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Sara Nathan
Chair of the Animal Procedures Committee
C/o APC Secretariat
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15 DEC 200

Dear Sara

**ADVICE ON THE OPERATION OF THE ANIMALS (SCIENTIFIC PROCEDURES)
ACT 1986**

The Home Office Simplification Plan, published on 11 December, commits the Department to a range of better regulation activities, some of which relate to the operation of the 1986 Act.

I would like the Committee to be involved in this, and I would particularly welcome your advice on issues where the Committee has informed current policy and practice; is already working on related issues; and where the advice of a broadly-based Committee properly balancing the legitimate needs of science and industry against animal welfare considerations should inform some of the decisions that will have to be taken.

At this stage I would like the Committee to consider and advise on three issues.

1. Personal licences and mandatory training.

Several stakeholders have made representations that the current personal licence (both the form of application, and the resulting licence authorities) might be simplified to grant broad general authorities in line with the training that has been successfully completed.

I would welcome, by April 2007, your initial thoughts on such proposals and, if you believe they have merit, whether the system should be changed now, or when the training courses are adjusted in line with the Committee's previous advice that training should be based on learning outcomes.

2. The criteria for the discharge of genetically altered animals from the controls of the 1986 Act

The Department regulates the production and use of genetically altered animals when such animals may, by virtue of being genetically altered, be predisposed to

pain, suffering, distress or lasting harm. Our current discharge criteria are, therefore, intended to make proper provision for genetically altered, protected animals produced and used for experimental and other scientific purposes. Since the current criteria were established, and considered when the Committee prepared its Biotechnology Report, progress has been made both with the means by which such animals are produced, and how animal welfare can be evaluated.

It is now timely to consider whether, without risking or compromising animal welfare – or damaging public confidence, the current discharge criteria should be revised. In order that this issue can progressed at an appropriate point in the delivery of the Home Office Simplification Plan, your advice should be available by October 2007.

3. Ethical Review Processes

There is general agreement that local ethical review processes play an important part in making proper local provision for animal welfare and good science. However, there is concern in some quarters that some local processes are particularly resource intensive, and in some cases that local processes may be unintentionally adding to the administrative burdens and might be an obstacle to realising the full potential benefits of some of the current better regulation initiatives.

I would be grateful if the Committee would consider, within the currently prescribed framework for local ethical review processes, whether there is evidence that some local processes may be wasting resources or, other than by design, imposing local requirements that run counter to efficient and effective regulation. I would welcome your advice, ideally in the form a guideline on good local ethical review process practices, by January 2008.

I have asked officials to prepare and provide you with the background documents, and more detailed guidance and instructions, on these three issues. As the delivery of the Simplification Plan progresses, I expect to commission further advice from the Committee as and when required.

In addition, I would ask the Committee to be mindful of the need not to increase the regulatory burden when it formulates its advice on other issues. Any proposal which would have the effect of increasing the regulatory burden is unlikely to be accepted.

Yours sincerely

A handwritten signature in black ink, appearing to be 'Joan Ryan', written in a cursive style.

JOAN RYAN



Animals Scientific Procedures Division
2 Marsham Street, Seacole Building Room 1.39, 1st Floor SW Quarter, London, SW1P 4DF

Sara Nathan,
Chairman
Animal Procedures Committee

Our Ref 20070111jdrSN
Date 11 January 2007

Dear Sara,

APC ADVICE - BETTER REGULATION

Joan Ryan wrote to you on 15 December commissioning advice from the Animal Procedures Committee on three issues to do with the operation of the Animals (Scientific Procedures) Act 1986 currently being considered within the Home Office's better regulation agenda^{1,2}. She indicated that officials would provide you with more detailed guidance on the advice required, timescales and the relevant background documents. The Minister stressed that it is essential that the delivery of the advice fits in with the timetable for the wider ASPD better regulation programme.

Background

Following recent reviews, including the Cabinet Office review of regulation in the pharmaceutical sector, the Davidson Review and the PWC administrative burdens project, the aim of the ASPD better regulation programme is to simplify current regulatory requirements and administrative processes under the 1986 Act and reduce compliance costs whilst maintaining animal welfare standards. As part of this we will also benchmark current best practice and evaluate specific proposals, including some put forward by stakeholders. We are not considering proposals that would require changes to the legislation, or other Parliamentary time, to deliver.

¹ The Davidson Review

² Home Office Simplification Plan

The project will be overseen and managed within the framework for implementation of the Home Office Simplification Plan, and will actively involve operational level practitioners from both industry and academia; licence holders and named persons; and (to further ensure that the protection of animals is not compromised) those with a special interest in animal welfare.

1. Personal Licences and mandatory training

As Joan Ryan explained in her letter, several stakeholders have made representations that the current personal licensing process (including the form of application, and the resulting licence authorities) might be simplified to grant broader general authorities in line with the modular training that applicants have successfully completed. We believe there may be some scope to do this within the provisions set out at section 4 of the 1986 Act.

The Committee previously considered this as part of its ten-year review of the 1986 Act³, and advised that:

- (i) personal licences should specify one of two levels of procedure (basic or advanced) which correspond to the required training modules (basic equating to modules 1-3 and advanced to modules 1-4)⁴;
- (ii) in some limited cases, animals should be specified by group (e.g. rodents) rather than by individual species;
- (iii) sponsors should be required to make more focused declarations about applicants' training and, possibly, eligibility; and
- (iv) conditions should be added to both personal and project licences to strengthen the arrangements for the supervision of licensees.

More recently, we have accepted the Committee's advice that modular training should be revised to incorporate a learning outcomes approach and, although the Committee may wish to reflect further on whether changes to the licensing system impact on training needs, feel that the time is now right to consider adjusting the personal licence system to reflect the impact of mandatory training.

As a result we are taking legal advice on what is permissible under the terms of section 4 of the 1986 Act with a view to standardising some generic lists of licence authorities at different levels of competence taking into account current training provision, and detailing consequential changes to licence conditions. The detailed work in this area will be taken forward by the Inspectorate working with a variety of stakeholders.

³ Chapter 7, Appendix F, APC Annual Report 1997

⁴ To help in this work a draft list of techniques which would fall into the basic and advanced categories will be produced shortly by the Inspectorate.

This matter is being raised with the Committee now for two reasons.

- First, to allow to Committee to reflect on whether it wishes to update its previous advice on the personal licence system.
- Second, in order that the Committee can take account of the possible changes to the licensing system when giving further thought to future training requirements.

2. The criteria for the discharge of genetically modified animals from the controls of the 1986 Act

The 1986 Act makes provision for the protection of animals used for experimental and other scientific purposes and subjected to regulated procedures which may cause pain, suffering distress or lasting harm. We take the view that genetically modified animals should be assumed to be potentially more prone to pain, suffering, distress or lasting harm (“harm”), as a result of the genetic alteration, than the background strain from which they are derived. As a result we regulate their production, breeding and use⁵.

Nevertheless, we have always accepted that there will be some lines of genetically modified animals that are not predisposed to these harms, and have made administrative provision for the discharge of such lines of protected animals (at least for breeding purposes) from project licences. To date no such lines have been discharged from the controls of the Act and some stakeholders have commented recently that the burden of proof required to release a strain from the controls of the Act seems to be set so high as to prevent anyone from trying.

In the circumstances, the Minister would welcome the Committee’s advice on whether the current discharge criteria should be revised in the light of the current state of knowledge on welfare assessments and phenotyping methods, in order to remove any unnecessary obstacles currently preventing strains being discharged from the controls of the Act without weakening the provisions for the welfare of protected animals.

3. Local ethical review processes

There is general agreement that the current framework for local ethical review processes helps to safeguard animal welfare and scientific validity. However, concern has been expressed in some quarters that some local processes are more resource intensive than they need to be and impose formal structures where more informal mechanisms would be more efficient and effective. Whilst we have always been clear that that there are some parts of an effective local

⁵ See “Guidance on Genetically Altered Animals and the Animals (Scientific Procedures) Act 1986”

ethical review process that are best delivered other than through formal committee structures (for example seeking and taking account of advice from named persons), in practice many places have instituted more formal and resource intensive solutions.

There is also evidence that some local ethical review processes, particularly with respect to project licences, duplicate activities that are already undertaken to better effect by others. Animal research is typically subjected to scrutiny at several levels before proposals for licence applications are finalised, licensing decisions taken and work commences, and each scrutiny is liable to cause delay. It was never the intention that local ethical review processes should duplicate or usurp the review undertaken by funding bodies, or the inspectorate – but in some places this seems to be happening.

Although we have no plans to formally revise the current terms of reference for local ethical review processes in advance of changes to the European Directive, we believe that there is scope for ensuring that the current system operates more efficiently in some places.

As part of the better regulation agenda we would like to ensure that places are made aware of contemporary good practice with a view to ensuring that their local processes are both efficient and effective. To that end, the Minister would welcome the Committee's considered view on how local ethical review processes can best add value without duplicating the scrutiny and consideration undertaken by others – and on where it perceives the boundaries to be between the input of the funders, local ERPs and others.

She would also welcome the Committee's advice on what elements of the local ethical review processes might best be delivered other than through committee structures.

The Inspectorate are currently undertaking a survey of the time and resources devoted to different ERP functions, and the local processes involved. You may wish to defer advancing too far on these issues before this is completed in April.

Timing

- To fit into the delivery of the Home Office Simplification Plan, it is essential that advice on item 1 (personal licences, etc) is provided by April 2007.
- Advice on item 2 (discharge of genetically modified animals) is required by October 2007.
- Advice on item 3 (local ethical review processes) is required by January 2008 – both to fit within the better regulation programme, and also to

contribute to thinking on how any proposed European initiatives on the same issue should be developed.

- Finally, advice on the other issues requested in the response to the Committee's education and training report should continue to be delivered by June 2007, as previously requested.

Useful links and background papers

I attach copies of the following documents which the Committee may find helpful:

- Chapter 7, Appendix F, APC Annual Report 1997
- Guidance on Genetically Altered Animals and the Animals (Scientific Procedures) Act 1986.

I will also provide you with a draft list of techniques which would fall into the basic and advanced categories of personal licence as soon as it is available.

The text of the Davidson Review and the Home Office Simplification Plan and Home Office Administrative Burdens of Regulation Report can be found at:

- http://www.cabinetoffice.gov.uk/REGULATION/reviewing_regulation/davidson_review/
- <http://www.homeoffice.gov.uk/documents/ho-simplification-plan/>.

Yours sincerely

Jon Richmond
ASPD
Head of Division

APC 10 Year Review of ASPA

CHAPTER 7

REVISION OF THE PERSONAL LICENCE SYSTEM

INTRODUCTION

1. Concern was expressed in the material submitted to the review about the level of bureaucracy that the Animals (Scientific Procedures) Act 1986 has introduced. One aspect of this was the personal licence system.
2. The Committee agreed that the present personal licensing system was unsatisfactory for a number of reasons including:
 - (i) it did not formally place sufficient responsibility on the project licence holder for the competence and conduct of those working under the authority of the project licence;
 - (ii) it did not take account of the mandatory training programme introduced in 1994;
 - (iii) it resulted in a number of technical infringements of the Act which had no animal welfare implications; and
 - (iv) it took up a disproportionate amount of Inspectorate and administrative effort in the Home Office when much of the control over animal procedures was exercised through the project licence.
3. We asked the Home Office to propose an alternative system. This chapter outlines, and gives a preliminary evaluation of, the proposed system. Further consideration and wider consultation will be necessary before we can offer our final advice on the proposals.

BACKGROUND

4. Under Section 3 of the Act, regulated procedures on living animals may not be performed on the authority of a project licence alone. Those carrying out regulated procedures must also hold a personal licence.
5. Section 4 of the Act requires that personal licence applications be endorsed by a suitably qualified personal licence holder who has knowledge of the applicant's qualifications, training, experience and character. The sponsor shall, if practicable, occupy a position of authority in the designated establishment where the individual proposes to work. A personal licence remains in force until revoked, but is reviewed by the Secretary of State at least every five years.

6. Applications are currently made on the attached form (Annex 1) which becomes a schedule to the licence itself.

7. Sections 6 to 9 of that form address the suitability of the applicant to carry out regulated procedures: specifically, the applicant's qualifications and experience. Section 21 provides for a character reference from the sponsor. It is impossible for the inspector assessing the application to confirm practical competence ahead of the licence being granted. Indeed, given the number of personal licence holders, it is unlikely that, after a licence has been granted, the Inspectorate will see sufficient work for any one individual to be able to assess that person's competence.

8. A requirement came into effect in April 1994 for personal licence applicants to have satisfactorily undertaken mandatory training courses. This bears directly on the competence of applicants but, at the same time, constrains the inspector's discretion; there can now be few grounds for querying the eligibility of a person who has successfully completed modules appropriate to their application, and whose qualifications, training, experience and character are endorsed by a suitable sponsor.

9. At the time of application, the inspector can only confirm that a person is qualified to undertake a procedure, has taken appropriate training, is sponsored by a suitable licence holder, and will be properly supervised. It is unreasonable to expect competence to exist without experience (which logically, can only follow the granting of licence authority to use a particular technique with a specified species).

10. The formal training requirements cannot guarantee prior competence. Nor can they overcome the disadvantages of experienced licensees ceasing to work with animals for periods of time or focusing their practice within a narrow band of particular techniques. Training remains the explicit responsibility of the designated establishment and supervision the responsibility of the project licence holder.

11. Currently, a record of techniques performed under supervision must be kept by personal licence holders (see paragraph 4.4 of Appendix V to the Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986) but there is no formal means of recording the achievement or maintenance of competence of a personal licensee to apply a technique to a particular species.

12. Section 15 of the personal licence application details and limits the techniques that the licensee will be allowed to perform and, in each case, the types of animal that can be used. Licensees are strongly encouraged to retain only those authorities that they are currently using. These, taken together, result in regular and repeated requests for minor amendments to the list of techniques or the types of animal.

13. It is important to stress that control over the severity of procedures applied to animals lies in the **project** licence and not in the **personal** licence. The personal licence holder has (and will continue to have) responsibilities for the welfare of animals undergoing regulated procedures, but their welfare is also addressed directly through the terms and

conditions of the project licence and through the statutory roles of the persons named in the certificate of designation for the establishment.

PROPOSED CHANGES

14. The following modifications to the personal licence system have been proposed by the Home Office:

- (i) licences will specify one of two levels of procedure (basic or advanced) which correspond to the required training modules (basic equates to modules 1-3 and advanced to modules 1-4) - an illustrative list of techniques which would fall into the basic category will be produced;
- (ii) in some limited cases, animals will be specified by group (e.g. rodents) rather than by individual species;
- (iii) sponsors will be required to make more focused declarations about applicants' training and, possibly, eligibility; and
- (iv) conditions will be added to both personal and project licences to strengthen the arrangements for the supervision of licensees.

15. Revised standard licence conditions will require assessments of competence to be noted in the personal licensee's records by the nominated supervisor. Inspectors will then be able to determine whether procedures have been authorised and whether licence conditions are being fully met.

EVALUATION OF THE PROPOSAL

16. Our first concern in evaluating these proposals was whether they might adversely affect animal welfare. We do not believe that they will. Implementing the proposals would allow Inspectorate resources to be re-deployed to deal more effectively with areas where their scientific expertise and professional judgement can best be used: the assessment of project licence applications and inspection. Their work will be directed, therefore, less at unnecessary bureaucracy and more towards the support of animal welfare and the implementation of the letter and spirit of the Act.

17. Modifying the personal licence system as proposed will achieve three ends. It will:

- (i) acknowledge that responsibility for ensuring supervision of technical competence lies with the project licence holder, and not with the named persons or the inspector who advises on a licence application;
- (ii) recognise the contribution and reinforce the importance of the accredited training programme; and

(iii) remove the mismatches which currently occur between the excessive detail in the personal licence and the technical requirement of the project licence by linking the personal licence authority with the wider grouping of techniques and species in the training modules.

18. There should also be a decrease in the number of technical infringements of licence conditions - essentially minor infringements caused by the present level of detail within licences and which do not cause any additional suffering or adversely affect the study being carried out.

19. We believe that the proposed changes to the personal licence will continue to meet the requirements of Section 4 of the Act.

20. No changes to the project licence or certificate of designation are proposed in this chapter. The personal licence will remain an integral part of the wider and comprehensive licensing framework.

21. No additional burden on the licence applicant, sponsor or supervisor is foreseen. This may not appear consistent with paragraph 17(i) above. We contend, however, that project licence holders should already be performing this function; the new arrangements reinforce this.

22. We will be asking our Education and Training Sub-Committee to consider whether, under the new system, the need for some form of periodic retraining should be explored with the accrediting bodies.

23. The main disadvantage lies in the perception of greater latitude in the application of the Act enabling the licensee to perform a broad range of procedures on several species. However this will always be balanced by the specification of authorities in the project licence and the supervisory role of the project licence holder. We must also be satisfied that certificate holders, assisted by their named persons, are not disadvantaged in meeting their obligation to take all reasonable steps to prevent the performance of unauthorised procedures.

24. We are concerned that these proposals might disadvantage those who have set up computerised or other systems to monitor licence authorities and to ensure that unauthorised procedures are not carried out. We welcome, therefore, the Home Office proposal to consult more widely on these proposals before deciding whether to implement them. We look forward to being able to comment further in the light of any responses received.

CONCLUSIONS

25. Whilst the proposed system does offer some advantages over the present system, particularly in terms of reducing unnecessary bureaucracy, the Committee does still have concerns about how it might operate in practice. We believe, however, that it is worth

exploring further through a wider consultation process which, we understand, the Home Office will carry out following the publication of this report. We look forward to seeing the results in the New Year and will offer further advice thereafter.

Guidance on Genetically Altered Animals and the Animals (Scientific Procedures) Act 1986

Introduction

Definition - For the purposes of this guidance, a *genetically altered animal* is defined as:- an animal in which the heritable DNA has been intentionally altered, or which carries a genetic mutation recognised as harmful, or the progeny of such an animal.

This definition includes

- animals produced by genetic modification [as defined in the Genetically Modified Organisms (Contained Use) Regulations 2000]
- animals produced by induced mutagenesis
- animals created by nuclear transfer procedures
- animals created by the use of certain selective breeding strategies
- harmful mutant lines arising from spontaneous mutations.

It excludes animals with changes that are not heritable, such as gene therapy or DNA immunisations.

This document describes the principles of how the Animals (Scientific Procedures) Act 1986 [ASPA] is applied to the generation, breeding, maintenance and use of genetically altered animals. It applies only in the context of scientific or other experimental procedures.

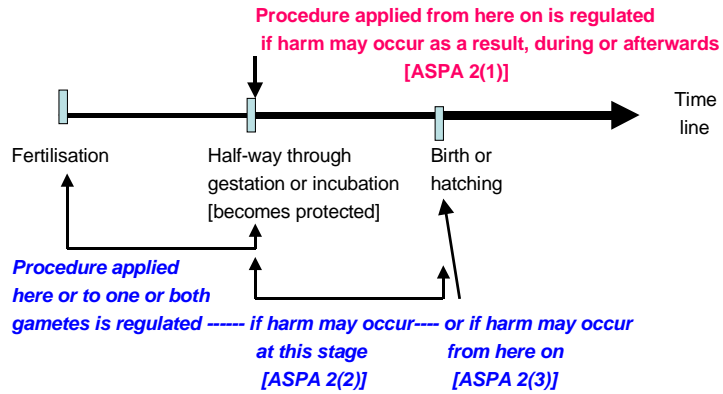
Genetically altered animals and ASPA

Policy statement - The presumption is that any genetic alteration “may have the effect of causing pain, suffering, distress or lasting harm” (see note 2) in the individual or its offspring. Therefore the production for a scientific purpose of genetic alterations which are intended to be present in protected animals (see note 1) will be considered to be regulated procedures unless and until it can be shown that no harm can be expected as a consequence of the alteration.

In defining regulated procedures ASPA takes account of when the procedure is initiated (see note 3) and when “protected animal” status (see note 1) is reached as indicated in these diagrams:

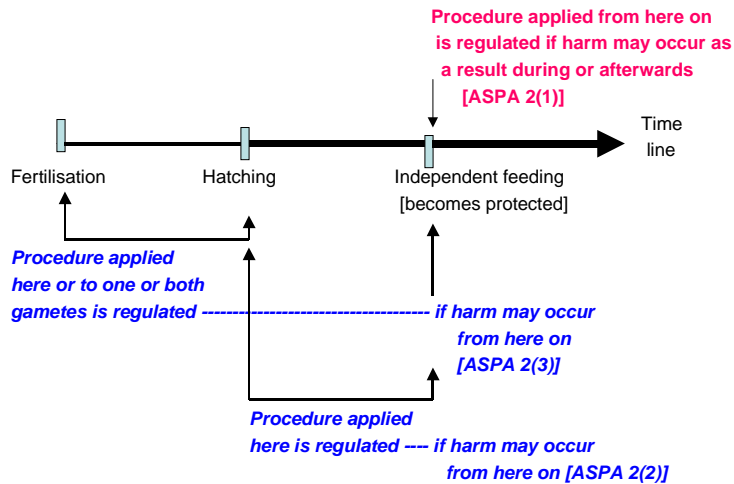
Regulated procedures under ASPA:

Fig.1 Mammals, birds and reptiles



Regulated procedures under ASPA:

Fig. 2 Amphibia and fish (and *Octopus vulgaris*)



The diagrams differ because the stage of development at which mammals, birds and reptiles become "protected animals" differs from that at which amphibia, fish and *Octopus vulgaris* do (see note 1). "Harm" encompasses pain, suffering, distress and lasting harm, and "procedure" means "procedure applied for a scientific purpose".

These definitions mean that, for genetically altered animals, the fusion of altered gametes (*in vitro* after manipulation, or through natural or assisted mating) and/or any zygote or early embryonic manipulations which alter the genetic makeup are regulated procedures if the individual will develop to the stage when it becomes a protected animal. This will apply even if only one gamete is altered and even if the individual is heterozygous for the genetic alteration.

Project and personal licence authorities are therefore needed for the generation of new genetically altered animals, and for the maintenance and breeding of such animals, irrespective of whether they are homo- or heterozygous with respect to the genetic change. A line of genetically altered animals can only be bred without licence authorities if it has been deemed by the Home Office not to be harmful and has been specifically discharged from ASPA controls.

When an intervention or omission is a regulated procedure, that regulated procedure is considered as continuing until the end of the effect of the intervention or omission. In the case of genetically altered animals, that is for the life of the animal.

Mutants arising during normal breeding

A genetic alteration may arise as part of a normal breeding programme. If this results, or may result, in adverse effects which would merit regulation under ASPA, and the animal is to be kept alive for a scientific purpose, the exposure to risk of harm (by not humanely killing the animal) is a regulated procedure under ASPA section 2 (1). Such animals are termed "harmful mutants" (nude and SCID mice are examples) and any production of offspring from them is a regulated procedure. If there is doubt, the Home Office should be asked to decide whether keeping alive a particular abnormal animal is a regulated procedure.

Observations and Records

Information project licence holders should record is given in paragraph 5.68 of the Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act (March 2000), and this applies to project work on genetically altered animals (see note 4). In addition, to enable compliance with the requirement for minimal severity (standard condition 6 applied to a project licence – see note 5), and with standard conditions applied to personal licences, it is expected that records of the phenotype, and any adverse effects associated with it, will be recorded for all lines of genetically altered animals. This may also help for keeping adequate health records (as required by condition 7 on the certificate of designation – see note 6). A systematic observation regime should be used

to detect adverse effects. Data on breeding performance should also be collected. The information obtained should be used to set humane endpoints and to guide management of the lines so that expression of adverse effects is minimised.

Fate of genetically altered animals

Genetically altered animals undergoing regulated procedures (i.e. all such animals unless specifically discharged – see below) have to be covered by project licence authorities. At the termination of the project licence they have to be transferred to another project or killed. The project licence to which the animals are transferred must carry authority to use and/or breed animals *of that type or description*. Specific authority for discharge from ASPA is needed from the Secretary of State before any such animal is maintained (or bred) other than under a project licence.

Notes

1. ASPA section 1 defines protected animals. It states that
“(1) "a protected animal" for the purposes of this Act means any living vertebrate other than man and any invertebrate of the species *Octopus vulgaris* from the stage of its development when it becomes capable of independent feeding.

“(2) Any such vertebrate in its foetal, larval or embryonic form is a protected animal only from the stage of its development when-

(a) in the case of a mammal, bird or reptile, half the gestation or incubation period for the relevant species has elapsed; and

(b) in any other case, it becomes capable of independent feeding.”

2. ASPA section 2 (1) defines a regulated procedure as “any experimental or other scientific procedure applied to a protected animal which may have the effect of causing that animal pain, suffering, distress or lasting harm.”

3. ASPA sections 2 (2) and 2(3) extend the definition in section 2 (1) to cover when the procedure is initiated before the animal reaches protected animal status.

ASPA section 2 (2) - “An experimental or other scientific procedure applied to an animal is also a regulated procedure if..” it “...may have the effect mentioned in subsection (1)” [i.e. ASPA section 2 (1)] “and the animal is a protected animal throughout or in the course of it attains the stage of its development when it becomes such an animal.”

ASPA section 2(3) - “Anything done for the purpose of, or liable to result in, the birth or hatching of a protected animal is also a regulated procedure if it may as respects that animal have the effect mentioned in subsection (1)” [i.e. ASPA section 2 (1)].

4. Paragraph 5.68 of the Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act (March 2000) concerns records project licence holders must maintain and states

“The records should include the following information:

the project number, the name of the project licence holder and, where applicable, the names

of the deputy project licence holders;

the names of the personal licensees performing regulated procedures authorised by the project licence;

details of the regulated procedures and protocols applied, including:

the type and species of protected animals used;

a running tally of the numbers of each species used in each protocol;

the sex and approximate age of the animals at the commencement of the protocols;

the identification numbers of the animals used (where appropriate);

the date of commencement of protocols;

a brief description of the procedures applied;

the morbidity or mortality produced;

the date on which protocols were concluded;

the fate of animals at the end of the regulated procedures (for example, killed within the establishment, released to the wild, released to private care, or released for slaughter);

details of any continued use or re-use;

copies of any veterinary (or other) certification and advice received.”

5. Standard condition 6 applied to project licences states “For any procedure, the degree of severity imposed shall be the minimum consistent with the attainment of the objectives of the procedure, and this shall not exceed the severity limit attached to the procedure. The minimum number of animals of the lowest neurophysiological sensitivity shall be used in procedures causing the least pain, suffering, distress or lasting harm.”

6. Standard condition 7 applied to the Certificate of Designation of scientific procedure establishments states “Records shall be maintained, in a format acceptable to the Secretary of State and under the supervision of the Named Veterinary Surgeon, relating to the health of all protected animals kept for experimental or other scientific purposes and accommodated or used in the establishment. These records shall be readily available, on request, for examination by an Inspector.”

June 2003