Parliamentary Office of Science and Technology

postnote

February 2004 Number 215

OPENNESS AND ANIMAL PROCEDURES

A number of developments – including the introduction of the Freedom of Information Act 2000 - have led to calls for more openness about the costs and benefits of animal procedures. This could require modification of the Animal (Scientific Procedures) Act (A(SP)A) 1986, which restricts disclosure of confidential information about animal procedures. This POSTnote looks at the pros and cons of greater openness, and analyses ways in which greater openness could be achieved.

Background

The Freedom of Information Act 2000 provides people with a statutory right to access information held by bodies in the public sector. As outlined in more detail in box 1, the Act sets out a number of conditions and exemptions whereby access to information need not be granted if disclosure might prejudice personal safety, commercial confidentiality, or some other interest.

Animal procedures are one area where there have been calls for greater openness. As detailed in box 1, all such procedures are regulated under the A(SP)A 1986. This Act includes a so-called 'confidentiality clause', which makes it an offence to disclose confidential information about animal procedures. As discussed later, one way of achieving greater openness about animal procedures would be to repeal or modify this clause

Currently published information

Annual statistics on the use of animals in Britain are published by the Home Office (HO).[1] These are based on detailed forms returned by licence holders at the end of each year, or when a project licence is terminated. As outlined in box 2, they include details of the number of animals used, the number of procedures conducted and the different types of species involved, details of the

Box 1 Relevant legislation

The Freedom of Information Act 2000

The Freedom of Information Act 2000 provides the right of access to information held by bodies across the public sector. It sets out how this can be achieved subject to certain conditions and exemptions. Information will be disclosed unless it is exempt; information is exempt if its disclosure would, or would be likely to, prejudice an interest, such as personal safety or commercial confidentiality. The Act also establishes an Information Commissioner (who will consider any complaints) and an Information Tribunal (to consider any appeals arising from the Commissioner's judgements). A key feature of the Act is the requirement on each authority to adopt and maintain a publication scheme, which sets out the information which the authority proposes to publish, and which must be approved by the Information Commissioner. The Act will be introduced in stages but must be in effect for all public authorities by the end of November 2005.

The Animals (Scientific Procedures) Act 1986

All experiments or other scientific procedures carried out on living animals which may cause pain, suffering, distress or lasting harm must be licensed under the A(SP)A 1986. Licences under the Act are issued by the Home Office (HO). There are three main types of licence: project licences (to authorise a programme of work); personal licences (to ensure that only trained individuals conduct animal procedures); and establishment licences (which apply to premises). Applications for project licences are considered by the HO's Animals (Scientific Procedures) Inspectorate, which weigh the potential benefits that might accrue from the programme of work against the likely costs (in terms of the pain and suffering of the animals involved). Licences are issued only where the potential benefits outweigh the costs, and if the use of non-animal alternatives is not possible. Under Section 24 of the A(SP)A 1986 (the 'confidentiality clause') it is an offence for anybody '*otherwise than for the purpose of discharging his functions under the Act*' to disclose confidential information about animal procedures.

Box 2 Information that is currently published

Number of procedures/species used
In 2002, over 2.73 million procedures were conducted involving a total of 2.65 million animals (some animals are used in more than one procedure). Mice, rats and other rodents accounted for the majority (84%) of procedures.

Primary purpose
These include fundamental biological research (842,222 animals in 2002), applied studies (817,097), protection of man, animals or the environment by toxicological or other safety or environmental evaluation (185,165), education and training (4,692), forensic enquiries (1), direct diagnosis (16,161), and breeding (790,538).

Target body system.
These include the: respiratory, cardiovascular and blood systems (which accounted for 6% of procedures in 2002); nervous and sensory systems (15%); alimentary and skin systems (3% each); reproductive system (7%); immune system (18%); and other single (7%) or multiple (16%) body systems.

Source, development, genetic status and breeding
In 2002, more than 99% of procedures used animals obtained from designated sources in the UK.[2] Genetically modified animals accounted for 26% (710,000) of all procedures. Most of these (64%) were used to maintain breeding colonies.

Severity
The HO assigns each project an overall severity banding when a project licence is being considered. This takes into account the number of animals, the amount and duration of suffering caused, and any steps taken to alleviate it (e.g. use of anaesthesia). There are four categories: mild, moderate, substantial and unclassified (where the protocol is performed entirely under general anaesthetic, from which the animal does not recover consciousness). The majority of projects in force at the end of 2002 were classified as being of moderate severity, with most of the rest being of mild severity (see table), and just 2% as of substantial severity.

Severity	No of projects	%of projects
Mild	1,233	39%
Moderate	1,768	56%
Substantial	60	2%
Unclassified	119	3%

primary purpose of the research, the body system involved, the source of the animals and their genetic status and the severity level of the projects licensed.

The pros and cons of greater openness

The Animal Procedures Committee (APC), which advises the Home Secretary about the workings of the A(SP)A 1986, formed a working group on openness in 1999. This group conducted a consultation exercise that reported in August 2001 (see box 3), outlining the cases for and against greater openness.[3] Similar issues were also considered by a House of Lords Select Committee on Animals in Scientific Procedures in July 2002.[4] This Committee concluded that publication of good quality information was "*vital to create an atmosphere in which the issue of animal experimentation can be discussed*".

Box 3 The APC consultation on openness

The APC consultation exercise was conducted between January and March 2000. It sought views on 5 scenarios for achieving greater openness in animal procedures:

- 1) full disclosure of information with no exceptions;
- 2) as 1) except of information revealing individual's identity/addresses;
- 3) as 2) with the additional exception of information about potentially patentable material before it is made public, or of information about investigations into non compliance before their completion;
- 4) as 3), with the additional exception of any other strategic research and development information of commercial value to competitors;
- 5) full disclosure of information except in relation to matters which have been the subject of a requirement from affected persons for confidentiality.

Over 2,300 responses were received, from animal protection groups, individuals, pharmaceutical organisations and researchers. In general, animal protection groups and individuals expressed a preference for options 1) or 2), while pharmaceutical organisations preferred 4) or 5). Responses from researchers that expressed a preference were spread evenly over options 3), 4) and 5).
Source: *APC Report on Openness*, APC, August 2001

The case for greater openness
The APC working group identified several potential public concerns arising from the perceived secrecy surrounding animal procedures. In particular it noted that this allowed scope for concerns:

- that unjustifiable work might be authorised;
- over the living conditions of animals;
- that licensing conditions may not ensure that procedures involve the minimum of suffering;
- over the compliance with and enforcement of licensing conditions in general;
- that the potential benefits derived from the harm inflicted may not actually be realised.

As the APC report noted, groups that express such concerns feel that greater public access to information about animal procedures would result in more effective public scrutiny. It also noted that there was another school of thought, which did not share these concerns and which felt that there are no serious problems with the current system, but which also favoured greater openness because they feel this would help to dispel what they see as public misconceptions about animal procedures.

The case against greater openness
Several potential reasons for being wary about moving towards greater openness in animal procedures emerged from the APC consultation exercise (box 3) and were considered by the working group. These included:

- Lack of need – the current legislation and culture already adequately protect the welfare of laboratory animals, so there is no need for greater openness.
- Welfare of researchers - divulging more information about who does what animal research and where might compromise the researchers' personal safety or lay them open to personal abuse or criticism.

- Commercial confidentiality – requiring commercial organisations to divulge more information could cause them problems when it comes to patenting and also be of commercial interest to their competitors.

Repeal of the confidentiality clause

Repeal or some other modification of the confidentiality cause in section 24 of the 1986 Act has been considered both by the APC and the Lords Committee. The former recommended that "*repeal or relaxation*" of the clause "*should be* considered" whereas the latter stated that "*We recommend that section 24 should be repealed*". In reaching this conclusion, the Committee noted that levels of secrecy surrounding animal experiments were "*excessive*". It received evidence from animal protection groups that the lack of information on animal procedures made it difficult for them to challenge HO decisions. However, some medical research groups suggest that greater openness can be achieved without repealing/ modifying section 24, and that the clause remains necessary to protect researchers' identities.

Overall, the Committee considered that there should be a reversal of the 'burden of proof' with the current statutory restrictions being replaced by a "*presumption in favour of complete openness*". Under such a system, it would be up to the scientific community to justify any information that it considered should remain confidential.

The government has been reviewing section 24 of the 1986 Act for some time. In its response to the Lords Select Committee on Animals in Scientific Procedures report the government announced plans to consult further on the future of section 24. The Home Office established a joint working group with scientific stakeholders which held its first meeting to examine this issue in March 2003. A progress report has been presented to the responsible Home Office Minister, who is expected to announce the outcome of the review soon.

What could remain confidential?

The Lords Committee concluded that certain information is likely to need to remain confidential:

- Personal details of researchers (to protect their safety).
- Information that would compromise intellectual property rights (IPR) if made public.
- Information that would compromise commercial considerations if made public.

In practice, the Lords Committee noted that the first of these is not controversial: none of the witnesses it took evidence from called for the release of personal information about researchers. However, groups such as the Royal Society for the Prevention of Cruelty to Animals (RSPCA) are concerned that IPR and commercial considerations could be widely used as a blanket reason for keeping all information confidential.

What could be published?

Information on cost/benefit decisions

As outlined in box 1, cost benefit analysis is at the heart of the current licensing system. Project licences will be granted only where the Inspectorate is satisfied that the potential benefits arising from a programme of work outweigh the pain and suffering caused to the animals used. But the House of Lords Committee heard evidence that the benefits of a particular project may be overstated while the costs over the full life of the animals may not always be fully taken into account. It concluded that there is currently "*too little information on how decisions on cost/benefit are reached*" and that the public should be better informed about such decisions.

The area of cost benefit analysis was also examined in detail by the APC in 2003.[5] This Committee identified a wide range of factors that need to be taken into account when assessing costs and benefits and called for the HO to produce (or commission) a comprehensive list of such factors to assist researchers. It also saw a need for greater transparency in the process by which cost benefit decisions were made, recommending that:

- The Inspectorate publish case material to illustrate the reasons for judgements that it makes. This could take the form of a section in an annual report, offering a commentary on particularly interesting or challenging judgements that the Inspectorate had made.
- Non-technical people be encouraged to become more widely involved in the cost benefit assessment. It noted that this could improve the process itself and engender wider trust, but that it would require clear, non-technical accounts of the costs and benefits of projects under review to be published (see below).
- The provision of more meaningful information about licences and the severity of procedures. As discussed in more detail below, the Committee saw a need for the publication of a clear account of why researchers considered that the benefits of their proposed project outweighed the costs to the animals involved. It also noted that there was a need to devise a better system for assessing the severity of the effects actually experienced by animals.

Publication of project licence summaries

Content

As outlined above, the House of Lords Committee and the APC have both identified a need for the publication of non-technical summaries of project licences. They envisage a two page summary, written in language accessible to a lay person, outlining the costs and benefits of the project. The APC has recommended that this summary should be published as part of the Home Office's publication scheme under the Freedom of Information Act (box 1). In particular, it noted that the summary should include:

- key objectives and possible benefits of the project;
- reasons for using animals, what alternatives have been considered and why these are not appropriate;
- reasons for the choice of species and strains;
- numbers of animals to be used for the project;
- estimated levels of the severity of the procedures, details of measures to minimise adverse effects and improve welfare;
- how the applicant has weighed the costs against the benefits to judge whether use of animals is justified.

In January 2003, the government announced proposals to publish project licence summaries subject to safeguards for personal and confidential information. It is currently consulting with the scientific community about the format and content of the summaries and arrangements for their publication.

Timing of publication
One option considered by the Lords Committee was to publish the proposed summaries of project licence applications while they are being assessed by the HO Inspectorate. This would allow interested parties to suggest replacements, reductions and refinements (the 3 Rs), and help ensure that the application doesn't duplicate research that has already been conducted. It would also allow members of the public and animal protection groups time to comment before a licence was granted and to see applications that were ultimately turned down.

However, there are concerns that this might hamper the iterative process of discussion between the HO and applicants and prolong the licensing process. Overall, the Lords Committee recommended that "*the substantive details of anonymised project licences, which describe the expected benefits of the research and harms to the animals involved, should be made public after they have been approved and funded*".

Better information on benefits and severity
Benefits
Some animal protection groups have called for assessment of the extent to which projected benefits actually accrue in practice. This would require an audit of the outcome of research projects some time after their completion. However, such a process could prove to be extremely difficult in practice because of the uncertain nature of research. For instance, the Medical Research Council has suggested that the full benefits of basic research can only be assessed over long periods of time. Nor can it be assumed that applied research will be any easier to assess. As the APC has pointed out, fundamental and applied research are inter-linked; benefits such as advances in knowledge or clinical practice can often be traced back to roots in both types of research.

Severity
Animal protection groups have suggested there is a need for better information to be collected and published about the severity of animal procedures. For instance:

- Information about the number of animals in each project. The current figures reveal the number of project licences in each severity band, but each licence can cover procedures on hundreds of animals.
- A breakdown of the severity banding covered by a project licence. The current system averages out the severity bandings into an overall banding for the project. The Lords Committee suggested that it would be helpful if the figures specified what proportion of animals within a project fell into each banding.
- Information about the purposes for which project licences will be granted for each severity banding.
- A better scoring system for assessing suffering and pain. The APC has suggested that the divisions of severity could be further subdivided, along the lines of the system adopted in New Zealand.[5] This system has 5 grades which take into account levels of stress and discomfort as well as the likely level of suffering.

The need for better information on severity and for a new system of recording the severity of the effects experienced by animals has been recognised both by the APC and by the Lords Committee. A recent APC consultation on the HO statistics addressed the issue of whether data on suffering needs to be collected in a different way; it will be published later this year.[6] The Lords Committee noted that it would be impossible for the HO Inspectorate to assess suffering for each of the 2.6 million animals used in procedures each year. Instead, it recommended the Inspectorate develop a scoring system for animal suffering which could be operated by local staff and audited by the Inspectorate.

Avoidance of duplication
Another issue considered by the APC is the avoidance of duplication of animal studies. This can arise in two main ways. First, researchers may simply be unaware of published research in the area in which they propose to work. While the current system makes project licence applicants responsible for avoiding unnecessary duplication of animal use, it can be difficult to locate all the relevant research, particularly if it has been published in non-English language journals.

Second, applicants may be unaware of animal studies because the results were never published. This can happen if studies yield negative results that are not deemed to be of sufficient interest to merit publication, or for reasons of commercial confidentiality. Animal protection groups have suggested that publication of results, whether positive or negative, should be made a condition of the project licence. On the issue of commercial confidentiality, the government set up of a UK inter-department concordat on data sharing to reduce duplication of animal studies in 2000. However, the APC has suggested that it is too early to assess what impact this initiative has had.

Endnotes
1 www.homeoffice.gov.uk/docs/animalstats.html
2 The A(SP)A 1986 requires that certain species be obtained from designated suppliers certified by the Secretary of State.
3 www.apc.gov.uk/reference/openness.pdf
4 Select Committee on Animals in Scientific Procedures, House of Lords paper 150-1, Session 2001-02, July 2002.
5 www.apc.gov.uk/reference/costbenefit.pdf
6 www.apc.gov.uk/aboutapc/consultation_letter.pdf

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