ANIMAL EXPERIMENTATION: Are EU Regulations Adequate?

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INTRODUCTION

Over the last four years, I and my colleagues in the Animals in Science Regulation Unit (ASRU) in the Home Office have been heavily engaged first in negotiating the new Directive (2010/63/EU) to protect animals used in research, and then in ensuring the proper implementation of that Directive into UK legislation.

The process of negotiation took two years and was completed on 10 November 2010 when the Directive came into force. Thus our new UK legislation has to be on the statute book by 10 November 2012 – no time to spare given the various steps we need to have completed to ensure the new legislation has the support not only of Parliament but also of our other stakeholders. This community covers the full spectrum of interests from those who are licensed to perform research procedures on animals to those who are morally opposed to any use of animals in research. Quite a challenge!

Since we are not attempting to make any revisions to the law other than those required by the Directive, we are able to amend the 1986 Animals (Scientific Procedures) Act as a Statutory Instrument under the European Communities Act. This involves the "affirmative resolution procedure" requiring the approval of both Houses. Since amendments to the Bill are not possible during either debate, we have to present to Parliament the best possible proposal, balanced to carry the widest support.

. . . animals do not suffer unnecessarily . . .

To achieve such regulatory balance, we follow a simple principle illustrated in the diagram.

Figure: The ASRU Regulatory Balance

On the one hand, it is essential to ensure that bureaucracy and rules do not become so burdensome as to inhibit scientists from proposing scientific projects which will address important questions. We still need to understand better diseases for which we do not yet have effective therapies. On the other hand it is important to ensure that animals do not suffer unnecessarily, and that only soundly justified projects are authorised to go ahead.

Thus the legislation needs to ensure a careful balance between the needs of the science and the needs of the animals. It is this balance between science and welfare which provides the public with confidence in the regulatory system. The public wants to benefit from scientific advances, but also to be reassured that animals are not suffering unnecessarily. Furthermore, there is strong evidence to show that good animal welfare leads to better scientific outcomes.

NO REDUCTION IN WELFARE STANDARDS

Given this need for balance, much of the new legislation will continue the strong regulatory control we currently exercise. A starting principle has been "If it ain't broke, don't fix it". Hence, regulatory processes which currently work well will remain largely unchanged. Where current UK standards are higher than those in the Directive, we have used Article 2 to retain those higher standards. However we have also sought ways to simplify the regulations where we have perceived no welfare cost in so doing.

One example is the personal licence. We have opted to retain the control which a personal licence offers but to propose significant simplification of the content. Current personal licences contain detailed lists of permitted techniques and consequently often require regular amendment. However, these lists are no guarantee of competence. By placing the responsibility for ensuring competence squarely on establishments (through the newly created role of named individuals responsible for training, supervision and competence), we have created a system which is less

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bureaucratic, more effective at a local level, and can be monitored by inspectors.

A second example is the protection for embryonic mammals, birds and reptiles which will in future be limited to the last third of gestation since there is no evidence of sensitivity prior to that point.

Many other standards will be strengthened. The ban on the use of great apes will continue. Likewise, the current upper limit on permissible severity will remain. However prohibition of both will now be part of the Act and it will not be possible to use any of the safeguard clauses in the Directive without the specific agreement of Parliament.

Special protection for cats, dogs, horses and primates will continue to be a feature of our new legislation. This will mean that any projects using these species will have to be especially justified and will be subject to retrospective assessment towards the end of the project. No use of stray cats and dogs will be permitted and this will now be prohibited by the Act. By contrast, the use of feral domestic animals may be permitted but only under very strict controls and largely for their benefit.

Many questions have been asked about the role of the Inspectorate under the new Act. The Directive introduces inspection in all Member States but at a lower minimum than we practise in the UK. We intend to continue our current approach to inspection, based on risk, and are committed to maintaining a well-resourced and professional inspectorate.

Likewise, concern has been expressed about the role and membership of the Animal Welfare Body under the Directive. We envisage this role being similar to that currently fulfilled by our Ethical Review Processes and we will retain Guidance to this effect.

The Code of Practice for housing and care of animals will retain all the current UK higher standards but it will be written in a way which clarifies those requirements which are mandatory.

Finally, we will not permit the use of neuromuscular blocking (paralysing) agents without appropriate anaesthesia and analgesia and then only by specially trained individuals.

WHAT WILL CHANGE LATER?

A few features of the new regulations can be implemented later. For example, a key aim of the Directive is to increase transparency about work which is performed under licences. Our current approach is compliant since we currently ask for lay abstracts of each authorised project. We currently have no powers to enforce this whereas, under the new Act, we will be able to require detailed non-technical summaries for all projects. We will publish these.

Nevertheless we are committed to reviewing Section 24 of ASPA (the so-called 'confidentiality clause') and to considering an extended range of penalties which can be applied. Under RESA (the Regulatory Enforcement & Sanctions Act) we may have additional sanctions available to us such as monetary fines for infringements.

Both these topics will require detailed consultation involving all stakeholders to ensure we take the right steps. We plan to do this once the current pressure for new legislation is relieved, commencing during 2013.

In addition, we are aware that documents such as a new Guidance to the Act and Code of Practice can be readily updated, using modern technology, in the light of experience and new knowledge. We therefore aim to create both these as 'living documents', accessible electronically and subject to regular review.

WHAT STILL NEEDS TO BE DONE?

In May 2012, we published the government's response to the 2011 public consultation on implementing the Directive. This outlined our proposed approach and the draft regulations, which aim to implement this approach, were published in July. We have now completed the Regulatory Impact Assessment and, also in July, it received a 'green flag' from the Regulatory Policy Committee. We will publish that assessment shortly.

Meanwhile, we are completing the draft regulations and gaining approval from the Home Affairs Committee, the Reducing Regulation Committee and the Joint Committee on Statutory Instruments. At the same time, we are drafting Guidance to the Act and will be sharing this with stakeholders shortly to seek their views.

We published a draft Code of Practice late last year and, based on the feedback, we are currently completing a final draft. We are also drawing up a working protocol for the new National Committee, based on advice from stakeholder discussions and from the Animal Procedures Committee, and we plan to appoint a Chair by the end of this year as well as some members shortly thereafter.

No debates can take place during the summer recess but these will occur soon after both Houses have returned in mid-October. Meanwhile we are working through a range of transitional arrangements to ensure that, by January 2013, existing authorities are either deemed to continue or have been amended.

Finally we are conscious of the need to communicate frequently and effectively with all our key stakeholders who will be directly affected by the new regulations. In addition to the many consultations outlined above, and our regular meetings with all our stakeholder groups, we have triggered a series of special newsletters to those holding certificates of designation to ensure that they and their colleagues are fully prepared for the changes ahead.

This is a very busy time but I am confident that, in January 2013, we will all be ready for the transition to our amended Animals (Scientific Procedures) Act. Furthermore, in answer to the question in my title, I am equally confident that the EU Directive, as it is being implemented in UK legislation, will not lead to any reduction in welfare standards. Indeed, we have successfully found ways to minimise much of the bureaucracy of our current system of authorisation while retaining our high standards of welfare.

I am grateful to all our stakeholders, as well as my colleagues in ASRU, for guiding this balance. It is through achieving this balance that we are able to reassure the public and to retain their confidence.

TRANSPOSITION OF THE EU DIRECTIVE: Backwards, Forwards or the Status Quo?

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The RSPCA has been closely involved with the revision of the Directive and currently participates in the European Commission's expert working groups drawing up guidance for some member states on some of the more complex issues. If implemented properly, the Directive should make a positive difference for animal welfare in many member states. However, it is weaker than the UK Animals (Scientific Procedures) Act 1986 (ASPA) in places, so simple 'copying out' could reduce UK standards in a number of areas. This would be to the detriment of animal welfare, public confidence and ultimately the UK science base.

Many of the RSPCA's concerns about reducing UK standards were shared by colleagues in the scientific community. The Home Office has responded positively and we are pleased that the ASPA now appears to be retaining much of what it currently has – although we have yet to see what the final texts of the revised legislation, Codes of Practice and Guidance actually say.

We do still have concerns over specific issues such as primate use, licence amendments, increased severity levels, potential use of neuromuscular blocking agents (that paralyse animals but have no anaesthetic or analgesic effect) without anaesthesia, re-use, and the use of animals for training. However, for this paper, I will focus on areas where there is an opportunity to use the transposition process to improve on what we have.

RETROSPECTIVE ASSESSMENT OF ACTUAL SUFFERING

The Directive requires the full lifetime experience of the animal to be taken into account when predicting harms, and classifies levels of suffering into mild, moderate and severe. It also introduces a new concept – a requirement to assess and report the actual harms suffered by animals rather than the predicted harms, as is currently the case. This should encourage closer focus on individual animals' experiences and provide a driver for better recognition, assessment and hence alleviation of suffering. It will supply information to prioritise procedures for refinement, and, if done honestly, will present a much clearer picture to the public of the levels of suffering that animals experience.

EDUCATION, TRAINING AND COMPETENCE

The need for achieving, demonstrating and maintaining competence is a key requirement in the Directive and will mean additional responsibility for implementation at the local establishment level. If taken seriously, it could mean major improvements to both animal welfare and science. Although UK legislation already requires staff to be 'competent' in the procedures they undertake, there are problems in some establishments, where some scientific staff seem not to understand or accept the need to spend time gaining an appropriate level of training for the sake of their science, let alone for animal welfare.

. . . the Directive should make a positive difference. . .

The Commission wants consistent standards of training and competence across the EU. This requires definition of training objectives, learning outcomes, competence criteria, criteria for reassessment, record keeping and roles and responsibilities – a significant task, on which an EU expert working group is working, with relevant UK organisations playing leading roles.

The functions of the AWB roughly map on to the ERP, but the key issue is whether it should consider project licences before submission to the Home Office. Some have lobbied hard to have this function removed, considering it an unnecessary duplication and extra bureaucratic step in the licensing process. However, most people find the ERP extremely helpful, provided the establishment understands that the review is intended to be from a local perspective; knows what it should be trying to achieve; and sets up a well designed and efficient process that will add value. Most establishments therefore want to keep their ERPs because of the benefits, shared responsibilities and greater public accountability they bring. This will be even more important in the future, given the greater responsibility relevant to existing ERP functions that is likely to be expected at an establishment level.

. . . full lifetime experience of the animal . . .

MAINTAINING EFFECTIVE LOCAL ERPS

Probably the RSPCA's biggest concern throughout the transposition process was that the UK would lose the local Ethical Review Process (ERP) in its current form. ERPs were set up in 1998 as a local framework "…to ensure that at a local level all use of animals is carefully considered and justified; that proper account is taken of all possibilities for the 3Rs and that high standards of accommodation and care are achieved". ERPs deal with ethics, welfare, 3Rs and public accountability, provide advice and support to staff, and have an educational and awareness-raising role. They are highly valued, and when set up well, have a very positive impact at establishment level. There are similar processes in many countries in Europe and we had hoped that some form of ethics committee would be formalised in the Directive. Unfortunately, the concept of 'ethics' was lost and replaced with an Animal Welfare Body (AWB), with a reduced remit and membership, lacking the range of expertise and perspectives that enables the ERP to make its positive contribution.

. . . better define their objectives . . .

It is therefore most welcome that the government plans to "align legislation and guidance as closely as the Directive allows to current arrangements for the ERP including its membership, functions and title", although at this stage we do not know what the final text of the legislation and Guidance will say. Looking to the future, it is important that the project review function remains, with the emphasis on local issues. ERPs could better define their objectives and outcomes, and how these are monitored, and develop more challenging and constructive discussion of projects. We would like to see establishments give more thought as to how they select and train their members and to be more adventurous in selecting lay participants. ERPs would also benefit from greater focus on issues other than just project review, eg reducing severity, aseptic surgery, environmental enrichment and 3Rs activities. They will need to grapple with the reality of retrospective assessment of suffering and will also need to accommodate a completely new requirement stemming from the Directive – to communicate with the new National Committee.

. . . additional responsibility for implementation . . .

THE NATIONAL COMMITTEE

The National Committee (NC) will replace the Animals Procedures Committee (APC). The APC provides independent, strategic advice to the Secretary of State and in doing so must have regard to the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use. Its advice covers: codes of practice, specific project licence applications, infringements, development of alternatives, enhancement of welfare and contentious issues or reports. It also has, or should have, a function in public accountability.

The role of the NC is to advise the Competent Authority and AWBs on acquisition, breeding, accommodation, care, and use of animals, which could be interpreted as similar to the APC, although it must also 'ensure sharing of best practice' which is new. It must also exchange information on operation of AWBs and project evaluation, and share best practice within the EU. The ASPA defines the APC membership, requiring at least 12 members (including those with appropriate biological qualifications, eg medics and vets, with at least one barrister/solicitor/advocate) plus the chair, but the Directive does not go into this detail, nor does it require the interests of animal welfare to be "adequately represented" as in the APC.

The APC runs on a shoestring and the Government has said it: "…assume[s] no additional resource…" for the NC. This is a pity because now is the time for a serious review of what a body like this should deliver, but progress will be stifled with insufficient resource. There are several challenges including: doing something useful that adds value in a reasonable time frame; achieving a balanced committee of people who are prepared to contribute time and energy; opening avenues of communication that do not exist (with ERPs, EU National Committees) to share best practice; deciding how to make judgements on what 'best

. . . The Commission wants consistent standards . . .

. . . information to prioritise procedures . . .

practice' is; and developing an informative and interactive public face. A well thought out 'protocol' of what it will do, and how, would be helpful.

HOME OFFICE INSPECTORATE

My last point is aside from the Directive. We are fortunate in the UK to have the Home Office Inspectorate and there is a broad consensus that it is fundamental to achieving an effective regulatory system that works. Inspectors are widely respected and play an invaluable role in reviewing licences, assessing compliance, providing expertise and advice and implementing many of the improvements for animal welfare that we want to see – not just in the UK, as their influence extends to the EU and other regions. Notwithstanding the current financial constraints, it is imperative that the UK maintains an authoritative, challenging and well resourced Inspectorate.

. . . some form of ethics committee . . .

To conclude, the UK has a good piece of legislation in the ASPA, with a history of world leadership in laboratory animal science and welfare and in establishing better standards in this field. This is a point often made by stakeholders in science, industry and government. Nevertheless, throughout the transposition process, we have seen some of those same stakeholders lobby powerfully to reduce UK legislation, ostensibly to promote a 'level playing field' within Europe. It is very hard to understand why one might want to compromise UK standards, especially since it is recognised that better animal welfare means better science and that high standards make good economic as well as scientific sense. The playing fields in Europe are never going to be level. We should look to enhance our leadership role, not reduce standards to the lowest common denominator.

ANIMAL EXPERIMENTATION: Are EU Regulations Adequate?

Dr Stephen Mitchell
Eli Lilly and Company

The EU Directive on animal experimentation, care and welfare is a very positive development as it standardises practice across many countries with wide variations in approaches and ethics. That much of the legislation is derived from the Animal (Scientific Procedures) Act 1986 speaks highly of the work done by the Home Office Inspectorate since its implementation and this will continue to have a positive impact on public confidence.

Ethically, the EU Directive is aligned with the major cornerstone of the UK's requirements and code of practice as it promotes the development, validation and implementation of alternative approaches to animal testing in line with the 3R's – Replacement, Reduction and Refinement. These include methods that avoid or replace the use of animals (eg computer modelling, in vitro methodologies), methods which minimise animal use (improved experimental design, imaging techniques, sharing data and resources), as well as improvements to scientific procedures and husbandry which minimise actual or potential pain, suffering and distress or lasting harm and/or improve animal welfare (eg using non-invasive techniques, appropriate analgesia and anaesthetic regimes for pain relief, appropriate accommodation, environmental enrichment).

. . . minimise actual or potential pain . . .

It is a requirement in the UK for those performing regulated procedures to hold an appropriate Personal Licence (PIL). The PIL essentially ensures that the holder has the necessary background and education to perform animal experimentation, and lists the

. . . speaks highly of the work done by the Home Office . . .

techniques that are to be used on a relevant Project Licence. Under the EU Directive the PIL will be replaced by one that documents a "demonstration of requisite competence". Although this is not currently a requirement per se, it is normal practice for an individual's competency to perform procedures or techniques to be monitored as part of their continuous training and development. However, the EU Directive makes it a requirement for this process to be formalised. Staff must be supervised until they become competent. All training will have to be documented, signed off and archived, and with a requirement for maintaining or checking the level of competency over time, especially if procedures are used infrequently (as yet undefined). In order to co-ordinate and monitor this process a designated Training Compliance Officer (or similar) with overall responsibility for maintaining such a record will need to be appointed. This new process makes sense ethically and scientifically, and formalises current practices. One additional benefit could be that the training records become transferrable across the EU – with the caveat that there will be a period of time to enable competency to be checked. The process should be less bureaucratic, as PIL's currently need to be sent back to the Home Office for amendment, or in order to change the designated establishment.

. . . a "demonstration of requisite competence" . . .

Under the EU Directive, Designated Establishments are required to set up an Animal Welfare Body (AWB). This is to be comprised of a minimum of only two people – a person responsible for care and welfare of animals and a designated vet, or appropriate expert. Their role is to provide advice on animal welfare, the 3R's, to establish and review internal processes and monitor projects. In the UK, current legislation requires that Designated Establishments have an ethical review process (ERP) with the operational requirements more involved and extensive than those for an AWB. For instance, local ERPs involve more people – including a lay person – and operationally, have more than just an advisory role – in particular there is a requirement from the Home Office that any project licence application or amendment has ERP approval prior to submission for authorisation. It is generally agreed that in establishing an AWB, those functions of the ERP which are beneficial and add value will be retained.

. . . functions of the ERP which are beneficial and add value will be retained. . .

The EU Directive also sets out requirements for the care and accommodation of animals kept in establishments. These differ in a number of respects to current requirements in the UK – but are generally higher, particularly with respect to living space. This may have cost and space implications where large numbers of animals – particularly rats – are bred/supplied or used, as the requirement for larger cages will reduce holding capacity. However, there are some differences in cage dimensions that may be detrimental, as the stipulated cage height is lower than current UK standards (for rats >250g), which may inhibit natural rearing behaviour.

There will be a requirement under the EU Directive for the retrospective assessment of projects involving non human primates (NHPs), using procedures that are categorised as "severe", and with the option to assess some classified as "moderate". This process is not currently a UK requirement, although it does occur for applications for the renewal of a project licence and as part of the ERP. It is also a requirement in the UK to collect and publish annual statistics on the use of animals in regulated procedures. Under the new Directive annual returns will now have to indicate the severity limit as well as the origin and species of NHPs used.

. . . This new process makes sense ethically and scientifically . . .

Currently, Designated Establishments can be visited by a Home Office Inspector at any time. The frequency of visits has in the past allowed the Inspector to establish a working relationship with care staff and licence holders alike so that advice on best practice, promotion of the 3Rs and reinforcement of compliance is maintained. However, this extremely useful relationship may have to change in the light of the EU Directive. Site visits will be based on a risk assessment and will be more formal – by appointment and run more like an audit, which could last several days. It seems unlikely that Inspectors will have the time to schedule separate consultation, training or advice sessions if the Inspectorate is not properly resourced. In my view, the benefits of the Animal (Scientific Procedures) Act 1986 have been almost entirely brought about by the direct contact between scientists and Inspectors with the latter's promotion of the 3Rs and good experimental design and analysis approaches. This needs to be maintained.

In summary, the EU Directive overall is a positive development – it strengthens the measures required to protect animals used in scientific procedures, and it promotes the development, validation and implementation of means to replace, reduce and refine animal use. It attempts to create a level playing field across the EU with respect to experimental control and animal welfare, and may be less bureaucratic. However, here in the UK we should be careful not to devalue the role of the Home Office Inspectorate and allow them the resource to maintain and cultivate close working relationships with the scientists involved.

. . . cultivate close working relationships with the scientists . . .