Home Office

Animals Scientific Procedures Division & Inspectorate

Annual Report 2010

Contents

We are grateful to the Moredun Research Institute and the University of Edinburgh for supplying some of the photographs used in this report.

Foreword

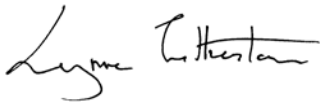
I am very pleased to introduce the 2010 Annual Report of the Home Office Animals Scientific Procedures Division (ASPD) and Animals Scientific Procedures Inspectorate (ASPI).

2010 has been a challenging year in which the policy and licensing teams and the Inspectorate have worked closely with external stakeholders and with colleagues across Whitehall to take forward a wide range of issues.

Of particular significance was the completion of the negotiation of the new European Directive to replace Directive 86/609/EEC on which current UK legislation is based and the work undertaken on plans to deliver the coalition agreement commitments to work to reduce the use of animals in scientific research and to end the testing of household products on animals.

At the same time, the routine work of licensing and inspection continued unabated and to established high standards, amply demonstrating the professionalism and commitment of the staff of both units.

Everyone deserves to be congratulated on a successful year.



Lynne Featherstone
Minister for Equalities and Criminal Information

Introduction

This report of our activities during 2010 describes significant progress made by the twin units of the Division (ASPD – comprising the licensing section and the policy team) and the Inspectorate (ASPI) working together to deliver our shared objectives in regulating the use of animals in the UK under the Animals (Scientific Procedures) Act 1986.

The volume of work in assessing, issuing and amending licences and certificates during 2010 has been typical of recent years and we are pleased to report that our performance targets have been well exceeded. Decisions on inspection are risk based and we describe in this report some of the factors which go into the process of risk assessment. We also provide details of non-compliance that occurred during the year.

A number of significant initiatives were moved forward during 2010 and are described in this report. These include advancing our IT Strategy to develop a web-based licence application process which will benefit our stakeholders as well as ourselves by improving overall access to information within a secure environment.

The adoption of the new European Directive 2010/63/EU was also a landmark followed, in the last quarter of the year, by the early stages of preparing for its transposition into UK legislation. The new Directive will strengthen the protection of animals used in scientific procedures and promote the development of alternatives. It will set the framework for the regulation of animal research for some years to come.

In June 2010, the new coalition government announced two commitments of relevance to us and we describe these as well as some important advances made during 2010 with implementation of the 3Rs (Reduction, Refinement & Replacement). In addition, the topic of animal research attracts great interest from the public and parliamentarians alike, and our communications role is immensely important, providing accurate and informative responses in a prompt and helpful manner.

Alongside these developments, our day-to-day business of licensing and inspection has continued unabated against the backdrop, from mid-year, of the government's deficit reduction programme to which we made our initial contribution in common with other Home Office units. It remains important that we make use of all our resources as efficiently and effectively as possible to ensure we continue to provide a high quality regulatory system which demonstrably delivers value for money.

Martin Walsh
Head of Animals Scientific Procedures Division

Judy MacArthur Clark
Chief Inspector, Animals Scientific Procedures Inspectorate

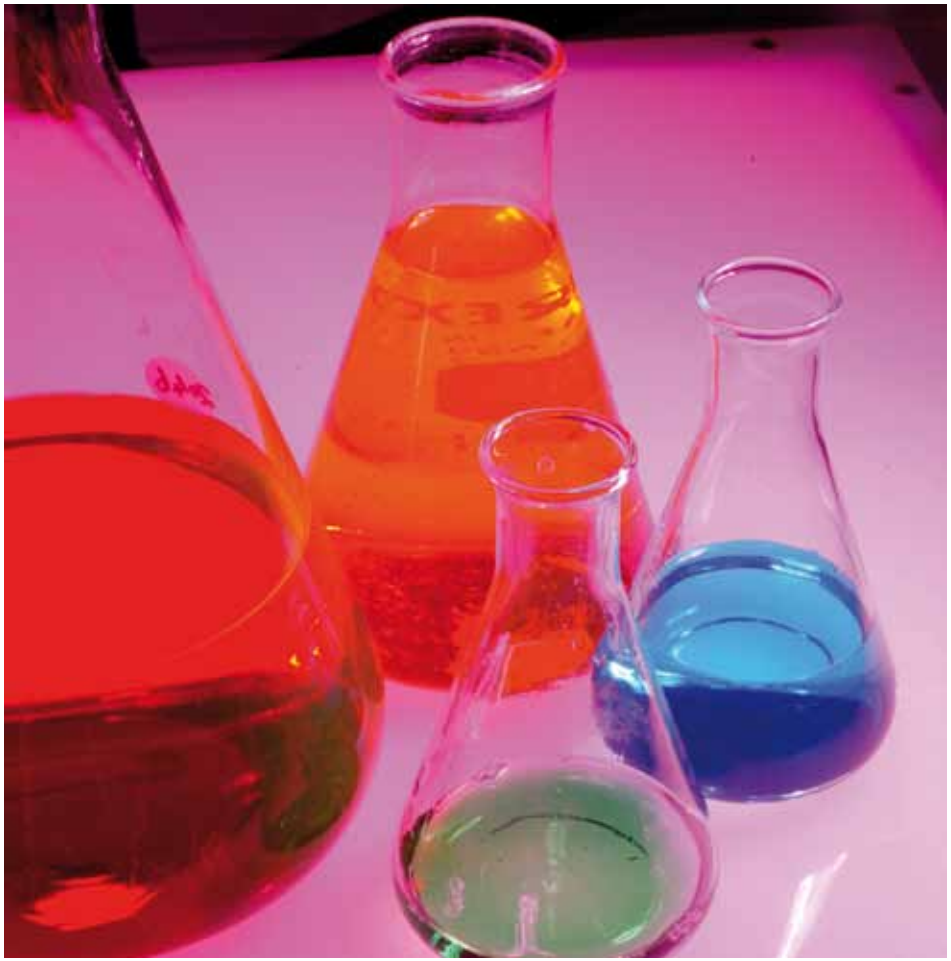
Section 1 Licensing and inspection

The Licensing Section

The Animal Procedures Licensing Section (APLS) is part of the Animals Scientific Procedures Division (ASPD). The section operates the licensing system on behalf of the Secretary of State under the Animals (Scientific Procedures) Act 1986 (ASPA). It authorises applications for new licences and certificates; authorises amendments to existing authorities; and revokes or varies licences and certificates as necessary, following advice from the Inspectorate, and sometimes from the Animal Procedures Committee. APLS staff are responsible for instigating executive action when there has been significant non-compliance.

APLS also administers the collection of annual fees from designated establishments and of annual statistical returns of procedures from project licence holders.

On 31 December 2010 there were 23 licensing staff in post, with four each based in Cambridge and Dundee, three in Shrewsbury, two in Swindon, and 10 (including the management team) in London.

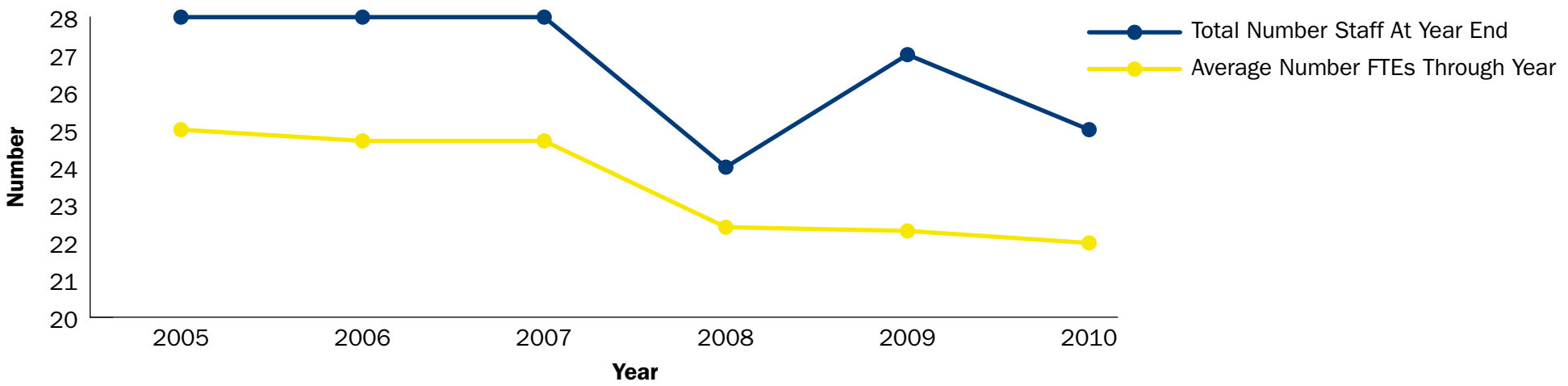


The Inspectorate

The Animals Scientific Procedures Inspectorate (ASPI) started the year with a total headcount of 27 inspectors, including the Chief Inspector and five Superintending Inspectors. Administrative support was provided to the Inspectorate by an executive officer. One inspector spent six months of the year on secondment to the Forensic Science Regulator and two inspectors left in October 2010. The average strength of the Inspectorate (number of Full-Time Equivalents (FTEs) actively inspecting) over the year was similar to previous years (22.1 in 2010; 22.7 in 2009; 22.4 in 2008) (Figure 1).

ASPI inspectors spend approximately one-third of their time visiting establishments and about one-third assessing applications for licences and certificates. The remaining third includes ASPI's significant outreach programme (e.g. supporting stakeholder

Figure 1 Inspectorate staff 2005-2010



initiatives on working groups), strategic initiatives to enhance ASPI's service delivery, and participating in continuous professional development events to ensure skills are maintained and developed.

On 31 December 2010 the total ASPI headcount was 25 with 21 FTEs actively inspecting, the remaining effort being assigned to management and implementation of the EU Directive.

Personal licences and certificates of designation

Table 1 summarises the unit performance and statistics in terms of personal licences and certificates of designation for 2010.

During 2010 ASPI advised on, and ASPD granted, 2,664 personal licences. This was a small increase (0.7%) compared with 2009. Of the personal licences granted in 2010, only 12 (0.5% of the total) were requested to be processed under "fast-track" procedures.

The Inspectorate provided advice on, and licensing staff granted, 3,754 personal licence amendment requests and reviews. This was a decrease (6.1%) of 244 compared with the number granted in 2009 (3,998).

Table 1 Breakdown of licence and certificate applications and amendments

	Total			Per FTE		
	2010	2009	Change	2010	2009	Change
PILs granted	2,664	2,645	+0.7%	117.4	118.6	-1.0%
PILs amended	3,754	3,998	-6.1%	165.4	179.3	-7.8%
PILs in force	15,721	15,492	+1.5%	692.6	694.7	-0.3%
PCDs granted	4	7	-43%	-	-	-
PCDs amended	375	347	+8.1%	16.5	15.6	+5.8%
PCDs in force	188	190	-1.1%	8.3	8.5	-2.4%
PPLs granted	515	541	-4.8%	22.7	24.3	-6.6%
PPLs amended	1,645	1,879	-12.5%	72.5	84.3	-14.0%
PPLs in force	2,614	2,658	-1.7%	115.2	119.3	-3.4%

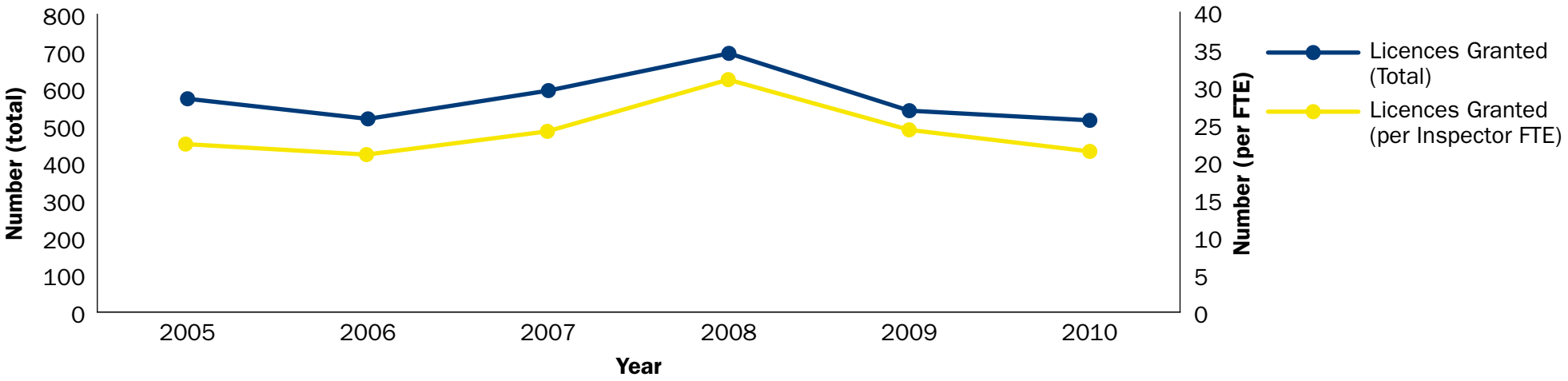
The Inspectorate provided advice on four applications for new certificates of designation in 2010, compared with seven in 2009. There were 375 requests for amendments to existing certificates in 2010, an increase of 28 (8.1%) on the 347 requests in 2009.

Project licences

Table 1 also shows performance and statistics in terms of project licences for 2010.

The assessment of project licence applications is by far the most time-consuming activity for inspectors and licensing staff. In total, the Inspectorate advised that 515 project licence applications should be granted, as well as providing initial advice on 44 preliminary applications that were not proceeded with (Figure 2). The number of project licences granted decreased by 4.8 per cent between 2009 and 2010. Inspectors also gave advice on 1,645 requests for amendments to existing project licences in 2010, a decrease of 12.5 per cent on the 1,879 requests in 2009.

Figure 2 Project licences granted 2005-2010



The APLS and ASPI shared performance target for project licence applications is for licensing decisions to be made within 35 working days of receipt in at least 85 per cent of applications. Figure 3 shows the performance trends against targets for the last six years.

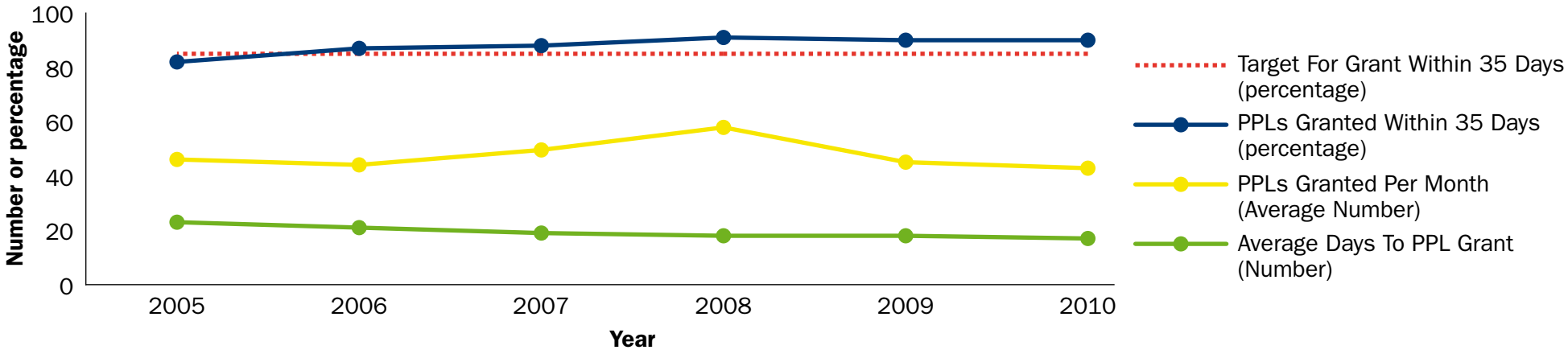
Average processing time is at an all-time best of 17 days, and this is the fifth consecutive year that the processing time has fallen. Consequently, the percentage of licences granted within 35 days continues to exceed the target.

Inspection

ASPI operates a risk-based inspection scheme for work conducted under ASPA (see Page 19). In the course of the 2010 inspection programme, ASPI inspected work being carried out by 15,721 personal licensees under 2,614 project licences at 188 designated establishments (figures correct at 31 December 2010 – see Table 1).

During 2010 the Inspectorate carried out 1,984 visits to places where scientific work

Figure 3 Project licence application processing 2005-2010



on animals was conducted. Seventy-five per cent of visits to animal units were made without notice (45.2% of all visits were unannounced). These inspections amounted to 5,690 hours of contact time with those holding licences or certificates under ASPA, in addition to 4,806 hours spent travelling. The overall number of visits and total contact hours were down very slightly from 2009 (0.5% and 1.3% respectively). The time spent travelling showed a small increase of 2.3 per cent (Figure 4). The average number of visits per FTE increased slightly (88.1 in 2009 compared with 89.7 in 2010) as did contact time per FTE (257 hours in 2010 and 255 hours in 2009) (Figure 5).

The amount of time spent travelling is related to the geographical distribution of inspectors and the locations of establishments that they inspect. Whilst every effort is made to reduce this to a minimum, decisions on inspection responsibilities cannot be based solely on geographical proximity.

Figure 4 Inspections 2005-2010 (Total)

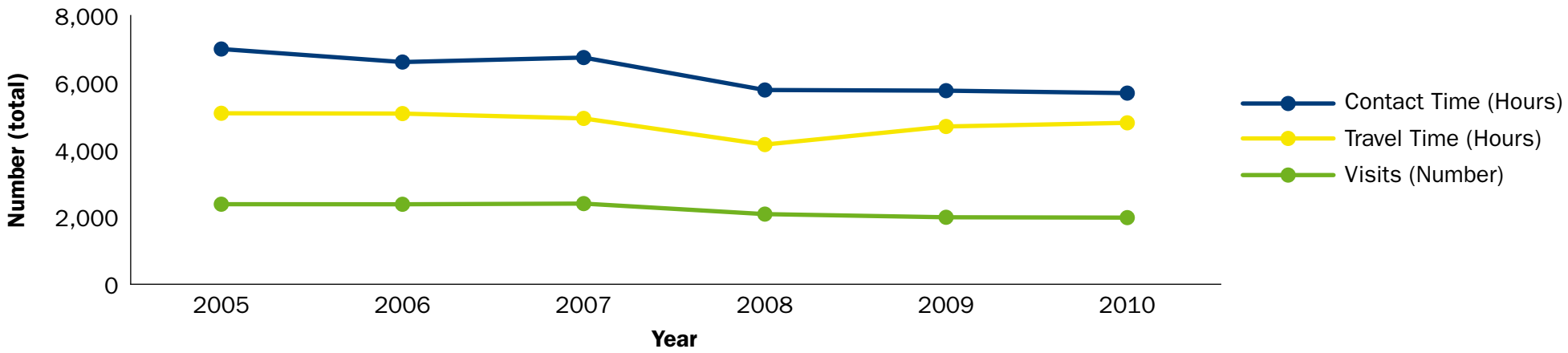
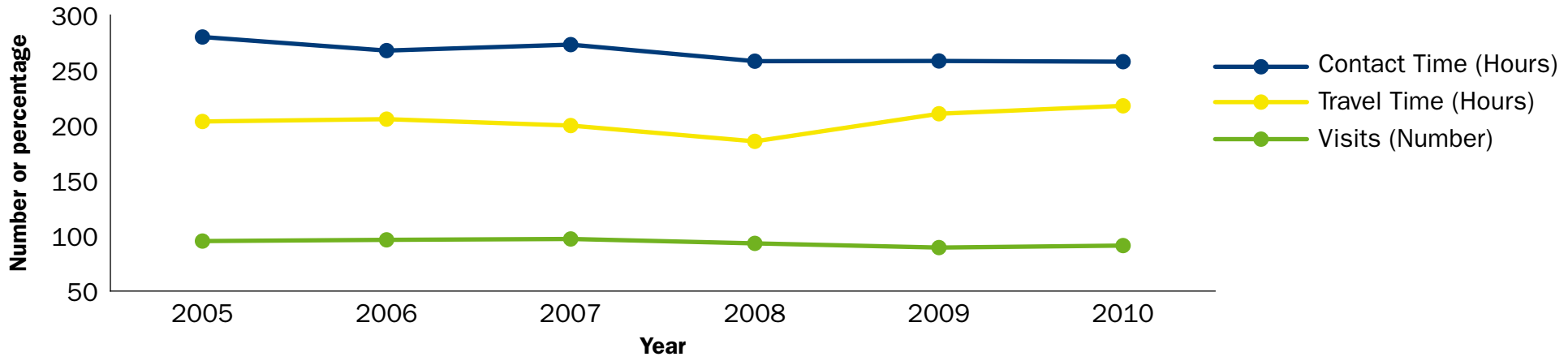


Figure 5 Inspections 2005-2010 (per FTE)



Section 2 Compliance and infringements

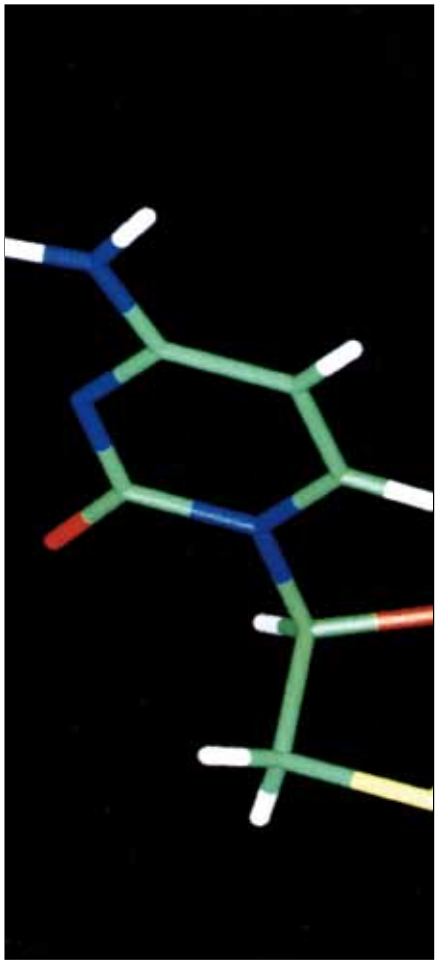
A major function of visits is to determine whether designated establishments and licensees are complying with the provisions of ASPA and with the conditions of their licences and certificates. This is a statutory requirement, under section 18 of ASPA. Inspectors report any non-compliance, and make appropriate and proportionate recommendations for the action required, which is generally aimed at the prevention of repeated faults. Inspectors also advise licensees and others how to comply, and generally promote a culture of compliance.

Compliance advice cases (those that are not categorised as A to D) are recorded in the inspector's visit report, and are collated and reported annually to the Secretary of State. In the case of category A to D infringements, formal reports are submitted to the Secretary of State as soon as the inspector's investigation is complete. The main characteristics of the categories can be found in Appendix 2.

In 2010, there were 108 cases where compliance advice was given (e.g. the fabric of a building was below the standards set out in the Code of Practice, the records of a project licence were not complete, or a cage label had not been filled in properly), and 33 infringement cases were completed (ten category A, 14 category B and nine category C infringements). In establishments with a good culture of compliance, it is very often the case that it is the licensees or the certificate holder or their staff who report suspected non-compliance to the Inspectorate: in 2010, 18 of the 33 infringements were self-reported. The Inspectorate found four category A, eight category B and three category C infringements.

Category A infringements

In eight of the ten cases, procedures (e.g. blood sampling, intraperitoneal injection) were carried out competently but without the necessary authorisations. In one case, some animals were held overnight in transport boxes, but were unharmed. In the remaining case, there was an unauthorised transfer from one licence to another of animals undergoing procedures.



Category B infringements

1 In a rack of individually ventilated cages, where food hoppers were at the back of the cage, technical staff mistakenly allowed the food to run out. Two mice died. A further seven were found without food in another cage, but made a full recovery after being fed. This case was self-reported. Improved standard operating procedures and staff supervision were put in place, and the Certificate holder was admonished.

2 Three rats, which had undergone cervical spinal surgery the previous day, were in poor condition and had not received the required post-operative analgesia. The animals were subsequently given analgesia, and when seen later by the inspector had recovered well. The incident was discovered by the inspector. The licensee was admonished, and was required to undergo re-training in modules 1 to 4 (See Annex J to Home Office Guidance).

3 Six horses had jugular cannulae inserted under local anaesthesia. The cannulae were held in place by stay sutures. Substances were administered, and blood samples were taken, via the indwelling cannulae, over a six-hour period. This was done without relevant personal or project licence authority. The incident, which was self-reported, occurred because the licensees did not check the personal and project licences before starting the procedure. The establishment reviewed and improved staff management and supervision. The project licensee and a personal licensee were admonished, and the project licence holder was required to undergo re-training in module 5.

4 A personal licensee attempted to take a blood sample by cardiac puncture from a conscious chicken. The supervisor intervened to stop the licensee, though the chicken at that stage had suffered a needle stick. The procedure was not authorised by either the personal or the project licence, and would not have been authorised, had licence authority been sought. The personal licence holder had, previously, performed the procedure while working in another country. The incident was reported to the inspector by the establishment's Home Office Liaison Officer. The personal licensee was admonished, and was allowed to work only under direct and continuous supervision for the next year.

5 An anaesthetised guinea pig was left unattended by a personal licensee. The work was done in an area not listed in the schedule to the certificate of designation. Furthermore, cage labelling, project records and supervision were found to be inadequate. The incident was discovered by the inspector. The project licence holder voluntarily undertook re-training in modules 1 and 5. Record-keeping by the project licensee was improved, arrangements were made to allow the tracing of animals from first regulated procedure through to termination, the supervision of the personal licensee was improved, and greater oversight by the Named Animal Care and Welfare Officer (NACWO) of the work was put in place. Both the personal licensee and the project licensee were admonished.

6 Through poor internal management, animals were allowed to be kept in areas not listed in the schedule to the certificate of designation and that did not meet Code of Practice standards. The incidents were discovered by the inspector. The establishment instituted new procedures to prevent a recurrence, including further training for laboratory staff with emphasis on the requirements of ASPA and the promotion of best practice. The Certificate holder was admonished.

7 The project licence controls on blood collection procedures in sheep and horses were not observed: the frequency of blood collection, and the volume of blood taken, was greater than authorised. The incident was discovered by the inspector. The project licence holder was admonished.

8 A personal licensee implanted minipumps into four mice without personal or project licence authority for that procedure. The licensee was an experienced surgeon, and the procedure was done competently. The incident was reported

to the Home Office by the licensee. The licensee was admonished and was required to undertake re-training in modules 1 and 5.

9 Over a period of six months, an experienced researcher, who had completed relevant training abroad and in the UK, performed regulated procedures on mice without personal licence authority. The researcher mistakenly believed that the UK training certificates constituted a personal licence. The incident was discovered by the inspector. Management systems were improved to reduce the likelihood of recurrence. The researcher was censured and required to re-take module 1 before an application for a personal licence could be considered.

10 A project licensee commissioned the breeding of a significantly greater number of genetically altered mice than authorised. The case was reported to the inspector by the establishment's Home Office Liaison Officer. The inspector also found that the project records were inadequate. The Certificate holder improved the establishment system of controls in order to minimise the likelihood of non-compliance. The project licence holder was admonished and required to review all the standard conditions of the project licence to foster future compliance with the Act.

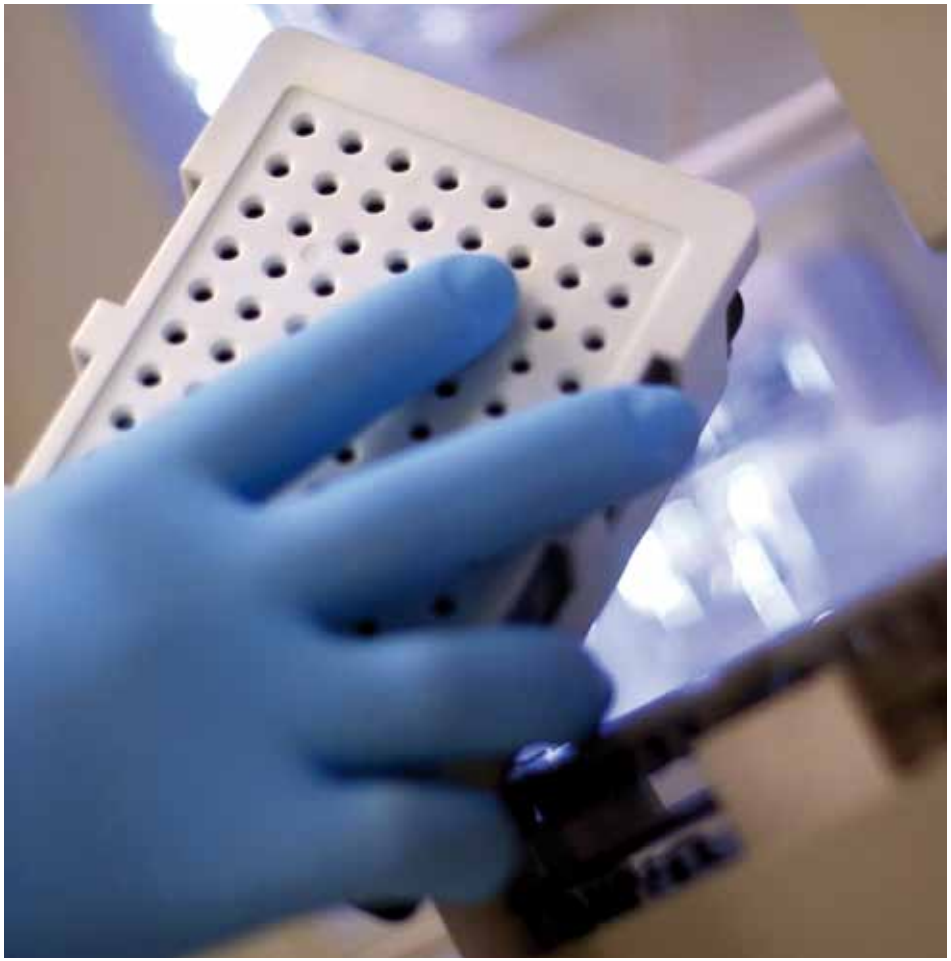
11 About 30 larval zebrafish, which had reached the stage of development at which they became protected animals, had a neurotoxin injected into the tissues adjacent to one eye under terminal general anaesthesia. This was done without project or personal authority. The incident was discovered by the inspector when discussing a draft application for a new project licence with the project licence holder. The project licensee and the personal licensee were admonished, and both were required to repeat training in module 1. They both voluntarily undertook module 4 training.

12 Twenty conscious adult rats were decapitated, without project licence authority, over a period of three months. The project licence holder and the personal licensee mistakenly believed that decapitation of adult rats was a Schedule 1 method of humane killing. The incident was reported to the inspector by the Certificate holder. The personal licensee, the project licensee and the Certificate holder were admonished. The Certificate holder took steps to improve the supervision and

management of programmes of regulated work, to reduce the likelihood of recurrence.

13 Two mice were inadvertently left over the weekend in an imaging chamber where they were discovered three days later. One mouse was found dead; the other mouse was alive and well and was returned to its home cage. The incident was self-reported to the inspector. The establishment revised its procedures to ensure that no animals could be left in the imaging chamber, or the procedure room, at the end of the day. The personal licence holder was admonished.

14 The holder of a project licence and a personal licence raised antibodies in rabbits using a regime with more frequent administrations of antigen than was authorised by the project licence. There had also been delay in the humane killing of a number of those rabbits showing adverse effects. Further investigation revealed inadequate labelling of pens and a failure to check licence authorities before proceeding. The incident was discovered by the inspector. The establishment acknowledged the operational deficiencies and took steps to remedy them. The licensee was admonished.



Category C infringements

1 Regulated procedures (ear biopsies and the administration of substances by injection) were performed on mice by a researcher who did not hold a personal licence. The procedures were competently performed and the animals suffered no ill effects. The incident was reported to the inspector by the Certificate holder. The non-licensee was sent a letter of censure and was told that any later application for a personal licence would require submission of evidence of recent training in modules 1 to 3, plus a written statement of support from the relevant Certificate holder and project licence holder indicating that they were both aware of the incident and describing the mechanisms they would put in place to ensure that the researcher would comply with ASPA and with the licence conditions.

2 A project licensee asked two personal licence holders to carry out regulated procedures on a number of rats and mice when the procedures were not authorised by the project licence. The project licence holder also failed to ensure that the details of the plan of work were made known to the two personal licensees. The infringement was discovered by the inspector. The personal licensees were admonished. The project licensee was admonished and was required to undergo re-training in modules 1 and 5.

3 Thirty-four genetically altered mice died, and a further 14 were killed humanely, as a result of a failure of the temperature control unit within the animal room which resulted in raised room temperature. The alarms had been switched off and the failure of the steam valve to close was attributed to faulty maintenance. The incident was self-reported to the inspector. A number of engineering and managerial changes were implemented to prevent a recurrence. The Certificate holder was admonished.

4 In a poorly designed experiment using 14 mice, six died and a further six were required to be killed humanely. The degree of severity imposed exceeded the severity limit attached to the procedure and notification to the Home Office was not provided. Furthermore, personal and project licence records were found by the inspector to be defective. The incident was reported by the Certificate holder who then took internal disciplinary proceedings. The licensee was admonished, and required to undergo re-training in modules 1 and 5. In addition, the project licence was varied, requiring greater detail of each experiment. The personal

licence was also varied, requiring supervision by an experienced personal licensee until such time as the licensee was considered to be competent.

5 On two separate occasions, the failure of a water pipe in an animal house resulted in the deaths by drowning of a number of guinea pigs. Both incidents were self-reported to the inspector. After the first incident, a programme of work was put in place to replace old pipe connections. The replacement programme was running behind schedule when the second incident occurred, following which the programme was completed the next day. A pressure alarm was fitted to detect any fall in the water pressure and trigger a call-out requiring a response from the recipient and to trigger isolation of the water flow if the pressure drop was to last longer than 30 seconds. The Certificate holder was admonished.

6 Two ferrets which drank a quaternary ammonium disinfectant (Super Q) that had mistakenly been put in their drinking water were, after some delay, killed humanely. After an internal investigation at the establishment, new standard operating procedures were put in place. The incident was self-reported to the inspector. The Certificate holder was admonished.

7 Twenty-four rats were given doxorubicin (a chemotherapy drug) at dose levels that were higher than specified on the project licence. The adverse effects which occurred, which included severe signs of toxicity or death, exceeded those permitted by the licence. The project licensee failed to notify the Home Office of the breach of severity limit. The infringement was found by the inspector. The project licensee and the personal licensee were admonished. The project licensee was required to undergo re-training in modules 1 and 5 and the personal licensee in module 1.

8 Failure to provide adequate food led to the death of 25 mice and failure to carry out daily checks resulted in the death of a further mouse from overgrown teeth. The infringement was self-reported to the inspector. The animal technician involved was

suspended while the establishment conducted an internal investigation. The technician was found to have falsified animal care records and was subsequently dismissed from the establishment. The Certificate holder instituted prompt and positive actions to prevent recurrence, implementing a full review of the animal facilities management and instituting the recommended changes. The Certificate holder was admonished.

9 Sixteen of 600 poultry used in an experiment were found dead over a two-week period. Had monitoring been carried out at appropriate times, unnecessary suffering could have been avoided through recognition of the signs of disease and humane killing. The infringement was discovered by the inspector. The Certificate holder put in place improved working practices. The project licensee was admonished and surrendered the licence which would otherwise have been revoked by the Secretary of State. The licensee was also told that re-training in modules 1 and 5 would be required before any future application for a project licence would be considered. The personal licensee was admonished, and was required to undergo re-training in modules 1, 2 and 3.

Section 3 Initiatives and progress

Risk-based inspection

As part of the Hampton Implementation Review of the Inspectorate, the external reviewers commented that, although stakeholders understood the reasons behind inspections in general, the rationale behind the risk assessments had not been fully shared with them and they would welcome further clarity on the risk basis.

The risk basis behind inspections is one of the important aspects which contributes to public confidence in the regulatory system and which, when applied consistently across all inspections with stakeholders, may help to allay any concerns over perceived inconsistency between inspectors.

Factors considered in determining levels of risk

Number of regulated procedures undertaken

Undertaking increasing numbers of regulated procedures under ASPA raises the risk profile for any establishment as a result of the likely incidence of any errors or lapses occurring during such procedures. There is a wide and variable – year-on-year – range for the number of procedures completed at each establishment, from zero to many tens of thousands and a similar wide range in the type of regulated work which is undertaken. (For example, breeding of phenotypically normal transgenic mice may represent many thousands of essentially similar procedures whilst surgical procedures may be undertaken on only a few occasions each year.)

The number of project licences alone held at each establishment is, however, a relatively poor indicator of risk as each licence is unique and may comprise a single protocol or may contain several protocols within a broad programme of work.

Severity of procedures undertaken

Undertaking regulated procedures of increasing severity under ASPA raises the risk profile for any establishment as a result of the likely consequences to protected animals of any errors or lapses occurring during such procedures. The current banding of severity ranges from Unclassified (all work under terminal general anaesthesia) through Mild, to Moderate, to the upper limit of Substantial.

Each project licence is assigned an overall Severity Band, with a typical range classifying licences as three per cent Unclassified, 35 per cent Mild, 60 per cent Moderate and two per cent Substantial. Those establishments conducting a higher proportion of their work in the Substantial category will generally be considered to carry a higher risk rating than those conducting work which is Unclassified or Mild.

Species

Undertaking regulated procedures on any of the species specially protected under ASPA (dogs, cats, equidae and non-human primates) also raises the risk carried by any establishment. Currently, no establishment carries out procedures in all four of these species groups, but a small number do have licence authorities for work in more than one of the species.

Overall, the use of these specially protected species is a very small proportion of the total regulated work conducted in the UK, with data for 2010 showing that the total for all regulated use of all these species was around 0.5 per cent of all regulated work in the UK.

Compliance history of an establishment

One of the most important factors to be considered in assessing the risks posed by any establishment is whether it has previously failed to fully comply under ASPA. Such failure raises the risk profile. Compliance history includes records of infringements (as reported under ASPA) as well as evidence from visits of inspection when specific compliance advice may have been given.

Infringements are classified according to the gravity of each occurrence (see Appendix 2), with an appropriate weighting applied to adequately reflect the nature and seriousness of the lack of compliance.

Setting and amending the risk basis for each establishment

As an outcome of each of their visits, inspectors review the risk status for each establishment, noting whether there has been any significant change in the relevant factors as outlined above. The three possible outcomes – increased, decreased or unchanged risk profile – are considered along with any recommended changes to control measures; to the frequency of inspections; or to particular aspects of work at that establishment.

Inspectors also discuss the risk profile with key individuals at the establishment, particularly the Certificate holder. The other factors which may be useful in managing down the risks are also discussed. These will include: the efficiency with which the Ethical Review Process functions across its breadth of responsibilities; the roles played by the Named Persons (NVS and NACWO); the focus on housing and care including environmental enrichment; whether proactive attention is being given to facilities issues; and the training and supervision of personal and project licence holders and those responsible for day-to-day care.

Changes to these factors may significantly alter the risk rating of an establishment and, more importantly, offer an opportunity for Certificate holders and others to actively manage the perceived risks carried at their establishment.

Better regulation

Project licences

The new project licence (PPL) application form has continued to be well received by applicants. It has been reported that the form is quicker and easier to complete, and the required information is more clearly explained. ASPI has reviewed the quality of applications on the new form, and evidence suggests that this has improved. The assessment form used by ASPI is also being assessed regarding consistency of approach. Another example licence, which contains examples of protocols for production of genetically altered rodents, has been added to our website.

Personal licences (PIL)

Inspectors are still encouraging applicants to use the suggested wordings for techniques in section 15 of personal licence (PIL) applications. The wordings are available on the Home Office website.

Value for Money project

ASPI and ASPD worked together with colleagues from the UK Border Agency and the Home Office Value for Money team to review current practices and implement efficiencies. The joint team analysed the processes used for all forms of licensing and identified opportunities for improvement. A programme of change was instigated which included:

improvements to PPL and PIL application forms to speed up processing and ensure robust version control; a new form for assessment of PIL applications which clarifies the role of licensing staff and inspectors, eliminates duplication, and hence speeds up recommendations; the development of an electronic storage system for applications; and an initiative to explore different systems for performance management of staff in ASPI and APLS. Changes to licensing systems which impact on stakeholders were communicated through e-newsletters and circulars.

Streamlining the acquisition of non-human primates

Non-human primates (NHPs) are listed in Schedule 2 to ASPA and must therefore be obtained from a designated breeding or supplying establishment in the UK unless formal exemption is granted. Before such exemption can be granted, users must demonstrate that no animal suitable for the scientific purpose can be obtained from a designated breeder or supplier.

Since 1996 the use, in regulated procedures, of NHPs acquired from overseas has been subject to additional controls to support the effective UK ban on the use of wild-caught primates. During 2010 we completed our review of those controls. A revision of the process for applying for approval to acquire NHPs from non-designated establishments and subsequent reporting has been completed and the final stages will be fully implemented during 2011. The effect will be to reduce bureaucracy whilst maintaining control over acquisitions.

Any source from which NHPs are obtained must have been previously deemed acceptable by the Home Office. Breeding centres are appraised by the Inspectorate against a series of qualifying standards based on those outlined in the International Primatological Society International Guidelines for the Acquisition, Care and Breeding of Non-human Primates using information from the centre, from prospective or current users or other interested parties, and sometimes from a visit made by the Inspectorate. These are described in detail in Appendix 3. The appraisal is risk based and underpins the advice Inspectors give. The Animals Procedures Committee may also be asked for advice on the suitability of a centre.

A single standard application form has been devised for use by both project licence holders and Certificate holders for each acquisition. The volume of information users are required to provide routinely to the Home Office after acquiring each consignment of primates has also been significantly reduced. Provided that there are no significant deviations from the agreed journey plan

or consignment details, nor significant welfare issues upon arrival, users will now be able to report the key information relating to animal health and welfare on just one occasion, rather than two, using a simple report form. Other record-keeping requirements have also been simplified.

Continued acceptability is assessed by reviewing information on the health and welfare of animals brought from the centre to the UK, periodic review of current details, and any other information supplied to the Home Office. Centres are typically reviewed every two years or more frequently if considered necessary.

Guidance on use of fish

During 2010 members of the Inspectorate participated in a working group appointed by the Norwegian Consensus Platform for the Replacement, Reduction and Refinement of Animal Experiments (Norecopa). This group produced a report entitled 'Guidance on the severity classification of scientific procedures involving fish' which has now been published online in Laboratory Animals http://la.rsmjournals.com/cgi/reprint/la.2011.010181v1.

We have also responded to DEFRA regarding draft guidelines on demonstration of target animal safety and efficacy of veterinary medicinal products intended for use in farmed finfish and had discussions with a range of government departments and agencies regarding the experimental use and monitoring of fish populations in the wild.

An ASPI reference document providing advice to inspectors on use of fish in research was finalised in order to enhance consistency.

Improving our Information Technology

Work towards improving our Information Technology (IT) and data-handling systems for both APLS and ASPI continued throughout 2010. As part of the wider ASPA IT project to deliver an electronic licence application system, we worked closely with colleagues in the UK Border Agency (UKBA) to adapt an existing web-based, portal application that has been operating successfully within the Home Office since 2003, delivering secure and effective data processing. Initial re-configuration work was completed towards the end of 2010 and it is anticipated that the new system will be piloted in establishments during the first half of 2011, with a decision on suitability for wider implementation taken in the autumn.

If successful, the proposed solution will enable establishments to securely upload electronic versions of ASPA licence applications and amendment requests, track

progress during processing, and access and download the current version of an authorised licence for day-to-day use. From our perspective, the new system should significantly reduce the time, space and additional administrative work involved in handling paper files as well as providing universal access to an electronic archive of current and past licences that can be used to better inform decision-making about new applications.

We have also continued to seek improvements to our IT resources to enable more effective, secure electronic communication and information access when routinely working with external organisations and operating out in the field. Achieving these goals has proved to be challenging, mainly due to the need to continue to operate within very stringent Home Office data security and network performance standards designed to meet the needs of the majority of our Home Office colleagues who normally work within the secure confines of the office-based internal network.

Nevertheless, during 2010 we worked hard to ensure that significant upgrades to IT systems in the wider Home Office, planned for deployment during 2011, will incorporate features which will benefit both ourselves and our stakeholders. These changes should enable us to access information (including licences, visit reports, policy documents and scientific reference sources needed for assessment and inspection work) much more easily and quickly.

Improved internal and external communication tools, based on the electronic licence application system, and access to a customised intranet should also make it easier for members of Inspectorate and licensing staff based in different locations to communicate and collaborate more effectively amongst themselves as well as with licensees and other groups. The work put into adapting these new tools to our needs should therefore help to enhance further the speed, accuracy, consistency and transparency with which advice can be given to all our stakeholders.

Europe: Revision of EU Directive 86/609/EEC

The early part of 2010 saw the completion of the UK parliamentary scrutiny process with a debate in the House of Lords, on 10 February, on the House of Lords Scrutiny Committee report published in November 2009. Lord West of Spithead responded for the government. The Commission's proposal was released from scrutiny in March, leaving UK Ministers free to support the adoption of the final negotiated text.

In Brussels, the finishing touches were put to the text by legal and linguistic experts throughout the spring and summer, with a final text being adopted by the European Parliament and Council in September. Following publication in the Official Journal of the EU in October, the new European Directive (2010/63/EU) entered into force on 10 November 2010. This started the countdown for transposition into UK legislation which must be completed by 10 November 2012 – in time for implementation from 1 January 2013.

Detailed analysis of the new Directive started immediately following its entry into force in preparation for a public consultation during 2011 on options for transposition. Work also began on a consultation stage impact assessment to accompany the public consultation paper.

Many of the provisions of the new Directive are similar to current UK legislation and practice, some are new or go further, and others are potentially less stringent than current UK requirements. Article 2 of the Directive allows Member States to retain current, more stringent national provisions in place on 9 November 2010 so long as they are not used to inhibit the free market. The implications of Article 2 and all of the other articles and annexes in the Directive will be explored in detail in the consultation paper.

Coalition agreement and the 3Rs

The coalition agreement adopted following the May 2010 general election included two commitments on animal experimentation: to work to reduce the use of animals in scientific research; and to end the testing of household products on animals.

Work on both pledges started in 2010 and will be covered in next year's report. Meanwhile, some significant examples of implementation of the 3Rs (Replacement, Reduction and Refinement) have been progressed during 2010.

Shellfish toxin testing – an example of implementing all 3Rs

The Inspectorate has continued to work with the Food Standards Agency (FSA) and testing laboratories to make progress towards replacing the in vivo mouse bioassays for toxins in shellfish with alternative methods.

For Paralytic Shellfish Poisoning (PSP), a fully quantitative chemical analytical method previously described (see our 2009 report) has been extended to a number of additional shellfish species. Further reductions are planned after an independent review of data relating to oyster species.

The in vitro screening method continues to be used where the quantitative chemical method is still not possible, with testing in animals only undertaken where at-risk samples are detected. In the very limited number of samples that still use the mouse bioassay, reduction strategies continue to be used so that 33 per cent fewer mice are used than would be in the standard testing methodology.

Hence, the number of mice used in PSP testing is significantly further reduced from the 2009 figure and, by the end of 2010, was less than five per cent of that which would have been needed for the same number of samples prior to the introduction of the chemical and in vitro methods.

For Diarrhetic Shellfish Poisoning (DSP), significant progress was achieved in November 2010 when, after much pressure from ASPI, the FSA, the UK shellfish industry and testing laboratories, the European Food Hygiene Regulations were changed to require the use of an analytical method from 2014. A public consultation by the FSA provided unanimous support for implementation of this analytical method as soon as possible in the UK rather than waiting until the 2014 deadline.

The method has now been validated for eight species of shellfish and will be implemented for these species in 2011. It is predicted that a greater than 97 per cent effective reduction in animal use for DSP testing will be achieved in 2011. Until this implementation is complete, reduction and refinement strategies continue to be used that mean that over 30 per cent fewer animals are used and the test duration is significantly shorter than in the standard methodology. Thereby animal suffering is considerably reduced.

Refinement of vaccine testing

The Inspectorate has participated in a joint BVAAWF/FRAME/RSPCA/UFAW working group on 'Application of the 3Rs to challenge assays used in vaccine testing' which resulted in a published article in Biologicals 2010, vol.38(6), pp 684-695. http://www.sciencedirect.com/science/article/pii/S1045105610000990

Our communications

Correspondence, Freedom of Information and parliamentary questions

Answering correspondence received from the general public either directly or through their Member of Parliament is an important function of the ASPD policy team. This includes dealing with requests for information made under the Freedom of Information Act. In 2010, we dealt with a total of 479 letters and emails and 20 requests received under the Freedom of Information Act.

We also responded to 73 parliamentary questions tabled during the year.

e-Newsletters

The circulation list for our ASPA e-Newsletter continued to grow during 2010. At the end of the year just under 2,000 stakeholders were receiving the e-Newsletter and initiatives will continue during 2011 to increase the number of recipients. As well as being sent electronically, each newsletter is also posted on our website.

Website

The election of the new government meant that all previous material on our website had to be archived on the National Archive website. That material, which includes licence application forms and related material, can still be accessed through our current website.

Abstracts of project licences

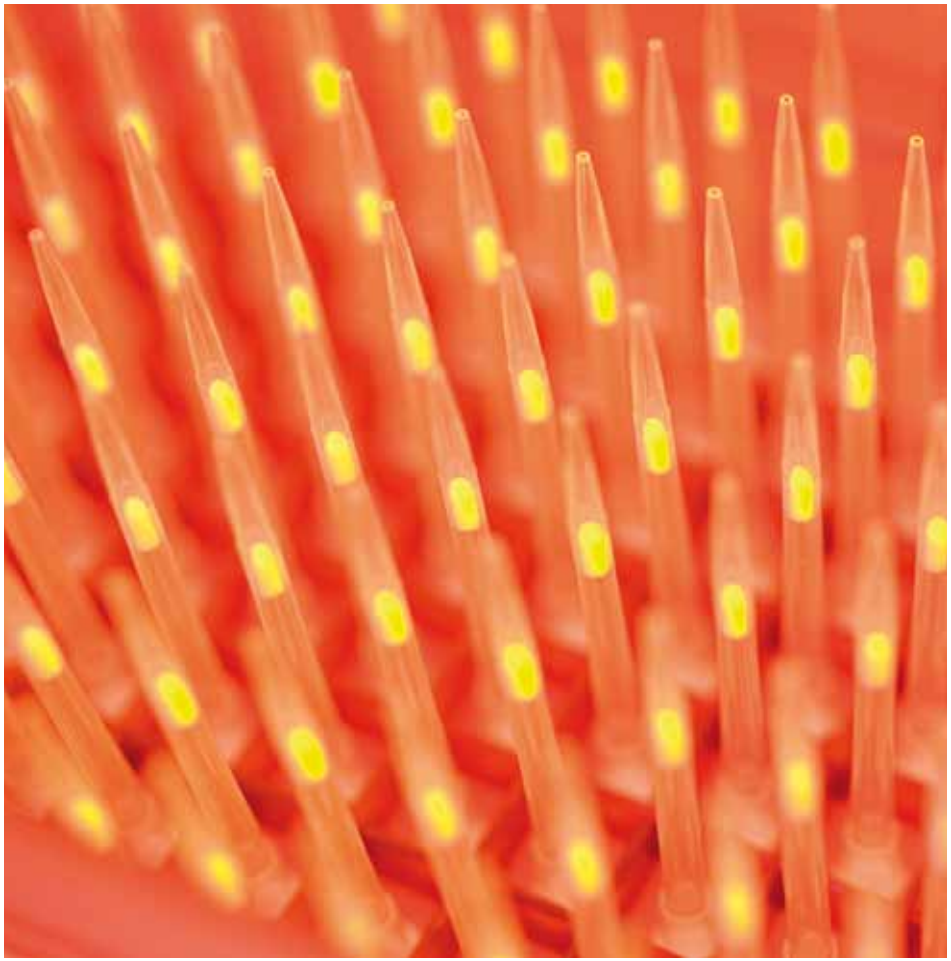
Project licence holders provided 447 abstracts throughout the year and at the end of 2010 a total of 2,380 had been posted on the website. We would like to thank all licensees who provided abstracts which we believe make a significant contribution to greater openness and greater public understanding of the use of animals in science and how it is regulated.

Wickham Laboratories

The ASPI review of the issues raised in the 2009 report received from the British Union for the Abolition of Vivisection (BUAV) entitled, 'The Ugly Truth' was published on 30 November 2010. The BUAV report was based on the findings of an undercover investigator employed as an animal technician at Wickham Laboratories for ten months during 2009.

Whilst the majority of concerns raised by BUAV in their report were not substantiated, the report identified a number of potential breaches of the conditions of Wickham Laboratories' certificate of designation and of one project licence held there. Action to deal with these issues has since been completed. Action is also being taken on the wider lessons to be learned from the review.

The written ministerial statement, and the ASPI review of the compliance at Wickham Laboratories, can be read at: http://www.homeoffice.gov.uk/science-research/animal-research/



Reference material

Appendix 1 How we regulate

Introduction

The Animals Scientific Procedures Division (ASPD) and Inspectorate (ASPI) implement the Animals (Scientific Procedures) Act 1986 (ASPA or 'the Act'). ASPD and ASPI are twin units within the Home Office Science (HOS) department of the Home Office, and work closely together to apply the requirements of the Act in England, Scotland and Wales.

The Act

The Act makes provision for the protection of animals used for experimental or other scientific purposes. It applies to **protected animals** used in **regulated procedures**. The Act operates through a three-level licensing system controlling the places where animals are bred and used (**certificate of designation**), the projects in which they are used (project licence) and the people carrying out the work (**personal licence**).

- Protected animals – all living vertebrates (except Man) and Octopus vulgaris.
- Regulated procedures – any scientific or experimental procedure that may cause pain, suffering, distress or lasting harm.
- Certificate of designation – held by a responsible individual at a place where work is carried out. Controls standards of facilities, equipment and staffing.
- Project licence – held by a person who takes overall responsibility for managing a project. Details the programme of work, costs and benefits, and **the 3Rs**.[1]
- Personal licence – held by anyone carrying out regulated procedures. Specifies qualifications, competencies and supervision arrangements.

1 The 3Rs – Replacement of procedures with non-animal alternatives; Reduction of the numbers of animals used in procedures; Refinement of procedures to minimise pain and suffering.

Animals Scientific Procedures Division

ASPD operates the licensing system on behalf of the Secretary of State, as well as developing and implementing policy and providing support to Ministers with respect to Parliamentary and other matters.

Animals Scientific Procedures Inspectorate

Inspectors are registered veterinary or medical practitioners who usually have first-hand experience of biomedical research, and possess higher scientific or clinical postgraduate qualifications. Their role is to provide scientific advice to the Secretary of State and to ASPD officials.

Inspectors assess all applications for new licences or amendments to existing ones, and advise the Secretary of State on whether and on what terms to grant the licences. When assessing scientific proposals inspectors ensure that full consideration has been given to the 3Rs.

Inspectors also conduct a programme of mainly unannounced visits to places where work under the Act is being carried out. Inspections are performed according to a formalised risk assessment approach in compliance with Hampton principles and are undertaken to check that the terms and conditions of licences and certificates issued under the Act are being complied with.

Further information

The Home Office Animals in Scientific Procedures website: http://www.homeoffice.gov.uk/science-research/animal-research/

Guidance on the Operation of the Animals (Scientific Procedures) Act 1986: http://www.archive.official-documents.co.uk/document/hoc/321/321.htm

National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs): http://www.nc3rs.org.uk/

Department for Business, Innovation and Skills summary of the Hampton Review and Principles: http://www.berr.gov.uk/whatwedo/bre/inspection-enforcement/assessing-regulatory-system/page44042.html

Appendix 2 Infringement categories

A range of sanctions is available to the Secretary of State, including measures aimed at deterring or otherwise preventing a recurrence. These include:

- referral to the prosecuting authorities;
- revocation, suspension or amendment of licences or certificates;
- addition of special conditions to licences or certificates;
- requirements for formal training or re-training; and
- letters of admonition, with or without requirements for further action to correct perceived deficiencies (such as additional training or altered management practices).

The gravity of an infringement will depend upon its origins, scale and any consequential animal suffering. Thus, deliberate infringements will be viewed more seriously than those due to negligence, ignorance, confusion or adherence to inappropriate instructions from those in authority; repeated failures will generally be viewed more seriously than single incidents; and any unnecessary animal suffering or attempts to conceal the facts will significantly increase the perceived gravity of any infringement. A view may be taken on whether or not the licensee is likely to observe legal and administrative obligations in the future.

Those involved in infringements, either directly or as the relevant project licensee or Certificate holder, will be notified that the Inspectorate has made a report and will be informed of the nature of the breach. They will then have the opportunity to provide any information they wish to be considered before the decision on the action to be taken is conveyed by the Animal Procedures Licensing Section. Those involved in the infringement will be notified of the action that the Secretary of State proposes to take. If this includes variation or revocation of authorities, then the rights to make representations under Section 12 of the Act will be explained (See Appendix H of the Guidance).

Once dealt with, infringements are reported in an anonymous form to the Animal Procedures Committee. The number of infringements each year and summary details are published by the Home Office.

Category A infringement

The characteristics of a category A infringement will include some or all of the following:

- no prospect of prosecution;
- no disputed facts;
- no evidence of intent to subvert the ASPA 1986 controls;
- no animal welfare implications;
- resolved or remedy in place within days of discovery.

Typically, the outcome of a category A infringement will be to note and record details of the infringement, with no further action being necessary.

Category B infringement

The characteristics of a category B infringement will include some or all of the following:

- animal welfare implications that do not necessarily involve avoidable or unnecessary pain, suffering, distress or lasting harm;
- future compliance concerns;
- facts not disputed;
- no likelihood of dispute over the course of action proposed;
- not sufficiently serious for referral for prosecution, revocation of licences or withdrawal of a certificate to be considered;
- not resolvable within days of discovery and further action needed;
- recurrent or persistent category A infringements.

Typically, the outcome of a category B infringement will be to send a letter of admonition (i.e. a warning) to the person or persons involved, although in some cases the Home Office may require further action (such as additional training, or altered management practices) or it might apply an additional condition to the licence or certificate.

Category C infringement

The characteristics of a category C infringement will include some or all of the following:

- serious animal welfare implications involving avoidable or unnecessary pain, suffering, distress or lasting harm;
- future compliance concerns;
- disputed facts;
- evidence of untruthfulness or attempt to evade responsibility;
- variation, suspension or revocation of licence or certificate is merited;
- referral for prosecution is not merited;

- recurrent or persistent problems of a lower category.

Typically, the outcome of a category C infringement will be to amend, revoke or suspend the licence or certificate, and to send a letter of admonition to the licensee or Certificate holder.

Category D infringement

The characteristics of a category D infringement will include some or all of the following:

- serious animal welfare implications involving avoidable or unnecessary pain, suffering, distress or lasting harm;

- serious contraventions which merit referral for possible prosecution;

- the Inspectorate undertakes a preliminary investigation only, sufficient to establish that prosecution is or is not an option;

- if prosecution is contemplated, further investigation is then undertaken by the police and the Inspectorate.

Typically, the outcome of a category D infringement will be for the Home Office to refer the case to the Crown Prosecution Service (in England and Wales) or the Procurator Fiscal (in Scotland) for them to consider prosecution.

Appendix 3 Qualifying standards applied in determining acceptability of overseas NHP breeding centres

As a guiding principle the centre should aim to meet the relevant standards set out in the Home Office Code of Practice for the Housing and Care of Animals in Designated Breeding and Supplying Establishments at least in respect of animals destined for the UK. Minor deviations from those standards may be acceptable provided that there are no adverse consequences for the welfare of the animals at the centre.

No primate shall be supplied to the UK as captive-bred if it has been bred or maintained in a semi-natural environment such as an island or equivalent bounded, free-range park or reserve.

Specific qualifying standards

- The centre should demonstrate that it understands the needs of the species and individual animals it breeds, maintains and supplies, and should document how those needs will be met through its animal housing and care procedures and staff training programme.

- Primates should be housed in harmonious social groups or compatible pairs in cages or enclosures providing sufficient space, complexity and environmental enrichment for them to express a wide behavioural repertoire. Animals should not be housed singly other than for veterinary reasons.

- Husbandry and care procedures, including handling, marking for identification and euthanasia, should be refined to minimise adverse effects.

- A varied and nutritionally adequate diet should be offered to the animals and presented in a manner that provides stimulation and environmental enrichment.

- The centre should operate a programme of timely planned preventative and remedial maintenance to ensure that the animal accommodation is maintained in a fully serviceable and safe condition.

- The centre should operate an effective breeding programme with documented provisions for the selection, maintenance and retirement of breeding animals and regular review of colony breeding performance.

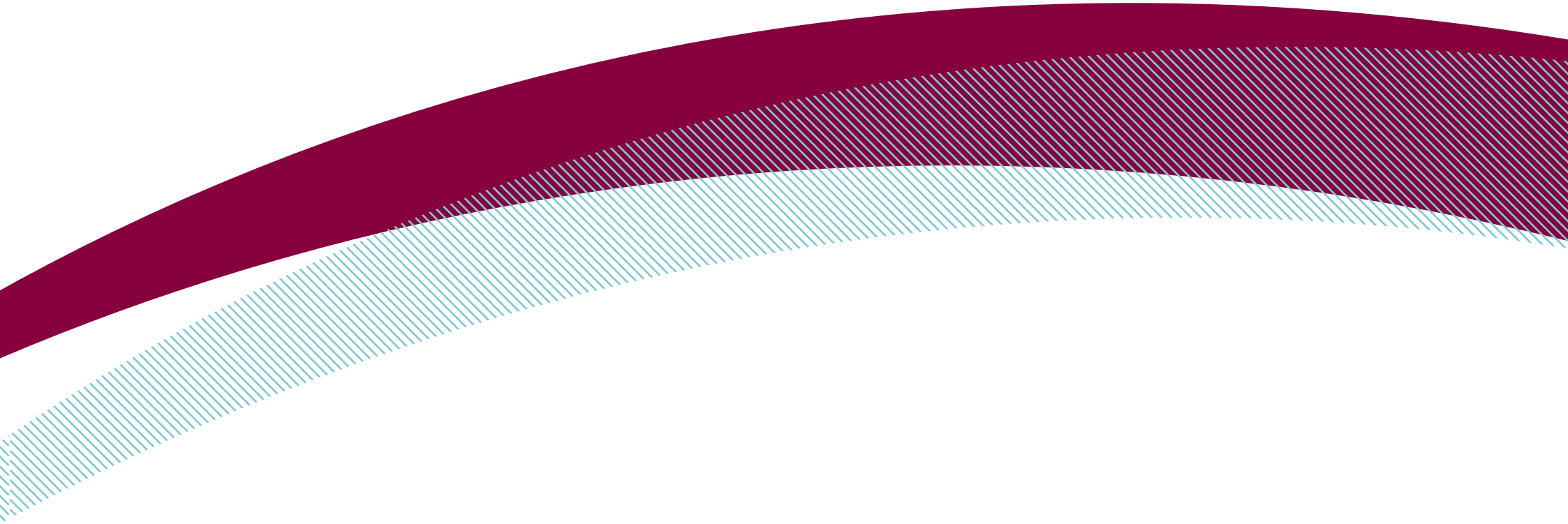
- Primates should not be weaned at an earlier age than is necessary. Specific justification will be required if weaning is at less than eight months of age.

- The breeding centre should have in place recording systems adequate to provide lifetime records.

- Where applicable, the breeding centre should have a policy of reducing dependence on wild-caught animals for future breeding stock. The number of wild-caught animals introduced into the colony for breeding should be in accordance with restrictions imposed by the national authority. Where the breeding centre is capturing wild or feral primates it should have a clearly defined and effective process for ensuring that any person trapping primates is adequately trained and supervised in humane methods of capture.

- If primates are held in quarantine or conditioning cages prior to shipment the period of confinement should be kept to a minimum. Cages should not be unduly restrictive and appropriate resources should be devoted to ensuring that animals' physical and behavioural needs are satisfied as far as possible.

- Transport of primates from the centre to the UK should be by the most direct means practicable, taking account of prevailing environmental conditions and the need to minimise both journey duration and number of stages. Transport arrangements should accord with the relevant sections of the LASA Guidance on the Transport of Laboratory Animals (2005).



ISBN 978 1 84987 462 5