

Animals (Scientific Procedures) Division
and Inspectorate

A Hampton Implementation Review Report

January 2010

Animals (Scientific Procedures) Division and Inspectorate

This review is one of a series of reviews of regulatory bodies undertaken at the invitation of HM Treasury which focuses on the assessment of regulatory performance against the Hampton principles and the Macrory characteristics of effective inspection and enforcement. The review process is designed to identify where a regulator is on the road to full implementation and the issues each needs to address to become Hampton-compliant.

The review focused on those aspects of the Animals (Scientific Procedures) Division's and Inspectorate's (ASP's) activities that impact the private sector. This meant, for example, that programmes of work oriented to the promotion and enforcement of public sector duties or to narrowing gaps in educational outcomes were out of scope.

Our methods included: interviews with ASP staff including senior managers; interviews with other stakeholders including Government departments, business and equality representative groups; and document review, including the ASP's high level strategies and plans.

The review team is grateful to ASP for its support and commitment over the review period. Its leadership team and staff were extremely helpful and generous with their time. We are also grateful for the contribution of the ASP's stakeholders for their helpful insights into the wider context within which the ASP operates.

EXECUTIVE SUMMARY AND CONCLUSIONS

Key findings from the review:

The Animals (Scientific Procedures) Division and Inspectorate (ASP) 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. There are issues to be resolved over consistency of advice, transparency, focus on outcomes and sanctions, but the overall impression is of an effective and well-respected regulator.

In contrast to this professionalism and expertise, ASP's processes for handling applications were not highly regarded by stakeholders and were compared unfavourably with other technical regulators. Poor IT provision emerged as the most serious concern in this area and undermines the standing of ASP.

It is striking that for all other aspects examined by the review team, we saw evidence from stakeholders of improvements in the regulator's performance and evidence from ASP of a strong desire to improve further the efficiency of its regulatory work. In contrast, on the IT problems we could see much less evidence of improvement or likely improvement. Although ASP is working towards an e-licensing system to be ready by end 2011, development funding has not yet been secured nor have stakeholders been consulted. Nevertheless, we understand that ASP shares stakeholders' concerns regarding the inadequacy of the current IT provision and work is already underway to fund, develop and deploy the IT solutions to securely undertake end to end e-licensing.

Key findings are:

- Recent evidence of good work being done to ensure the revised EU Directive is suitable for the UK and includes contributions from key stakeholders. The design of the regulatory approach should be set to allow better use of delegated powers and more effective appeal procedures. This is discussed in more detail in the 'design of regulation' section below.
- Stakeholders valued the support provided by the

Animals Scientific Procedures Inspectorate (ASPI), particularly on licence applications. The provision of better supporting material from ASP for applicants would allow inspectors to be more focussed on inspections and licence principles (as opposed to the compilation, submission and approval process). Stakeholders perceived that there was inconsistency in advice, which potentially undermined the authoritative nature of the regulator. ASPI are clearly aware of this issue, and have made efforts to resolve it, but further consideration is needed on how improvements in consistency can be achieved and particularly on how stakeholders can be given more confidence in the consistency of advice.

- ASP has made efforts to improve the current licence application process for personal and project licences and certificates of designation. However, in order to comply fully with the Hampton principles, significant improvements need to be made in IT. There is no secure electronic application process. Furthermore, the Home Office's internal systems currently create inefficiencies in effective data sharing within ASP, which slows down application processing.
- Although stakeholders understand the reasons behind inspections in general, the rationale behind the risk assessments had not been shared with them and action needs to be taken to reduce the disquiet this causes.
- ASP has made important steps in defining the outcomes that it seeks to achieve but has made little progress in actually measuring and reporting on these outcomes. The review therefore concluded that this aspect of work within ASP was not fulfilling the requirement of this Hampton principle.

Issues for follow-up identified during the review:

The key follow-up issues identified during the review are:

- The IT provision for ASP urgently needs to be reviewed. The internal data transfer within ASP must be improved to allow for efficient case handling and to speed up application processing (currently, in spite of the paucity of IT provision, more than 90 per cent of project licence applications are processed within 35 working days from formal submission to approval with the mean turnaround time being 18 days). This internal improvement need not necessarily be held up by the broader issue of how applications could be

made on-line. In considering the external application process, ASP might be able to draw on stakeholders' experience of web-based research grant applications which handle material of comparable sensitivity.

- There may be opportunity through forthcoming implementation of the EU Directive to give consideration to the 'one size fits all approach' in regard to delegation of licensing powers for lower risk applications to allow inspectors to focus more on the most important and technical cases.
- Although stakeholders' mailings and web-based material is used to publicise changes to the system, the continued delay in the revision of the Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 further weakens the provision of material to help applicants. While there are strong grounds for ASP not issuing a version that could soon become out of date, this approach comes at the cost of increased work for inspectors and applicants. The cost-benefit rationale for this delay should be re-examined.
- Stakeholders do not find the ASP website as user-friendly or informative as comparable regulators' sites, which in turn increases work for inspectors and applicants when preparing applications. Although stakeholders did not detail specific shortcomings, improved advisory material on the website could speed up applications and would also assist in reducing the perceived inconsistency between inspectors.
- The risk-based approach behind inspections needs to be set and applied consistently across all inspectors and shared with stakeholders. This could significantly reduce the concerns over perceived inconsistency between inspectors.
- The balance between announced and unannounced inspections should be reviewed, in the light of ASPI's advisory and enforcement functions, to make sure that opportunities for targeted advice through pre-arranged visits can be taken.
- Enforcement policy and details of infringements, currently communicated through the ASP Annual Report, the annual Statistical Returns and on the website, should be better communicated to

stakeholders to increase their ownership and understanding. In particular, ASP could better explain how prosecution decisions are taken between ASP and prosecuting authorities.

- Animals Scientific Procedures Division (ASPD) should continue to work closely to improve relations with prosecuting authorities with a view to securing better understanding and ownership, between ASP, stakeholders and the prosecuting authorities, of decisions over the progression of cases to a criminal prosecution.
- ASP should review the appeal procedures, especially with regard to applications that are not proceeded with on the basis of ASPI's advice, to help secure faster application processing and greater transparency. The conclusions of this review should be fed into the design of new regulations. This point is discussed in more detail under 'transparency and accountability' section below.
- The outcomes that ASP seeks to achieve, especially in terms of the 'Three Rs', should be formalised through measurement recording and publication, drawing on the existing good shared understanding that ASP has established with stakeholders. This will help demonstrate the value of this regulatory work in facilitating good research. The value of the expert advice that the inspectors provide should be reported on.

INTRODUCTION

Introductory background information about the regulator such as the rationale for establishing it:

This review examines the work of the Animal Scientific Procedures Division (ASPD) and the Animals Scientific Procedures Inspectorate (ASPI). Both bodies are part of the Home Office's Science and Research Group (SRG). For the purposes of this report the organisation as a whole is referred to as ASP.

ASPD was set up in 2003 replacing earlier structures that embedded the ASP functions within more generic Home Office groups. It then comprised the Licensing staff (APLS), the Inspectorate (ASPI), the Policy Group and the Secretariat supporting the Animal Procedures Committee, the Secretary of State's independent advisory body. The APC Secretariat has since been transferred to a central support group within SRG, and ASPI, under the Chief Inspector, reports direct to the Home Office Chief Scientific Adviser (CSA). ASPD now therefore comprises APLS and the Policy/Ministerial Support Group, and the Head of ASPD reports direct to the CSA. The role of ASPI is primarily advisory whereas the role of ASPD is primarily executive.

Both ASPD and ASPI continue to work closely with the Animal Procedures Committee (APC) which is supported by the Science and Research Group Secretariat.

The legislation establishing the regulator:

There is a long history of legislation in the area of animal scientific procedures dating back to 1876. The 1876 Act was replaced with the Animals (Scientific Procedures) Act 1986 (ASPA).

The regulator's statutory remit or objectives:

ASP operates under the Animals (Scientific Procedures) Act 1986 (ASPA). This Act regulates scientific work on "protected animals" which includes all vertebrates, one invertebrate species and some embryonic/foetal stages (a wide range from fish to monkeys) which may cause pain, suffering, distress or lasting harm ("regulated procedures") by a mandatory licensing and monitoring arrangement. Licences are required for the programmes of work ("project licences"), and the persons who do the work ("personal licences") and certificates are needed for the establishments ("designated establishments") where such work is carried out and where the common

laboratory animals are bred or held for supply. Inspectors advise the Secretary of State on applications for these licences and certificates. They visit the places where the work is done, or animals bred or supplied, to check that the procedures undertaken and the local arrangements accord with what is authorised, and report when they do not. ASPD staff, acting on behalf of the Secretary of State, formally take licensing decisions.

The regulator's budget:

The baseline costs of ASPD for 2009/10 are £1.439 million, and the budget for ASPI for 2009/10 was £2.719 million.

Number of staff (including breakdown of policy and frontline staff):

The ASPD comprises of 4 Policy staff and a licensing team of 24. The ASPI team contains 23.5 Frontline staff, 3.5 management staff and 1 person as clerical support. Staff are dispersed through five regional offices (Cambridge, Dundee, London, Shrewsbury and Swindon) with both APLS and ASPI staff at each location. The Policy Group is located centrally at Home Office Head Quarter in London and in Dundee.

The sectors and number of businesses regulated either directly or indirectly:

There are around 200 Designated User or Breeding/Supply Establishments, who between them operate under around 3,500 Project Licences authorised under the 1986 Act. These establishments are both public and private sector and include a number of SMEs. The work is conducted by holders of Personal Licences – currently around 16,000 such licences are in force.

THE HAMPTON VISION

“Both the Hampton and Macrory reports are concerned with effective regulation – achieving regulatory outcomes in a way that minimises the burdens imposed on business. Key to this is the notion that regulators should be risk-based and proportionate in their decision-making, transparent and accountable for their actions and should recognise their role in encouraging economic progress.”

Any findings relevant to whether the review team believes the regulator is risk-based:

ASP understands the need to become more risk-based in its approach to inspections and regulations. It has recently implemented a revised inspection regime which seeks to regulate licence holders based on a formal quantitative assessment of risk – replacing an earlier non-formalised system which may have led to inconsistency between inspectors. This is a positive move in channelling resource at the higher risk testing facilities/licence holders but the basis of this risk assessment has not been made known to stakeholders and the review team suggests that more transparency is provided to stakeholders in relation to the risk assessment.

Any findings relevant to whether the regulator is transparent and accountable:

ASP openly and willingly offers some material eg application guidance, to its stakeholders through communication channels such as the website and e-newsletter. However, ASP is not consistent or comprehensive in its approach to transparency, leading to claims by the stakeholders that whilst ‘things are improving, there is still some way to go’. An illustrative example of this is the unwillingness thus far to publicise the risk based assessment criteria for inspection frequency although the review team accepts that ASP should not be required to make individual risk ratings publicly available, neither generally nor to the relevant stakeholders.

In recent years, efforts have been made to simplify and share general guidance material which seeks to explain the advancement and improvements made.

Inspector’s advice and guidance form a large part of ASPI’s activity but it is openly accepted that inconsistent advice can and does result. A Consistency Monitoring Group was initially established in 1987 to promote consistency, identify best practice

and streamline administrative practices. ASPI has recently invested increased effort in this area as part of its response to Better Regulation but it is less than transparent how the Group operates and what its outcomes and governance arrangements are. Equally, the Group does not involve nor report directly to stakeholders although it does report on some of its activities in the ASP Annual Report.

The formal appeals procedure, which should provide transparency and accountability, does not in practice function as the Act may have intended since it applies only to completed applications which have been rejected. In practice, the advice provided by inspectors is a critical factor in determining whether a stakeholder will secure a licence. The current statutory provisions do provide for independent appeals when the stakeholder decides to proceed with an application despite contradictory advice from the inspector. The stakeholders' perception is that adverse advice from the inspector constitutes a de-facto refusal. Furthermore, the current statutory guidance does not advise potential applicants on the courses of action open to them when advised by ASPI that an application is likely to be unsuccessful. This gap needs to be explored, but without prejudicing the delivery of the free expert advice which is so highly valued by stakeholders.

Any findings relevant to whether the regulator encourages economic progress:

ASP acknowledges and responds to the need to support the UK bio-medical research industry whilst safeguarding the best welfare of the animals. This is one of the regulators clearly stated outcomes. However, measurement and reporting of outcomes is unclear so it is difficult to positively state whether this Hampton approach is satisfied.

ASP actively seeks to work with licence holders to refine licence applications before submission. This is with a view to streamlining the approval process but it can conversely result in a considerable delay in the consideration stage.

Overall the review team acknowledge efforts towards encouragement of economic progress but reporting needs to be tangible and measured.

DESIGN OF REGULATIONS

Hampton Principles

“All regulations should be written so that they are easily understood, easily implemented, and easily enforced, and all parties should be consulted when they are being drafted.”

“When new policies are being developed, explicit consideration should be given to how they can be enforced using existing systems and data to minimise the administrative burden imposed.”

Key findings on design of regulations:

ASP primarily acts under the Animals (Scientific Procedures) Act 1986 (ASPA). At the request of the European Commission (EC), the Act was revised in 1997 to embed existing administrative controls into the legislation. The EC is currently revising Directive 86/609/EEC that governs the protection of animals used for scientific purposes across the European Union (EU). Revision of the Directive will ultimately lead to changes in UK legislation.

ASP was found to be actively engaging in comprehensive consultation with stakeholders regarding the forthcoming EU Directive.

There is a strong perceived desire within ASP to improve regulatory performance, however, action has not necessarily been shown to be consistent with this desire. Consideration should be given to a review of the ‘one size fits all’ application of regulations when the EU Directive is implemented. For example, APLS could be delegated the power to take licensing decisions on simple applications without needing to seek ASPI’s advice. It is the view of the review team that delegation of licensing powers should be further explored, to speed up licence processing and allow Inspectors to focus more on the most important and technical cases.

Background information such as the regulator’s role in developing regulations:

ASP’s approach to policy development has improved over recent years, although many stakeholders are of the view that change could be brought about more quickly.

The current revision of the EU Directive provides an opportunity to apply Hampton principles to new

regulations. ASP has been working since November 2008 to set up a structure of consultation and engagement with stakeholders. This includes the establishment of working groups that are focussed on different areas of the Directive. ASP issued a formal consultation in May 2009 seeking input and about 1,000 responses were received from about 100 organisations and a large number of individuals.

ASP is working at the EU level to negotiate the most appropriate terms of the Directive for the UK and is looking to limit scope of the Directive where appropriate. ASP acknowledges that the Directive offers the opportunity to provide a better framework for a more proportionate approach to regulating and it is important that these opportunities are followed through.

Any examples of significant good regulatory practice:

Stakeholders overwhelmingly commented on positive steps by ASP in attaining input toward the revised EU Directive.

Review findings:

The extent to which the review team believes the regulator is acting in line with the Hampton principles:

There is evidence that historically ASP has been less consultative in their approach to the design of regulations, policy and administrative practices. However, recent evidence and examples cite the good work being done to ensure the revised Directive is suitable for the UK and includes contribution from the whole range of key stakeholders. It will be important to sustain momentum during the negotiating process. The new regulatory approach could allow better use of delegated powers and more effective appeal procedures.

ADVICE AND GUIDANCE

Hampton principle

“Regulators should provide authoritative, accessible advice easily and cheaply”

Key findings on advice and guidance:

ASP provides advice cheaply (based on the existing level of licence fee and comparable input primarily from the inspectors).

Use of different communications channels are welcomed by stakeholders and in particular, receipt of a regular update was considered helpful. Although ASP website holds a great deal of data for licence holders and applicants, it was not particularly user friendly to access and/or intuitive to navigate and therefore resulted in a level of user frustration and apathy to interaction with the facility, despite efforts to improve clarity of existing documentation eg applications process. Navigation was identified by stakeholders as a ‘key issue that should be improved’. ASP website did not compare favourably in terms of usability and customer experience to other similar websites.

A general stakeholders’ view was that greater guidance and/or advice documents should be published or made available, although the stakeholders’ detailed needs were not specified. There are other forms of advice, not least of all, face to face inspector visits which offer the opportunity for quality interaction with applicants and licence holders. In this instance, advice was considered to be easily accessible and highly valued and if anything, should be increased and/or strengthened, eg greater consistency of advice provided.

In terms of authoritative advice, the inspectors were generally held in high esteem, although some stakeholders commented on the lack of scientific knowledge of some inspectors, as many were perceived to be from a veterinary clinical background. It was questioned as to whether the right skills and experience mix was being sought in the role of the inspector.

The Act requires the Secretary of State to “appoint as

inspectors ... persons having such medical or veterinary qualifications as he thinks requisite". In practice, this has been taken to require full registration as a veterinary surgeon or medical doctor and most appointees also have relevant post-graduate qualifications and/or experience in biomedical science fields.

Some stakeholders suggested potential benefit in having a wider pool of 'subject experts', as might be the case if there were a central point of contact on new animal facilities. This might address stakeholders' concerns on inconsistency and knowledge. In fact, the Consistency Monitoring Group has a sub-group responsible for consistency of decisions on new animal facilities, but clearly this is not apparent to stakeholders.

The Guidance on the Operation of ASPA 1986 (last published in 2000) is considered to benefit from revision or re-launch, pending the finalisation of the new EU directive.

Background information such as the means by which the regulator provides advice and guidance:

ASP provides formal and supplementary advice, for which no charge is made to stakeholders or the public. This can be accessed through a number of means, such as the Home Office website (with links to ASPD and ASPI), regular e-news letters sent out every 4 to 6 weeks to around 1,500 stakeholders, the ASP Annual Report, inspections, stakeholders' group meetings, outreach work at conferences and on expert working parties, direct contact with policy professionals and inspectors, FOI requests and general correspondence.

Advice and guidance is generally provided and directed towards certificate and licence holders and others with responsibilities under ASPA, especially during the process of licence construction and submission. However, the stakeholder base is much wider, in that it also extends to other interests such as animal welfare and animal protection groups. Advice is also provided to these groups through stakeholder meetings and other means.

The provision of ASPI advice and guidance tends to be largely through face to face contact, undertaken during inspections (in the order of 2,000 inspections pa). However, all licence holders and designated research facilities have one or more 'local' inspectors and contact can be made at any time for general or specific

advice and guidance.

ASPD administers the licensing system and ASPI advises ASPD on the approval of applications. However, licensing decisions are formally taken by the Secretary of State (i.e. by ASPD staff under the Carltona Principle). Nevertheless, it is clear that the inspectors' advice, guidance and recommendations form the basis for decisions on almost all licence applications received.

One of the main sources of information for stakeholders is ASPA 1986 and the associated statutory guidance. However, although ASP considered the guidance to be correct, the 'format is not necessarily helpful'. The stakeholders' perception was that it was 'out of date'.

Any examples of significant good regulatory practice:

Stakeholders overwhelmingly valued the face to face advice provided by inspectors. The value of this advice is somewhat countered by acknowledged concerns from stakeholders about inconsistency of advice. The Consistency Monitoring Group plays a role in reviewing and considering issues of contention and/or uncertainty to improve consistency in this complex, sensitive and diverse area.

The use of advice and guidance in advance of licence applications being submitted was considered to be a more responsible and effective way of working, as applications were more likely to be approved if advance input had been gained from the inspectors.

The use of e-news letters was well received by stakeholders.

Review findings:

The extent to which the review team believes the regulator is acting in line with the Hampton principle:

ASP regulates the use of protected animals for experimental and other scientific purposes in Great Britain. Furthermore, stakeholders most certainly viewed the supporting advice and guidance provided, particularly on individual licence applications, as being highly valued and easily accessible. However, stakeholders struggled to sometimes understand the inconsistency (or perceived inconsistency) of advice, which potentially undermines the authoritative nature of the regulator and the advice that it provides. The inspectors were aware of this perception and conceded that inconsistent advice had been given in some instances. This is an area that should be re-assessed and consideration should be given to how

improvement in consistency can be achieved.

The diversity of science in which inspectors are expected to provide advice means that it is not feasible for any single inspector to have expertise in all fields. However, the Inspectorate as a whole can be expected to cover most of this range of expertise, and therefore greater collaboration between inspectors in reaching decisions on their advice may lead to better decisions and greater consistency. Such collaboration should be risk-based to avoid introducing unnecessary bureaucracy.

There is no doubt that the licence fee is relatively low and reflective of cost recovery only. The ASP resource set-up is small in number and range of functional roles but nonetheless, appears effective in delivery of its purpose, despite opportunity for refinement and improvement being possible, eg greater focus on supporting material and improved delivery channels that would allow the inspectors to be more focussed on inspections and licence principles (as opposed to procedural aspects of compilation, submission and approval). More regular newsletters would be welcomed by stakeholders as one means of communication.

DATA REQUESTS

Hampton principle

“Businesses should not have to give unnecessary information or give the same piece of information twice.”

Key findings on data requests:

The consistent message from stakeholders and the regulator itself is that there is an urgent need to improve the process and system of data requests across ASP.

In particular, there is strong evidence that current IT systems are not ‘fit for purpose’. The impact of poor systems has led to: slow and inefficient processing, duplication of data, reduced flexibility and an increase in negative perceptions associated with the regulator. However, ASP staff achieve a standard of 90 per cent of project licence applications being processed within 35 working days, with a mean turnaround time of 18 days.

It is of utmost importance that improvements in IT are prioritised and that stakeholders have the opportunity to input into the improvement process.

Opportunities to share data with other organisations, for example funding bodies, should again be explored in depth.

Background information such as the data required by the regulator or the means by which business can return data:

Data requests from ASP fall into three main categories: personal licences; project licences; and establishment certificates.

Although personal licences weren’t seen as particularly burdensome, stakeholders were of the view that there was some duplication between personal and project licences and there would appear to be merit in simplifying or removing personal licences. It is recognised however that ASPA currently requires that all individuals do hold personal licences in order to perform procedures on animals.

There have been ongoing improvements in the project licence application process over recent years and ASP has been working with stakeholders over the last two years in preparation for launch of a new project licence application form in November 2009. This version is

expected to be the basis for an e-licensing system in due course. We understand that funding has been secured in 2009-10, and work is currently underway, to move to end-to-end e-licensing (subject to further funding being secured in 2010-11) within 12 months. One common complaint was actually that there had been too many changes and that existing forms needed time to bed in. There is still opportunity for improvement however, in particular, to include some project licence information into guidance.

The key improvement identified was to introduce an electronic system for all licences, particularly personal and project licences. Currently some data are duplicated due to hard copy requirements and this could be streamlined considerably, allowing for electronic approval and improved reporting of data.

An electronic system would also provide the opportunity to balance workloads across regions as required. The current hard copy system prevents sharing of workloads at peak times. This could also lead to efficiency improvements in time to process applications and consistency may also be improved. ASP has made efforts to improve the current licence application process for personal and project licences and for certificates of designation.

Review findings:

The extent to which the review team believes the regulator is acting in line with the Hampton principle:

The most significant improvements to be made in order to comply with the Hampton principle would be to introduce an electronic application process for all licences.

INSPECTIONS

Hampton principle

“No inspection should take place without a reason.”

Key findings on inspections:

All site visits by inspectors are termed ‘Inspections’, but in practice the inspections comprise a mixture of regulatory and advisory work. Stakeholders really value inspections and rely on them to maintain public confidence in animal experimentation.

The high frequency of unannounced inspections gives a good impression of regulatory rigour. This was cited by both ASP and stakeholders as creating confidence in the inspection system.

Unannounced inspections work well at assessing welfare standards. However, unannounced inspections are less likely to detect problems over procedures. This can simply be because, with infrequent procedures, the visits are unlikely to coincide with when the procedures are actually undertaken. This can mean that the inspector will not see the individual licence holders in action.

Stakeholders did not have information from ASP to enable them to relate the frequency of visits they experience to their individual risk status. The risk assessment process has not been published and, although stakeholders were aware of its existence, they had little understanding of how it worked.

Stakeholders from academic, industry and pressure-group backgrounds all stressed inconsistency between inspectors as an issue in their relations with ASPI. This was summed up in a stakeholder’s comment ‘the individual inspector’s word is law’.

Any relevant background information such as the number of inspections and the number of businesses inspected or the regulator’s risk model:

There are formal inspections for compliance (including facilities, staffing and welfare) plus visits for advice and guidance, plus visits to consider future projects. One inspection may in practice cover all these aspects of ASPI’s work. The reason for inspections is not normally stated. Instead reliance is placed on the legal right to inspect.

Stakeholders typically expect to be subject to inspections on average at least every six weeks, and more frequently for large institutions. About 50% of

inspections are unannounced. The split between advisory and regulatory time is recorded by ASPI in time records.

In practice, many visits are not absolutely without warning because the establishments need to maintain rigorous security and hygiene controls. Thus there is inevitably a delay between arrival and the actual inspection of animals.

All establishments are risk-assessed. Over the last 18 months, risk ratings have been formally discussed among inspectors and recorded, and a common ASPI standard for determining inspection frequency against risk is in the process of being developed.

Any examples of significant good regulatory practice:

The inspectors have established a high reputation for professional expertise in animal welfare. They are seen to work closely with those who are inspected, but without any apparent weakening of their regulatory authority.

Review findings:

ASPI inspections have important advisory functions as well as regulatory functions relating to the detection and investigation of non-compliance. There was a strong stakeholder desire to see inspections continue and no desire for the rate of inspections to be reduced. No stakeholder expressed the view that inspections were a burden. We can be confident that this is a genuine view, because, in contrast, the stakeholders did express considerable disquiet over licence application procedures.

The extent to which the review team believes the regulator is acting in line with the Hampton principle:

Stakeholders did understand the reasons behind inspections in general. However, they did not understand the rationale behind individual inspection frequencies. This is not surprising, given that ASPI do not yet have a fully formalised risk-based inspection frequency that is applied consistently across ASPI. Nevertheless, individual inspectors do apply risk judgements using their individual professional expertise, and discussions between inspectors, especially at regional office level, are leading to the development of an increasingly consistent risk-based approach.

The reports of inconsistency between inspectors' advice and findings were common across stakeholders from all backgrounds. This however is more an issue for sanctions and advice than for inspections, and so it

is covered elsewhere.

SANCTIONS

Hampton & Macrory principles

“The few businesses that persistently break regulations should be identified quickly, and face proportionate and meaningful sanctions.”

“Regulators should be transparent in the way in which they apply and determine administrative penalties.”

“Regulators should avoid perverse incentives that might influence the choice of sanctioning response.”

“Regulators should follow up enforcement actions where appropriate.”

Key findings on sanctions:

ASP has access to a number of sanctioning options. The ultimate sanction, criminal prosecution, has to be undertaken by the Crown Prosecution or the Procurator Fiscal Services, rather than by ASP itself. ASP can revoke, vary or decline to issue licences. The revocation or withdrawal of license, or very lengthy advisory discussion over an application, can make a research project unviable or seriously affect both funding and the reputation of the researcher or establishment. Revocation of a licence is thus a particularly powerful way of addressing non-compliance.

We identified two different stages at which sanctions are applied. These operate differently and raise different Hampton’s issues. Firstly, there is an administrative sanction applied through the time taken to issue a licence, or to refuse it. In effect, this delay or refusal acts as a sanction by delaying the commencement of work. Secondly, there are punitive sanctions that apply if procedures are undertaken outside the terms of a licence. These include delays whilst non-compliance is investigated and remedied.

With licence applications, the Act provides the framework to appeal against the refusal of a licence. However, it is clear that the appeal system provided by the Act is rarely pursued. We found that in practice ASP and applicants did not operate in that way and applicants therefore do not submit applications they believe will be rejected. Instead, applicants will drop or modify applications they believe that inspectors will not support. Inspectors have, in effect, near-absolute

control over what licences are granted.

It is not the role of this review to question the judgement of the Inspectorate. Indeed, stakeholders expressed clear support for the inspectors' professional judgements. However, stakeholders frequently identified inconsistency between inspectors as a serious issue. This comment was common across academic, commercial and voluntary backgrounds. In the absence of an effective appeal procedure in the face of ASPI's advice before an application is formally made, the control exerted by individual inspectors makes this reported inconsistency a serious problem with transparency in Hampton's terms.

On punitive sanctions, the ASP position on enforcement policy and practice raised far fewer concerns and indeed stakeholders said that the ASP approach to enforcement has shown significant recent improvements.

Stakeholders understood the ASP enforcement policy, but did not understand the policy as it applied to severe cases. This led to the unfair perception, notwithstanding the fact that the Crown Prosecution and Procurator Fiscal Services are the decision makers, that insufficient prosecutions take place. Given the excellent level of consultation and cooperation with stakeholders, it should be possible for ASP to identify ways to remove this misconception whilst protecting the prosecution authorities' discretion.

The two elements of sanctions, the administrative processing time and enforcement, do overlap. When enforcement after breaches of licences are being considered, ASPD can suspend the granting of new authorities. This can have a more significant punitive impact than the formal enforcement action that may eventually be taken. Since 2002, ASP has revised their procedures to ensure that this sanction is applied in a risk-based way. This ensures that minor technical breaches do not cause disproportionate delays to applications without prejudicing the withdrawal of licences or withholding of new authorities where serious breaches are involved. Additional changes introduced in 2008 have further refined these procedures to make them even more proportionate.

Background

Although Section 12 of the Act provides for appeals

information such as a summary of sanctions available to the regulator and any data on sanctions imposed by the regulator:

against the refusal of licences, we found only a small number of such appeals had in practice been mounted both in relation to applications and infringements. Indeed, one stakeholder remarked that it was 'more than their job was worth' to appeal. We also found little evidence of the Secretary of State issuing a licence contrary to the advice of the Inspectorate except in a very small number of cases where the advice of the APC or external experts had differed from that of ASPI. Thus applicants generally feel they must in effect obtain the agreement of the inspector if they are to obtain a licence.

The sanction of declining to agree a licence, especially a project licence, can significantly impact upon research. Delays can affect both the funding and viability of a project. In contrast to infringement procedures, where ASPI and ASPD have established tight processing deadlines (see below), the timescales for obtaining the agreement of the inspector over a project licence seem to be less clear. However this may be due to procrastination on the part of applicants in responding to inspector's advice and requests for information. It is already acknowledged that the use of advice and guidance in advance of licence applications being submitted was considered to be a more responsible and effective way of working as applications are more likely to be approved if advance input has been gained from inspectors (see the "Advice and Guidance" section).

Once the content of an application has been broadly agreed, the time from formal submission to approval for 90 per cent of applications is within 35 working days with a mean turnaround time of 18 days.

When a breach in licence conditions is detected, ASP now works to a well defined five category approach, with a corresponding severity of interventions. These are (in increasing order of severity): Compliance advice; A grade breach; B grade breach; C grade breach; and D grade breach.

Compliance advice is recorded in the inspector's visit report and triaged into a monthly summary report for management.

Category A and Category B are dealt with at the local regional office level. Following a simple breach (Category A/B), ASPI may take up to 20 working days

to investigate and construct a report, which is sent to ASPD and results in action being taken within a further 15 days. Typically these infringements are managed within 2-3 weeks.

The more serious infringements (Category C/D) are dealt with centrally by headquarters staff and are typically managed within a 6-8 weeks period although this can take significantly longer as this is dependent on the nature and complexity of the investigations. Following receipt of the ASPI report from the local inspector, ASPD Head Quarter invite those involved to provide, within 20 working days, any additional factors in mitigation in advance of a final decision being made.

All infringements are included in the inspectors' visit reports. There is a monthly review of all visit reports by senior inspectors and a summary goes to ASPI management as well as being shared with inspectors to promote consistency. A higher level summary goes to ASPD management.

The infringement handling process is set out on the ASP website and details are also provided in the ASP Annual Report. Information on infringements is thus regularly passed to stakeholders. The changes introduced relating to internal processes for managing infringements have been made known to stakeholders.

ASPI and ASPD operate a risk-based approach to enforcement, based on clearly-stated principles that the stakeholders understood:

- the intention to deliberately breach the Act or to conceal what has happened;
- the extent of avoidable suffering;
- disagreements over matters of fact.

The range of penalties includes: letters of admonition; requirements for re-training; variation, suspension or revocation of licences; or prosecution. The most severe cases are referred to prosecuting authorities, the Crown Prosecution Service (CPS) in England and Wales and the Procurator Fiscal Services (PFS) in Scotland.

Any examples of significant good regulatory practice:

An area of good regulatory practice is considered to be the proactive way of inspectors working with the licence holders to discuss and avoid any requirement for formal sanctions.

Review findings:

The extent to which the review team believes the regulator is acting in line with the Hampton principles and Macrory characteristics:

In practice, the procedures for obtaining a licence begin before a formal application is submitted. Rather than an application being submitted without consultation resulting in a timely but perhaps unfavourable decision followed by the opportunity for a formal appeal, inspectors and applicants instead work to an informal pre-application consultation process, which can in some cases lead to significant delays in decisions. These delays may be due to procrastination on the part of applicants in responding to advice and requests from inspectors for additional information. Nevertheless, there is perceived inconsistency between inspectors, and the lack of a functioning appeal system for the pre-approval stage means that the decisions of individual inspectors, and the causes of any delays, are not “transparent”.

ASPI are confident that they “know the universities and commercial establishments which have lower compliance rates”, and thus can apply proportionate and meaningful sanctions to those few places which persistently break regulations.

The sanctions available to ASPI for breaches of licences do appear to be proportionate and meaningful, save only in the most extreme cases where the CPS and PFS decide whether or not to take action. The range of penalties includes: letters of admonition; requirements for re-training; variation, suspension or revocation of licences; or prosecutions. However, experience has been that the prosecuting authorities tend to decline to prosecute because they judge that it is not in the public interest to make public either the offences or the identity of the offender. We recommend that ASPD should continue to work closely to improve relations with prosecuting authorities with a view to securing better understanding and ownership, between ASP, stakeholders and the prosecuting authorities, of the decisions over the progression of cases to a criminal prosecution.

ASP maintains an active supervision of enforcement actions. These records inform ASPI’s risk-based inspection programme. 40 to 50 per cent of breaches of licences are self-reported. Establishments that make licence infringement automatic internal disciplinary offences can create a culture that leads to a failure to report breaches. ASPI takes steps to avoid this, through inspections and close working with licensees and named persons, and thus avoid creating perverse

incentives that could undermine the effective operation of the regulations.

FOCUS ON OUTCOMES

Hampton principle

“Regulators should measure outcomes and not just outputs.”

Key findings on focus on outcomes: ASP defines the main outcomes that it seeks to achieve and also attempts to demonstrate evidence of how it has impacted on them. However, it does not tangibly measure outcomes or regularly report on any of its four stated outcomes (see below).

In fairness, it is difficult to know what measures could be used or easily gathered to demonstrate some of the desired outcomes, eg maintaining the success, sustainability and competitiveness of UK bio-science. However for others, such as maintaining public and political confidence in regulating the scientific community, it may be possible to measure outcomes, eg through public/ministerial opinion surveys.

The value of the expert advice that the inspectors provide should be reported on.

Improved measurement and reporting on outcomes will require a sophisticated IT system. The current IT infrastructure within ASP is considered substandard and unfit for purpose.

The review team are of the view that more can and should be done in this area of Hampton, to demonstrate the regulator’s focus on outcomes by not only defining outcomes but determining measures of outcomes **and** collecting data to report on those measures. It was not clear to the review team the extent to which the four outcomes identified by ASP were driving consistent behaviour across both ASPD and ASPI and the degree to which objectives were aligned with these outcomes.

Background information such as the regulator’s key objectives:

ASP has identified four main areas for measuring **outcomes**, namely:

- Maintaining the success, sustainability and competitiveness of the UK bio-science community (both academia and pharmaceutical industry) through efficient regulation;
- Regulation of the scientific community whilst maintaining public and political confidence;
- Ensuring conduct of scientific work with high

standards of animal welfare achieved and no unnecessary animal suffering through sharing best practice and implementing the Three R's;

- Promoting high standards of accommodation and care (including environmental enrichment).

Any examples of significant good regulatory practice:

The four main outcomes are openly stated, shared with, promoted and largely subscribed to by stakeholders. It is largely in everyone's interest to maintain a high standard of animal research and welfare, which ultimately leads to all four outcomes.

Quantifying outcomes is a necessary and important 'building block' in being able to determine and capture subsequent measures. ASP has defined the first half of the task but needs to now directly address and satisfy this Hampton principle.

The Three R's are an excellent example of an outcome set and determined by the regulator and therefore should be able to be captured and reported on.

Over 2,000 inspections are conducted each year, allowing for potential direct assessment and measurement of the outcome(s).

Although not expressly stated as an outcome, advice and guidance contribute greatly to the outcomes and yet this is only reported on in the visit reports prepared by each inspector for internal use.

The extent to which the review team believes the regulator is acting in line with the Hampton principle:

ASP has made an important step in defining the outcomes that it seeks to achieve but has made little, if any, progress in measuring and reporting on the stated outcomes.

The review team therefore concludes that the regulator is not acting in accordance with this Hampton principle.

Appendix 1: Review team membership

Craig Riggs is HR Business Partnership Manager in the Driving Standards Agency, responsible for a team of HR Business Partners and professional Health & Safety Advisors. His background is in HR spanning 20 years in both private and public sectors, involving a number of roles, including Policy, Employee Relations and Business Partnering. He is shortly due to broaden his professional experience by undertaking a secondment to head up a new Business Improvement & Efficiency unit in DSA.

Victoria Milner was, at the time of the review, an Assistant Director working in the areas of Employment Law, Consumer and Competition policy and Corporate Law and Governance. Victoria comes from a private sector background and has worked in the UK for Microsoft Corporation as a Program Manager and for EMI Music in Global Digital Operations. Victoria's background before that included time at a large children's charity based in Sydney, Australia, and five years in the mining industry working on global IT programs.

John Finnie is a Target Delivery Manager in Natural England, responsible for the effective delivery of £267 million in Environmental Stewardship agreements that are paid to farmers in England. His background is in nature conservation regulations, ranging from advice and enforcement action with individual land managers up to appeal cases in the House of Lords. He has also specialised in obtaining and making use of data on how incentives and regulations can secure better management of wildlife sites.

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