Animal Research – the Role of a Professional Inspectorate

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The latest statistics on the use of animals in research in the UK were released by the Home Office in July. The raw figures show that regulated procedures rose by 6% in 2007, continuing the upward trend seen since 2000. However, the annual total is still only about half what it was 30 years ago.

The main area where animal research is increasing lies in the use of fish and genetically modified mice which now account for nearly half of all procedures. Genetic modification is a very powerful tool that enables scientists to find out the function of genes and to create better animal models of diseases. It may actually reduce the number of 'higher' species used, such as monkeys (currently 0.1% of procedures), because mice with human genes may better mimic specific aspects of human diseases. It is also important to recognise that animal research is a small, but necessary, part of the total UK research effort which is increasing at a much greater pace.

Many think it is the responsibility of the Animals Scientific Procedures Inspectorate (ASPI) to reduce the numbers of animals used in research. However, it's a bit more complicated than that. There is no mechanism under the Animals (Scientific Procedures) Act 1986 to reduce overall numbers or to meet numerical targets. Instead, the regulatory controls aim to ensure that animals are used only when there is no alternative, that the fewest number of animals consistent with the scientific objectives are used, and that any harm caused is minimised. These principles are known as the '3Rs' of animal research – *Replacement, Reduction and Refinement* – first articulated in the late 1950s by British scientists William Russell and Rex Burch.

All Inspectors are professionally qualified, either medically or as veterinarians, and all have extensive relevant experience when they enter the Inspectorate having worked previously in areas such as biomedical research, clinical practice and animal welfare. With such a rich and diverse background, I believe we are ideally placed to ensure that a suitable balance is achieved between any compromise to animal welfare and potential scientific benefits.

On the benefit side, the use of animals in research continues to contribute greatly to medical advances, including the development of improved anaesthetics, antibiotics, vaccines, a wide range of other modern medicines, and surgical advances such as open heart surgery, joint replacements and organ transplants. In addition, animals are used in other areas of research unconnected with healthcare but where their use is still justified. We should also remember that animals, as well as humans, have benefited.

However, there is still much unmet medical need – just starting at A we face life-threatening and debilitating conditions such as Alzheimer's disease, AIDS, atherosclerosis and arthritis. Whilst many alternatives to animals have been developed for significant elements of modern research programmes, there remain many examples of really important research where the use of animals is absolutely necessary to achieve the objectives.

Under the 1986 Act, a regulated procedure is any scientific procedure that has the potential to cause pain, suffering, distress or lasting harm to a protected animal. In the UK, protected animals include all vertebrate animals and one species of octopus and central to the application of the Act is the principle of the '3Rs'. Hence all applicants for project licences must show they have taken steps to avoid using animals wherever possible (Replacement), to use the minimum number of animals (Reduction) and to refine their procedures to minimise the impact on the animals (Refinement). Therefore, whilst on the welfare side it cannot be denied that animals may suffer in some research, a main role for the Inspector is to make sure that any suffering is minimised as much as possible.

So, what does ASPI actually do? When the annual statistics were released earlier this year, we also published our annual report detailing many aspects of our work during 2007. The 28 inspectors carried out over 2,400 visits to scientific establishments, primarily to check for compliance and to ensure the 3Rs are being effectively applied. The majority of visits were unannounced. They also provided advice on over 3,200 applications for personal and project licences as well as over 6,550 amendments.

Under the rigorous controls of the 1986 Act, an important part of the Inspectorate's work lies in the triple

licensing system: research must generally take place in research institutes or companies which have appropriate animal accommodation and veterinary facilities, and have gained a **certificate of designation;** procedures must be part of an approved programme which has been given a **project licence**; and procedures must be carried out by people with sufficient training, skills and experience as shown in their **personal licence.**

It is clear then that, in addition to visiting establishments, much of ASPI's work is in assessing licence applications. However we are concerned that the way the licensing system has been administered in the past may have, for a variety of reasons, become more bureaucratic than may be necessary. A remarkable feature of ASPI is the day to day contact we have with our stakeholders as part of our role as regulators. And the range of those stakeholders is immense – including internationally renowned scientists performing research which may literally change the world, veterinarians and animal care staff who devotedly care for animals on a daily basis, and representatives of animal welfare and protection bodies who are passionate in their concern for animals. Working with these stakeholders, we are actively seeking ways to improve the licensing process without compromising animal welfare. We have already made good progress but we are conscious that applicants, particularly for project licences, still find preparing their applications challenging. We believe this is largely due to difficulties in achieving the right level of detail in the information which we require to properly assess the application. So there is need for better communication at many levels.

On the other hand, many stakeholders also want to be reassured that any measures to reduce bureaucracy will not compromise animal welfare. Unnecessary red tape may threaten the competitiveness of UK research but equally it is the rigour of the regulatory system which assures public confidence. So there is much to be done in achieving the right balance whilst meeting the challenge of better regulation.

A further big challenge is to ensure consistency in our recommendations. All Inspectors are professionally qualified which is important because we are working in very complex fields. However, as professionals, we exercise judgment in formulating our advice and this may lead to apparent inconsistency. In reality, this inconsistency is often not real since the circumstances surrounding a particular recommendation may explain why it differs from an apparently similar situation elsewhere.

Nevertheless, we recognise the need to demonstrate consistency wherever appropriate but without creating a set of inflexible rules. A solution lies in teamwork so we are performing thematic reviews of specific areas of work, often in association with stakeholders, to ensure our advice is both consistent and of a high standard. We are also prioritising our resources to focus particularly in areas of higher risk such as those involving substantial suffering or sensitive species, such as dogs, cats and non-human primates. In addition, we make use of joint visits, meetings and assessments to enable Inspectors to benefit from each other's specialist knowledge and to share best practices.

The Inspectorate is also involved in a number of special projects, sometimes providing advice to the Animal Procedures Committee (APC), our statutory independent advisory committee. The range of these special projects is very wide, from advice on the acquisition and use of primates to the training of licensees; from guidance on ethical review processes within establishments to retrospective review of licences. We have recently offered advice to the APC on improving the welfare and refining the use of genetically altered rodents and advice to stakeholders on the pitfalls that may arise when building new facilities or renovating existing buildings. And, importantly, we support our colleagues in the policy section of the Animals Scientific Procedures Division (ASPD) in advising ministers and responding to parliamentary questions and external enquiries, particularly with respect to operational and technical issues.

The Inspectorate also plays a central role in advising on the current revision of European Directive 86/609/EEC on the Protection of Animals used for Experimental and other Scientific Purposes. The main aims of the revision are to achieve an improvement across Europe in the welfare of animals undergoing scientific procedures and to promote a level playing field throughout Europe for researchers using animals. The Commission has sought advice from a number of experts and has undertaken a public consultation. The Inspectorate plays an important role in an Inter-Departmental Group, convened by the Home Office, which co-ordinates the UK Government's views on the revision of the Directive. This group also works closely with a wide range of UK stakeholders to determine and understand views and align them wherever possible.

The Commission had originally intended a rapid revision of the Directive but we now realise we may have to wait several years before a new version is finally agreed. At that point, it may be necessary to seek changes to the UK legislation in order to transpose and implement the new Directive.

In conclusion therefore, it can be seen that the role of ASPI, whilst primarily advisory, is fundamental to the effective operation of the UK regulatory system to protect animals used in research. Many initiatives are under way to improve the efficiency of the system through better regulation. In addition, the European dimension means that we are likely to see some significant changes to our regulatory system in the coming years. Whilst many of these changes may lead to improvements in animal welfare, the major benefit for UK research, both in academia and industry, has to be in achieving a more level playing field for research across Europe.