process, knowing that a European framework has been outlined to facilitate Europe-wide action and collaboration.

Above all else it is important that thematic review is a practical measure, maximising the opportunity to cut specific uses of animals in research, involving all stakeholders and wider scientific and ethical input to the process. This means that Article 58 of the Directive can bring a fresh approach to reviewing animal experiments and build on, rather than replicate, work previously carried out in the UK by the National Centre for the 3Rs (NC3Rs) or the Animal Procedures Committee (APC), or independent non-animal research funding bodies.

Outcomes for thematic review

It is necessary to consider outcomes, in order to focus the approach to the review. The considerations listed below, for example, will help to define the criteria for selection:

- The identification of an alternative, non-animal approach to the procedure(s) or uses of animals.
- Acceptance of the alternative – this is broader than the frequently limiting term 'validation' and could, for example, be based on common usage.
- Determining the availability of such non-animal alternatives. Stakeholders may wish to include the experience of an expert currently utilising any of the identified non-animal methods.
- Identifying the barriers, both real and perceived, to implementing the non-animal alternatives.
- Demonstration of how any barriers to implementation of non-animal alternative(s) can be overcome.
- A timetable for phasing out the candidate animal experiment(s) in favour of the alternative(s), taking into account all of the aspects mentioned earlier. Dependant upon the degree of development of the alternative method(s), and/or the nature of the barriers to implementation, recommendations can be made for phase out; either imminently, or over months or years.
- Alternative outcome: There may be a case where an alternative method is not available but due to the experiment or procedure being scientifically poor, a replacement is not actually necessary. For some animal use there will be a case for establishing that the procedure or use is defunct. This may also apply to experiments where alternatives are already available anyway.

Biennial Thematic Review

The biennial submission of candidate protocols or areas of animal use provides a reasonable period of time for investigation and assessment of the potential for replacement.

Every two years sets a moderate but regular pace. It gives assurance to a concerned public that active and measurable steps are being taken to achieve progress and that the time frame is reasonable. The adoption of new targets for review every two years also maintains momentum. Thematic review every two years was the frequency supported by the European Parliament and the European Commission.

Knowing that another band of reviews is scheduled for the not too distant future will encourage all parties to break down candidate subjects and/or protocols into manageable areas of research. It will also discourage attempts to undertake too many reviews at the same time, thus overloading the system and hindering progress. It would also allow for postponing or re-scheduling of candidates for thematic review, where extra time may be needed to develop or establish alternatives. This avoids the risk of indefinite delays and should lead to more measured submissions.

Application Process

An online application process should be available to all stakeholders with the application form used to identify suitable candidates for thematic review. See appendix for sample application form.

Whilst the application should indicate that there is a reasonable expectation of success, or something worthy of investigation, a lack of available data (or ability to answer every question) should not preclude that specific candidate protocol or area of research from consideration. A lack of access to estimates of the number of animals being used in a particular procedure does not have a bearing on the viability of, for example, an alternative method.

Review Panel

A review panel, with representation from all stakeholders, should consider all applications and determine the candidates to go forward for thematic review.

The minimum requirement for this should be, for example, a lay person, an expert in alternative techniques and a member representing the field of animal protection, in order to ensure that the decision on applications are not made solely by those with a vested interest in the continued use of animals in research. There would also be a role for a member of the inspectorate in an advisory capacity.

Bodies such as the APC and others have failed to benefit from representations made by those working for the replacement of animal experimentation, because such bodies are perceived as being closed shops, sanctioning or deflecting criticism of animal experiments. In this context individuals or groups represented on the panel would be committed to driving forward the reviews that they believe have the most chance of a positive outcome in terms of replacement or reduction in animal experiments.

The review panel should be free, and indeed encouraged, to consult with additional experts, set up investigation sub-panels, to examine each candidate. This is especially important if the procedure being put forward for thematic review is not one which is commonly used, or is novel, or used by a small number of researchers. This would ensure that the most comprehensive, relevant data is available for consideration.

Names and CVs of the members of the review panel must be made public and hosted on the internet so that it can be seen whether any knowledge gaps exist. The members should be able to sit for at least three years, and the number of terms in office should not be restricted. This would enable to accumulation of a wide body of knowledge and also ensure that public confidence was maintained in the process.

Selection of candidate procedures

A minimum of five candidates for thematic review, every two years, would go forward to the Review Panel. The Panel would select a minimum of four or more candidates with one candidate confirmed by popular vote – an online vote. This could be either a public vote or could be open to stakeholders (or both). This would ensure public participation. Although by consulting with stakeholders only would ensure that the process retains its focus, the inclusion of the public is also an important element. As has been seen during the Home Office consultation on the transposition of the directive into UK law – the public clearly feels very strongly about vivisection and welcomes the opportunity for input.

The “popular vote” would serve to engage public and stakeholders and demonstrates that the Government is open to public input and is ensuring that this process does not become a ‘closed shop’, with good opportunities for thematic review simply discarded simply because the process is dominated by those with a vested interest.

The Review Panel would have the option of combining, or breaking down, areas for thematic review. We do not think an upper limit need be placed on the number of thematic reviews, unless there are practical considerations that would affect the completion of reviews to a sufficiently detailed degree in order to allow proper consideration. It should be noted that the complexity and work required for a review will vary greatly from subject to subject, and as a result, the number of topics put forward for review may vary in each review period.

The UK Review Panel would co-ordinate with the European Commission, which is responsible for Europe-wide coordination and facilitation of collaborations between Member States.

The Process

We see three possible options for undertaking the review process:

(a) Outside expert / outside expert panel

(b) NC3Rs

(c) Home Office

With a three stage process:

Part 1: Verification of issue/candidate (is the basic premise of the candidate correct?)/is this candidate something that indicates strong potential for the procedure to be phased out or stopped?

Part 2: Additional Research (to include the following)

- the animal procedures – the number, their nature and the severity banding.
- the replacements – those in use and those in development with timetable to completion
- availability of alternatives – costs of these may be a consideration if the alternative is only at the development or prototype stage
- the obstacles (cost of replacements, skills required, need for specialized equipment, inertia etc.). It should be recognized that the barriers may be real or perceived and as such, the ability to overcome them may be more protracted for some topics than others.

Part 3: Establishing a timetable to overcome any obstacles

Transparency

This process must be transparent, with applications, selection decisions, the outcomes of reviews, and any deliberations made public. The names of individuals submitting and their contact details could be made confidential on request. The timelines for the review process and the topics available for the "popular vote" should be available on the internet.

Recommendations to the Commission for EU action

The UK should be prepared to act unilaterally on this in the event of the Commission not moving forward with a review, undertaking thematic review in the UK and implementing the results with timetables for phase out etc. Levels of animal experimentation are variable across Europe with the UK one of the largest users and so too are the availability of replacements. Thematic review in the form outlined here would enable the UK to better undertake its broader responsibilities under the Directive to ensure animal experimentation is minimised and alternatives are sought and used wherever possible.

As one of the largest users of animals for scientific purposes in the EU, it is the UK's responsibility to show that we can and do work to phase out animal experiments, starting with those that are defunct and serving no real purpose, those where there are alternatives available, and those that are unsustainable or have no foundation.

However, the UK should also press the Commission for Europe-wide action in areas where the UK is considering/undertaking thematic review or where thematic review has successfully identified candidate protocols or areas of use.

This mechanism was strongly endorsed by the European Commission and article 58 calls for action by the Commission. If the UK were to be successfully replacing or reducing animal experiments, the UK-devised process could form a blueprint for the rest of Europe.

Refs:
1. Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.
2. Council of the European Union, "Proposal for a Directive of the European Parliament and of the Council on the protection of animals used for scientific purposes" 7 October 2009.
3. European Parliament, Committee on Agricultural and Rural Development "Report on the proposals for a directive of the European Parliament and of the Council on the Protection of animals used for scientific purposes" 3.4.2009

APPENDIX overleaf - sample form

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APPENDIX

DRAFT - Application for a candidate procedure for thematic review

Description of candidate for review		
Purpose of Review **(please tick those which apply)**	Replacement technique exists	
	Replacement technique emerging/in development	
	Partial replacement technique exists	
	Partial replacement technique emerging/in development	
	Refinement of procedure	
	Reduction in animals used	
	Data available from other sources	
	Scientific basis for the procedure is unsound	
	Other (describe)	
Number of animals used (state if this is an estimated or actual figure and the area to which it pertains i.e. UK or elsewhere)		
Purpose of procedure(s)		
Specific impacts upon on the animals (both the physiological and physical nature of the procedure, how the animals are used and the severity of the procedures etc)		
Evidence that animals continue to be used for this procedure or potential for future use		
Identification of non-animal approach(es). Reference examples where possible		
Details of Validated alternatives (e.g. by ECVAM or similar body)		

Details of acceptance of the non-animal method. Please include details of non-validation acceptance such as common usage, publications etc.
Availability of non-animal alternatives
Barriers to the implementation of non-animal alternatives
Solutions to overcoming the barriers to non-animal alternatives
Timetable for the phase out of the animal use in favour of the non-animal alternative, including goals for each step of the phase out
If the experiment is not necessary because it is scientifically unsound, or has been replaced, please state the alternative outcome and possible consequences
Any additional information that may assist with assessing this thematic review application
Submitted by: Please submit your contact details (we may wish to contact you for additional information / supporting documents):
References