ANIMALS IN SCIENCE REGULATION UNIT
ANNUAL REPORT 2011

Home Office

Contents

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

Foreword

I am very pleased to introduce the 2011 Annual Report of the Home Office Animals in Science Regulation Unit.

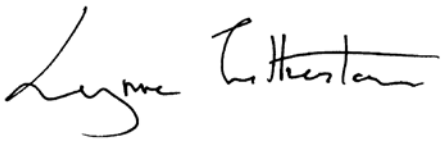
A major change in 2011 was the amalgamation in September of the Animals Scientific Procedures Division and the Animals Scientific Procedures Inspectorate into a single body – the Animals in Science Regulation Unit (ASRU). The Unit, in both its old form and new, has continued to work closely with a wide range of external stakeholders and with colleagues across Whitehall to take forward a number of issues.

Of particular significance during the year was the public consultation on the options for transposition of the new European Directive (2010/63/EU). The new Directive replaces Directive 86/609/EEC on which the Animals (Scientific Procedures) Act 1986 is based. I have met with a number of stakeholders during the year and have been impressed by the commitment all have shown to ensuring we achieve the right balance in revised legislation transposing Directive 2010/63/EU.

Also of significance has been 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.

The routine work of licensing and inspection, applying risk-based principles, has also continued to the established high standards, amply demonstrating the professionalism and commitment of all the staff in ASRU.

Everyone deserves to be congratulated on another successful year.



Lynne Featherstone
Minister for Equalities and Criminal Information

Introduction

The year 2011 has been a year of change for all involved in the use of animals in research. An obvious change for the Home Office staff has been the merger of our two sections into one unit – the Animals in Science Regulation Unit (ASRU). This brings together the professionalism and expertise of those involved in policy, inspection and licensing to be able to work more collaboratively in delivering our objectives as the regulator of the use of animals under the Animals (Scientific Procedures) Act 1986.

Decisions on inspection are risk based and, in this report, we further describe the process of risk assessment and the outcomes in terms of the nature and frequency of inspection. An important initiative has been to introduce formal risk management meetings between inspectors and senior staff at designated establishments. These meetings have helped to develop action plans to mitigate risks where appropriate.

Change for our stakeholders was flagged up by the public consultation about Directive 2010/63/EU. Based on what we learnt, we commenced the early stages of preparing draft regulations. These will ensure no reduction in the standards of care and protection of animals used in scientific procedures, and will help to promote alternatives.

The development of a web-based licence application system (CBP e-Licensing) has progressed significantly during 2011 with a number of establishments piloting the system by the end of the year. We expect to roll out the system more widely during 2012, which will benefit both our stakeholders and ourselves by improving overall access to information within a secure environment.

In July 2011 Lynne Featherstone, Home Office Minister for Equalities and Criminal Information, announced arrangements for delivering two coalition government commitments relating to the use of animals in research. In this report we describe some important advances made with implementation of the commitments towards promoting the 3Rs (Reduction, Refinement & Replacement).

As in previous years, significant effort has gone into the granting and amending of licences and certificates and it has been important to ensure the quality of this work does not suffer amidst all these other challenges. I am pleased therefore to report that our performance in 2011 has continued to improve and exceed our targets

As ever, it is 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 that sustains public confidence and clearly delivers value for money. I believe this report demonstrates our approach in achieving this objective.

Judy MacArthur Clark CBE
Head, Animals in Science Regulation Unit

Section 1: Licensing and inspection

THE LICENSING TEAM

The Animals in Science Regulation Unit (ASRU) Licensing Team operates the licensing system on behalf of the Secretary of State. It grants applications for new licences and certificates; grants amendments to existing authorities; and revokes or varies licences and certificates as necessary, following advice received from the Inspectorate, and sometimes from the Animal Procedures Committee.

The Licensing Team is responsible for instigating executive action when there has been significant non-compliance. It also administers the collection of annual fees from designated establishments and of annual statistical returns of procedures from project licence holders.

On 31 December 2011 there were 21 licensing staff in post, with 3 each based in Cambridge, Dundee and Shrewsbury, 2 in Swindon, and 10 (including the management team) in London.

THE 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.

The Inspectorate started the year with a total headcount of 25 inspectors, including the Chief Inspector and 3 Superintending Inspectors. The average resource assigned to normal inspection duties (full-time equivalents – FTEs) over the course of the year was 19, which was somewhat lower than in previous years (22.1 in 2010; 22.3 in 2009; 22.4 in 2008), see **Figure 1, Appendix 4**.

Inspectors spend approximately one-third of their time visiting establishments and about one-third assessing applications for licences and certificates. The remaining third includes work on ASRU's significant outreach programme (e.g. supporting stakeholder initiatives on working groups), strategic initiatives to enhance the Inspectorate's service delivery, and participating in continuous professional development events to ensure skills are maintained and developed.

In 2011 a significantly greater proportion of time compared to 2010 was spent by inspectors in providing strategic advice on key business issues, including:

- implementing the EU Directive and analysing the public consultation responses;
- preparing for the ASRU restructuring programme; and
- developing the e-Licensing system.

Inspectors assigned to these special duties remained part of the Inspectorate and will return to normal inspection duties at the appropriate time.

On 31 December 2011 the total Inspectorate headcount was 23 with 21 inspectors actively inspecting, the remaining effort being assigned to management and implementation of the EU Directive.

PERSONAL LICENCES AND CERTIFICATES OF DESIGNATION

Table 1, Appendix 4, summarises the unit performance and statistics in terms of personal licences and certificates of designation for 2011.

During 2011 we granted 2,550 personal licences. This was a small decrease (0.4%) in assessments leading to granted licences compared with 2010. Of the personal licences granted in 2011, 108 (0.5% of the total) were requested to be processed under the 'fast-track' procedure.

We also granted 3,810 personal licence amendment requests and reviews. This was an increase (1.49%) of 56 compared with the number granted in 2010 (3,754).

In 2011, two applications for new certificates of designation were granted compared with four in 2010. There were 481 requests for amendments to existing certificates in 2011, an increase of 106 (28.2%) on the 375 requests in 2010. In addition, nine certificates were revoked during 2011, all at the request of the certificate holders. There is often a significant amount of work for ASRU staff in closing such establishments to ensure that work is properly concluded and reported, and that animal welfare is appropriately safeguarded.

PROJECT LICENCES

Table 1, Appendix 4 also shows performance and statistics in terms of project licences for 2011.

The assessment of project licence applications is by far the most time-consuming activity for inspectors and licensing staff. In total, inspectors advised that 564 project licence applications should be granted, see **Figure 2, Appendix 4**. The number of project licences granted increased by 9.5 per cent between 2010 and 2011. Inspectors also gave advice on 2,184 requests for amendments to existing project licences, an increase of 32.8 per cent on the 1,645 requests in 2010.

The 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, Appendix 4** shows the performance trends against targets for the last six years. Average processing time in 2011 was an all-time best, at 16 days, and this was the fifth consecutive year that the processing time has fallen. Consequently, the proportion of licences granted within 35 days (91%) continued to exceed the target.

INSPECTION

During 2011 the Inspectorate carried out 1,437 visits to places where scientific work on animals was conducted. Of the visits made to animal units, 66 per cent were made without notice and 45 per cent of all visits were unannounced. These inspections amounted to 4,428 hours of contact time with those holding licences or certificates under ASPA, in addition to 3,644 hours spent travelling. The overall number of visits was lower compared with 2010 (26%), but the total contact hours were not reduced by as much (22%), indicating that the average visit in 2011 was longer. Time spent travelling showed a similar decrease (24%), see **Figure 4, Appendix 4**. The average number of visits per FTE also decreased (90 in 2010 compared with 75 in 2011) as did contact time per FTE (232 hours in 2011 compared with 257 hours in 2010), see **Figure 5, Appendix 4**.

These changes reflect a number of factors including the implementation of the risk-based approach to inspection based on objective measures of risk, see **Appendix 2**. The risk-based approach to inspection is reviewed in Section 3 of this report. In addition, the higher number of applications for project licences and amendments significantly increased the workload for inspectors.

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

Section 2: Compliance and infringements

INTRODUCTION

A major function of visits is to determine whether designated establishments and licensees are complying with the provisions of the Animals (Scientific Procedures) Act 1986 (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, see below) are recorded in the inspectors' visit reports, and the numbers 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, or earlier in severe cases if appropriate. Infringements are categorised according to severity – the main characteristics of the categories can be found in **Appendix 3**.

In 2011 there were 155 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 investigations into 39 infringement cases were completed (21 category A, 11 category B, 6 category C infringements and 1 category D infringement), see **Table 2, Appendix 4**. In establishments with a good culture of compliance, it is very often the case that the licensees, the certificate holder or their staff report suspected non-compliance to the Inspectorate.

In 2011, 25 of the 39 infringements were self-reported. The Inspectorate found seven category A, three each for category B and C, and one for category D. Figures for 2011 are compared with those for previous years in **Table 2 Appendix 4**.

CATEGORY A INFRINGEMENTS

In 15 of the 21 cases, procedures (e.g. blood sampling, intraperitoneal injection, cannulation, re-use) were carried out competently but without the necessary authorisations. In two cases there was a failure to report unexpected adverse effects. In the remaining four cases there was one case each of: animals maintained after the expiry of the project licence; the severity limit on one of the protocols classified as moderate being unexpectedly exceeded; animal cages being incorrectly labelled; and animals left overnight in a scanner.

CATEGORY B INFRINGEMENTS

1 In a period of 2 weeks, 474 fish died after being transferred to water at a temperature inappropriate to their needs or due to secondary infection. The majority of the fish died within 24 to 48 hours of transport, and were not on procedure at the time of the incident. This case was self-reported. Improved standard operating procedures and staff retraining were put in place, and the certificate holder was admonished.

2 In another case 20 rats were given what was believed to be an overdose of anaesthesia, blood was then taken and euthanasia was completed by cervical dislocation. There was a failure to check that this procedure had been properly carried out and only 19 bodies were placed in a clinical waste bag. The remaining rat was discovered alive in the room two days later and was immediately euthanased. The incident was self-reported by the establishment. The personal licence holder was admonished and required to undergo retraining in modules 1, 2 and 3.

3 Over a period of 2 weeks, 8 of 15 mice were found dead, and a further 3 had to be culled due to the moderate severity limit assigned to the protocol being unexpectedly exceeded. The project licence holder failed to notify the Home Office that the moderate severity limit had been exceeded. The project licence holder had conducted his own very thorough investigation into the incident but did not appreciate that he was required to report the incident to the Home Office. The inspector discovered the incident. Those involved put new procedures in place to reduce the likelihood of any such recurrence. The project licence holder was sent a letter of admonition.

4 Over a period of around 3 weeks, substances were administered intraperitoneally to 21 mice as 2 injections per day, around 6 hours apart. While the project licence permitted such a procedure, it was limited to a maximum of one injection per day. The inspector discovered the case during an inspection of the animals' records. The infringement occurred because of a failure by staff to adequately check the project licence before commencing regulated procedures. A letter of admonition was sent to the project licence holder and also to the personal licence holder who carried out the procedure.

5 Following a magnetic resonance imaging session, two rats were inadvertently left in an unattended procedure room without access to water from Friday to Sunday. The failure to remove the rats from the room on the Friday was due to pressures of other work on the part of the personal licence holder and a lapse in concentration. When the animals were discovered, effective action was immediately taken to alleviate the suffering to the animals. The incident was self-reported by the establishment, and a number of remedial steps were instituted by the establishment to reduce the likelihood of any such recurrence. The personal licence holder and the holder of the certificate of designation were each sent a letter of admonition.

6 While conducting a routine inspection, the inspector noticed ulceration on the skin of around 50 per cent of an experimental group of mice. This exceeded the moderate severity limit set out in the project licence protocol. These had not been reported to the Home Office as required, and the personal licence holder involved admitted that he was unaware of the protocol endpoint. Those conducting the research agreed to modify the method of administration of substances so as to refine the endpoint and reduce the likelihood of ulceration. The personal licence holder and the project licence holder were each sent a letter of admonition and required to undergo retraining in module 1within three months of the date of their letter.

7 In another case two mice were injected with a fluorescent marker and then anaesthetised by inhalation in order to demonstrate the functions of new imaging equipment that had recently been purchased by the establishment. The procedures to demonstrate the equipment were not authorised by a project licence. The infringement was discovered by the inspector during a routine inspection, and resulted from a misunderstanding of the Act rather than any attempt to circumvent the controls. The certificate holder arranged for retraining of all the relevant licence holders at the establishment. A letter of admonition was sent to the personal licence holder and project licence holder involved.

8 Two groups of three rats were each placed in a warming box to prepare them for a procedure. The personal licence holder involved left the room, and assumed that another personal licence holder would monitor the rats. However, this was not formally arranged and did not happen. On her return to the room it was discovered that one group of three was dead or dying. The incident was self-reported by the establishment, and there was no evidence that the establishment procedures were at fault but rather that the personal licence holder involved had not followed internal or licence procedures. The personal licence holder was sent a letter of admonition and required to undergo training in modules 1, 2 and 3 within three months of receipt of the letter.

9 Cannulae were implanted into 15 hamsters using injectable anaesthesia. One of the anaesthetic agents used was out of date, and recovery of the hamsters following administration of a reversal agent was problematic. A number were found dead and the remainder had to be humanely killed. The personal licence holder failed to seek veterinary advice and also failed to keep adequate records. The incident was self-reported by the establishment. The personal licence holder was sent a letter of admonition, required to undergo retraining in modules 1, 2, 3 and 4 within three months of receipt of the letter, and a condition was added to the licence requiring supervision by the project licence holder or an experienced personal licensee until competence had been achieved.

10 A personal licence holder anaesthetised three rats in order to implant an intracranial cannula in each. During fixation the faces of all three were damaged, including an eye injury in one animal. A cannula was not implanted in this rat but one was implanted in each of the other two, both of which recovered uneventfully. The licence holder failed to seek any veterinary advice or treatment for the three animals and, following advice from animal care staff, the rat with the eye injury was humanely killed. There were no records of the anaesthesia or procedures associated with the intended surgery for this rat, and the records for the other two rats were inadequate in both cases and inaccurate in one case. The incident was self-reported by the establishment.

Whilst it may be debatable as to whether this event constitutes a category B or C infringement, the penalty would likely have been the same in either event. The project licence holder and personal licence holder were each sent a letter of admonition. Additionally, the personal licence holder, who carried out the procedures on the rats, had two conditions varied on their personal licence. The first removed all those permissible techniques requiring module 4 (surgical procedures) training, and the second required their supervision by another experienced personal licensee until such time as the Inspectorate assessed them as having achieved the required level of competence.

11 A pig was re-used (from a protocol on project licence 'A') on a protocol of project licence 'B' without the necessary project licence authority to allow the re-use of that animal. The infringement was self-reported by the establishment. Inspection of the establishment records revealed that it was not possible to identify who had blood sampled the animal. The two personal licence holders involved were each sent a letter of advice, and the certificate holder was sent a letter of admonition and required to provide, within 28 days of the letter, details of the actions taken to improve the company directors' understanding of the scope and requirements of ASPA.

CATEGORY C INFRINGEMENTS

1 Over a period of a week on 2 separate occasions, as a result of a failure of the drinking water system, 24 cages flooded causing death due to drowning for 208 mice. One week later, as the result of a leak in the roof space, a number of cages flooded resulting in the death of eight rats due to drowning. Subsequently, a further 188 rats were euthanased because of concerns about contamination with the dirty water from the roof space. The incidents were self-reported to the Home Office. Following these incidents the establishment initiated a review of all automatic watering systems on site and instituted a programme of renewal and upgrade to minimise the possibility of any similar recurrence. The certificate holder was sent a letter of admonition and the certificate was varied, requiring the establishment to submit a formal report to the Home Office setting out the actions taken immediately following the incidents and a time course for completing all outstanding remedial actions.

2 In another case 3 birds died, 62 were killed on humane grounds and 41 required treatment for injuries sustained after white lights were inadvertently left on overnight in a poultry room leading to feather pecking and fighting. The incident was self-reported to the Home Office. The establishment instituted a number of measures to avoid any recurrence, including the installation of motion detectors that selectively pick up human activity and automatically extinguish the lighting after staff have left. The certificate holder was sent a letter of admonition.

3 Regulated procedures were carried out on rats, resulting in two separate events in which one rat developed a large tumour and five others developed lesions surrounding their catheter entry sites. The personal licence holder failed to monitor and properly care for the single rat and initially failed to take advice from the Named Veterinary Surgeon (NVS) and the Named Animal Care and Welfare Officer (NACWO) to kill the rat with the tumour humanely when it became apparent that the moderate severity limit attached to the project licence had been exceeded.

Instead, the personal licence holder requested that the animal be permitted to live for a further two weeks to enable the experiment to be completed. The NACWO rejected this request and euthanased the animal. With the group of five rats, concerns were first raised by the NVS about the condition of these animals and the deputy project licence holder agreed that the animals should be euthanased. The incidents were self-reported by the establishment. The project licence holder and personal licence holder were each sent a letter of admonition. Additionally, the personal licence holder, who carried out the procedures on the rats, was required to undergo retraining in module 1 within three months of receipt of the letter.

4 The holder of a personal licence commenced regulated procedures on mice when the project licence they were working under had only four days to run before expiry. They then transferred the animals under experiment to another project licence in order that they might continue with their work. They failed to seek permission from either of the project licence holders to undertake this transfer. They also mislabelled cage cards in an attempt to cover the facts. When the work was being lawfully carried out on the original project licence, they failed to check properly on the condition of the mice to the extent that a number died from infection while others had to be humanely killed. The infringement was discovered by the Inspectorate. In this case the Secretary of State revoked the personal licence.

5 Regulated procedures were performed on two sheep, without the appropriate project licence authority, which resulted in bone fracture and unnecessary suffering. The work was undertaken at an establishment

under secondary availability and there was a failure by staff at the second establishment to confirm that the proposed work was authorised there. The infringement was discovered by the inspector. The project licence holder and personal licence holder at the primary establishment were each sent a letter of admonition. Additionally, the personal licence holder who carried out the procedures on the sheep was required to undergo training in module 1 within three months of receipt of the letter. The project licence holder was additionally required to undergo training in modules 1 and 5 within three months of receipt of the letter, and had the secondary availability permission removed from his project licence. The certificate holder at the secondary availability establishment was sent a letter of admonition.

6 Staff at an establishment were identified as applying inconsistent humane endpoints to mice and poor practice was identified in the killing of these animals. The project licence holder was sent a letter of admonition and required to undergo training in modules 2 and 5 within three months of receipt of the letter. The certificate holder was also sent a letter of admonition and required to undertake a review of the killing of animals in order to achieve a consistent improvement in both the processes and the outcomes within three months from the date of receipt of the letter. In addition, they were required to make appropriate adjustments to the responsibilities of some individuals working at the establishment.

CATEGORY D INFRINGEMENT

1 A number of mice were found dead, while others had to be euthanased because their condition exceeded the severity limit stipulated on the project licence. These deaths were self-reported. However, subsequent investigation by the inspector revealed a further number of animals for which the personal licence holder had responsibility had died or had to be euthanased because of a failure to take proper responsibility for the animals' care. The investigation also revealed a culture of very poor practice and knowledge of surgical procedures by this licensee. Additionally, there was a disregard for record keeping. The project licence holder failed to discharge properly their responsibilities to ensure an appropriate level of supervision, and failed to ensure that the personal licensee adhered to the severity limits and maintained adequate records.

In view of the seriousness of this infringement the details were reported to the Crown Prosecution Service. However, on this occasion it was considered appropriate for the Secretary of State to deal with the matter under the powers contained in ASPA. The holder of the personal licence had their licence revoked and was informed that should they ever seek to make a fresh application, they would need to inform the Home Office that any future certificate holder was aware of their past conduct and was prepared to support that fresh application. The project licence holder was required to transfer control of the project to their deputy and was also informed that, should they apply for a project licence at some future date, any such application would only be considered after they had been interviewed by an inspector who would assess, and advise the Secretary of State, on their suitability to hold such a project licence.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Section 3: Initiatives and progress

RISK-BASED INSPECTION: A REVIEW

Background

In 2010 a formal system of risk assessment of establishments based on criteria, most of which could be objectively measured, was piloted and described in the 'Animals Scientific Procedures Division & Inspectorate Annual Report 2010' (see **Appendix 2**). These criteria were then refined and compared with those given in Article 34 of the EU Directive, which also requires a risk-based approach to inspection, see **Table 3, Appendix 4**.

During 2011 our risk-based approach to inspection was reviewed by the Inspectorate. There were a number of drivers for this including the 2009 Hampton review, which concluded that further clarity on the rationale behind the risk-based approach to inspection would be welcomed by stakeholders.

In addition, the number of establishments that needed inspection had fallen to 188 in 2010 compared with about 260 in 2000, 10 years previously. During this ten-year period there has been little change in the number of inspection visits (2,235 in 2000 compared with 1,984 in 2010). Hence a 28 per cent decrease in the number of establishments had been accompanied by only an 11 per cent decrease in visit numbers – a significant net increase in the average number of inspection visits per establishment (8.6 visits per year in 2000 compared with 10.6 in 2010).

Furthermore, there is no evidence of a decreased incidence of non-compliance over this period to accompany the higher frequency of inspection visits per establishment (33 infringements in 2010 compared with 39 in 2000). The number of infringements per year fluctuates but appears to bear little direct relationship to the frequency of inspections, see **Table 2, Appendix 4**.

Inspectors have always practised a risk-based approach to their inspections but this was largely based on their individual professional judgement of the risks that establishments presented. Prior to 2010 not many objective data were being collated and analysed to underpin these judgements and to foster a consistent approach to risk by all inspectors.

Progress during 2011

In early 2011 the Inspectorate applied its risk criteria to categorise all designated establishments in terms of high, medium or low risk, which could then be translated into frequency of inspections needed. A formula was used to assist this process with respect to the objective criteria such as number of procedures, use of special species, etc. For the more subjective criteria, such as those listed as 'management' factors in **Table 3, Appendix 4**, advice was sought from the locally-assigned inspector.

The Inspectorate Management Team, which routinely reviewed inspection visit reports and carried out joint inspections with other inspectors, applied some final adjustments to achieve a consistent approach to all establishments.

During all these considerations it was recognised that the frequency of inspection was a significant factor in maintaining effective working relationships with key staff in establishments, and that inspection visits were a primary source of the evidence that informs decisions on risk. The Directive permits a much lower minimum frequency of inspection than currently practised in the UK. However, based on experience under the Animals

(Scientific Procedures) Act 1986 (ASPA), it was acknowledged that public confidence would be unlikely to be maintained if establishments in the UK were inspected at the minimum frequency permitted in the Directive.

The prospective level of inspection was determined for each designated establishment, and these principles were put in place from July 2011. This indicated a total number of required inspections per year of about 1,300 visits. It was accepted that this number would normally be exceeded since additional inspections would be required to deal with infringement investigations, whistleblower reports and other unpredictable events.

Broadly, it was anticipated that inspection visits would be needed no more than an average of once per month at any one site of an establishment. Also a small establishment conducting low levels of regulated procedures might need an inspection visit no more than once per year.

Throughout the latter half of 2011 locally-assigned inspectors continued to make risk adjustments for their individual places based on current operational information. For example, they might have decreased inspections when little or no regulated work was taking place for prolonged periods, or conversely they increased visits where they needed to investigate and follow up non-compliance or infringements, or to do targeted inspections for novel or high severity work. This flexibility is an important part of the risk-based programme.

Details of the total number of inspections carried out in 2011 and other inspection performance data are provided in **Section 1** of this report. This confirms a somewhat lower number of inspection visits compared with recent years.

A further review of the effectiveness of this objective approach to risk-based inspection is planned to take place during 2012.

IMPROVING OUR INFORMATION TECHNOLOGY

Work towards improving our information technology (IT) and data-handling systems for both licensing staff and inspectors in the Animals in Science Regulation Unit (ASRU), and for our external stakeholders, continued throughout 2011.

As part of a wider IT project to deliver an electronic licence application system (CBP e-Licensing), we worked closely with colleagues in the UK Border Agency (UKBA) to upgrade and adapt an existing web-based portal application that has been operating successfully within the Home Office since 2003. Development work continued throughout 2011 and latterly involved a small pilot group of external users. The aim is that, following a number of enhancements, the new system will go live for a wider range of external users during the second half of 2012.

The proposed solution will enable designated administrators within establishments to securely upload electronic versions of licence applications and amendment requests, and to track progress during their assessment and authorisation. They will also be able to access and download the current version of an authorised licence for day-to-day use.

From the ASRU perspective, the new system will significantly reduce the time, space and additional administrative work involved in handling paper files. It will also provide universal access to an electronic archive of current and past licences that can be used as reference material to inform better, consistent and prompt decision-making about new applications.

During 2011 we also endeavoured to ensure that significant upgrades to IT systems in the wider Home Office incorporated features that will benefit both ourselves and our external stakeholders. These changes, once implemented, will enable us to access information (including licences, visit reports, policy documents and the scientific reference sources needed for assessment and inspection work) much more easily and quickly.

EUROPE: IMPLEMENTATION OF DIRECTIVE 2010/63/EU

As reported in our 2010 annual report, European Directive 2010/63/EU on the protection of animals used for scientific purposes (the Directive) was adopted in September 2010 and came into force on 9 November 2010. It replaces Directive 86/609/EEC, which is transposed into current UK legislation by ASPA.

Member States must transpose the provisions of the new Directive into national legislation by 10 November 2012. This will entail revising ASPA. The majority of the new Directive's provisions must be implemented from 1 January 2013. The mandatory standards of care and accommodation set out in Annex III to the Directive must be implemented by 1 January 2017.

A public consultation on the options for transposition of the Directive was launched on 13 June 2011 and closed on 5 September 2011. Over 13,000 individuals and nearly 100 organisations responded to the consultation. Analysis of the consultation responses, in itself a mammoth task, was completed during the autumn and, at the same time, work began on preparing draft regulations to transpose the Directive's provisions into UK legislation by revising ASPA.

Work also began on a new code of practice on the housing and care of animals bred, supplied and used in scientific procedures, and on a revision to Schedule 1 of ASPA on methods of humane killing. Consultation on both was initiated and the final versions will accompany the new legislation.

COALITION AGREEMENT AND THE 3Rs

In July 2011 Lynne Featherstone, Home Office Minister for Equalities and Criminal Information, announced in a Written Ministerial Statement that the commitment to work to reduce the use of animals will be delivered through a science-led programme headed by the UK's National Centre for Replacement, Refinement and Reduction of Animals in Research (NC3Rs). The NC3Rs is closely involving many others, including ASRU, in this delivery. The programme is focusing on refinement as well as reduction and replacement and is coordinating action to minimise and reduce animal use and suffering.

The NC3Rs' CRACK IT initiative and ARRIVE guidelines are key elements of its plans to deliver the commitment. CRACK IT, launched in 2011, aims to speed up the translation of new ideas, technologies and methods into practice by linking the identified needs of industry with those who may be able to develop 3Rs solutions.

The ARRIVE guidelines are intended to improve the reporting of animal research. Previous work by the NC3Rs showed that many publications lacked key information, which could limit their value in informing future scientific studies and policy. ASRU are promoting the guidelines to project licence holders, as well as being supported by the Home Office's Chief Scientific Adviser, Professor Bernard Silverman.

The Written Ministerial Statement also announced that the commitment to end the testing of household products on animals would be implemented using the licensing powers provided in ASPA. Views were sought from all relevant stakeholders between November and December 2011 to confirm the impact of such an approach.

We sought comments on a draft licence condition that would prohibit the testing of household products without specific authorisation and with the expectation that such authorisation would only be granted very exceptionally. In addition, a draft definition of 'household product' was proposed, which was designed to avoid conflict with the requirements of UK safety testing legislation.

HOW WE PROMOTE AND DELIVER THE 3Rs IN ASRU

ASRU's assessment of project proposals and routine inspection of authorised studies are both important components in ensuring the effective promotion and implementation of the 3Rs.

In order to promote internationally some of the successes achieved in this area, and to add to our knowledge of new technologies and emerging 3Rs strategies, two inspectors contributed to the 8th World Congress on Alternatives and Animal Use in the Life Sciences in Montreal, Canada in August 2011.

The five themes of the Congress were:

I. Safety and Efficacy Testing of Chemicals, Pharmaceuticals and Biologicals;
II. Policy/Law on Animal Use, Public Engagement and Ethics Review;
III. Incorporation of the Three Rs in Education and Training;
IV. Animal Welfare for Refinement and High Quality Science;
V. Replacement and Reduction in Basic Research.

Work by ASRU was highlighted within the first theme by a presentation on our successful efforts, through partnership with all stakeholders, to replace the mouse bioassay for shellfish toxin testing with non-animal methods. A presentation in the second theme emphasised the role of individuals in influencing the implementation of the 3Rs.

In addition the ASRU attendees chaired two programme sessions and presented two posters: one on lessons learned from the shellfish toxin efforts, which offer new approaches to 3Rs for regulatory toxicity testing more broadly; and a second as, a member of a European working group Norecopa, on developing guidance on the severity classification of procedures using fish.

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 ASRU Policy Team. This includes dealing with requests for information made under the Freedom of Information Act. In 2011 we dealt with 1,292 letters and emails and 12 requests received under the Freedom of Information Act.

We also responded to 107 parliamentary questions tabled during the year.

e-Newsletters

The circulation list for our ASPA e-Newsletter continued to grow during 2011 and several initiatives were undertaken to increase the number of recipients. At the end of the year just over 2,500 stakeholders were routinely receiving the e-Newsletter and initiatives will continue during 2012 to grow the database still further. As well as being sent electronically, each newsletter is also posted on our website.

e-Newsletters are an important way in which ASRU communicates with the stakeholder community and we encourage all to sign up to the circulation list by contacting the ASRU team at:
aspnewsletter@homeoffice.gsi.gov.uk

Abstracts of project licences

Project licence holders provided 488 abstracts throughout the year and at the end of 2011 a total of 3,084 had been posted on the website since we first started seeking these in 2004. We would like to thank all those licensees who provided abstracts which we believe make a significant contribution to greater openness and public understanding of the use of animals in science and how it is regulated.

Appendix 1: How we regulate

INTRODUCTION

The Animals in Science Regulation Unit (ASRU) implements the Animals (Scientific Procedures) Act 1986 (ASPA or 'the Act') in England, Scotland and Wales.

ASRU comprises an Operations Group consisting of inspectors and licensing officers who, together, assess and grant licences and certificates on behalf of the Secretary of State. The ASRU Policy Team coordinates advice to Ministers on policy development, drawing on the skills and experience of other members of ASRU as appropriate. In addition, a Business Support Team provides technical and administrative support to the entire Unit. ASRU is a unit within the Home Office Science (HOS) division of the Home Office.

Inspectors assess applications for new licences and certificates, or amendments to existing ones, and advise Licensing Officers on the granting. When assessing proposals, inspectors ensure that full consideration has been given to implementing the 3 Rs (Replacement, Refinement and Reduction of animals in research). 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 Implementation Review principles, and are undertaken to check that the terms and conditions of licences and certificates issued under the Act are being complied with.

THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986

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 Replacement of procedures with non-animal alternatives; Reduction of the numbers of animals used in procedures; Refinement of procedures to minimise pain and suffering

FURTHER INFORMATION

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

Guidance on the Operation of the Animals (Scientific Procedures) Act 1986:
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://nc3rs.org.uk

Appendix 2: Risk-based inspection

As part of the Hampton Implementation Review of ASRU, 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 that contributes to public confidence in the regulatory system and that, 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 the Animals (Scientific Procedures) Act 1986 (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 that 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 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 3 per cent Unclassified, 35 per cent Mild, 60 per cent Moderate and 2 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 that 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 comply fully 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 3**), with an appropriate weighting applied to reflect adequately 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 – an increased, decreased or unchanged risk profile – are considered along with any recommended changes to: control measures; the frequency of inspections; and 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 that 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 Veterinary Surgeon (NVS) and the Named Animal Care and Welfare Officer (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 manage actively the perceived risks carried at their establishment.

Appendix 3: 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 retraining; 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 on 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 Animals (Scientific Procedures) Act 1986 (ASPA or 'the Act') will be explained (see Appendix H of the 'Guidance on the Operation of the Animals (scientific Procedures) Act 1986').

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 in the ASRU annual reports (see Section 2 of this report).

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 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 may 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 that merit referral for possible prosecution;
- the Inspectorate undertakes a preliminary investigation 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 4: Tables and Figures

Table 1: Licence and certificate applications and amendments, 2010 and 2011

	Total			Per Inspector FTE		
	2011	**2010**	**Change**	**2011**	**2010**	**Change**
PILs granted	2,550	2,664	-0.4%	134.2	117.4	+14.4%
PILs amended	3810	3,754	+1.49%	200.5	165.4	+21%
PILs in force	15,403	15,721	-2%	810.7	692.6	17%
PCDs granted	2	4	-50%	-	-	-
PCDs amended	481	375	+28.2%	25.3	16.5	+53 %
PCDs in force	181	188	-4%	9.5	8.3	+14%
PPLs granted	564	515	+9.5%	29.7	22.7	+30%
PPLs amended	2,184	1,645	+32.8%	114.9	72.5	+58.5%
PPLs in force	2,624	2,614	+0.4%	138	115.2	+19.8%

Note: FTE = full-time equivalent; PIL = personal licence; PCD = certificate of designation; PPL = project licence.

Table 2: History of infringements, 2006–2011

Year	Compliance advice**	Total infringements	Category A	Category B	Category C	Category D
2006*	n/a	29 (17)				
2007*	n/a	30 (15)				
2008*	n/a	37 (24)				
2009	36	29 (26)	18 (15)	8 (8)	3 (3)	0
2010	108	33 (18)	10 (6)	14 (6)	9 (6)	0
2011	155	39 (25)	21 (14)	11 (8)	6 (3)	1 (0)

Note: Figures in brackets indicate self-reported infringements (versus those discovered by inspectors).

* For these years, infringements were categorised differently and therefore only total numbers can be compared. Frequency of providing compliance advice was not recorded prior to 2009.

** Frequency of providing compliance advice was not recorded prior to 2009.

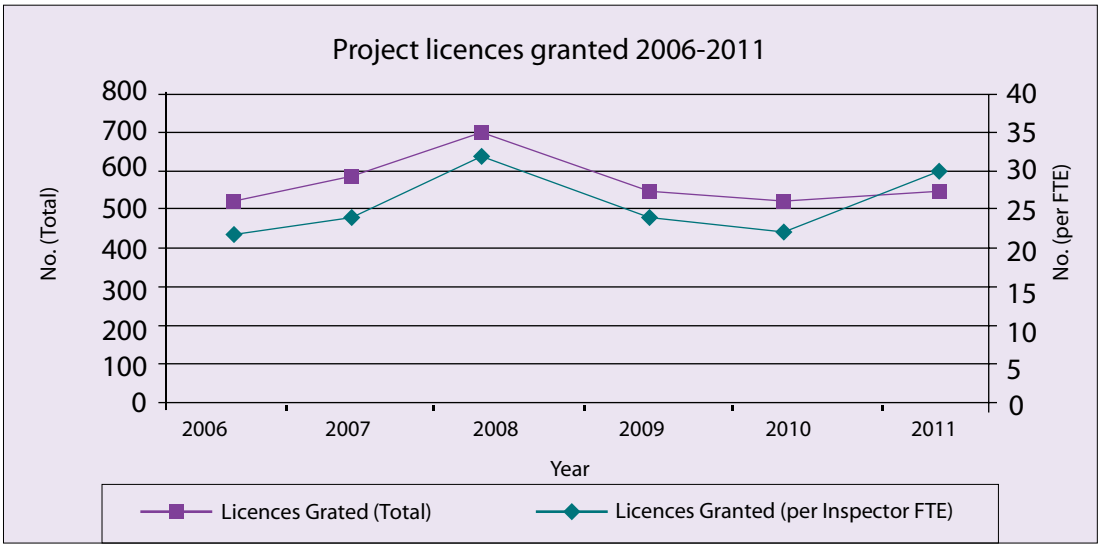
Table 3: Comparison of EU and Animals in Science Regulation Unit (ASRU) criteria for risk-based inspection

Directive 2010/63/EU inspection risk criteria – Article 34	ASRU risk-based inspection criteria
• Number and species of animals housed	• Number of regulated procedures undertaken annually • Species used
• Compliance record	• Compliance history
• Number and types of projects	• Number and severity of projects • Species used – specially protected species
• Any information that might indicate non-compliance	**Management factors:** • Effectiveness of certificate holder, Named Persons, Ethical Review Process (ERP) • Quality of working relationships at all levels • Maintenance of facilities and environmental enrichment • Quality of training plans, supervision and records • Policies and practice for surgical and breeding procedures where relevant

Figure 1: Inspectorate staff, 2006–2011

Note: FTEs = full-time equivalents.

Figure 2: Project licences granted, 2006–2011



Note: FTE = full-time equivalent;

Figure 3: Project licence application processing, 2006–2011

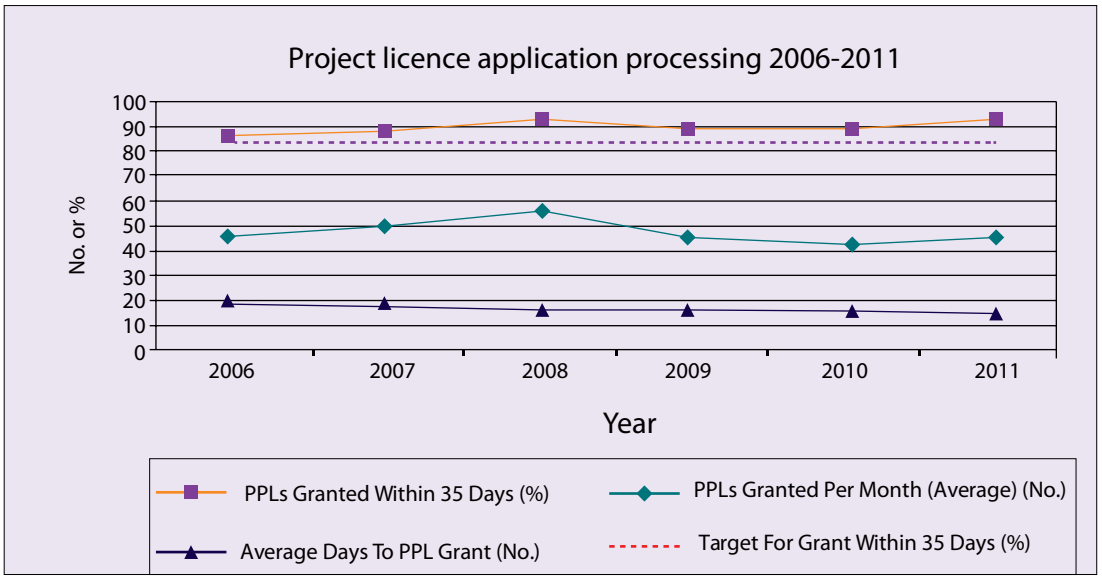
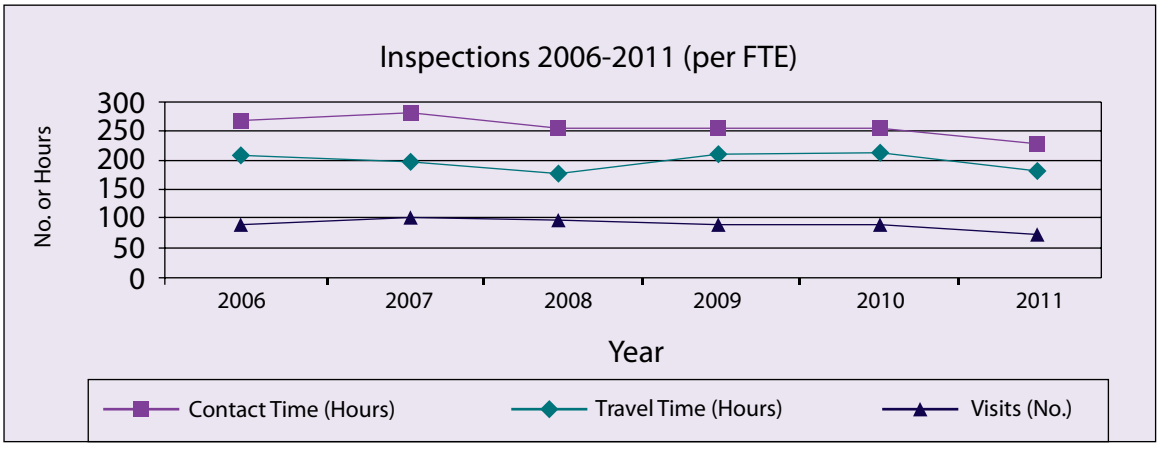


Figure 4: Total inspections, 2006–2011

Figure 5: Inspections per FTE, 2006–2011



Note: FTE = full-time equivalent.

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