Home Office

Animals Scientific Procedures Inspectorate & Division

Annual Report 2009

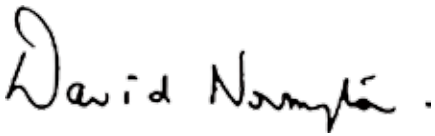
Foreword

I am very pleased to introduce the 2009 Annual Report of the Home Office Animals Scientific Procedures Division (ASPD) and Inspectorate (ASPI). The report shows that 2009 was another year where much was accomplished above and beyond the required regulatory outputs.

Two issues stand out: the negotiation of a new European Directive for the protection of animals used in scientific procedures; and the Hampton Review of the Division and Inspectorate's regulatory performance.

Negotiation of the Directive was a major activity throughout the year involving detailed discussions in Brussels and with other Whitehall departments, with stakeholders, and regular dealings with the European Scrutiny Committees of the House of Commons and the House of Lords. I am pleased to note that by the end of the year a successful outcome was in sight which delivered almost all the key UK high-level negotiating objectives.

The Hampton Review focused on the Division and Inspectorate's regulatory performance against the Hampton principles and the Macrory characteristics of effective inspection and enforcement. I am glad to say that this independent review concluded that the Division and Inspectorate are effective and well respected regulators and highly regarded by their stakeholders. Everyone involved deserves to be congratulated on this outcome which demonstrates their continuing commitment to effective, efficient and impartial regulation.



David Normington

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Introduction

This is the second year in which our two units, ASPI and ASPD, have come together to produce one report of our year's work. This joint venture symbolises the cohesive way in which we work together.

Whilst the Inspectorate is often viewed as the 'public face' of our regulatory system, routinely visiting establishments and meeting with our stakeholders, it is the hard work and achievements of the ASPD licensing staff in each of our regional offices that is equally essential to the efficiency with which we can process licence applications and enquiries.

Likewise, the ASPD policy team plays an indispensable role in dealing with issues of public and parliamentary concern, and has worked closely with the Inspectorate and others this year to negotiate a satisfactory revision to the EU Directive. This has involved numerous meetings with the whole range of our partners, a fact which was recognised and applauded by the team performing our Hampton Review.

Meanwhile, the day to day work of our combined units continues and this report provides details of our core statutory work in terms of licences issued and inspections performed during the year. We regulate a generally compliant community and this is reflected in the relatively low number of infringements in comparison with total numbers of procedures performed, and also the fact that most infringements involve little or no animal suffering and many are self-reported.

A number of better regulation objectives have been achieved in 2009, perhaps most notably the publication of a new project licence application form in November which has clarified and simplified the process for applicants. We have also made much progress in the phasing out of animal movement transfer forms. Both these advances are described in more detail in this report.

The Home Office is committed to delivering efficient, effective and impartial regulation of animal research and 2009 has been a year of substantial achievement for both ASPI and ASPD. We look forward to building on the foundations we have established, and to many new challenges in 2010.

Judy MacArthur Clark
Chief Inspector,
Animals Scientific Procedures Inspectorate

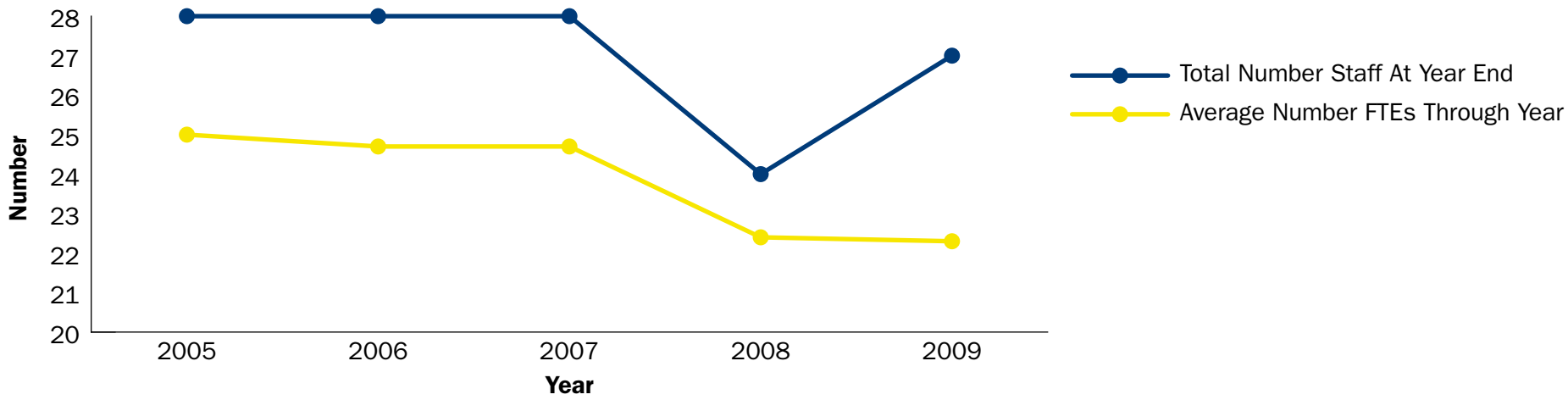
Jon Richmond
Head of Division,
Animals Scientific Procedures Division

Licensing and inspection

Inspectorate staff

Three new Inspectors joined ASPI in 2009 bringing the total headcount on 31 December 2009 to 27, including one Chief Inspector and five Superintending Inspectors (Figure 1). In addition administrative support was provided to the Inspectorate by one Executive Officer. However, the average strength of the Inspectorate over the year (number of Full Time Equivalents, FTEs) was approximately the same at 22.3 in 2009 compared to 22.4 in 2008. This was due in equal parts to the time of the year that the new recruits joined, some cases of long-term leave, and two Inspectors moving from full-time frontline duties to the management team.

Figure 1 Inspectorate staff 2005-2009



Personal licences and certificates of designation

Table 1 summarises performance and statistics in terms of personal licences and certificates of designation for 2009.

During 2009, ASPI advised on and ASPD processed 2,645 personal licences. Inspectors also provided advice on 13 preliminary applications that were later withdrawn. This was a small decrease (6.7%) in assessments leading to granted licences compared with 2008, but within normal year-to-year variation.

Of the personal licences granted in 2009, 134 (5% of the total) were processed under "fast-track" procedures, taking an average of just five working days. In addition, Inspectors provided advice on, and APLS processed, 3,998 amendment requests and reviews, approximately the same number as in 2008 (3,959).

The Inspectorate provided advice on seven applications for new certificates of designation in 2009, compared with two in 2008. There were 347 requests for amendments to existing certificates in 2009, a very similar level of activity to the 339 requests in 2008.

Table 1 Breakdown of licence and certificate applications and amendments

	Total			Per FTE		
	2009	2008	Change	2009	2008	Change
PILs granted	2,645	2,835	-6.7%	118.6	126.6	-6.3%
PILs amended	3,998	3,959	+1.0%	179.3	176.7	+1.5%
PILs in force	15,492	14,910	+3.9%	694.7	665.6	+4.4%
PCDs granted	7	2	+300%	-	-	-
PCDs amended	347	339	+2.4%	15.6	15.1	+3.3%
PCDs in force	190	191	-0.5%	8.5	8.5	0%
PPLs granted	541	695	-22.2%	24.3	31.0	-21.6%
PPLs amended	1,879	1,642	+14.4%	84.3	73.3	+15.0%
PPLs in force	2,658	2,652	+0.3%	119.3	118.4	+0.8%

Project licences

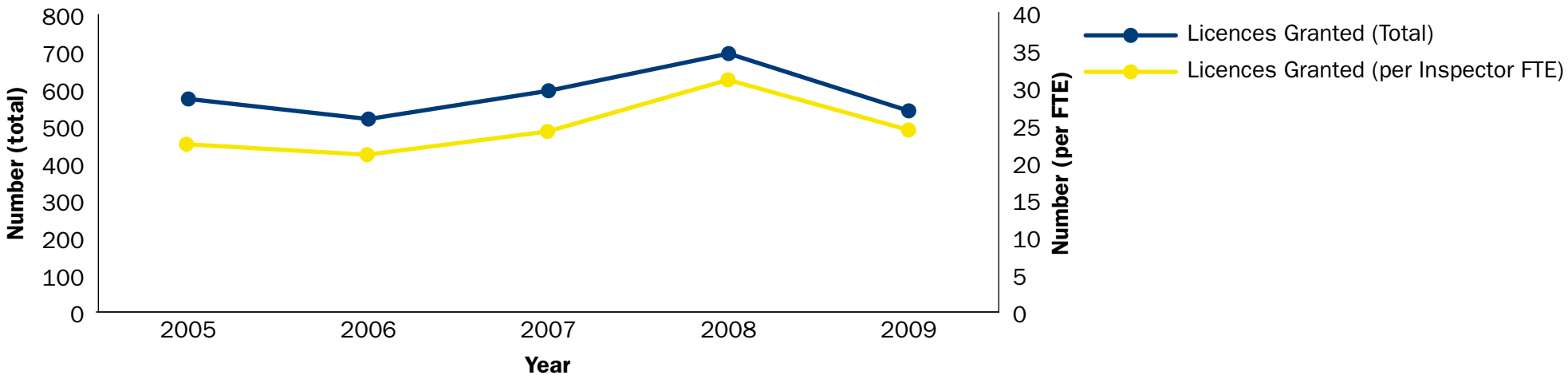
Table 1 shows performance and statistics in terms of project licences for 2009.

The assessment of project licence applications is by far the most time-consuming activity for Inspectors and licensing staff. 2008 was the busiest year in this respect in recent years, and activity in 2009 has returned to more typical levels. In total, the Inspectorate advised on whether and on what terms 541 project licence applications should be granted, as well as providing initial advice on 27 preliminary applications that were not proceeded with (Figure 2).

The number of project licences processed reduced by 22.2 per cent between 2008 and 2009. The Inspectorate remained broadly similar in strength between 2008 and 2009 (Figure 1) therefore the number of project licence assessments per FTE that led to a granted licence showed a similar decrease of 21.6 per cent.

Inspectors also gave advice on 1,879 requests for amendments to existing project licences in 2009, a 14.4 per cent increase

Figure 2 Project licences granted 2005-2009



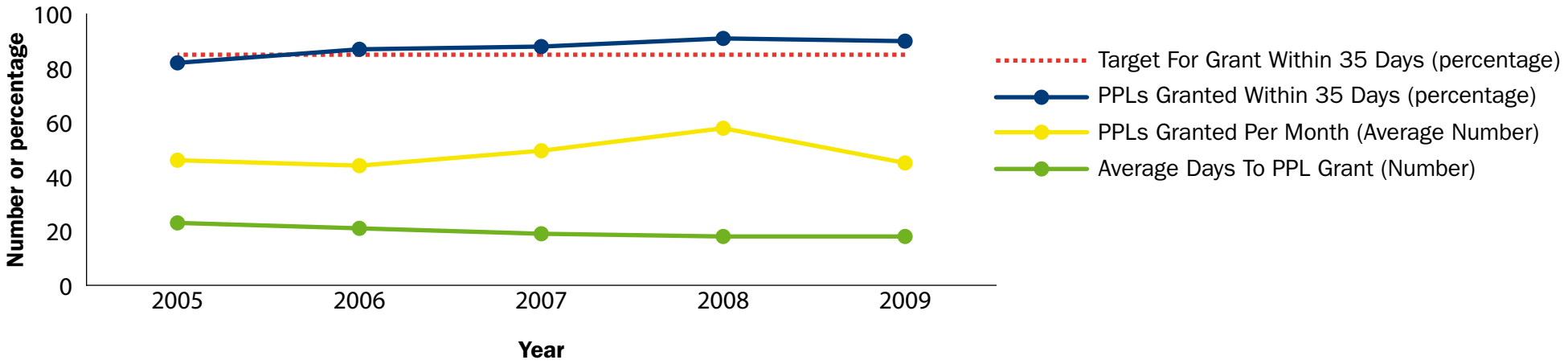
on the 1,642 requests in 2008. A proportion of these amendments were requests to add new conditions relating to animal transfers (see below).

ASPD and ASPI performance targets for project licence applications are to take licensing decisions within 35 working days of receipt for at least 85 per cent of applications. Figure 3 shows the performance trends against targets for the last five years. Average processing times remain at an all-time low of 18 days while the percentage of licences granted within 35 days continues to exceed targets.

Transfer forms

Additional project licence conditions relating to the transfer of animals were developed with legal advisers in 2009 as part of the Better Regulation agenda to reduce

Figure 3 Project licence application processing 2005-2009

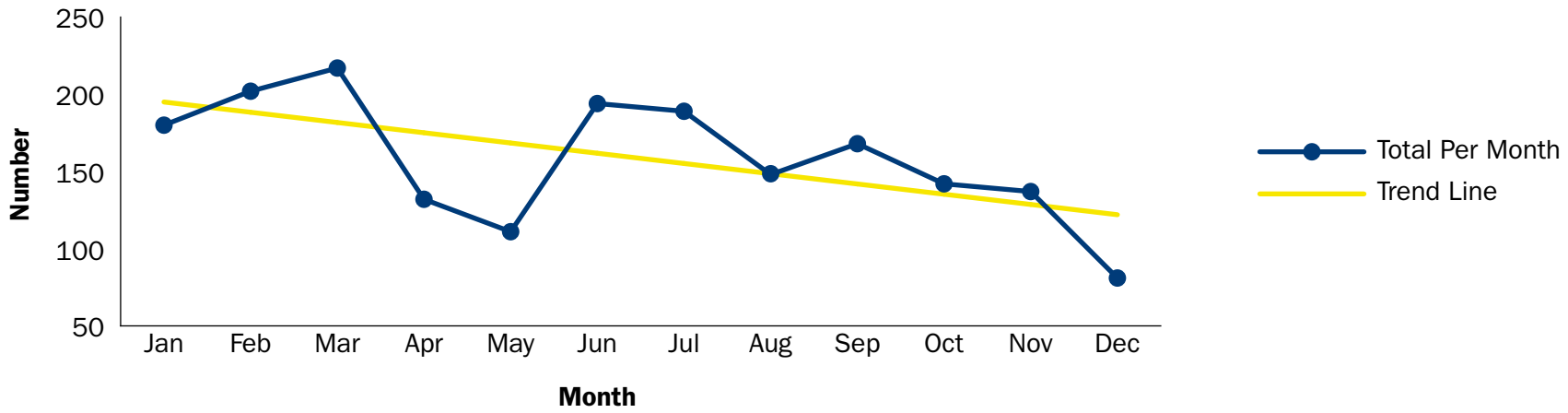


unnecessary bureaucracy without weakening the system of controls. The new conditions, built in to all new-style project licences (see page 21) and available for addition on request to existing project licences, greatly reduce the need for the use of "transfer forms" for the import and export of small rodents. Figure 4 charts the steady decline in the number of transfer forms submitted over 2009, reflecting the uptake of the new conditions and corresponding decrease in regulatory burden. By the end of the year, the trend shows a 37 per cent reduction in the number of transfer forms being used.

Inspection

ASPI operates a risk-based inspection scheme for work conducted under the Animals (Scientific Procedures) Act 1986 (ASPA) (see page 18). In the course of the 2009

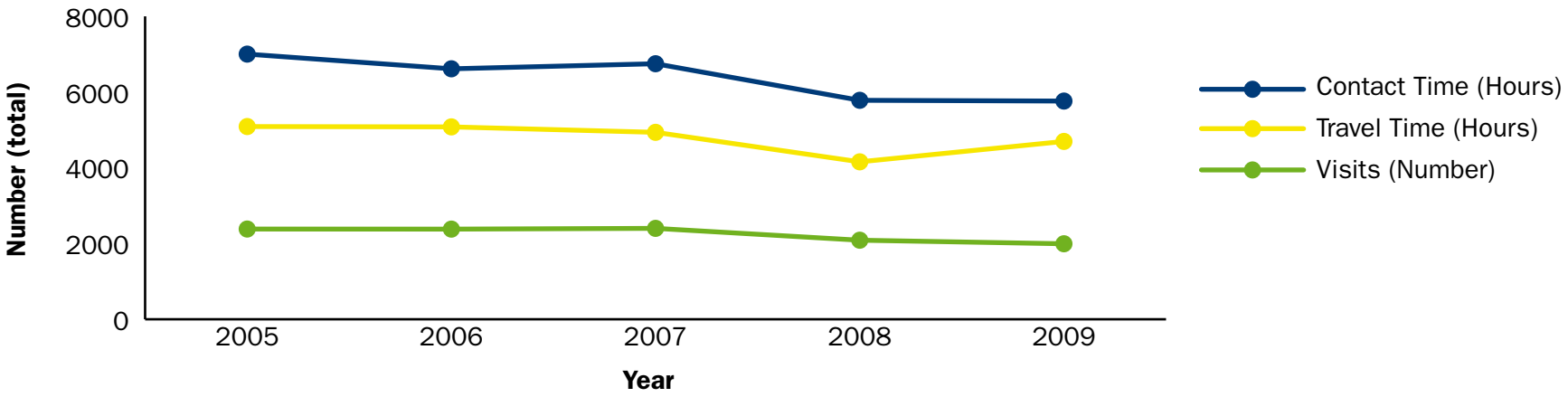
Figure 4 Transfer forms authorised 2009



inspection programme, ASPI inspected work being carried out by 15,492 personal licensees, under 2,658 project licences, at 190 designated establishments (figures correct at 31 December 2009).

During 2009 the Inspectorate carried out 1,994 visits to places where scientific work on animals was conducted, and 70.6 per cent of visits specifically to animal units were made without notice (41.9% of all visits were unannounced). These inspections amounted to 5,763 hours of contact time with those holding licences or certificates under the ASPA, in addition to 4,697 hours spent travelling. The overall number of visits and total contact hours were down very slightly from 2008 (4.5% and 0.3% respectively), although the time spent travelling showed an increase of 13.0 per cent (Figure 5). The average number of visits per FTE fell slightly from 93.2

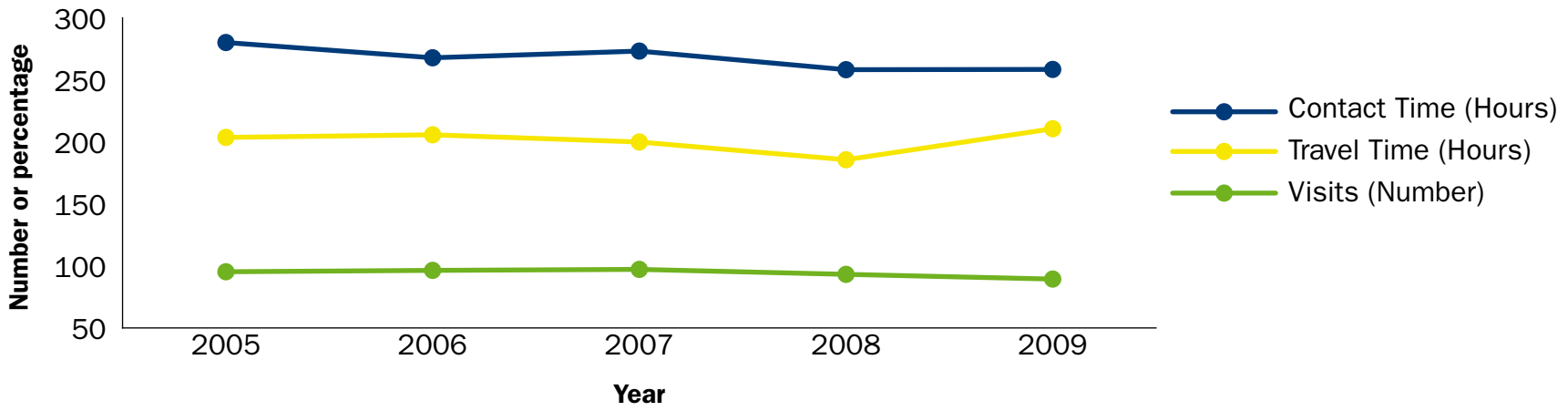
Figure 5 Inspections 2005-2009 (Total)



in 2008 to 89.4 in 2009, but contact time per FTE remained steady at 258.2 hours in 2008 and 258.4 hours in 2009 (Figure 6).

The training of three new Inspectors in 2009 was a significant time commitment for a number of staff members, and contributed to the modest shortfall against guideline targets for visits and contact hours. The increase in travel time is accounted for by the geographic dispersion of Inspectors around the country in relation to the locations of establishments that they inspect.

Figure 6 Inspections 2005-2009 (per FTE)



Compliance and infringements

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

Inspectors check compliance and investigate and report non-compliance. Their reports to the Secretary of State on any non-compliance make an appropriate and proportionate recommendation for the action required, which is generally aimed at the prevention of repeated faults. They also advise licensees and others how to comply, and generally promote a culture of compliance.

During 2008 the administrative arrangements for handling infringements and offences were reviewed to ensure that:

- non-compliance is dealt with fairly, efficiently, effectively, and in a timely manner;
- the resources required to investigate and take action are proportionate to the nature and significance of the non-compliance; and
- the nature of the resulting executive action is fair, consistent and proportionate to the nature and significance of the non-compliance.

The 2008 revisions reduced bureaucracy without weakening the system of control. Significant cases (those where the infringements are serious enough to warrant revocation, suspension or referral to the prosecuting authorities or where there is a dispute over the facts) are still referred to ASPD Headquarters in London for consideration and executive action. Other cases, which tend to be straightforward and of a less serious nature, are dealt with at a local level. The revised framework expedites the handling of minor infringements whilst retaining a higher level of decision making in more significant cases, thus improving the efficiency and maintaining the rigour required to handle non-compliance.

Since July 2008, infringements have been reported in four categories, A-D (see Appendix 2).

A minor adjustment to the system of reporting infringements was introduced in 2009. Inspectors recorded on visit reports occasions where compliance advice was given as a consequence of finding or being informed of a trivial breach of licence or certificate conditions. In such cases, there are no disputed facts, no evidence of intent to subvert the controls of the ASPA, no significant adverse consequences for animal welfare and the issue is resolved or a remedy put in place soon after discovery. In 2009 , in addition to the

category A-D infringements, compliance advice was given on 36 occasions. Most commonly, this advice related to poor cage-labelling practices.

In 2009, for categories A-D action was completed on a total of 29 infringements, of which 18 were recorded as category A, 8 as category B and 3 as category C.

In establishments with a good culture of compliance, it is very often the licensees or the certificate holders who inform Inspectors of any apparent non-compliance. In 2009, 26 of the infringements were self-reported.

Category A infringements

Category A infringements involved minor non-compliance issues, such as breaches of conditions, unauthorised procedures competently done or variations from authorities with little additional suffering. These were all genuine mistakes made by licensees who had not previously been involved in non-compliance issues. A number of cases resulted from over-detailed licence authorities, for example limitations on standard routes of administration where no additional welfare cost would have been involved had these been authorised, and others due to very restricted personal licence authorities. The use of the "standard" personal licence techniques list as discussed later under Better Regulation would have avoided a number of these.

Other examples included:

- performing procedures in rooms that were not authorised for such use;
- performing procedures without appropriate authority to do so at the designated establishment in question;
- failure to notify the Home Office of unexpected adverse effects encountered while animals were under anaesthesia;
- mistakenly beginning work before personal licence amendments had been approved;
- transfer of animals without appropriate project licence authority.

Category B infringements

All the category B infringements were promptly reported to the Home Office, all licensees expressed regret for their error and adopted measures to prevent recurrence.

1. A licensee conducted procedures without appropriate personal licence authorities. As this was not the first time there had been a misunderstanding over licence authorities the individual was required to complete further training.

2. A licensee mistakenly re-used a macaque on a procedure without appropriate project licence authority. This was due to an oversight in the drafting of the licence, as the intention was to request re-use following mild procedures where no adverse effects had been encountered, as indeed was the case here. Record-keeping requirements were reviewed within the establishment with all health and procedural records now integrated within each individual animal's records, and an additional independent sign-off required for all re-use.

3. Subcutaneous tumours were allowed to grow in size in mice beyond the end-points defined in the project licence. Although no animal welfare issues were noted, this was indicative of inadequate monitoring by the personal licence holder. The research group reviewed their internal observation programmes to prevent recurrence.

4. A group of 17 mice was not killed after the necessary scientific data had been collected, and the mice were subjected to additional unnecessary dosing. The volume of blood taken from a few animals slightly exceeded the specified maximum in the project licence. No adverse clinical effects were noted. This occurred in a well-managed establishment and was caused by an incomplete local protocol form, the design of which has subsequently been improved to prevent recurrence.

5. A licensee undertook procedures in four mice to investigate problems being encountered with wound closure in an embryo transfer programme. Instead of seeking advice from care staff, the individual tried to resolve the problem by practising different closure techniques. The individual failed to appreciate that there was no authority to conduct such investigations, but felt under pressure to resolve the problems which were delaying the research programme. As a consequence the licensee has undertaken re-training and now has an improved appreciation of the need for good communication with care staff.

6. Four guinea pigs died of asphyxiation after power to an air-conditioned chamber was accidentally switched off. This was a genuine error in a well-managed establishment – additional oversight was introduced to prevent recurrence.

7. A scientist asked an experienced colleague (a personal licence holder)

to perform a surgical procedure. Unfortunately, the experienced licensee did not check the relevant project licence – this procedure had been removed during a recent renewal. Three mice were ovariectomised – the surgery was competently performed, good post-operative care was provided and no adverse effects were recorded. The licensee subsequently completed a Module 1 course to reinforce the responsibilities of a personal licence holder.

8. In a similar situation to the case described above, two scientists misunderstood the legal requirements for conducting procedures. Twenty-four rats were injected by the intra-peritoneal route by a non-licensee (although the individual had previously held a licence and was competent to conduct the procedure). Both individuals mistakenly believed that injections could be delegated to non-licensed individuals. Both individuals were required to complete refresher training. In the case of the non-licensee, any future application will not be considered until confirmation of satisfactory re-training is received.

Category C infringements

Three category C infringements were dealt with in 2009. All were reported to the Home Office.

Two cases involved individuals where evidence supported the view that there was deliberate intent to circumvent the controls of ASPA. The third case involved unnecessary avoidable suffering in a marmoset.

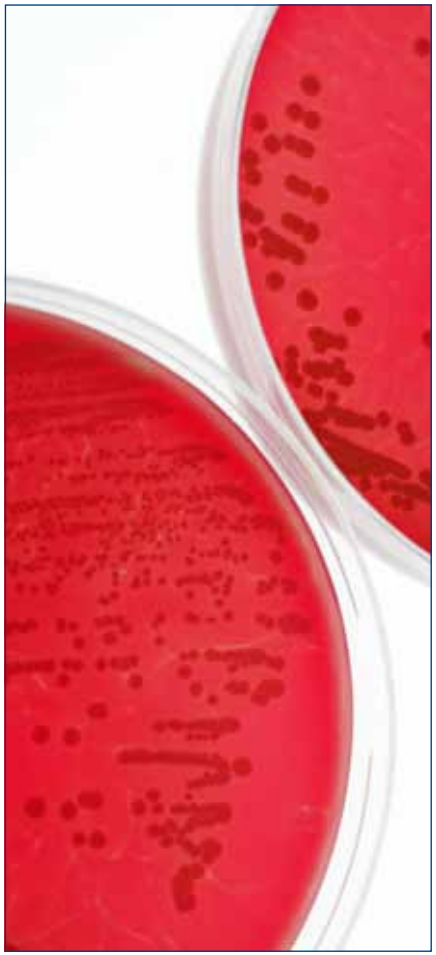
1. A scientist knowingly conducted a surgical procedure without appropriate personal licence authority. The surgery was conducted competently. The project licence holder had requested sight of the personal licence prior to authorising work to begin. Only after the surgery had been completed did the project licence holder realise that the document provided was not the original licence document. On further enquiry it was discovered that the original licence did not contain the relevant surgical technique. Prior to beginning work, the personal licensee had been advised by staff at the other establishment where they were authorised to work, that there was no authority to conduct the surgical procedure on the personal licence. The certificate holders at both establishments at which the licensee was authorised to work requested that the Home Office remove

authority to work at their establishments. The personal licence was subsequently revoked.

2. A marmoset was being used to provide tissue and blood for use by various scientific groups. While under deep non-recovery anaesthesia, the animal was to be exsanguinated. Unfortunately, the animal began to recover consciousness; movement was observed. An overdose of anaesthetic was administered by injection and death quickly ensued. The personal licensee was placed under close supervision, and the certificate holder introduced a number of measures to prevent recurrence.

3. An experienced visiting scientist killed two mouse pups by a method which the scientist knew required licence authorities. Both the project licence and certificate holders had good systems in place to prevent such an incident. The individual acknowledged that they had been instructed in these systems, yet had chosen to proceed. Access to the animal unit was immediately withdrawn. The scientist received a letter of censure and was warned about future conduct. Any future application for licence authorities would require careful consideration and reassurances provided regarding supervision.

Very serious infringements continue to be infrequent. There was generally a high level of compliance with authorities and conditions, and where contraventions occurred, unauthorised procedures were usually competently done and involved no, or minimal, additional suffering. 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.



Events and initiatives

Hampton Implementation Review

In 2006 the Government announced a performance review framework for all national regulators based on the Hampton principles (of regulating effectively while minimising regulatory burdens) and the Macrory characteristics of effective inspection and enforcement (i.e. they should be risk-based and proportionate).

In September 2009 an independent external review team evaluated the regulatory performance of ASPD and ASPI. The resulting ASPD/ASPI Hampton Implementation Review has been published by the Department for Business Innovation and Skills (BIS). The full report is available at http://www.berr.gov.uk/files/file54362.pdf

The review methods included: interviews with staff including senior managers; interviews with stakeholders including government departments, business and academic representative groups; and examination of the documentation and strategies of the units (ASPD and ASPI).

The review team concluded that:

"the Animals (Scientific Procedures) Division and Inspectorate demonstrate good compliance with the Hampton criteria that could be strengthened by further progress in key areas. Overall, the review team saw evidence of the work of a highly regarded team of experts in animal scientific procedures and animal welfare. Their advice was valued and respected by stakeholders, from industry, academic and the voluntary sectors."

In further comments, the reviewers concluded that substandard IT for licensing is the most significant problem facing ASPD and ASPI, requiring improvement as a matter of urgency. Work is progressing to develop a new IT system (see IT Group report, page 25) to carry out licensing tasks securely and efficiently. However, once the development phase is completed further resources will be needed to scale-up and roll-out the new system for operational use.

Recommendations were also made to enhance the range and consistency of advice given by ASPI and ASPD through emails and the website and to consider ways of better sharing the risk basis on which inspections are conducted.

Recommendations of the Hampton review process are now being implemented and will be reported widely to stakeholders and through future annual reports.

ASPD and ASPI wish to extend their thanks to the many stakeholders who responded

to the requests from the independent review team for their opinions and their time during the review.

ASPI review of Wickham Laboratories

On 9 November 2009, Meg Hillier MP requested that a review be undertaken by ASPI into issues arising from a British Union for the Abolition of Vivisection (BUAV) report, *The Ugly Truth*. In this, the BUAV set out its concerns relating to animal care and use at Wickham Laboratories, a designated establishment licensed under ASPA. The BUAV also raised concerns about the Home Office licensing and inspection of animal care and use at Wickham Laboratories.

A Superintending Inspector from ASPI was appointed to lead the Inspectorate review of matters arising from the BUAV Report. Following consideration of the material in the BUAV Report this ongoing review will set out its findings and advise on possible actions with respect to Wickham Laboratories, the Home Office, or elsewhere.

The final report will be reviewed by two independent persons appointed by the Minister, and will be presented to Ministers for consideration in 2010.

Risk-based inspections

Risk management has been reviewed by ASPI and it is considered that the scope, frequency and depth of inspections should be dependent on how each establishment is working in compliance with ASPA, with its specified licence authorities and with any conditions placed upon those licences.

The 'compliance history', overall management and appropriate discharge of their duties by those holding positions under ASPA are therefore key determinants in assigning relative risk ratings to an individual establishment. Added to this are considerations of the nature of work undertaken, the species and numbers of animals used for the regulated procedures and the severity of those procedures.

Risk ratings identify the degree of surveillance required within the licensing and inspection programme for each designated establishment. There is no intention that establishments be rated against each other as a result of risk ratings assigned to them, and specific risk ratings will not be published. Risk ratings can change following inspection, resulting in either increased or decreased risk, and correspondingly an increase or decrease in the frequencies of future inspection.

Europe: Revision of EU Directive 86/609/EEC

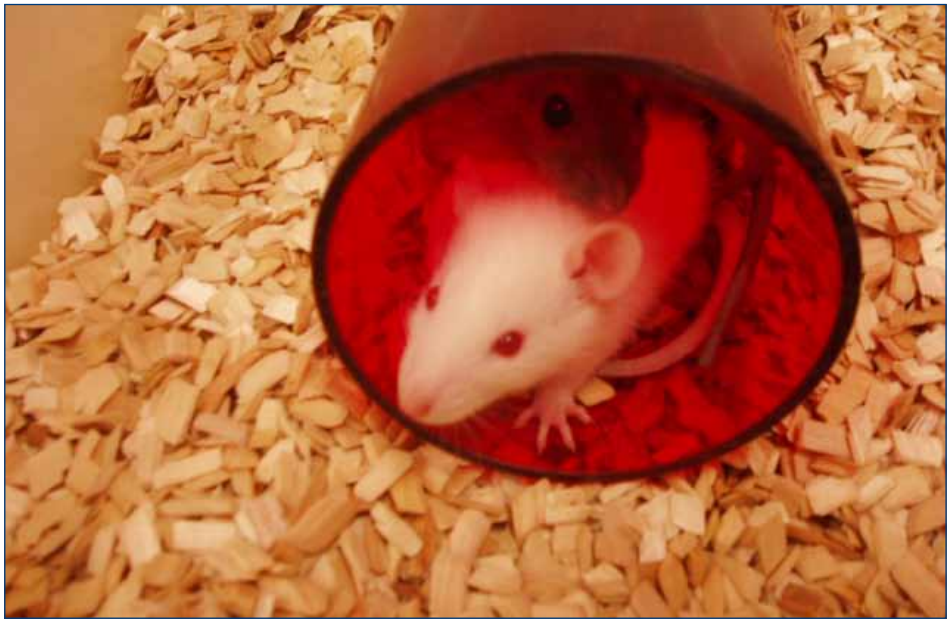
As reported in the 2008 Annual Report, the long-awaited proposal for a new directive to replace Directive 86/609 was finally published by the European Commission in November 2008. This set the scene for a busy year as the proposal worked its way through the European legislative process in Brussels and parliamentary scrutiny at Westminster. By the end of 2009, after an intensive series of negotiations, the main unresolved issues were procedural provisions governed by the Lisbon Treaty.

Under the co-decision process, both the European Parliament and Council of Ministers have to agree the wording of new directives before they can be adopted. They have up to three separate rounds of discussion and negotiation – known as 'readings' – in which to reach agreement. In the UK, the parliamentary scrutiny process has also to be completed in both the House of Commons and the House of Lords before the UK Government can sign up to new European legislation.

It was this latter process which got underway first in 2009 with a debate in the House of Commons European Union Scrutiny Committee on 3 February. In the debate, Meg Hillier MP, explained that the Government's key priority in negotiating the revised directive would be to develop practical,

proportionate and enforceable legislation making proper provision for the welfare of laboratory animals, facilitating their responsible use and adaptable to further technical progress. This approach was endorsed by adoption of the Government motion.

Detailed consideration of the Commission's proposal then began in parallel in the European Parliament and the Council of the European Union. The Council working party, chaired initially by the Czech Republic, was attended by officials and veterinary experts representing all 27 Member States and by representatives of the European Commission. The UK was represented by a Home Office team reporting back to and supported by an inter-departmental group representing other Whitehall and Northern Ireland departments.



Because of the impending European elections, the European Parliament's Agriculture Committee worked quickly to produce its report on the proposal which was presented to and adopted by a plenary session of the European Parliament early in May 2009.

The resulting report proposed more than 150 amendments to the Commission's proposal and struck a balance between the need to protect animals and the interests of the research community

Also in May 2009, the House of Lords European Scrutiny Committee began its inquiry into the Commission's proposal and the Home Office launched a public consultation on its provisions. The consultation closed at the beginning of July 2009 in time to inform UK input to the further Council working party discussions. These became more frequent and intensive in the second half of 2009 under the Swedish Presidency.

In October 2009, Lord Brett gave oral evidence to the House of Lords Scrutiny Committee on behalf of the Government and the Council working party concluded its discussions. From this point negotiations were taken forward by Member States' permanent diplomatic missions in Brussels.

The House of Lords Scrutiny Committee published the report of its inquiry in November 2009 when so-called 'trilogue' or 'trialogue' discussions also began between the Presidency, the European Parliament and the Commission to agree the final details of a 'first reading agreement' on the text. These discussions were successfully concluded just before Christmas 2009.

The House of Lords scrutiny continued into 2010, and will be described in the 2010 report.

Overall, the revised text provides a regulatory framework which is more flexible and less prescriptive than the Commission's proposal and will allow the UK to maintain high standards of welfare and animal protection without the imposition of unnecessary bureaucracy.

Better regulation

Certificates of designation (PCD)

As part of the 'Better Regulation' agenda a new simplified PCD form was introduced in 2007 to reduce the number of amendments needed and simplify the paperwork when the only amendments requested were changes to the named persons. It is not mandatory to use the new form and existing certificate holders were given the choice to retain the existing certificate format or make use of the new form. The option to have different parts of the certificate on the new and the old form was also allowed.

Because changing to the new form was likely to be a major burden to larger establishments having many buildings with facilities for animal holding and use, a commitment was given to review uptake and assess whether the form had made a positive contribution to better regulation. This was undertaken in the final quarter of 2009 when opinions were also collected from selected certificate holders. At that time the majority of designated establishments (62%) were continuing to use only the old form, 25% were exclusively using the new form with the remainder (13%) using both formats. Information obtained from establishments still retaining the old form suggested that for many the

time and resources needed to change was perceived to outweigh the benefits of changing to the new format. Nonetheless, many certificate holders make use of the new form when requesting PCD amendments.

Project licence (PPL)

During 2009 we developed a new PPL application form and released it for general use. During the two-year development period a wide range of internal and external stakeholders was involved in a series of workshops and in providing feedback. The new application form therefore reflects this consultative process. It was launched in November 2009 and early indications are that it has been well received. Applicants have reported that the questions are more clearly worded so that they know precisely what information to include to enable the Inspectorate to carry out a comprehensive assessment against the criteria set out in ASPA. A number of minor teething problems with the new PPL form have been pointed out to us and we aim to resolve these when the initial pilot phase is completed in 2010. The new form includes the additional conditions allowing the transfer of small rodents referred to on page 8 in the discussion of transfer forms.

At the same time as the launch of the new form, three theoretical example applications were posted on the Animal Scientific Procedures section of the Home Office website to illustrate the level of detail required by Inspectors to enable them to make their assessment. It is planned that more examples will be added in due course including licences for education and training, genetically-altered animals and pharmaceutical/contract research.

To promote consistency, the new PPL form has been complemented by a new form for Inspectors to record their assessment. An internal review of a cross-section of these assessment reports from all Inspectors is planned for 2010. Feedback from this will be used to further refine the assessment process.

Personal licence (PIL)

Inspectors have continued to monitor the use and value of the suggested wordings for techniques in section 15 of PILs. An increasing number of licence applicants are using the suggested wordings which are available on the Home Office website. Minor improvements in wording clarity have been made. Future work includes expanding the list to include techniques in other species e.g. fish, and preparatory work in anticipation of changes to EU Directive 86/609.

Reports from ASPI work groups

Accommodation and Care Group

The scope of the work carried out by the group in 2009 included advising individual Inspectors on a range of issues relating to the accommodation and care of animals used in research. In addition, the group considered novel designs for cage accommodation and enrichment for rodents, and developed guidance intended to supplement the advice given on the Home Office website on points to consider when seeking designation of new or refurbished animal facilities. This will be circulated to certificate holders in 2010.

Aquatics Group

In 2009 the aquatics group responded to many queries from external stakeholders and Inspectors on aspects of the use of aquatic animals including advising on whether procedures reached the threshold requiring regulation under ASPA. Members of the group gave presentations on the challenges of the use of humane endpoints in fish and on experiences relating to inspection of UK fish research facilities at a meeting convened by the EU group '*Harmonisation of the Care and Use of Fish in Research*'. Discussion of this and other aspects of fish research resulted in the production of a consensus document which

has now been published on the group's website (http://www.norecopa.no/norecopa/vedlegg/Consensus-sep09.pdf). The group continued to contribute to the consultation process regarding revision of the EU Directive, with particular emphasis this year on providing advice about invertebrate species. External stakeholders were informed about proposed changes and encouraged to formally express their views.

Shellfish Toxin Testing

In relation to the safety testing of shellfish for toxins, the Inspectorate has continued to work with the Food Standards Agency and testing laboratories to make further progress towards the replacement of the in vivo mouse bioassays with in vitro analytical testing methods.

For paralytic shellfish poisoning (PSP), a fully quantitative chemical method is now used for the majority of shellfish samples tested. Validation of the alternative method for additional shellfish species is ongoing. Where this has not yet been achieved, an in vitro screening method is used, with testing in animals only undertaken where at-risk samples are detected. In the limited number of samples that still use the mouse bioassay, reduction strategies in place mean that 33 per cent fewer mice are used than in the standard testing methodology.

In total, there has been a reduction in animal use from 5 years ago of over 80 per cent, with a further reduction expected in 2010.

For diarrhetic shellfish poisoning/ lipophilic toxins (DSP) it is hoped that a replacement method will be fully validated for the major species of shellfish during 2010 to allow a substantial reduction in animal use in testing for this toxin group from early 2011. In the meantime, reduction and refinement strategies mean that over 30 per cent fewer animals are used and the test duration is significantly shorter than in the standard methodology thereby reducing animal suffering.

Consistency Group

The Chief Inspector, in the 1997 Animal Procedures Committee Report, wrote that:

"Consistency is essential for the equitable treatment of licence and certificate holders, and is a quality measure of the service provided by the Inspectorate to the Secretary of State".

This statement still remains true, particularly following the Hampton Implementation Review Report (see page 16) which emphasised the need for consistency within the Inspectorate and for greater transparency about the efforts we make to achieve that consistency.

The Consistency Group (CG) operates within a wide framework including the following key areas:

- It reviews outputs from discussions within ASPI and from other ASPI "teams" and with officials in ASPD. Where appropriate it enters the key findings into our information resource and disseminates these to the Inspectorate;

- The CG maintains information on policy, precedents and practice with regard to the application of the 3Rs (Reduction, Replacement and Refinement) in animal models. During 2009, the CG reviewed this information resource, revised and updated it as necessary and identified areas where new entries would be helpful;

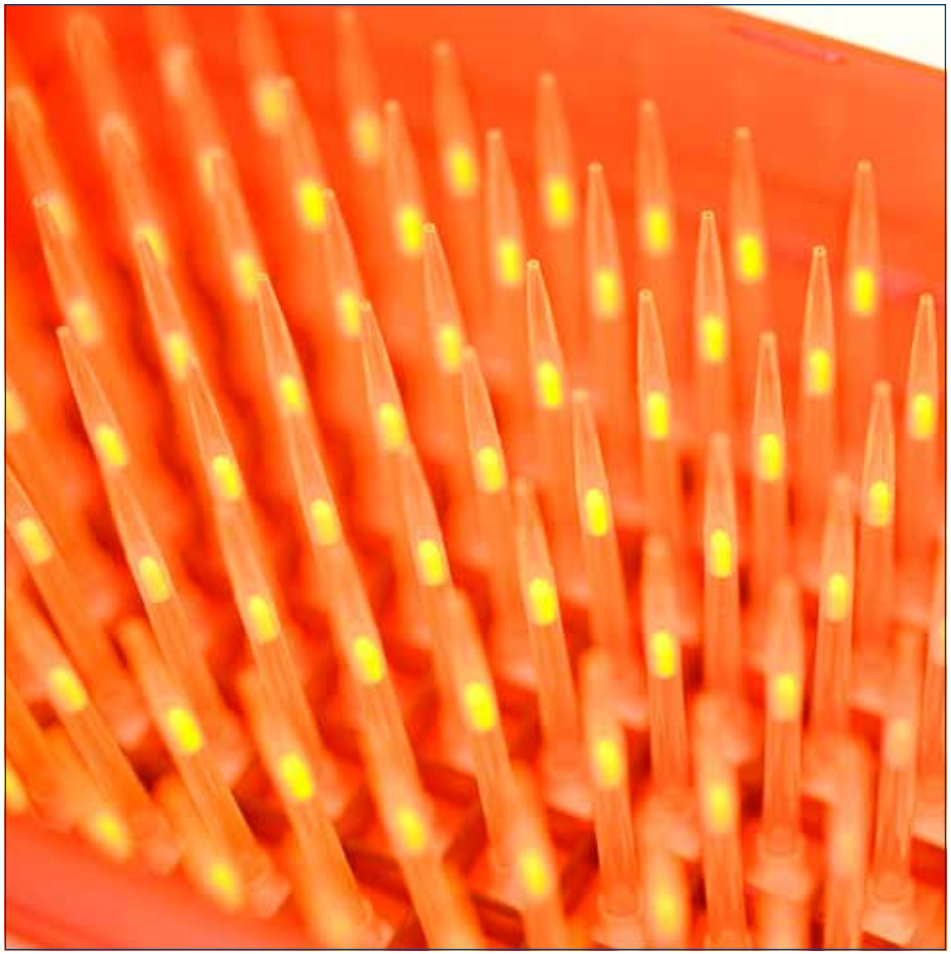
- It provides feedback to Inspectors, individually or in groups, through case studies, summaries and workshops;

- It monitors consistency of outputs of Inspectors in relation to applications for licences or certificates under ASPA by reviewing a sample of assessment reports. As part of this remit the CG will continue to develop recommendations on severity limits. The Group also looks at the application of administrative practices, including referral of an application within the Inspectorate, to the Animal Procedures Committee or to external assessors;

- It monitors consistency of outputs of Inspectors in relation to inspection by reviewing a sample of visit reports;

- It monitors consistency of outputs of Inspectors in relation to reporting of non-compliance. All Inspectors are expected to follow a common approach to reporting non-compliance with ASPA or the conditions of licences or certificates;

- It maintains a watching brief over the interface between ASPA and other legislation such as the Veterinary Surgeons Act (1966) and disseminates relevant information to ASPI.



Education and Training Group

As part of its remit to ensure consistency with respect to education and training project licences, in 2009 the group considered and offered advice on six such project licence applications. Additionally it provided advice to Inspectors on exemptions from mandatory modular training requirements for personal licence applicants not covered by Appendix F (Sections 22-24) of the Guidance on the Operation of ASPA. Several licensed courses were visited to learn more about the diversity of education and training offered in the UK and to hear at first hand the perceived educational benefits accruing from education and training licences. The information gleaned will be used in the production of an example project licence application due for inclusion on the Home Office website in 2010.

The group also provided advice and technical expertise to the Animal Procedures Committee (APC) on the revision of Module 5 training and on the revisions to the European Directive. It liaised with the Association of the British Pharmaceutical Industry (ABPI) and the Department for Business, Innovation and Skills (BIS) to offer advice on policy and licensing requirements to the *in vivo* sciences task group.

Information Technology (IT) Group:

Prior to the Hampton Review, it had already been acknowledged that ASPD and ASPI faced challenges with respect to updating and improving IT and data-handling systems. As a consequence, a working group was set up to review current systems and to develop an IT Strategy for improving the situation. Since its inception, the group has worked closely with IT service providers and other experts based both within the Home Office and elsewhere to identify, develop, and implement suitable technical solutions designed to meet the needs of everyone working under ASPA more effectively. Within the IT Strategy, there are currently three significant ongoing projects which are likely to have the greatest impact on external stakeholders as we strive to meet our objectives relating to better regulation, the Hampton Review and Cabinet Office requirements for enhanced data security.

Electronic licence application system: The ultimate aim of this project is to develop a fully electronic, secure, licence-processing system which will enable applicants to apply for new ASPA licences and licence amendments online. It is hoped that the ability to fill in and submit applications online will prove to be far more convenient for most applicants and should significantly reduce processing delays and other frustrations associated with the time, effort and expense of physically transmitting paper files. The first stage of this project has been completed and we will shortly be moving towards developing a 'model office' environment to find out whether the work processes necessary for appropriate handling of case files can be successfully implemented. System testing prior to launch will involve significant input from Inspectors, the ASPD licensing team and external stakeholders. Further progress will continue to be reported via ASPD e-newsletters, project-specific e-communications and stakeholder workshops.

Remote working: ASPI work often involves a lot of time spent travelling and working away from the office, yet continuous access to email and other information resources is imperative if we are to be able to continue to work as efficiently as possible. This year the IT Group has worked hard to facilitate the procurement and deployment of suitable secure mobile-working technologies designed to make it much easier for Inspectors to respond as quickly as possible to requests from licensees and other stakeholders.

Data encryption: Following the publication in June 2008 of the Hannigan Report into Data Handling Procedures in Government,

its recommendations for ensuring enhanced protection for sensitive personal data and other protectively marked information have been reviewed and implemented. This project has included revising and publishing new, more secure information-handling procedures for ASPA-related work and making email encryption services available to stakeholders so they can communicate with us securely.

Non-Human Primates (NHP) Group

The Non-Human Primates Group has continued to act as the information source for Parliamentary Questions, and Freedom of Information Act requests relating to primates. The Group comprises two subgroups, one focussing on issues to do with the breeding and supply of NHPs, and the other concentrating on the scientific use of these animals.

The breeding and supply subgroup operates a visiting programme to overseas primate breeding centres, which contributes to the appraisal of the suitability of such centres as sources of purpose-bred NHPs for scientific use in the

UK. In 2009 several primate breeding establishments were visited in China, Vietnam and Cambodia. In addition reviews of overseas primate breeding centres were conducted to confirm their continuing acceptability. The breeding and supply subgroup also considers requests from project licence holders to acquire NHPs from overseas sources, and reviews details of the consignments received to monitor the performance of the breeding centres involved.

The scientific use subgroup has continued to work with the National Centre for the 3Rs (NC3Rs) on the preparation of a publication about refinements to water control regimes in NHPs. The subgroup also prepared posters on the concept of 'cumulative severity' for display at the VII World Congress on Alternatives in Italy, and has begun collating information as a basis for selecting key areas of research work for thematic review in 2010.

PODE Group

The PODE Group reviewed and updated internal advice to Inspectors on work carried out at Places other than a Designated Establishment (PODE). The result is a comprehensive document that includes advice on assessing applications to conduct work at PODEs. Such advice contributes to ensuring consistency across the Inspectorate when considering project licence applications.

When assessing work intended to be done at a PODE, Inspectors need to give special consideration to a variety of additional issues as some of the controls and protection afforded by ASPA to animals kept at a designated establishment are not practicable at a PODE. For example there is no provision for a named day-to-day care person, also known as the Named Animal Care and Welfare Officer (NACWO), or a named veterinary surgeon at a PODE. Alternative arrangements must be agreed on a case-by-case basis to address the health, welfare and care needs for the animals to be used. In addition, the nature of the work often means that it is done irregularly and infrequently; consequently additional information in the project licence application is needed to ensure that such work can be inspected.

Nesting fulmar; photograph copyright University of Aberdeen

Animals Scientific Procedures Division activities

Communication with stakeholders

Our principal means of communicating with our external stakeholders has been the ASPA e-newsletter. The newsletter contains a variety of information that we feel is of interest and includes relevant items from other organisations such as the RSPCA and the NC3Rs. Newsletters are sent at regular intervals and subsequently appear on our website. Currently, we distribute the newsletter to over 1,800 stakeholders. Licensees and others who have not already done so are encouraged to send their contact details to: aspnewsletter@homeoffice.gsi.gov.uk if they wish to receive the e-newsletter.

When we need to convey information directly to certificate holders we distribute PCD Circulars electronically.

Communication with the general public

The Home Office Direct Communications Unit answers approximately 80 per cent of the correspondence received directly from members of the public. The remainder, which often deals with specialist topics or technical issues, is dealt with by ASPD in consultation with ASPI or colleagues in, for example, Home Office Research Development and Statistics.

Some communications from members of the public are submitted by their MP. In such situations we provide the Minister with the advice to ensure an accurate and timely reply is sent.

Freedom of Information requests

In 2009 we received eight requests under the Freedom of Information Act (FOIA). On receipt of such requests our aim is to first establish exactly what information we hold and then to disclose as much information as possible within the parameters of the Act. In doing so we must take into consideration section 44 of FOIA that provides that information is exempt information if its disclosure (otherwise than under FOIA) is prohibited by or under any other enactment. In particular, information contained in applications and licences and certificates issued under ASPA may be exempt from disclosure under section 24 of this Act.

Should any request result in the disclosure of information not previously in the public domain then the Home Office Information Access Team will consider whether it is appropriate to publish the information on the Home Office Freedom of Information Publication website.

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 parallel units within the Science and Research Group (SRG) 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 which 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.

ASPD staff grant, vary and revoke licences and certificates on behalf of the Secretary of State, and instigate executive action when there has been significant non-compliance.

They also oversee the collection of annual fees from designated establishments and assist in the collection of annual statistical returns of procedures from project licence holders.

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 3 Rs.

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 (see Hampton Inspection Report article), 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://scienceandresearch.homeoffice.gov.uk/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

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 significant refinement or reduction consequences;
- resolved or remedy in place within days of discovery;
- no likelihood of representations being made.

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:

- significant refinement or reduction concerns;
- 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 refinement or reduction concerns;
- 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.

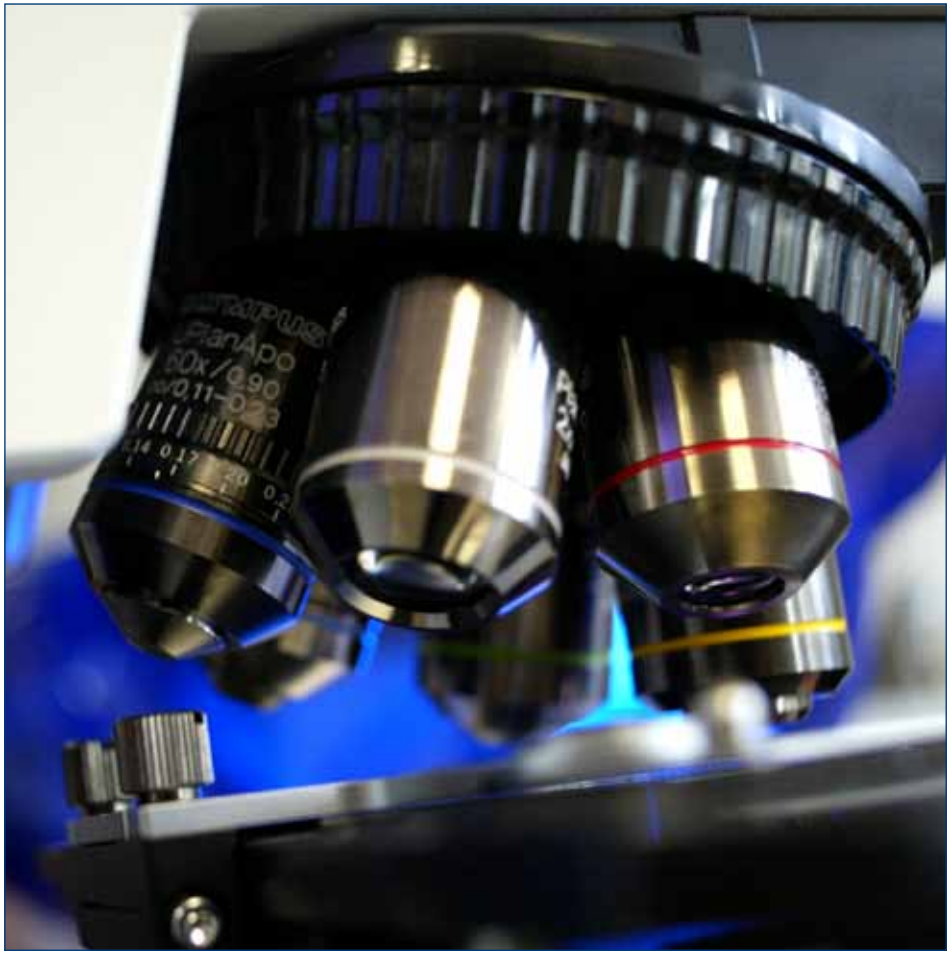
Typically, the outcome of a category C infringement will be either to amend, revoke or suspend the licence or certificate, and to send a letter of admonition to the licensee or certificate holder.

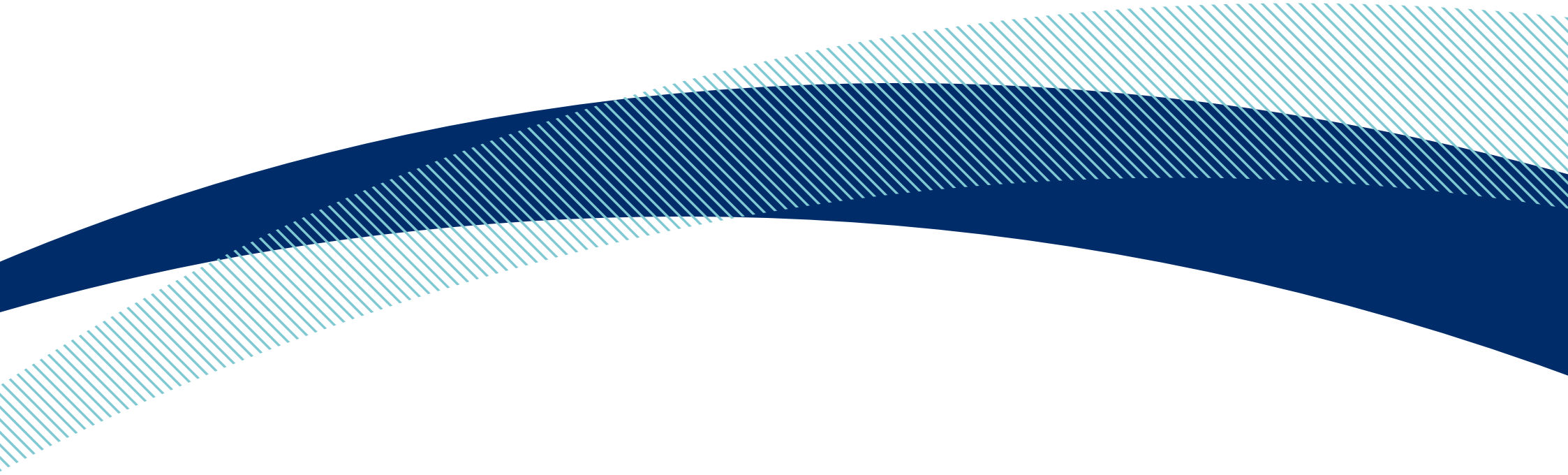
Category D infringement

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

- serious 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.





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