Animals (Scientific Procedures) Inspectorate
Annual Report 2006

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Introduction

This is the third annual report of the Animals (Scientific Procedures) Inspectorate and covers the period January to December 2006. It includes sections on each aspect of the work of the Inspectorate during 2006, and some chapters focussing on particular issues. Background to the Inspectorate and the nature of its work was provided in the first report, which can be found in full at http://scienceandresearch.homeoffice.gov.uk/animal-research/publications/publications/reports-and-reviews/annual-report. Some knowledge is presumed of the Animals (Scientific Procedures) Act 1986 under which the inspectors are appointed and operate, and any who may be unfamiliar with it will find the text of the Act and Guidance on its operation on the Home Office website (http://www.archive.official-documents.co.uk/document/hoc/321/321.htm). Briefly, this Act regulates scientific work on "protected animals" (a wide range from fish to monkeys)[1] which may cause pain suffering distress or lasting harm ("regulated procedures")[2] by a mandatory licensing and monitoring arrangement. Licences are required for the programmes of work ("projects"), and the persons who do the work, and certificates needed for the establishments ("designated establishments") where it is carried out and where the common laboratory animals are bred or held for supply. Inspectors are required to advise the Secretary of State on applications for these licences and certificates. They must visit the places where the work is done, or animals bred or supplied, to check that the procedures undertaken and the local arrangements accord with what is authorised, and report when they do not[3].

As in previous reports, care has been taken to anonymise examples and preserve confidentiality, conscious that the 1986 Act prohibits the unauthorised disclosure of confidential material. It is also sadly necessary to safeguard places and personnel (including inspectors) against the activities of animal rights extremists. For this reason no names or location details are included in the report and confidential information or anything that might identify places or individuals has been omitted.

On 31 December 2006 there were 28 inspectors, including some working part-time. During 2006 one inspector retired and one moved to another post. We were sorry to lose these experienced staff and miss their particular skills. However the two new inspectors recruited in 2005 joined the Inspectorate and completed their six months' initial training during 2006, so the Inspectorate complement remains steady. Inspectorate strength during the year has been, on average, 24.7 full-time equivalents.

During 2006 the Inspectorate carried out 2381 (mainly unannounced) visits to places where scientific work on animals was conducted, spending in total 6615 hours on site, with a further 5081 hours spent travelling. Inspectors provided advice on 519 project and 2171 personal licence applications, and 3 applications for certificates to designate establishments for scientific work. Inspectors have also advised on numerous amendments to granted licences and certificates.

Inspectors have continued to put considerable effort into advising licensees and potential licensees on how to meet the provisions of the Animals (Scientific Procedures) Act [ASPA] and keep to the conditions on licences. During 2006 they ran further day or half-day events designed to help participants understand these matters and why particular questions were asked about their work - and how these questions could most easily be properly answered when applying for new work or when questioned during visits. Both project licensees and certificate holders have indicated how valuable attendees had found these inspector-led workshops.

A recurring theme in comments from designated establishments has been the appreciation of inspectors' advice on visits and the way in which they interact with staff. Several comments have mentioned that inspectors have helped care staff and licensees to address local concerns, and alerted establishments to urgent issues. Certificate holders have valued the degree of mutual trust and informality in their contact with local inspectors, and the support inspectors provided. The Inspectorate at all levels has been found available, approachable and helpful. Inspectors provided good advice, gave useful guidance on level of information needed and helped people steer through the system. They assisted with flexible wording which would avoid the need for amendments. They

[1] Actually all living vertebrates except man and one invertebrate (Octopus vulgaris) , including some immature forms,
[2] but note that "the administration of an anaesthetic or analgesic" for a scientific purpose is itself a regulated procedure
[3] The Act also provides for penalties if work is not authorised or conditions placed on licences or certificates not met. Licences and certificates can be varied or revoked, and for serious offences fines or imprisonment are options.

could give good scientific input and recognised research needs. The presence of the local inspector at ethical review process meetings was also found helpful.

As with last year's report, this annual report provides some more detailed information on particular topics, as well as giving an account of the year's work. In January 2006, in response to the Report by the Animal Procedures Committee's on the Statistics of Scientific Procedures on Animals, which in recommendation 9 called for enhanced information on various types of work, the minister stated we would consider how the "main benefits of making available additional information under these headings" could be realised. A review of a particular topic in the Inspectorate's Annual Report is one way of doing so. The headings in the Committee's Report included work in the wild and procedures on birds, and this year the focus in the Inspectorate's Report is on regulated procedures undertaken outside of designated establishments, much of which is work in the wild, and the use of poultry for research and testing, which is a major use of birds.

Events and Initiatives in 2006

As well as the main statutory tasks of advice and inspection, inspectors are expected to act in a representational role, in outreach and educational activities, and to encourage good practice in science and animal welfare. A selection of the numerous events and initiatives to which the Inspectorate made significant contributions during the year is given below. For the range of participation by inspectors in meetings and ongoing initiatives see the representation and education sections.

Laboratory Animal Science Association (LASA) Activities
Several inspectors are members of LASA and one inspector is tasked to liaise with the association and acts as observer on LASA Council and its section meetings. In 2006 the Inspectorate made a strong contribution to the LASA Winter Meeting, with one inspector presenting a poster on refinements in primate husbandry, another running a workshop session on taking refinement in animal scientific procedures forward, others helping with a workshop on how different establishment's Ethical Review Processes undertake retrospective project licence review, and several inspectors contributing to the other sessions.

During the year one inspector participated in the LASA Transgenic Section meeting in September, and another acted as observer on the LASA group preparing a document "Guiding Principles on the Supervision Requirements for Personal Licensees" intended to help both personal licensees and supervisors understand the legal and practical issues of supervision and improve practice. The document is due for publication in 2007.

An inspector has continued to act as an observer on the **APC/LASA Suffering and Severity Working Group**, providing a valuable input on technical matters and contributions to the discussions which the group has greatly appreciated.

Laboratory Animal Veterinary Association (LAVA)
LAVA provides a forum for Named Veterinary Surgeons and has an annual weekend which one or more inspectors attend. In 2006 inspectors gave the usual update on Home Office issues and a well-received session on housing and care of fish and how fish were being used in scientific studies, as well as providing technical input to the discussions.

The National Centre for the Replacement, Refinement and Reduction of Animals in Research
The Inspectorate tries to have one or more inspectors at all the varied NC3Rs events open to them and have contributed widely to NC3Rs activities during the year. For example the NC3Rs workgroup looking at experimental design has two inspectors in its membership along with scientists and statisticians, there is considerable input from the Inspectorate to the group examining how to refine food and fluid control in macaque monkeys, an inspector is involved with the NC3Rs/ABPI Collaborative Project on the use of primates in the pharmaceutical industry and two inspectors contribute to the Safety Evaluation Working Group.

NC3RS/BTS/IVTS Meeting The Three Rs: Recent Developments, September 2006
This meeting covered new initiatives in the 3Rs, testing strategies to reduce animal use; and case studies for 3Rs in regulatory studies. As well as contributing to the discussions generally, an inspector gave a presentation on reduction arguing that the key questions were: what results are required; and what is the minimum number of animals required to produce satisfactory results.

BPS/Committee of Heads of Physiology Meeting, Hot topics in Pharmacology and Physiology, March 2006.
In a wide-ranging meeting dealing with translational research (the process of applying ideas, insights and discoveries generated through basic scientific inquiry to the treatment or prevention of disease or injury), the inspectorate presentation described some considerations about animal models and their uses in such research. Whether the results are transferable from animal to man in general turns on reliability (the results are consistent) and validity (the results measure what they are claimed to measure). It was pointed out that translational research demands a really good model, but that it is important not to overstate the predictive value and transferability of animal research to man. Ignoring the model's limitations may lead to delay, wrongly interpreted results and missed chances to refine the model.

The Association for the Study of Animal Behaviour (ASAB), Easter Postgraduate Workshop, March 2006
ASAB, founded in 1936 to promote the study of animal behaviour, has a membership of some 2000, the majority from Britain and Europe, including professional biologists working in universities, research institutes or schools. The Association has an Ethical Committee to promote the ethical treatment and conservation of the animals and encourages the teaching of animal behaviour in schools. The ASAB organizes three scientific meetings per year of which one is preceded by a postgraduate workshop, designed to educate new research workers in various aspects of research in this particular field. Two inspectors presented at a session during the post graduate workshop on "Ethics in Research on Animal Behaviour", talking particularly about the interface between regulated and non-regulated procedures. They also contributed to the discussions, both in and outside of the programmed talks. These meetings are a useful forum for interaction with many behaviourists whose work may only rarely fall under ASPA.

Institute of Animal Technicians Events
The Institute runs an annual congress which a few inspectors attend to meet with animal technicians and provide technical input to the discussions. In 2006 the Congress was held outside Great Britain for security reasons and the Chief Inspector gave an update on Home Office issues which was much appreciated, and he and an inspector stayed for the whole event, contributing to the workshops and learning about the Institute's educational outreach and initiatives. The Inspectorate also provided a speaker and workshop facilitator for the Institute's 2006 Conference for continued professional development for named care persons.

Royal Society for the Prevention of Cruelty to Animals/Universities Federation for Animal Welfare (RSPCA/UFAW) Rodent Welfare Group
Inspectors have continued to participate in a number of RSPCA activities during this year. One of these, in this case jointly with UFAW, is the Rodent Welfare Group, to which in 2006 a main contribution was a detailed presentation of the changes to husbandry and care in the new Appendix A to the Council of Europe's Convention ETS123 (see European Initiatives below), the ideas behind these changes, and the welfare benefits they could bring.

Certificate Holders' Forum and Training Day
The Certificate Holders' Forum provides an opportunity for certificate holders or their deputies to meet once a year to consider current issues. As usual, this year the Chief Inspector provided an update on operational matters. In addition, the Inspectorate provided a training morning the previous day specifically for new certificate holders. Unlike the previous training events linked to the Forum this was mainly in workshop format. It attracted such good feedback that it is expected that the same format will be used in future new certificate holder training events.

American Association for Laboratory Animal Science National Meeting, Salt Lake City, October 2006
Two members of the Inspectorate attended the annual meeting of AALAS and took the opportunity of inputting to other discussion groups arranged around this meeting. Their participation in the debates on husbandry and care and the use of carbon dioxide for euthanasia provided a useful European view often more welfare conscious than that from the US speakers.

Joint Meeting of the International Council for Laboratory Animal Science (ICLAS) and the World Organisation for Animal Health (OIE), October 2006
ICLAS promotes international collaboration in laboratory animal science, trying to achieve consensus, and aiming for harmonisation rather than standardisation. This meeting with representatives of the World Organisation for Animal Health (previously Office International des Epizooties and retaining the acronym OIE) discussed the potential for collaboration between these groups. Two inspectors were invited and acted as UK representatives. OIE now have a remit to cover animal welfare issues and are taking an interest in laboratory animals. ICLAS are involved in development of harmonised guidelines in the area of laboratory animal science. This was an initial meeting to exchange views and look at the role of each organisation and the potential areas for collaboration such as dissemination of information, raising the profile of laboratory animal science and improving international understanding of laboratory animal welfare.

Institute for Laboratory Animal Research International Focus Group, October 2006
This meeting was arranged to progress, or come up with a strategy for progressing, harmonisation of guidelines on husbandry and care of laboratory species. The Inspectorate's presentation and input

into the discussions was seen to be valuable due to experience in the recent development of European guidelines. It was agreed that guidelines should focus on the general principles of housing and care, and that performance standards should form the backbone of any future guidelines, although many stakeholders find engineering standards easier to measure. It is unlikely that there will ever be a scientific study designed which would define absolutely the minimum dimensions for any species group but there is a general feeling that determining the minimum enclosure size to meet performance needs of animals was conceivable.

Liaison with Regulators from other Countries

The Inspectorate has continued to maintain links with regulators in other countries. We have had a number of discussions with European inspectors on the possible revisions to the European directive relevant to our work and continued our links with the US Department of Agriculture's inspectorate which covers animal experimentation work. In autumn two inspectors attended the USDA Inspectors' Conference, which concentrated on avian influenza and the basics of care of and research work on birds, avian influenza being a very real concern in the US at the time.

Technical Input to the Animal Procedures Committee's Activities

The Animal Procedures Committee (APC) provides independent advice to ministers, but inspectors attend its meetings and subcommittees to offer their expertise on technical and operational matters. They provide input on technical accuracy and operational feasibility, but take care not to affect the independence of the Committee's advice. As in previous years, a significant amount of Inspectorate time in 2006 has been spent on this and some subcommittees have been heavily reliant on inspectors' expertise, with inspectors able to inform the Committee's considerations on, for example,

- housing and husbandry,
- non-human primate use and care,
- methods of euthanasia,
- education and training of potential licensees.

For the first and last of these the inspectors have been major contributors to the documents produced by the groups during the year.

Better Regulation Initiative

In accord with the Government's Better Regulation Initiative, in 2006 the Home Office commissioned an external assessment of the administrative burden its regulations imposed. This indicated regulations controlling scientific procedures on animals contributed a minor but significant part of the overall Home Office burden. The Home Office Simplification Plan for reducing the administrative burden, which was published in December 2006, had a section on the Animals Scientific Procedures Division, addressing points where the regulatory burden might be eased without compromising animal welfare. The Inspectorate contributed to the development of this part of the Simplification Plan and from its own internal initiatives was able to offer two important better regulation improvements ready for consultation with stakeholders. These were a standard list of personal licence technique wordings (see the 2005 Annual Report) and a simplified form for the Certificate of Designation, which would radically reduce the detail on the schedule of premises and the number of amendments solely due to changes in named persons. In addition ASPI could point to useful approaches to ASPA licensing, and to wordings for proposed work under project licences that allowed flexibility with good overall control, that could ease the burden on designated places and licensees if taken up more widely. These were being used in several places and in a number of instances were already in the public domain, but there would be benefit from wider dissemination.

Inspectors also acted as facilitators and provided technical input for groups on the Away Day organised by stakeholders to explore better regulation issues.

Freedom of Information Requests

In 2006, the second year of the Act being in force, the number of requests under the FoI Act was 14, down from 26 in 2005. However they occupied a significant amount of ASPI time providing relevant information and advising on personal data and intellectual confidentiality issues. As in 2005, the requests focussed mainly on who holds licences, specific projects or types of work, infringements and inspection reports. As last year the applicants split fairly evenly into three groups – journalists, animal protection groups and members of the public. Following advice from the Inspectorate, the Home Office Animal Scientific Procedures Division after consulting with licensees has released information about specific licences and certain areas of work under ASPA, and has undertaken some additional

breakdown of figures to give general information on licensing in Scotland, but provided no specific information about individuals or establishments holding licences.

Preparation of the Annual Statistics
The collection, collation and reporting of the Statistics of Scientific Procedures on Living Animals is the responsibility of the Home Office's statisticians in the Science and Research Group, but inspectors have, as usual, provided an important input into the interpretation of the results and analysis of trends for the 2005 statistics, which were published in July 2006.

Testing for Shellfish Toxins
Inspectors continued to help progress the use of non-animal methodologies for testing shellfish for marine biotoxins. Those with particular expertise in this field have worked actively with other UK agencies, the European Centre for the Validation of Alternative Methods, EU Regulators and other expert groups. Progress continued on application of 3Rs within the shellfish toxin testing programme. A pre screen has been introduced throughout the UK for the PSP (Paralytic Shellfish Poison) test and has reduced animal numbers on tests by approximately 75%. Changes to the European Food Hygiene Legislation in 2006 provided further opportunities for validated *in vitro* alternatives to replace the use of mice for toxin testing. Progress is being made towards full implementation of replacements for PSP tests which should occur in the near future.

European Initiatives:
During 2006 there has been progress towards development and adoption of changes in European instruments, and members of the Inspectorate have been involved both at the European level and in explaining the proposals to UK stakeholders and listening to their comments.

a) Revision of Appendix A of Council of Europe Convention ETS 123
The 4th Multilateral consultation of the Parties to the European Convention for the Protection of Vertebrate animals used for Experimental and other Scientific Purposes was held in Strasburg on 15th June 2006. The draft revised Appendix A was adopted unanimously by the parties to the Convention. It shall enter into force 12mths after its adoption i.e. 15th June 2007. This is the culmination of some 10 years of work for the Inspectorate who have been involved in discussions and development of these proposals. It will influence future standards of care and accommodation throughout Europe including the UK.

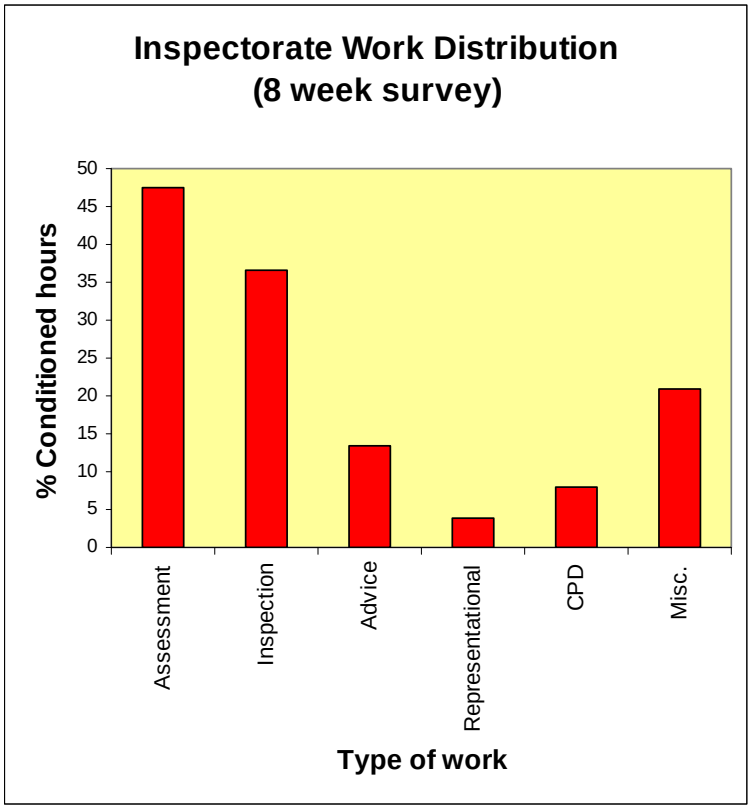
b) Revision of European Union Directive 86/609EEC
During 2006, the Commission continued with work towards the revision to Directive EC86/609. This project, had reached the stage where preliminary findings about the impact of certain options needed to be verified and further data collected. It was progressed through a multilateral consultation that took the form of two questionnaires one aimed at the public and the other for experts and organisations in the area of animal welfare, animal testing, animal science, natural sciences (especially biology, medicine, pharmacology and toxicology), legal and economic affairs related to these areas. The experts were expected to be able to either confirm the identified impacts or provide factual, quantifiable information to the contrary. Together the information collated from the completed questionnaires was to verify, redirect and complete the preliminary findings of the impact assessment of certain options to revise the existing legislation. Several Inspectors provided expert input in their particular areas of knowledge and experience together with a consolidated reply from the Inspectorate reflecting their views on how the suggested options would impact on the situation in the UK. In addition during this process there was considerable discussion within the scientific community in which the Inspectorate was involved. Overall the response rate was very high and time to analyse the results had to be extended. The expectation was that answers would be used by the European Commission to complete the impact assessment of the revision of Directive 86/609/EEC on animals used for experimental and other scientific purposes. (An impact assessment aims at providing a transparent and rational basis for political decision-making. It is then for political decision makers to choose the best options in the light of their likely predicted impacts.) The process of revision of the Directive could then continue with a draft revised Directive expected in late 2007or early 2008.

Inspectorate Work Patterns in 2006

The structure of the Animals Scientific Procedures Inspectorate (ASPI) was detailed in the 2004 Annual Report (and for a link to this see the Introduction section of this report). The basic pattern of a unit of inspectors headed by a Chief Inspector and Superintending Inspectors remains unchanged, but changes from leaving and recruitment have altered the distribution of inspectors in the different regional offices. By the end of 2006 there were 5 inspectors and one superintending inspector in London, 5 inspectors in Swindon, 4 in Shrewsbury, 4 inspectors and a superintending inspector in Cambridge, and 5 inspectors and 2 superintending inspectors in Dundee, with the Chief Inspector spending much of his time in London. A few inspectors work part-time, half the superintending inspectors' and nearly all the Chief Inspector's time is not for the statutory inspectorate functions, and with the loss during the year of two inspectors from the London office balanced by two new inspectors taking up their posts the number of full time equivalent inspectors for the year came to 24.7.

Inspectors assess and advise on applications for licences and certificates, and visit the places where the work is done, or animals bred or supplied, to check that the procedures undertaken and the premises accord with what is authorised. Inspectors also disseminate good practice, promulgate and explain ministerial initiatives and policies (both during visits and when representing the unit at external meetings and events), and advise on animal experimentation issues. An inspector is expected to spend time keeping up to date with relevant science and animal welfare issues and undertaking suitable continuing professional development (CPD).

Every two years or so, the Inspectorate conducts an internal survey of how inspectors' working time divides between these activities. Such a survey was undertaken for two months early in 2006, and the results are shown in the graph. Note that the percentages are of the time for which inspectors are contracted to work ("conditioned hours") and that they add up to considerably more than 100% - i.e. inspectors are working well over their conditioned hours. Much of the excess is due to miscellaneous activities: inspectors do not allow these to erode the time for their main tasks of assessment and inspection. Also note that the survey data does not include any from the chief inspector, much of whose time is spent on representation and advice.



Assessment work is demand-led and inspectors have to balance the priorities of dealing with licence applications and amendments, delays in processing which will hold up programmes of work, and the need to inspect work in progress. In 2006, on average nearly half an inspector's conditioned hours were spent on assessing requests for authorities, with over a third taken up by visits of inspection. Advising ministers and officials on animal experimentation issues, and representing the Inspectorate externally took nearly a fifth of ASPI time.

Unlike in 2004, in this 2 month survey of time allocation none of the time was devoted to training of the new inspectors. The new inspectors joining the Inspectorate in 2006 took up their posts after the end of the survey, so this does not show the considerable effort which went into their three months' initial training, which included taught sessions at each of the offices and joint inspection with many of the experienced inspectors.

Providing Advice

1. Advice on licensing

Under Section 9 of the Animals (Scientific Procedures) Act 1986, before granting a licence or issuing a certificate the Secretary of State is required to consult an inspector, and under Section 18 of the Act the inspector should advise him or her on whether and under what terms the licence or certificate should be granted.

> "It shall be the duty of an inspector-
> to advise the Secretary of State on applications for personal and project licences, on requests for their variation or revocation and on their periodical review;
> to advise him on applications for certificates under this Act and on requests for their variation or revocation;"
> Animals (Scientific Procedures) Act 1986 Section 18 (2) (a) & (b)

Note that the Act does not empower inspectors to issue, vary or revoke, licences or certificates (licensing decisions are taken by officials on behalf of the Secretary of State).

Inspectors also assess, as necessary, proposed experiments on protected animals which do not appear to involve regulated procedures. This is to evaluate whether such work, or a likely development of it, does actually need to be regulated under the Act.

Assessments in 2006

Personal licences and establishment certificates of designation

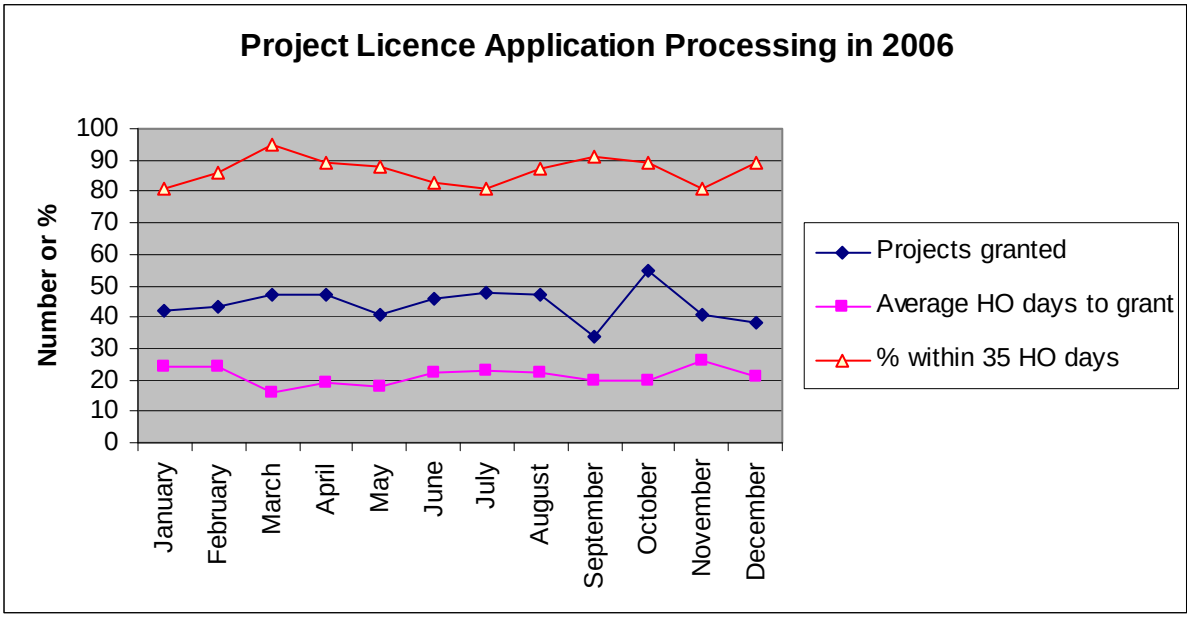
During 2006 inspectors assessed 2171 personal licence applications and 3900 amendment requests and reviews. They also recommended that certificates of designation be given to 3 new establishments, and evaluated 356 amendment requests to existing certificates. As there were 213 certificates in force at the end of 2006, on average the number of amendments per certificate in 2006 was less than two.

Project licences

In 2006 inspectors evaluated and recommended for grant 519 project licence applications, and assessed 1572 amendment requests. In addition to evaluations that culminated in granting of licences and amendments to licences, an unrecorded number of project licence proposals were not pursued after discussion with an inspector (see the 2004 report for an example of this).

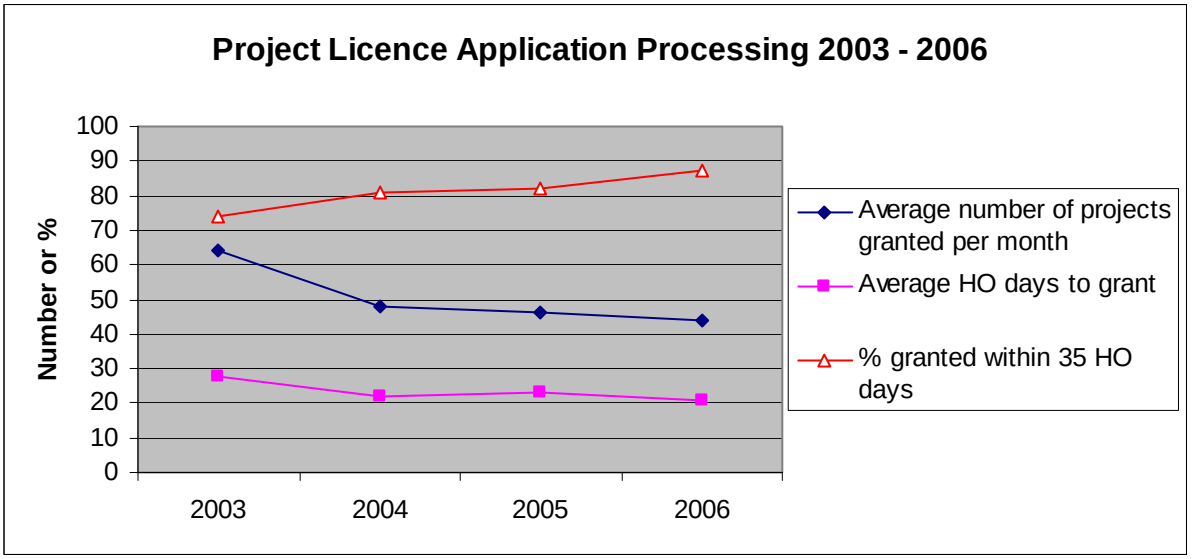
Targets for Assessment

The inspectorate aims to assess proposals for new work so that those authorities which can be recommended are in place by the time the applicants need them. This is to avoid wastage of animals on continuing programmes of work, missing of key dates for progress of new medicine developments,



or delaying time-dependent funded programmes. In addition for the past few years inspectors have

worked with licensing staff to a target of 35 working days for processing within the Home Office of 85% of new project applications. As the graphs show this was achieved for 2006 as a whole, with average processing time steadily decreasing over the last few years.



2. Advice on animal experimentation issues

The Inspectorate provides advice to ministers and officials, acting as a source of professional and scientific expertise for the formulation of policy on the care and use of animals in laboratories. Inspectors also provide advice to officials and ministers on technical matters and licensing issues, and assist in drafting answers to parliamentary questions and public correspondence.

During 2006 the advice on a number of topics that featured in previous years has continued – for example on the use of animals for testing samples of shellfish for toxins; and on housing and conditions provided in overseas centres breeding non-human primates. Other areas include the impact on animal scientific procedure work in the UK of European developments (not only those directly affecting animals in science but also where there may be an indirect effect, such as the regulations on transport of animals); the regulation of work on stem cells and chimeras; the possible effects on scientific work of changes in regulations concerning veterinary medicines. Advice has also been given on the recorded information that could be disclosed under the Freedom of Information Act, and on the matters raised by a judicial review sought by the British Union for the Abolition of Vivisection. Inspectors also communicate information gathered during visits to establishments, or provided by scientific contacts, such as the likely impact of scientific developments on animal use and welfare, the reaction of the scientific community to policies and practices and the level and nature of animal rights extremist activity at an establishment.

Inspection

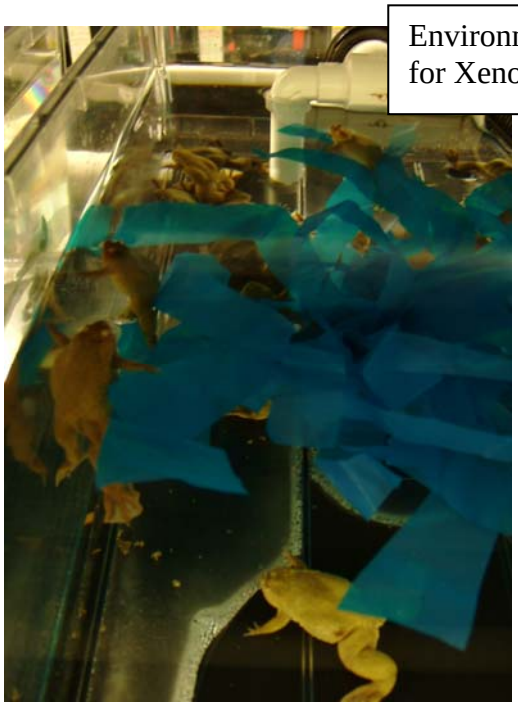
a) Visiting

> "It shall be the duty of an inspector…..
> to visit places where regulated procedures are carried out for the purpose of determining whether those procedures are authorised by the requisite licences and whether the conditions of those licences are being complied with;
> to visit designated establishments for the purpose of determining whether the conditions of the certificates in respect of those establishments are being complied with;"
> Animals (Scientific Procedures) Act 1986 Section 18 (2)(c)&(d):

Inspectors aim to spend some 40% of their time on visiting functions, which includes preparation for visits, actual visiting, relevant travel and subsequent reporting. The majority of departmental inspections, especially to animal holding areas, are unannounced, in keeping with the expectation of Ministers and the public.

Inspection
During the year inspectors were inspecting work under some 3000 project licences carried out by around 14000 personal licensees at over 200 designated establishments (actual figures in December were 2800, 14311 and 213 respectively). The establishments include breeding and supplying establishments where some scientific work is also carried out, and in addition there are establishments designated only for breeding animals for scientific use - which are also visited regularly.

A wide range of species has been inspected - from fish, through amphibians, birds, small mammals, wild mammals, agricultural species to those species afforded special protection by the Act – dogs, cats, equidae and non-human primates. These differ considerably in their housing, husbandry and handling needs.



Environmental enrichment for Xenopus

During inspection visits, inspectors encourage good practice such as providing suitable environmental enrichment and care arrangements.

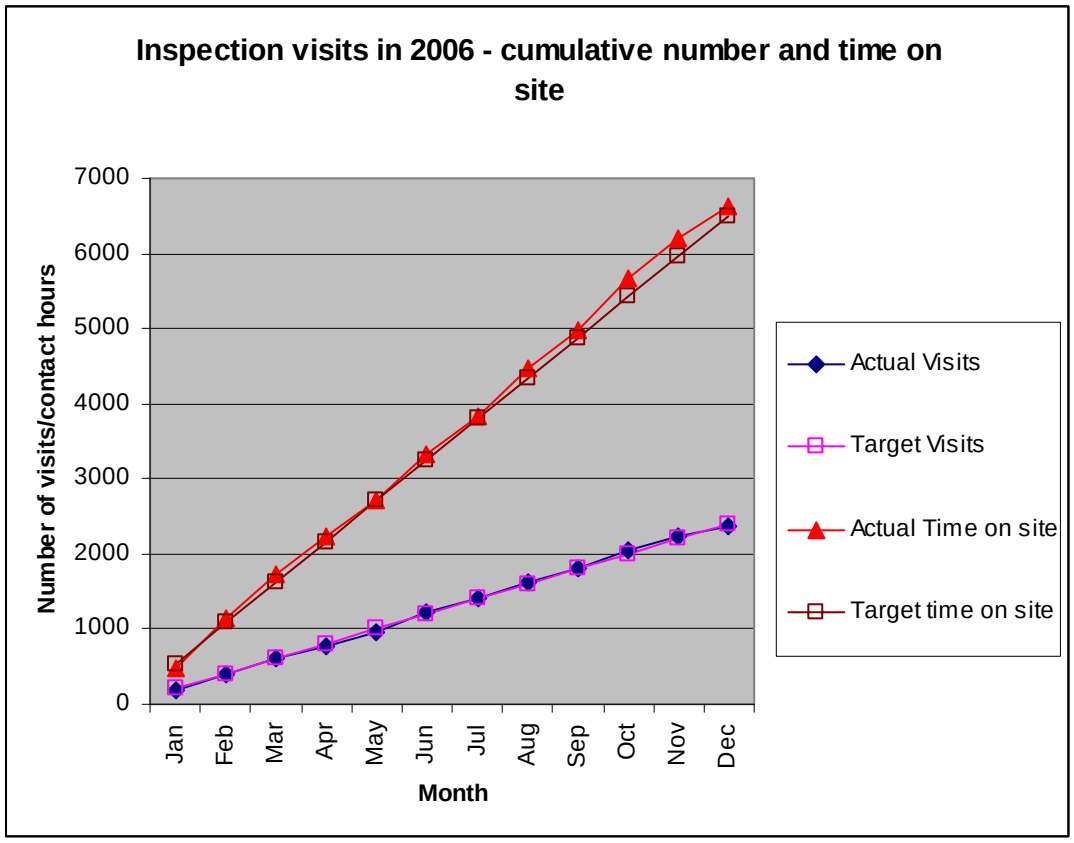
Cats benefit from a complex environment and good play arrangements

The distribution of establishments and of projects and personal licences per establishment does not differ greatly from year to year, and the pattern can be seen in the figures provided in the 2004 annual report (a link to which is provided in the Introduction section of this report). Nearly a third of designated establishments have only one project licence holder and a few personal licensees, and

travel times to many of these are considerable, but all that were carrying out regulated procedures in 2006 were visited. As in previous years there were also visits to sites which were not designated, for example to inspect blood sampling from animals in the wild, the tagging and tracking of fish, and studies of sea-bird colonies and roosting bats, and more details of the type of work inspected are given in the section below on Scientific Work Outside Designated Establishments.

Visits of Inspection in 2006

The aim is for a full time inspector to do on average about 100 visits of inspection per year and for the inspectorate's cumulative contact hours, i.e. time on site, to exceed 6400 hours in the year. This was achieved in 2006 with 2381 visits to places and 6615 contact hours. As the graph below shows, the numbers of visits and the time spent at establishments were above or on target throughout the year. The average visit time was 4.9 hours, with 2.1 hours of this spent travelling.



The majority of visits to establishments as a whole were unannounced and three quarters of the visits to animal houses were unannounced.

b) Reporting

A major purpose of visiting is to check that establishments and researchers are complying with the provisions of the Act and the terms and conditions of licences and certificates.

> "It shall be the duty of an inspector…..
> to report to the Secretary of State any case in which any provision of this Act or any condition of a licence or certificate under this Act has not been or is not being complied with and to advise him on the action to be taken in any such case."
> Animals (Scientific Procedures) Act 1986 Section 18 (2)(e):

Inspectors advise on how to comply and generally promote a culture of compliance, but also look out for and investigate non-compliance, making an appropriate recommendation to the Secretary of State. However, in establishments with a good culture it is often the licensees or the Certificate Holders who inform inspectors of any apparent non-compliance.

This was the case again in 2006, with 17 of the 29 infringements which come within the scope of this report[4] self-reported or notified by the establishment. As there were over 3 million animals used on procedures in 2006, the low number of infringements indicates a high level of compliance with the Act.

Twelve of the infringements involved minor breaches of conditions, unauthorised procedures competently done or variations from authorities with little additional suffering. These included:

- Failure to label cages of genetically modified mice sufficiently for the responsible licensee to be identified, poor record keeping, inadvertently obtaining rodents from a source that was not designated for breeding or supply
- Immunising an animal of a type not specified on the personal licence, inserting a cannula competently but without specific authorisation, performing an unauthorised injection competently prior to euthanasia.

Seven of the twelve were self-reported or reported by the establishment. The advice given to officials was that these cases merited no more than a letter of admonition.

The other 17 infringements in the 2006 group, of which 7 were discovered by inspectors and the rest reported by the persons involved or the establishment, were considered more serious because additional action needed to be taken to avoid recurrence or because of welfare issues.

Some of these involved little or no avoidable suffering, but indicated defective controls or understanding for which remedial measures were thought necessary. For example,

- some animals were obtained on more than one occasion from an overseas supplier without prior authorisation, indicating poor control on the acquisition of animals,
- genetically altered animals which should have been kept under a project licence were allowed to continue breeding after the project had expired, and some improvement in controls was needed to avoid recurrence,
- mice were subject to aversive stimuli differing from the specific authorisations in the project, with the risk that if the importance of project licence constraints were not re-emphasised a further variation could cause significant suffering.
- a repetition of minor deviations in environmental controls and defects in facilities raised concerns about general compliance with the Code of Practice, with the need for a clear requirement to improve standards before animal welfare was compromised

For these in addition to appropriate admonition a requirement for improved local arrangements or additional licensee training was included in the recommendation, except in one case where the certificate was voluntarily revoked.

A number of infringements involved unauthorised procedures competently performed, in two cases by a non-licensee but under appropriate supervision. These included decapitation of mouse pups and ear biopsy of wild rodents. For these it was considered that admonition or a letter of censure to the non-licensee concerned should be supplemented by measures to help avoid recurrence. Where local controls were insufficient the advice was that the Certificate Holder be required to strengthen them, and where it would help to emphasise the need for good management of the work being done and recognition of the legal constraints further training for the project licence holder was advised.

Several infringements however did produce significant avoidable suffering. In some the holding and care arrangements were at fault. Thus guinea-pigs were in one instance found in poor condition (and euthanased) after being removed from the animal facility and mistakenly held without daily observation or topping up of food and water, while in another Xenopus toads died when, as a result of an accident, the water temperature was inadequately controlled. In others the failure was that licensees did not properly care for their animals or exceeded the project licence constraints. These involved

- unauthorised re-use of rodents and unexpected adverse effects over several months that were not reported, coupled with poor record-keeping.
- mice left with locomotor problems and others with skin damage after unsuitable restraint under general anaesthesia.

[4] Note that as the Inspectorate's function is to report and advise on appropriate action, this Annual Report covers those infringements for which the Inspectorate's investigations, report and advice were completed within 2006. Numbers therefore differ slightly from those reported in the Annual Statistics report, as that covers the ones for which action has been completed.

- sheep which should have been considered as continuing under project licence controls and personal licensee care held as stock and not given adequate diet. Their poor condition was not recognised and a few died.
- adverse effects of procedures on mice and ferrets exceeding the severity limits, leading in one case to deaths or a need to kill the animals on welfare grounds, with the problems compounded by keeping poor records or not seeking veterinary advice.
- poor post-operative monitoring of a procedure in rats that carried risk of substantial suffering.

For these the licence holders to blame voluntarily surrendered their licences: revocation would have been recommended otherwise. Where there were faults in the institutional controls the advice was that the certificate holder be required to rectify these.

Serious infringements are however infrequent. There was generally a high level of compliance with authorities and conditions, and, as indicated above, where contraventions occurred unauthorised procedures were usually competently done and involved minimal severity. It is encouraging that remedial measures seem generally to be effective at preventing recurrence of non-compliance, and that many problems continue to be self-reported.

Non-statutory Activities

Representation

Inspectors have represented the Inspectorate, and often the Home Office, at numerous meetings throughout the year. This included presentations or attendance at several meetings abroad, notably:

American Association of Laboratory Animal Science National Meeting
Congress of the European Societies for Toxicology
European Congress on Immunology
European Federation of Pharmaceutical Industries Associations
Federation of European Companion Animal Associations
International Council for Laboratory Animal Science /World Organisation for Animal Health Joint Meeting

A brief sketch of some of these events has been included in the Events and Initiatives section.

In addition to the meetings mentioned in Events and Initiatives section, within the UK members of the Inspectorate have acted in a representative capacity and attended or spoken at meetings of:

British Association for Cancer Research
British Poultry Association
British Small Animal Veterinary Association
British Society of Immunology
British Toxicological Society
British Veterinary Association
British Veterinary Association Animal Welfare Foundation
Central Veterinary Society
Certificate Holders Forum
Chemical Stakeholders Forum
Clinical Research Outreach Programme
Genome to Systems Conference
Institute of Biology – Accreditation Board
Laboratory Animal Breeders Association
National Extremism Tactical Coordination Unit – stakeholders' meeting
Pain Society
Sheep Veterinary Society
Universities Training Group Quality Assurance Group
Universities UK and Biosciences Federation
Universities Federation for Animal Welfare

Inspectors act as Home Office observers on a number of external groups, providing legal, scientific and technical advice on matters related to animal experimentation. The observer status allows them to participate in the discussions without commitment to the conclusions or actions the group as a whole takes. NC3Rs, LASA, and RSPCA/UFAW groups have been mentioned in the Events and Initiatives section. Others include the Scottish Named Veterinary Surgeons group and a working group of the UK Co-ordinating Committee on Cancer Research discussing the revision of its Guidelines for the Welfare of Animals in Experimental Neoplasia. All the groups have said how much they value the contributions made by inspectors.

There are also a number of liaison groups or joint discussion meetings at which inspectors are key players. Externally for example there is a Home Office Laboratory Animals Liaison Group and an annual meeting with the Royal College of Veterinary Surgeons. There have been many meetings during the year with representatives of the Food Standards Agency concerned with shellfish toxin testing. Internally inspectors sit on several interdepartmental groups, such as the Interdepartment Group on Health Risks from Chemicals and the Interdepartmental Group on the 3Rs, and there has been Inspectorate participation in the Government Veterinary Surgeons Steering Committee and the Bovine TB Vaccine Steering Group, both run by DEFRA, as well as several meetings and contacts with DEFRA staff.

Education

An important role of inspectors is to encourage good practice and to educate those involved in work regulated under the Animals (Scientific Procedures) Act about possibilities for improvements in scientific practice or housing and care. This is not just a matter of passing on information and ideas on how lesser severity, reduced numbers, or replacement by non-animal methods might be achieved,

but also of stimulating those involved to think of different ways of achieving results, and arguing the value of standards above the required minima.

Inspectors educate in the talks they give and discussions they have in their representational role, but they also contributed directly to specifically educational events, for example the Institute of Animal Technician's and the ScotPIL Committee's training meetings, providing both technical input and assistance with material. An inspector also acts as observer on the Institute of Biology, Universities Training Group, and Scottish Accreditation Boards, which are concerned with the modular training that licence applicants have to undertake before a licence application will be considered. This year there was a major contribution from the Inspectorate at the Training the Trainers Day run by the Universities Training Group Quality Assurance Group.

As well as continuing the involvement in specific educational events such as the Institute of Animal Technology and the ScotPIL Committee's training meetings, the Inspectorate has again provided significant input to the APC Education and Training Sub-committee, which is reviewing licensee training and during 2006 moved to consideration of desired learning outcomes for Module 5 training.

During the year inspectors have continued to run, in various parts of the country, refresher training courses and workshops on ASPA provisions relating to work under project licences and how to provide information on how such provisions would be met when applying for authorities under the Act. In addition inspectors have organised or participated in a number of events on particular topics for licensees and care staff, including what an inspector is looking for on a visit, experimental strategy and design for project licence holders, fish research and the husbandry and care of fish, regulation of work on genetically altered animals, and issues around the killing of animals for tissue for scientific use.

In October 2006 the Inspectorate was asked to participate in the first joint British Veterinary Association and Coalition for Medical Progress meeting for undergraduate veterinary students, in Cambridge, on the subject of animal use in experiments. The Home Office presentation outlined the legal constraints place on animal experimentation by the Animals (Scientific Procedures) Act 1986 and highlighted how this act and the Veterinary Surgeons Act interface.

The feedback from various sources about these workshops and other inspector-led events has been very good. Participants have found them interesting and valuable, and appreciated the work inspectors put in to make them successful. The number of repeat invitations to inspectors to run such events speaks for itself in that respect. Inspectors who participate in these consider the improvement in understanding by licensees of the nature of work under ASPA and the greater ease with which applications and amendment requests from attendees can often be dealt with makes these events a worthwhile use of time.

Surveying the Ethical Review Process

In 1999 a condition was placed on the certificate for every establishment designated under the Animals (Scientific Procedures) Act 1986 (ASPA) requiring the certificate holder to "have instituted, and to maintain, local ethical review processes acceptable to the Secretary of State". The aims that these local ethical review processes (ERPs) should have were set out, as were the required personnel and general functions. These can be seen in the process statement reproduced in Appendix J of the *Guidance* . Within these general constraints, places were free to make their own arrangements for how the process operated locally, with no requirement for a committee structure.

The Inspectorate reviewed local ethical review processes in 2001 and recommended that ERPs should continue to be a requirement, that the process statement in Appendix J should be unchanged, and that the ERPs should be seen as an evolving process. There was general appreciation of the value of ERPs and no establishment wished to dismantle theirs. The report, however, found wide variation in practice and provided a number of pointers to good practice. Now that ethical review processes are well established a more quantitative survey was begun in 2006, to gain some insight into the resource involved and the extent to which delays in obtaining new project authorities might be attributable to the ethical review process stage. This survey was completed in 2007 but is being included in the 2006 report to allow the results to inform the current debate on better regulation of scientific procedures on animals.

How the survey was carried out

Selection of Sample

At the time of setting up the survey there were 215 establishments designated under ASPA, including a few that were solely designated for the breeding and supply of experimental animals. The extent to which these establishments undertake work under ASPA is very varied, and the Inspectorate has developed a rough estimate of the workload represented by a place that fairly encompasses both sites where there are many personal licensees working under a few projects (usually commercial establishments) and those (usually in academia) where there are many projects but not many licensees working under each. An arbitrary figure equivalent to the work involved but based on experience has been used for places which are breeding and/or supplying establishments only.

Using these figures the designated establishments (DEs) can be placed into size categories, and for convenience three such categories have been used with workload ranges as indicated in the table below.

Size Category	1	2	3
Workload Unit Range	<30	30 - 300	>300
Total number of DEs in that category	109	89	17
Total workload units in that category	1248	10170	9883
Sample size	10	26	5
Sample as % of DEs	9	30	29
Sample as % workload	9	36	41

Within each category the places to be sampled were picked at random, aiming for a 30% sample in the size 2 and 3 categories and a 10% sample in the size 1 category, which includes over half the establishments designated under ASPA but only 6% of the workload. The actual sample percentages are given in the table. (A few places chosen did not provide data - after the survey was set up a couple rescinded their designations and one had major local changes.) For the size 1 and 2 groups, the selection provided a good mix of academic and commercial establishments along with those, such as research institutes and government laboratories, which came into neither category. However, the size 3 category is made up almost entirely of academic establishments, and only academic places were among those randomly selected. The size 1 group included one breeding establishment. In total there were 41 places in the sample.

Questionnaire

The box below shows the questionnaire used (slightly modified for presentation purposes).

Review of ERP

PCD Size Code: Inspector:
Type of Establishment by Code: No. of project licences:
[Primary availability only]

1. If you provide advice to PPLh's at an early stage, i.e. when they are drafting their applications prior to ERP
is it on an outline of the project? Usually Sometimes Rarely
is it on the full draft(s)? Usually Sometimes Rarely
Comments if appropriate:

2. Appendix J to the Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 requires ERP's to undertake a number of processes (see section 7).
Could you please try to find out roughly how many man hours the ERP spends in **total doing all the processes listed in section 7(1) to (7) of Appendix J?**
Please tick the relevant box).

<5hrs/month	
5 to 10hrs/month	
10 to 30hrs/month	
30 to 50hrs/month	
> 50hrs/month	

If more than 50hrs per month roughly how long are they spending?

3. If the ERP did not exist what percentage of the above time do staff at the establishment estimate that they would spend addressing these tasks anyway?
[You might find it useful to ask – How much time would you save if you did not have to fulfil the Home Office requirements for ERP?]

4. In particular section 7(2) of Appendix J requires ERP's to undertake the following process:

- *Examining proposed applications for new project licences and amendments to existing licences, with reference to the likely costs to the animals, the expected benefits of the work and how these considerations balance*.

Could please you try to establish what percentage of the ERP's time is taken up with this particular process? (Please tick the relevant box).

Less than 20%	20 to 30%	30 to 40%	40 to 50%	50 to 60%	60 to 70%	70 to 80%	More than 80%

5. If more than 30% of time is spent by the ERP on the process in section 7(2) then:
Could you please try to establish, for the last **three** licences, the time that elapsed (in working days) from when the licences were first submitted into the ethical review process to when they are sent, signed by the Certificate Holder, to the Home Office?
[Please note this is not just the time spent by the committee dealing with the project but the total time that elapses.]

Note if the ERP spends a relatively short length of time on this process is there a reason (e.g. each study is carefully planned and discussed by study groups as part of GLP)?

6. If one or more of these applications did NOT go through ERP first time, how many times was each application considered (e.g. by the full committee or an equivalent virtual system)?

7. For the above licences:
Did the ERP assess the costs (e.g. consider refinements, adverse effects, address monitoring) if so how/what?

Did the ERP assess the benefits (e.g. weighing value of outcome, importance of the work etc) and if so how/what?

Did the ERP contribute to helping internal management and if so how/what?

8. Where any of the additions made by the ERP not required by ASPA (e.g. constraints on numbers of treatments to any one animal or for example did the ERP stop any procedures which ASPA would permit), if so please specify:

9. Please outline how the ERP conducts it business (e.g. standing committees which meet vs virtual committees vs some other arrangement)?

10.. How does the ERP deal with applications for additional availability

The details and first question were for completion by inspectors. Inspectors and those organising the local ethical review processes collaborated in completed the other questions. Questionnaires for size 1 places differed slightly in that only the days elapsed for the last project (not the last three) was asked for.

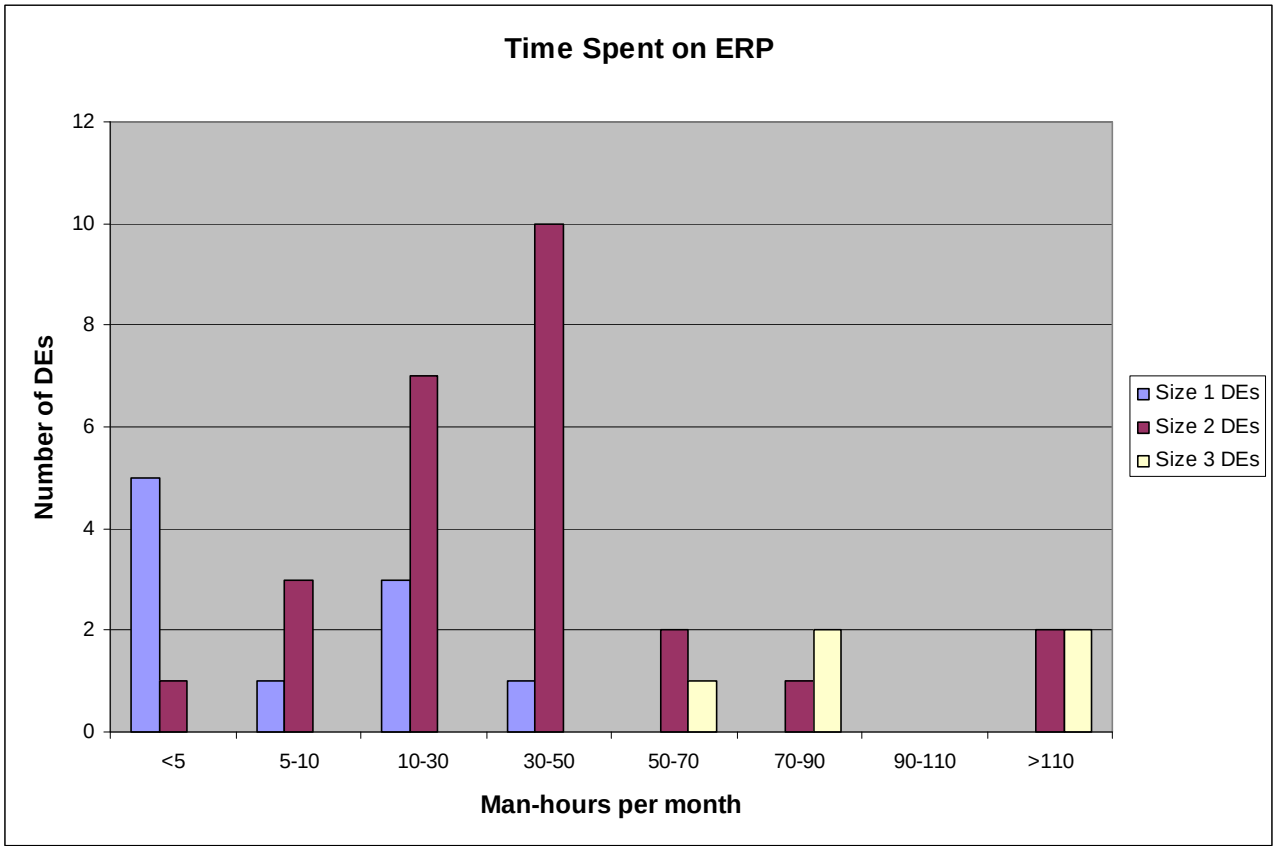
The questions asked for broad estimates so that providing the information was not too much of an imposition on the places selected. It was recognised that this meant the results would not be amenable to rigorous analysis. A pilot run using 8 places was undertaken and the questionnaire refined in the light of the responses obtained.

The only discrete quantitative data sought was on the elapsed time for new project applications to pass through the local process. This was asked of those ERPs which spent more than 30% of their time on project applications on the grounds that places which spent less than 30% of their time on this activity were likely to be the small places with only one or two projects and where the last consideration of a project application may have been some years ago. This assumption was borne out by the responses obtained – only one size 1 establishment fell into this category, but all size 2 and size 3 places provided data. Elapsed time was requested because project applicants were expressing more concern over the delay at the local level than over the amount of time they spent dealing with the ethical review process. The figures may not be a fair reflection of the efficiency of the ERP as delay caused by the project applicant not responding to correspondence is included, but they do reflect the delay produced by the existence of the process, and especially any delay caused by mandatory consideration by committees that met infrequently.

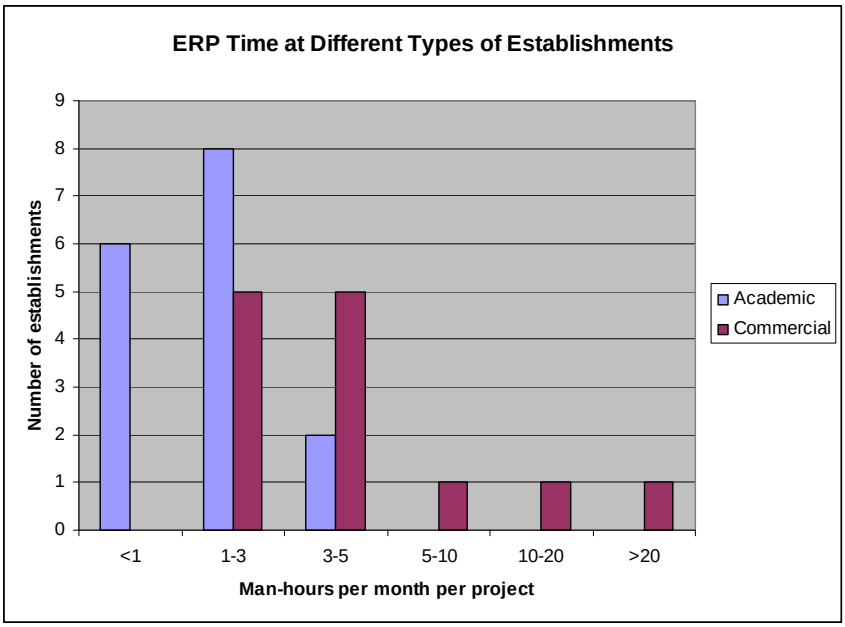
Responses obtained

The survey was looking for general patterns, and several emerged from the responses. The first question showed considerable variation in inspector practice. When the response to this question was compared to other responses it seemed the time considered to be spent on project work by the ERPs at places where there was usually inspector input at an early stage of project application preparation, was about half that spent by ERPs at places where the inspector rarely provided input at an early stage.

Resource devoted to the local ethical review process
The resource spent on ERPs is considerable. In the graph below the man-hours per month is shown in range categories, with the height of the columns giving the number of establishments in that category. Even allowing for the rough estimates used for the responses, it is clear that for some (not always the large places) this amounts to over half a full time equivalent member of staff. The size 1



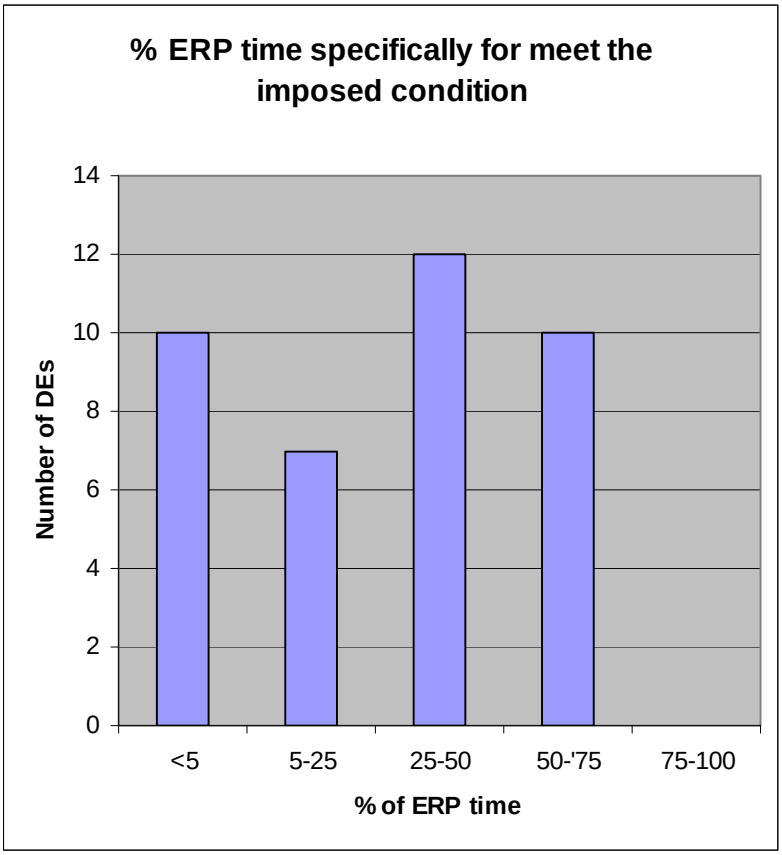
places mainly fall into the <5 hours per month group, but some spend 30-50 hours, as do most size 2 establishments. The large universities forming the size 3 group all spend over 50 hours per month, with one recording 220 hours.



For reasonable comparison between types of establishments, account has to be taken of the widely different amounts of work under ASPA undertaken at different places. The size groupings are too broad to provide this, so the number of projects held at the establishment has been used. The mid-point of the range given in the questionnaire response (or the estimated number of man-hours if this was provided) was divided by the number of projects at the establishment. This provided the distribution for the two major types of establishment (academic and commercial) shown in the adjacent graph. It seems that commercial places generally expend more hours on their ERPs than academic ones do. Note though that the number of projects at the larger academic places is often over 100, so the resource implications of ERPs for the academic sector is significant.

Resource needed solely to meet the Certificate condition

It is important to consider if all this resource is needed to meet the condition for an acceptable ERP. Many places had internal scrutiny of projects before this became a requirement and many ERPs would devote time to the specified functions as part of their normal practice irrespective of any Home Office requirement, or have included in their ERPs tasks that are additional to those in Appendix J, such as scrutiny of personal licence applications. Question 3 asked for an estimate of the amount of ERP time that would be spent even if there were no central requirement. Half the size 1 places and 3 out of the 26 size 2 places reckoned that they would spend the same amount of time on the functions even if the ERP did not exist. No establishment reckoned all the time was on the required functions, and only one size 1, two size 2 and one size 3 places thought more than two thirds of the time was attributable to the required functions.

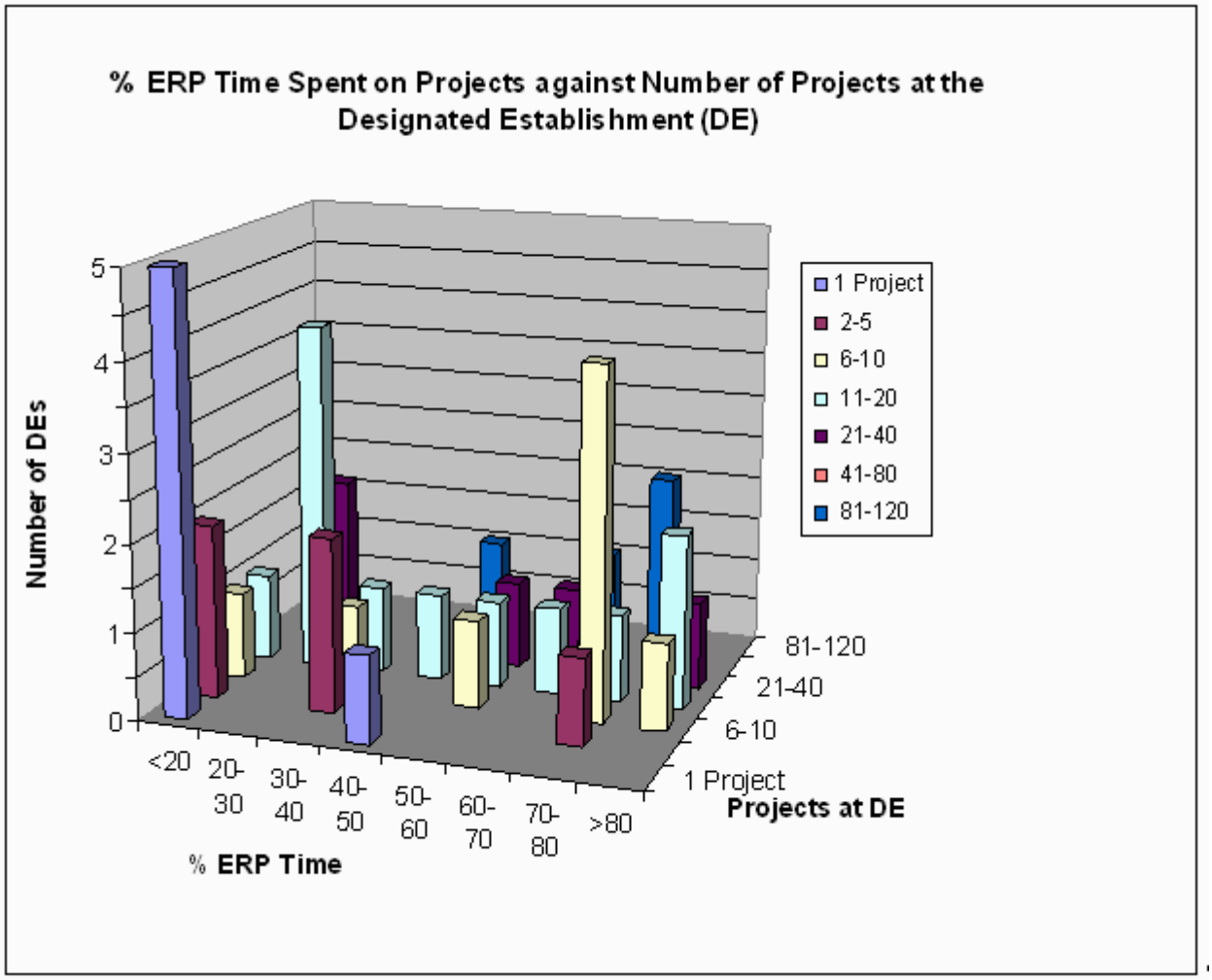


Two places did not respond to this question. For the others, the percentage of ERP time needed to meet the Home Office requirement was

calculated by subtracting the response given from 100. The distribution of results is shown in the graph. Overall less than half the time spent on the local ethical review process is solely to meet Home Office requirements.

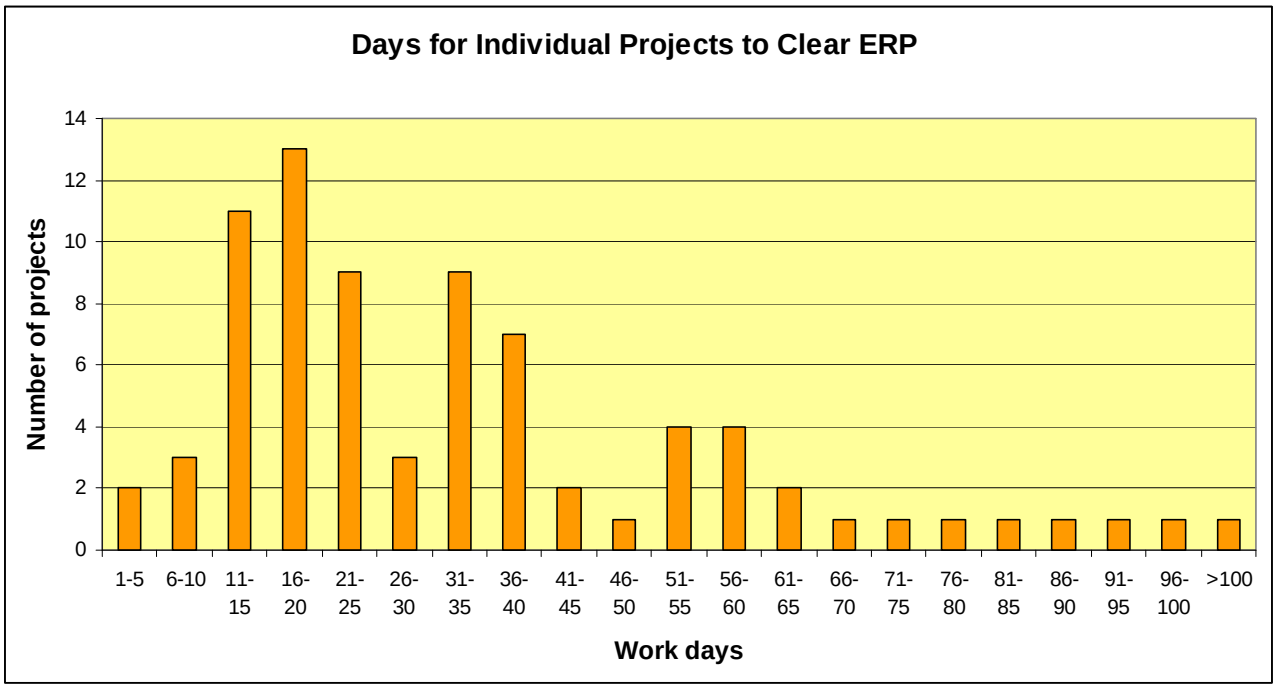
Resource involved in examining project applications.
Question 4 asked for an estimate of the proportion of ERP time spent on examining project licence applications and amendments. The responses indicated that this was not simply related to the number of projects at the establishment. As might be expected most places with only one project and nearly half those with 2 to 5 projects indicated that less than a fifth of ERP time is devoted to this function, while in the large academic institutions with 80 or more projects, most of the ERP is spent on project applications. Note that this would include consideration of amendments as well as new applications. Places with between 5 and 80 projects varied considerably in the percentage of ERP time given as spent on projects.

The graph below shows the number of designated establishments (DEs) against the response given, but separated according to the number of projects held at the establishment. It excludes the single breeding establishment in the sample. The first group seen in the graph are those places with only one project. Five spend less than 20% of the ERP time on projects, but one 40-50%. The next group in the graph shows in three columns places with 2 to 5 projects. One of the five spends 70-80% of ERP time on project work (about three times the group average). In the next group, with 6-



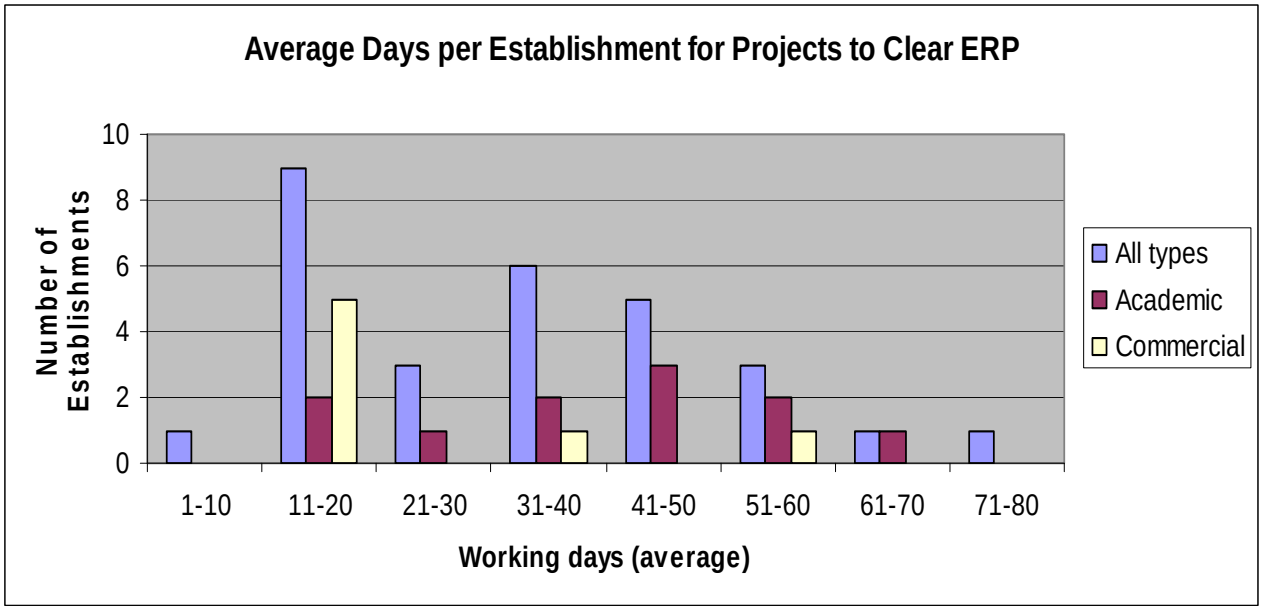
10 projects, one place spends less than 20%, one place over 80% of the time on projects, and four out of the eight 70-80% of the ERP time on projects. The next group, places with 11 -20 projects, also ranges widely but for this group the peak, four of the twelve, is at 20-30%. There were no evident reasons for this variation. The places spending a greater proportion of ERP time on this function were not, for example, those with special species like non-human primates or work which raised difficult ethical issues. There may be scope for guidance in this area.

Time delays from ERP consideration of new applications
Where more than 30% of the ERP time was devoted to projects, the number of workdays from first entry of a new application into the ERP process to passing the application on for Home Office



consideration was sought (Question 5). The responses show an enormous variation. Although the median was 16-20 working days, and many passed through in around a fortnight, a fifth of the applications took three months or more to pass through the ERP, with one taking nearly six months (see graph above). The longest times were at academic places, but the universities also had some of the quicker times and widely differing times for the individual projects was noticeable in some academic responses.

A better comparison between types of establishments is from the average passage time for the three

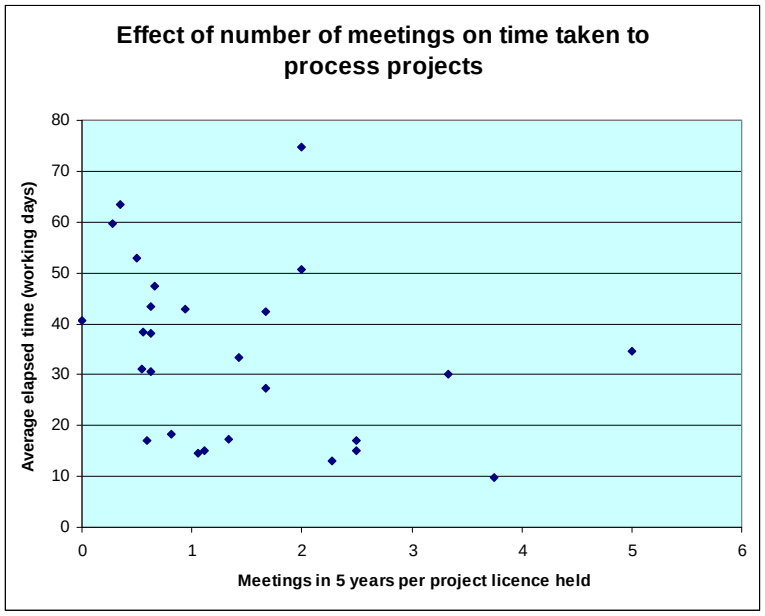


projects from each establishment. This is shown in the above graph, with the responses from academic and commercial establishments shown alongside. The only place with an average elapsed time of more than 70 working days was a government establishment. The 11 academic establishments show a wide spread with an average of over two months for projects to clear ERP. In contrast, 5 of the 7 commercial places cleared within one month. This may reflect the longer time per project that commercial places spend on the ERP (see above).

There was no evident correlation between the number of iterations and the delays, nor did the questions in section 7 help to explain the differences between establishments.

Structure of the ERP
Five designated establishments gave e-mail as the main vehicle for the ERP, with occasional committee meetings, but for all the rest of the places surveyed there was a committee structure. Some responses did not indicate the frequency of meetings, but of the many that did the commonest arrangement for the ethical review process was a committee meeting quarterly with e-mail exchanges around these meetings. Larger places reported monthly meetings with additional e-mail exchanges. Six small and medium-sized establishments indicated they had committee meetings twice a year, while in a two places ERP committees met as frequently as the work required.

There were some indications of a relationship between frequency of committee meetings and the use of e-mail and the project processing time (the number of working days elapsing between submission of a project to the ERP and it passing on to the Home Office). Two of the three longest average processing times (around 60 days) were at places that only had a committee structure without significant e-mail communication. The third (and the longest average time of the whole survey) had among the three projects one that took 150 days, but the elapsed time for the others was average. Those establishments with many projects to deal with might be expected to meet more frequently. However, given the range of establishment size and number of projects the ERPs see, it is difficult to show any relationships without standardisation. For this the number of meetings per project held has been used. As projects have a maximum five year duration and nearly always are held for five years, the number of meetings over the five year cycle has been taken. The graph shows the average elapsed time for the three projects at the place set against this measure of committee frequency, and although there are some evident outliers, there does seem to be a trend.



For second availability requests for projects, most ERPs concentrated on the particular work to be done at the local site, but a number ethically reviewed the whole of the proposed work.

Summary
This was a survey, not a review, and most of the questions were not seeking well-evidenced or quantitative responses. So it is inappropriate to give definite conclusions, but there are some general patterns and points worth noting.

- Places put considerable resource into their ERPs but there is wide variation in time devoted to the ERP without evident relationship to the need posed by the tasks it should perform.
- No establishment surveyed spends all the time regarded as part of the local ethical review process solely to meet Home Office requirements, and most spend 50% of the time or less.
- Compared to academic establishments in the survey, commercial establishments of similar size put about twice the number of person hours into the ERP.
- In terms of working days elapsed, new project applications pass through the ethical review process in the commercial establishments in the sample twice or three times faster than in academic places.
- The median elapsed time for new projects at the local stage is 3-4 weeks, about twice the median time for the Home Office stage.
- As with processing of projects by the Home Office there is a long “tail” to the graph of elapsed time distribution, and this was particularly the case with projects at academic places. No single factor could be seen as determining this but frequency of committee meetings and

ability to make progress by e-mail or discussion outside of such meetings could be significant contributors.

There would seem to be scope for many establishments to have more efficient arrangements, and it would be worth certificate holders comparing their local arrangements and discussing possible efficiency gains with the Home Office. The emphasis of this survey was on new project applications, but an important consideration for project licence holders is how amendments are dealt with, as delays could inhibit adapting the project work to new discoveries or published methods.

Procedures on Poultry

Introduction

In the UK the poultry industry has grown significantly in the last two decades and there is considerable research effort supporting this industry. From the figures in the Statistics of Scientific Procedures on Living Animals for 2006, procedures on birds accounted for 4% of the total, and of these 87% were on domestic fowl.

The great majority of regulated procedures on birds are done on domestic fowl.

In 2005 in excess of 174 million birds were produced with around 64% table chickens, 28% laying birds and 8% of other poultry such as turkeys, ducks and geese. Poultry enterprises can be split into different categories depending on the product and type of production - egg or meat. Egg production can be sub divided into free range, barn or cage systems. There are also other relevant businesses that support these poultry enterprises such as poultry breeding companies and hatcheries. The industry invests in research and development to support and improve production in many areas including disease prevention and control, bird genetics and animal welfare. Some of this research requires licensing under the Animals (Scientific Procedures) Act 1986 (ASPA). Poultry can also be utilised for other research work and this article provides an overview of aspects of both these types of work in poultry species.

In the UK context the definition of poultry includes the domestic chicken (Latin name *Gallus domesticus*), turkeys, geese and ducks. Interestingly the term “domestic fowl” can have either the narrow meaning of chicken and hens (as used in the Annual Statistical Return of Procedures) or a broader meaning of “birds utilised for food” and this would include chickens, turkeys, ducks, geese and game birds (e.g. pheasants, partridge and quail).

Within UK legislation, transposed from the relevant European Directive, the common European quail *Coturnix coturnix* is included in Schedule 2 to ASPA. This means that they are given particular protection so that birds utilised in research must be obtained from designated breeding or supplying establishments. This is why data on this particular species is included in the annual statistical information (see below).

Major Usage of Poultry under ASPA

The total number of regulated procedures performed on birds of all types is given in the Statistics of Scientific Procedures on Living Animals. For 2006 it was 114,400, i.e 3.8% of the total procedures reported for that year. The figure has varied in the last 10 years from 141,200 in 1998 to 105,300 in 2004. The statistics subdivide to some extent the usage of birds for scientific procedures, and show that the greatest proportion of procedures, 87% (99,933), used domestic fowl, with most of this use (79%) for applied veterinary studies, primarily in the field of parasitology. Microbiology and immunology were also prominent uses.

Consequently it would appear that most poultry use under the Animals (Scientific Procedures) Act was for investigations into diseases of chickens for the benefit of chickens. The table below provides

further information of the particular areas of research that utilise poultry. The statistical tables separate information on domestic fowl, turkeys and quail but usage of other species of poultry e.g. ducks and geese, is included in the overall figure for birds. However, from visiting designated places inspectors are aware that the number of ducks and geese that are used is low.

There is some research on captive ducks.

The broad category of "birds" in the statistics covers a wide range of species including various songbirds, garden and field birds, waterfowl, game birds, exotic passerines, pigeons and sea birds. Some of this work is on populations of wild birds and information on this type of work is included in the section on Scientific Work Outside Designated Establishments in this Report.

The Table below shows the numbers of procedures started in 2006 in the main types of scientific work on different bird groups.(taken from Statistics of Scientific Procedures on Living Animals 2006).

Purpose of Work	**Domestic Fowl (*Gallus domesticus*)**	**Turkey**	**Quail**	**Other birds (includes ducks)**
Fundamental Biological research	18314	3256	14	6772
Applied studies – human medicine or dentistry	9	51		
Applied studies veterinary medicine	79260	336		442
Protection of man, animals or environment	134		413	2331
Education	137			
Direct diagnosis	1657	200		680
Breeding	422			
Totals	99933	3843	427	10225

Birds were used in 6500 studies conducted for regulatory purposes (toxicology) or other safety or efficacy evaluation procedures (2% of total). There were just under 6000 procedures on chickens for toxicology purposes and 94% of these were for pharmaceutical safety and efficacy. From our experience in inspecting poultry work we would expect that these studies were for the benefit of chickens, testing potential new vaccines or drugs to treat diseases suffered by chickens. Other toxicological usage of poultry would be for the assessment of environmental toxicity of agricultural chemicals. Ducks are typically used for this type of work.

Scientific Work on Poultry

Poultry Diseases

The majority of the procedures conducted on poultry are to study the diseases that affect these species and investigate ways to prevent, control or treat the diseases. In commercial poultry production, groups of birds are very large and veterinary treatment of individual animals is not

practical or economically realistic. In general, methods that prevent disease in the whole group of birds, e.g. vaccination or medication in food or water, are the preferred options. The increasing popularity of free range systems of housing has led to an increase in certain diseases e.g. worm infestations.

Free range systems though generally welfare friendly may expose the birds to a higher risk of some diseases.

A range of important diseases caused by a variety of organisms including parasites (e.g. coccidiosis, red mite) viruses (e.g. avian leucosis) and bacteria (e.g. necrotising enteritis) are being studied in the UK. All these diseases are of significant economic importance in commercial units and can have serious welfare implications for the birds.

For example red mite infestation is one of the most important skin parasite diseases affecting egg-laying birds. This parasite is found in many poultry sheds and is a blood feeder. The mites attack birds, mainly at night, causing blood loss, reduction in condition, irritation and stress to the birds and reduction in egg laying. In addition the mites occasionally bite humans causing painful skin irritation. Red mites live in cracks and crevices in poultry buildings and are very resistant to cleaning and disinfection processes. They can be killed utilising various chemicals but this treatment may not be fully effective (some mites have developed resistance to some common treatments) and the chemicals may have toxicity issues. Research work is aimed at understanding the biology of the parasites and in the longer term investigating and developing sustainable control strategies such as vaccination.

For this type of work researchers study the particular disease and obtain biological samples from birds that have been exposed to the mites. For novel vaccine testing, groups of vaccinated and unvaccinated birds are exposed to mites to determine if the vaccine is effective at reducing mite numbers or preventing deleterious mite feeding.

One of the main issues for inspectors when assessing and inspecting this type of work is to ensure the welfare of the birds, as the majority of these types of studies involve producing disease in the birds or mimicking the conditions experienced by the birds. Researchers need to ensure that the disease models they are using are as mild as possible, that birds are monitored very closely and any seen to be deteriorating in health beyond acceptable limits are killed promptly and humanely.

Animal production studies

Within the poultry industry there is a continual drive towards improving the production characteristics of the birds. This is particularly true for chickens and turkeys utilised for meat production, but is also relevant for egg laying hens. The rate of growth, feed conversion efficiencies and carcase qualities are very important for the industry and support work is done to identify the traits that are desirable and select for animals that show these. The majority of this work is done under commercial conditions but some of the basic scientific studies trying to determine the effect of the genetics of the birds on their performance and characteristics need procedures for collecting biological samples such as blood sampling or tissue biopsies which when done for a scientific purpose require licensing under ASPA.

Nutritional Studies

Manufacturers of feed have a wide range of materials that can be incorporated in diets for poultry and there is ongoing development in the design and testing of a variety of diets designed for specific types of poultry. The diet can have a profound impact on the quality of the end product be that eggs, e.g. egg shell quality, or meat. There are also specific issues relating to the impact of the diet on the health and welfare of the particular types of birds; extremely rapid growth in broilers (chickens for

meat production) may lead to particular deficiencies and laying birds that are producing large numbers of eggs can develop problems due to an imbalance of nutrients such as vitamins or calcium and phosphorus. Much of this work can be done in commercial flocks with relevant measures, such as growth rate, used to provide information. When these types of dietary studies are conducted in scientific establishments the effect is generally measured using feed intake and weight of birds. This enables the growth rate and feed conversion to be determined. These types of studies do not involve procedures that require regulation under ASPA. Studies that do require regulation under ASPA include those where biological samples such as blood are required and some nutritional studies where experiments are designed to study, scientifically, the nutritional requirements of the birds. This may include studies to determine the impact on birds of specific deficiencies, i.e. physiological studies. In addition, studies where new dietary constituents that might adversely affect bird health are being trialled require authorisation under ASPA, at least until it can be shown that they are not deleterious. Examples of such studies are the inclusion of alternative sources of protein that may not be digested properly or use of minerals in a form that they may not be absorbed after ingestion.

Behavioural and welfare Studies
One of the biggest issues for intensive poultry production is ensuring adequate welfare of the birds. Particular issues of concern are normal behaviours which become accentuated or adversely affect a minority of birds in an intensive management system, such as feather pecking.

Other studies are done to try to identify the types of conditions that would be favoured by poultry to improve their welfare. Many of these types of studies are funded by the Department of the Environment Fisheries and Rural Affairs (DEFRA) or its Scottish equivalent in order to provide information for those preparing legislation, policy or guidance documents for agriculture. The results are also useful to ASPI in that they can provide information on space requirements or the benefits of particular environmental enrichment methods or materials.

In general such studies are observational, involving little or no distress, and do not come within the scope of ASPA. However those which involve induction of particular behaviours, or altering housing or care conditions with the intention of determining the impact on the bird's welfare, usually need to be regulated.

This type of welfare and behaviour work includes studies aimed at improving housing and welfare of birds in a range of commercial situations. Examples are investigation of lameness and leg health in broilers, bone damage in laying hens in non-cage systems, laying hen welfare in enriched cages or in different housing systems, effect of rearing system on pecking behaviour, incidence of foot lesions in broilers and the comparison of showers with water troughs for ducks.

Regulatory work
Regulatory work falls into two main categories. The majority of the work is for development of veterinary products for use in poultry. Prior to a product being authorised for use in animals it has to be shown to be safe and effective. Studies are required to provide information to allow these criteria to be assessed. A range of poultry products, such as vaccines, antibiotics, antimicrobials, antiparasitics and vitamins, need to be tested in the target species. Some studies are done to ensure that the particular drug or vaccine given to the chicken will not pose a risk to humans who consume the poultry meat or eggs. In general, for each veterinary product a period of days (or weeks) after treatment must be observed before the meat or eggs can be sold for human consumption.

Some regulatory studies are required to test the environmental toxicity of particular chemicals. This work is for assessment of safety of materials and some of these studies use ducks.

Production of Biologicals
A small number of birds are used to provide biological materials for various laboratory tests. The growth of particular microbes or the detection of particular viruses may require materials that include blood obtained from particular poultry species e.g. goose blood used in tests for particular virus infections.

Hen's eggs have widespread use in scientific research. Antibodies are produced in the eggs and this can be a very effective method to provide materials for use in laboratories for e.g. diagnostic tests. If a mouse is utilised to provide antibodies after vaccination the yield of specific antibody when the mouse is killed and blood collected is in the region of 0.5mg whereas in chickens approx 200mg of specific antibody can be extracted from each egg, and the bird can lay an egg per day for several months. With respect to volume production, the use of hens for antibody production has a huge advantage. However, antibody from chickens is in a different configuration (immunoglobulin Y from birds rather than immunoglobulin G from mice and other mammals) and can be very difficult to extract from eggs. Although use of the chicken would seem to be a refinement, the suitability of the antibody product for a particular research project is important and the scientific requirements will dictate the most appropriate species for this work.

Hens transfer antibodies to their eggs, providing a relatively welfare-friendly way of producing large amounts of antibody for research use.

Fertilised eggs form a suitable environment to grow a variety of viruses. This has potential for the testing of biological materials to ensure they are not contaminated with viruses and also for use in research where growth of viruses is required. In addition, a large number of eggs are needed to grow virus stocks which are used in the production of some human or animal vaccines. The use of eggs in many of these indications will not require licensing under ASPA. An animal only becomes a 'protected animal' under ASPA, when 'half the gestation or incubation period for the relevant species has elapsed'. Developing embryos up to this time were not expected to have developed sufficiently to be able to perceive pain. So experiments that are completed before mid-incubation do not come within the scope of ASPA, and such studies may be considered to be a replacement for animal studies under ASPA. However, experiments on embryonated eggs that are kept beyond the mid-stage of incubation will require licensing unless they will not cause pain suffering distress or lasting harm.

Studies on Genetically Altered (Transgenic) Poultry

The aim of this research is to develop improved transgenic technologies for use in domestic poultry. Various methods are employed to alter the genetic make up of animals and may be used for, or investigated for applicability to, poultry. Current work includes improving the process of developing transgenic animals and investigating alternative gene delivery options. This technology is being used in studies of vertebrate developmental biology, disease resistance, and production traits in domestic poultry. Proof of concept studies have been performed using the gene for green fluorescent protein (GFP) as this allows a simple means of identifying the transgenic chicks i.e. chicks with the implanted gene glow green under special lighting. Future studies are likely to use genes of interest that may be involved in development and include those of relevance to commercial traits, including sex determination, reproduction, and bone and muscle development.

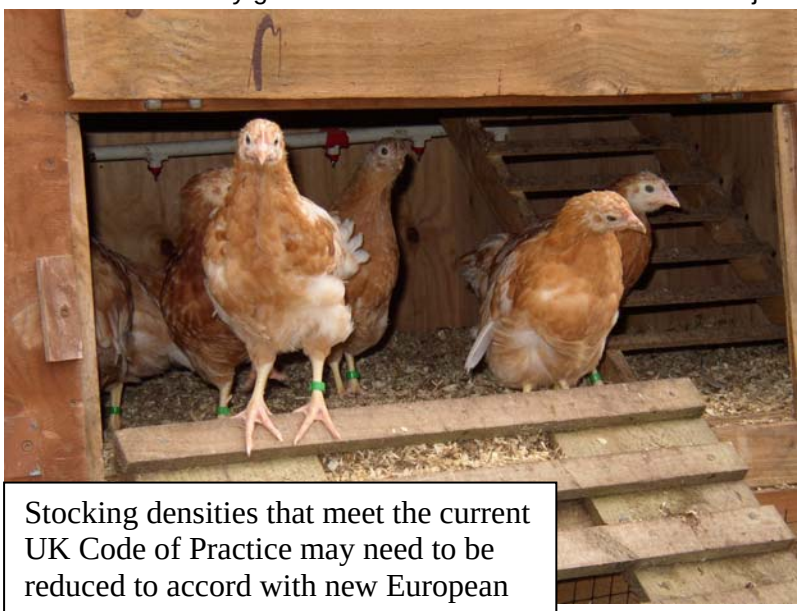
A major application of transgenesis in livestock species has been the development of transgenic animals that express pharmaceutical products in the mammary gland, allowing the products to be recovered from the milk. In poultry the introduction of genes for human therapeutic proteins driven by promoters such as ovalbumin may permit the use of laying hens for producing such proteins in eggs more efficiently, safely and economically than by current production processes.

Housing and husbandry

Poultry used in research are maintained in a range of housing systems. For some work there is a scientific need to mimic commercial conditions and guidance on required standards is provided in the DEFRA Welfare Codes and relevant authorities in Scotland, Wales and Northern Ireland. For the majority of work under ASPA the standard of facilities and environmental conditions as set out in the Code of Practice for the Housing and Care of Animals used in Scientific Procedures (CoP) should be adhered to. The challenge for inspectors when checking work on poultry at establishments is to ensure that the housing conditions are suitable both for the welfare needs of the birds and for the scientific requirements of the particular studies.

During 2006 the revised Appendix A to the European Convention ETS123 was agreed and the expectation is that these standards will be implemented in the UK in the future. Appendix A includes general recommendations on housing and care and specific recommendations for a range of bird species including chickens, turkeys, quail, ducks and geese. The recommendations include, the need to rear chicks on solid floors with litter, implementation of measures to reduce feather pecking, avoiding the use of low level lighting for prolonged periods and preventing beak trimming.

Specific recommendations are made on housing conditions. These include provision of enrichment and encouragement of natural behaviours through the inclusion of, for example, perches, dust and water baths, nest sites, nesting material, pecking material and substrate for foraging. Birds should also be housed in social harmonious groups (birds should not be single housed unless justified on welfare or veterinary grounds or where there is sound scientific justification).



Stocking densities that meet the current UK Code of Practice may need to be reduced to accord with new European provisions.

The current UK CoP has tables detailing the recommendations for the minimum sizes of enclosures for chickens and ducks (combined), quail and pigeons. However, the new Appendix A makes specific recommendations for space allowances for a wider range of species including domestic fowl (chickens), turkeys, quail, ducks and geese. Overall there is an increase in the recommended space allowances and figures for housing of chickens are compared below. There are also differences in the minimum height recommendations. Appendix A requires birds over 1200g to be given at least 75cm whereas in the CoP birds up to 1800g require a minimum of 50cm and it is only when birds reach a weight of 2400g that 75cm is required. To meet the standards in Appendix A it is anticipated that changes will be required to the facilities and conditions provided for poultry used in research the UK.

Comparison of space allowances for chickens between the CoP and Appendix A

Body Mass (g)	**CoP (m2) Group/singly**	**Appendix A (m2) Min size/ per bird**
Up to 200		1.00 / 0.025
Over 200 to 300	0.025 / 0.035	1.00 / 0.03
Over 300 to 600	0.047 / 0.07	1.00 / 0.05
Over 600 to 1200	0.083 / 0.125	2.00 / 0.09
Over 1200 to1800	0.095 / 0.145	2.00 / 0.11
Over 1800 to 2400	0.12 / 0.17	2.00/0.13
Over 2400	0.19 / 0.28	2.00/0.21

In the CoP space allowances are given for animals housed in groups and a minimum for a single housed animal whereas in Appendix A there is a minimum enclosure size (whether for single animal or small group) and a recommendation per bird in a group housing situation.

Avian Influenza

Avian Influenza refers to a large group of different influenza viruses that primarily affect birds but in some instances may become altered and can infect other species including pigs and humans. The vast majority of avian influenza viruses do not infect humans. The stain of current concern throughout the world is H5N1 which is a bird virus but can cause disease in humans in very close contact with infected birds. However, this bird virus has not been passed from human to human. Experts believe that the H5N1 strain has the potential to adapt and some time in the future may become a new human influenza virus that could spread throughout the world. H5N1 emerged in South East Asia in 2004 and has spread west through Europe and Africa.

Holding geese outside may be welfare friendly but carries a higher risk of contracting avian influenza.

There is a new European Directive in place to implement control measures in the event of outbreaks of Avian Influenza in Europe in domestic poultry and wild birds. This has been transposed into UK legislation by DEFRA and relevant bodies in Scotland, Wales and Northern Ireland. The Inspectorate were involved in consultations during the drafting of this legislation to ensure there was the possibility of protecting poultry being used for research from general culling of birds should there be an outbreak of disease. This was with the important proviso that there were adequate biosecurity measures in place in the research environment to reduce the risk of infection and disease spread.

Scientific Work Outside Designated Establishments

Introduction

Various aspects of scientific research cannot be done in the controlled confines of a laboratory or institutional premises. Animals may need to be studied in their natural habitat or under conditions that cannot be replicated in the laboratory. Such research is permissible under the Animals (Scientific Procedures) Act 1986 (ASPA) if the "programme or procedures ….. require" it (ASPA section 6 (2)). The places involved are in the countryside, on the open sea or can be commercial establishments such as farms and stables. These places have to be specified on the licences for the work, although that may have to be in general wordings. For example a study involving blood sampling of barn owl nestlings to determine what diseases they suffered might specify "Farms in south-west England where barn owls are recorded". For administrative purposes the places are categorised as Places Other than a Designated Establishment, or PODEs.

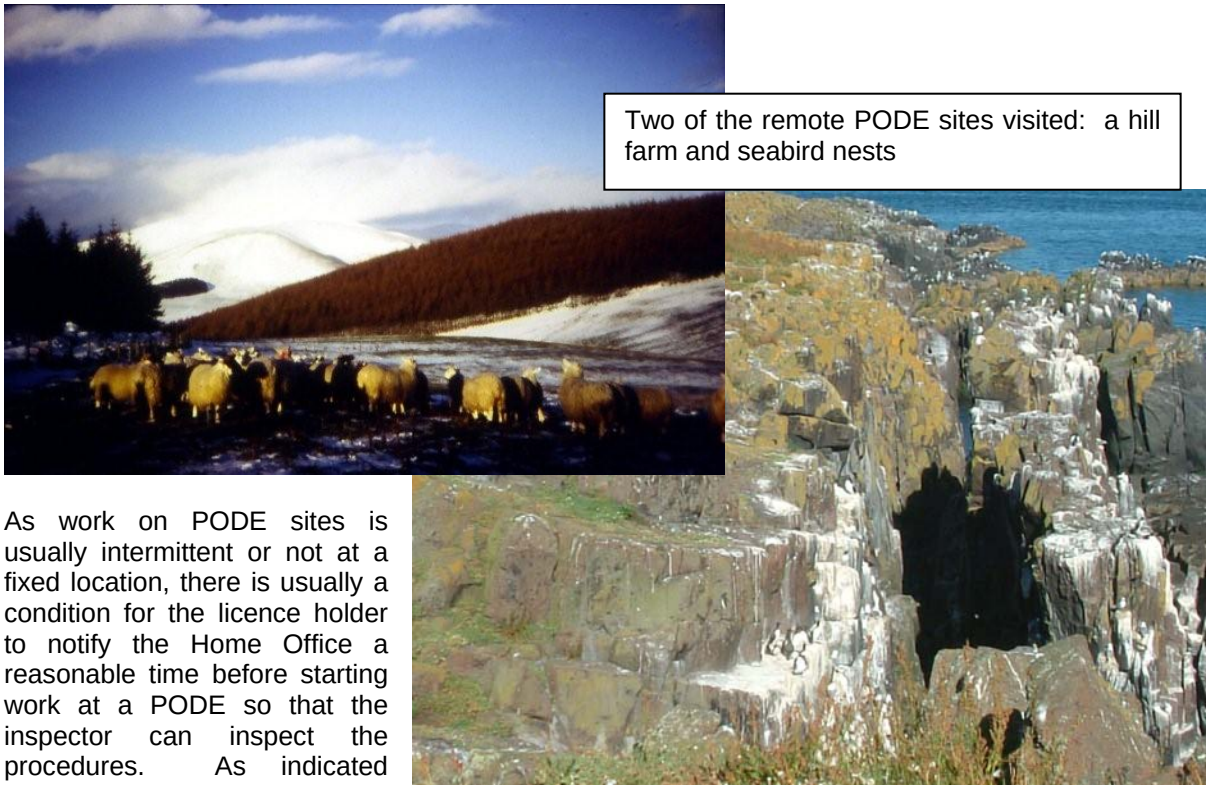
Monitoring of PODEs by inspectors is particularly important as in work outside of a designated establishment there are fewer safeguards for the animals studied. The places where the work is conducted do not have a Certificate of Designation so;

- there is no certificate holder, named-day-to-day care person (NACWO) or named veterinary surgeon (NVS);
- the conditions for the care and husbandry of the animals may not meet the standards in the Codes of Practices for care and husbandry.

For example, for some agricultural research it is important that housing conditions are those of a typical farm. In these cases, space allowances may be less than those required for other licensed work. There are, however, controls through the licensing system. Project licences for such work are only granted if there is a good case for research outside of a designated establishment, and all the personal and project licences must be held at a designated establishment, so the certificate holder can exert some management control and the Named Veterinary Surgeon there can advise on the nature and conduct of the procedures.

Inspection of Work Outside Designated Establishments

To inspect the research at PODEs, Inspectors often need to visit remote locations, and out of normal working hours.



Two of the remote PODE sites visited: a hill farm and seabird nests

As work on PODE sites is usually intermittent or not at a fixed location, there is usually a condition for the licence holder to notify the Home Office a reasonable time before starting work at a PODE so that the inspector can inspect the procedures. As indicated

above, work at a PODE may be considered of higher priority than similar studies at a designated establishment due to the lack of designated establishment controls. Decisions are influenced by likely public interest, e.g. species, level of intervention, expected adverse effects, when sites may be subject to public scrutiny and / or the work may be politically sensitive.

Whilst inspectors have the right to enter designated establishments at reasonable times, they do not have the right to "trespass" on PODEs. Therefore, as part of the licensing process, inspectors require that the owner's permission is received to allow the Inspector to inspect the work at that site.

Inspectors also may need to make appropriate biosecurity measures to prevent spread of diseases, particularly where livestock may be at risk.

Disinfecting wellingtons before inspecting farm animals on a PODE site

Types of Studies

In 2006 there were 88 projects in force with authority to work at PODEs, although nearly a third of these did not make use of that authority during the year, either because no studies took place or because the work was conducted at designated establishments.

Active projects included:

- welfare research in farm animals;
- pathogenesis, epidemiology and control of diseases of farm and companion animals;
- efficacy and safety studies of pharmaceuticals in companion and farm animals;
- ecotoxicological studies
- population studies on wild mammals, birds, amphibia and reptiles;
- behaviour and ecology studies on wild mammals, birds, amphibia and fish;
- pathogenesis, epidemiology and control of diseases of wild animals, fish and birds;

Investigating the decline in red squirrel populations requires work in the wild

As can be seen from this overview of the projects, broadly speaking there are two types of work outside designated establishments

- farm or companion animal studies
- work in the wild

In the former the work is at places where people own, have charge of, or

are caring for the animals, and they have access to veterinary care. In the latter, there is generally little direct human interaction with the animals under study, unless captured and held the animals do not have veterinary care, and the sites are often remote.

PODE work on Farm and Companion Animals

Where farm or companion animals have to be studied in their farm or home environment sampling, and in a few cases administering agents such as vaccines, has to be done at the establishment where they are kept and this is designated as a PODE. The species of animals authorised for use in the latter types of studies include:

- farm animals such as poultry, cattle, sheep and pigs;
- companion animals such as horses, donkeys, cats and dogs.

A major reason for studies on farm or companion animals outside of designated places is to investigate a particular disease which cannot be reproduced at a designated place or where it is important to investigate the natural disease in the environment in which it is occurring. Often the cases are sporadic and unpredictable. Researchers will go out to sites where an animal with the disease has been diagnosed and examine it, take blood samples or tissue biopsies, and in some cases initiate an experimental treatment. After sampling the animal will be observed to check for, and deal with, any evident ill-effects, and the local personnel given appropriate instructions on how to safeguard the animal's welfare should adverse effects become apparent later. In the unusual cases where some form of experimental treatment is set up (one that cannot be deemed recognised veterinary practice, or be covered by an Animal Test Certificate granted under the Veterinary Medicines Regulations, such as a novel formulation for which further data is needed to meet the requirements for an ATC) this will be with veterinary involvement and specific monitoring instructions.

For some studies samples need to be taken from farm animals in the environment in which they are normally kept.

Sometimes the animal could in theory be transported to a designated establishment for study, but the work requires only one or two samples, which can be taken in the field, and the distress to the animal of travelling is not warranted. In these cases, sampling on site is needed to minimise adverse effects. For example, in an investigation of the genetic diversity in a rare breed of sheep, the farms or smallholdings where the breed is held would be specified as PODE sites and a single blood sample will be taken from the sheep there.

Work in the Wild

The sort of work conducted on wild animals is generally very different from that undertaken on farm and companion animals. The table below shows the major types of work conducted, and the types and numbers of animal involved as reported by project licence holders in their individual annual returns of procedures. In addition some ecotoxicology work on fish may have been done in the wild. This has been excluded from the table as the returns do not distinguish between procedures done at designated establishments and those performed off-site, and for toxicology there was no other available information to allow those procedures conducted at PODE sites to be separated from the

rest. For the same reason the figures in the table for wild fowl disease work and studies on deer and sheep may include procedures undertaken at designated establishments.

Nature of study	Animals used	Numbers in 2006
Disease and parasite studies; Field trials;	Amphibians Frogs, Toads Newts Fish Badgers Bats Water voles Bank voles, field voles, woodmice Wildfowl	 114 122 2505 339 452 160 1108 609 (66 CITES species)
Factors affecting health and behaviour	Songbirds, garden birds Game birds Seabirds Wildfowl	975 120 200 16
Ecology, population studies Migration	Fish (mainly fresh water species but including salmon and 226 marine fish) Songbirds, garden birds Game birds Birds of prey Seabirds Polecats, pinemartens, mink Bats Hares Bank voles Seals Deer Sheep	24671 2169 50 32 233 35 1028 65 209 219 88 63
General physiology, reproduction, olfaction	Fish	1260

Watervole being carefully handled before taking a small blood sample as part of an epidemiological study.

<u>Particular considerations for work in the wild</u>

Animals to be studied – any CITES listed species

Rarely, work may be done on more unusual species including species listed in CITES[5]. Such animals may only be used for "research

[5] CITES Appendix 1 to EEC Council Regulation No. 3626/82

aimed at preservation of the species in question or essential biomedical purposes where the species in question exceptionally proves to be the only suitable for the purpose" (ASPA S10(3)). Past studies using CITES listed at PODEs have included studies to tag and mark endangered birds to understand movements and behaviours, enabling the protection of, or provision of additional, protected environment.

Trapped badger – sleeping.

Capture of wild animals.
Unless the method of capture is itself under scientific study, capturing of wild animals is regarded as husbandry and the capture method used is not regarded as a regulated procedure. It is the responsibility of the licensee to ensure compliance with all other legislation, such as that administered by English Nature, Scottish National Heritage, or the Countryside Council for Wales.

Release to the wild in the course of regulated procedures.
Animals may be released back to the wild with the expectation of obtaining further information from at least some of them. This will include animals with transmitters and those from which sequential blood and tissue samples or physiological and clinical monitoring data may be required. These animals are considered to be still undergoing regulated procedures. Safeguards are required to protect the animal's health and well-being and ensure its release poses no danger to people or the environment.[6]

Anaesthetised badger with tracking collar fitted.

Re-capturing and consequences of failure to recapture animals.
Re-capture can add to the welfare cost of the procedures although in some situations some animals appear not to find the experience too aversive and are trapped at a high frequency.

Failure to re-capture can affect the number of animals used. For example if the required experimental group size is 10, and the recapture rate is 10%, then scientific procedures will need to be carried out on 100 animals.

It may also have welfare or environmental implications. For example a failure to recover and remove equipment that has been attached for the purpose of collecting data may impact on the animal or the equipment or may contaminate the environment. Some transmitter collars can be made to release over time thus reducing the welfare implications of re-capture failure.

[6] Under ASPA s10 3(B)&(C) setting these animals free needs the "prior consent of the Secretary of State" who "shall not give his consent …… unless he is satisfied-
(a) that the maximum possible care has been taken to safeguard the animal's well-being;
(b) that the animal's state of health allows it to be set free; and
(c) that the setting free of the animal poses no danger to public health or the environment."

Some General Considerations for Scientific Work Outside Designated Establishments

Arrangements for checking animals at the end of the procedures
Once the use of an animal at a PODE is finished the animal may be discharged from the controls of ASPA, if suitable. This can be back to the wild or, for example, to a farm. Animals may also be killed but this is rare. For some species, such as badgers, legislation will prevent the killing of the animal without licence.

A veterinary surgeon, or, if none is available, another suitably qualified person[7] should determine the suitability of an animal for discharge, and provide an appropriate certificate. For farm and companion animals a veterinary surgeon may well be available for this but for work in the wild it is usually an expert on the team. Normally such an expert is designated beforehand as a "suitably qualified person" by the project licence holder after consultation with a veterinary surgeon. Suitable documentation must be kept to avoid inadvertent re-use (see below).

Some species studied in the wild, such as mink and grey squirrels, may require a licence under other legislation before they can be set free due to concerns about adverse environmental impact arising from their release.

Records
Records need to be kept of the regulated procedures performed and of whether animals released in the course of procedures or discharged at the end of the procedure met the legal criteria (see footnote above).

Recording details of the procedure and the animal after blood sampling a pig at a farm.

Re-use
ASPA requires that use of an animal for a second or subsequent time should have permission from the Secretary of State, and must meet the conditions detailed in ASPA s14. Re-use is thus normally authorised in advance in the project licence.

Provided good records are kept and documentation showing that the animal has been subjected to regulated procedures accompanies the animal throughout its life, inadvertent re-use should not occur with farm or companion animals, but it is a particular risk in studies involving wild animals. Various strategies are used to try and minimise this and usually involve marking the animal in some way.

Public access and view, and security
A secluded site that cannot be seen from public areas and where there is controlled access is usually preferable in the interests of science and animal welfare. However inspectors have found that where this is not possible the public has usually been interested and supportive of the work being done, and neither scientific quality nor quantity has been compromised.

[7] Under section 10(3D)(a) of ASPA, a veterinary surgeon or if none is available, another suitably qualified person, determines whether an animal should be killed or kept alive.

Work in the wild may have to be done near a public road to allow access to anaesthetic or marking equipment which is not portable. This is a site used for studying salmon.

Facilities at the site

Inspectors usually make a judgement as to whether the buildings and/or work areas and/or equipment are likely to be adequate for the work to be performed. Such facilities may not be to recognised Code of Practice standards but must be suitable for the proposed studies.

Pig in crush prior to taking a blood sample. A farm site should have facilities like this or other suitable arrangements so that the animals can be handled and sampled with the minimum of stress.

Arrangements for recognising and dealing with sick animals.

Occasionally wild animals may be caught that are suffering from a natural illness such as phocine distemper in seals. Whilst the Named Veterinary Surgeon attached to the designated establishment where the project licence has availability has no legal responsibility at PODEs, he or she will often help with personal licensees' training, ensuring that there is a licensee able to recognise ill health in the relevant species and deal appropriately with such animals.

A local vet may have under his care the animals that are on scientific procedures at a farm site. He/she may attend and assist in recognising problems and providing appropriate medicines and care.

Summary

Work outside designated establishments is wide-ranging both in type and species involved. In general it is well conducted, with few instances of non-compliance. Inspectors make a point of visiting to see the procedures being conducted and strive to ensure animal welfare is as near as practicable to the standards reached in designated places.