

The **A P C**
Animal Procedures Committee

ANIMAL PROCEDURES COMMITTEE

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CONSIDERATION OF POLICY CONCERNING STANDARDS OF ANIMAL
HOUSING AND HUSBANDRY FOR ANIMALS FROM OVERSEAS NON-
DESIGNATED SOURCES

Consideration of policy concerning standards of animal housing and husbandry for animals from overseas non-designated sources

Summary

The Animals (Scientific Procedures) Act 1986 requires that animals of the types listed in Schedule 2 should be acquired from a designated establishment. Standards of husbandry and care at these establishments, which are inspected by the Animals (Scientific Procedures) Inspectorate, are informed by Home Office Codes of Practice. However, it is sometimes necessary for researchers to obtain animals from overseas where the Home Office has no jurisdiction and in these circumstances the Secretary of State can approve the use of animals from non-designated premises. For ethical, scientific and welfare reasons, it is important that all establishments supplying animals for research in the UK, whether they operate within this country or abroad, should provide husbandry and care that meets animals' needs. It is also important that the mechanisms for ensuring that animals are only acquired from establishments with good animal welfare conditions should be transparent. The Housing & Husbandry Sub-Committee of the APC has, therefore, enquired into the mechanisms by which the Inspectorate currently assesses the standards of overseas suppliers of Schedule 2 species.

The Sub-Committee have found that the Inspectorate applies a hierarchical approach based on:

- type of animal,
- their protection under the Act,
- the number of animals being supplied,
- the ability of the Inspectorate to exert an influence in different source countries, and resource issues.

The Sub-Committee have also established that some users not only obtain information from their suppliers on health status but also seek information regarding housing and husbandry and other welfare issues. This we consider to be good practice. We have provided a number of recommendations to encourage this good practice which if implemented would provide greater reassurance regarding the welfare of animals imported for scientific research. The additional information would enable users to minimise stress caused by changes of husbandry and could help to improve the quality of science obtained from these animals.

Background

Currently, most animals used in research in the UK are bred in the UK, although in other countries there is more cross-border movement, especially within continental Europe. Looking to the future, there are a number of pressures that could lead to an increase in the proportion of animals imported into the UK. It has been argued that animal rights extremism may have increased the need to import animals but more general factors include the increased regionalisation and globalisation of research and trade.

In its Annual Report of 2003, the APC considered the issue of perceived over-breeding of laboratory animals leading to wastage. It concluded that for a number of reasons, including ethics,

cost, regulation and reputation, laboratory animal breeders try to avoid over-breeding animals and that there is a tendency for underproduction rather than overproduction. It follows, that overseas supply of a number of the most commonly used species, will often be needed to accommodate a shortfall in availability within the UK. On the one hand, this can be seen as beneficial as it contributes towards avoiding overproduction but the welfare costs of transport, etc., also have to be taken into account. Animals are also imported when a particular species, strain or line is only available from an overseas supplier. This is often the case for genetically altered (GA) animals and certain species of non-human primates. The vast majority of imported animals are rodents (Table 1)¹. In contrast, the numbers of procedures carried out on imported non-human primates, dogs and cats (species for which there is particular public concern) are comparatively small. This reflects the different scales of use for these animals (over 80% of procedures are carried out on rodents). Nonetheless, imports of non-human primates, dogs and cats amount to a significant fraction of the total numbers of these species used in the UK, and therefore importation is an important consideration in their use.

The Animal (Scientific Procedures) Act (ASPA) requires that types of animal listed in its Schedule 2 (Table 1, column 1) are obtained from a breeder or supplier designated under the Act. Designation requires compliance with a Code of Practice for housing and husbandry. However, if an animal listed in Schedule 2 is not bred in, or is not currently available from such designated premises, then the Home Office can approve the use of such animals from non-designated premises. The majority of such animals will be supplied from outside the UK, although there may be times when a UK non-designated source is used, for example, wild rats for rodenticide studies and breeds of dogs other than beagles. In all cases, approval of the Secretary of State is required. This is often facilitated by use of the Home Office *Application Form For Authority To Transfer Protected Animals*². This form enables assessment of the justification for the need to transfer the animals and provides information on transport arrangements so that a view can be taken as to whether the transport is likely to result in health or welfare problems for the animals involved. The Inspectorate has no jurisdiction outside the UK, and therefore, where animals are supplied from outside the UK, any site visits by the Inspectorate depends on negotiation and cooperation, and information is often provided in confidence to the Inspectorate.

¹ n.b. The number of animals used in experiments is not identical to the number of procedures carried out, as a small proportion of animals are reused.

² <http://scienceandresearch.homeoffice.gov.uk/animal-research/application-forms/auth-trans/>

Table 1. Scientific procedures by Schedule 2 species acquired from outside the UK (Source: Home Office Statistics of Scientific Procedures on Living Animals Great Britain 2005).

Species	Total Number of Procedures	Number of procedures on animals acquired from outside the UK	% of total procedures on that type of animal	% of total procedures on animals obtained from outside the EU or Council of Europe
Mice	1,961	13,479	0.7	0.4
Rats	424	2,333	0.5	0.3
Guinea pig	29	0	0.0	0.0
Hamster	4	1,527	36.1	0.0
Gerbil	5	1,133	22.4	1.3
Rabbits	22	454	2.0	0.2
Cats		110	22.0	0.0
Dogs	7	1,053	13.7	10.8
Ferrets		6	0.6	0.6
Pig (genetically modified)		-	-	-
Sheep (genetically modified)		0	0.0	0.0
Non-human primates	4	3,398	73.0	69.8
Quail (<i>Coturnix coturnix</i>)		0	0.0	0.0

It could be argued that, because of harmonisation of standards, there should be less concern regarding the import of animals from the European Union (EU) and Council of Europe countries. Currently, the UK has, in some aspects, more stringent standards of accommodation and care than some other EU and Council of Europe countries, but the reviews of Appendix A to the Council of Europe Convention ETS 123 and the European Directive 86/609 are expected to promote greater convergence towards common standards. Whilst the majority of non-human primates are obtained from outside the EU or Council of Europe countries, most mice and rats are obtained from within the UK, the EU or Council of Europe countries. Even so, in 2005, 9,931 procedures were carried out on animals obtained from outside the UK, EU or Council of Europe countries signatory to ETS123³.

It is most important for ethical, welfare and scientific reasons that the standards of housing and husbandry of animals supplied from non-designated sources should be satisfactory. To this end, the APC Primates Sub-Committee (PSC) has recently considered the process by which the PSC and the Inspectorate inform themselves, and advise, on the acceptability of overseas suppliers of primates⁴. Expanding on this work, the Housing and Husbandry Sub-Committee has considered the welfare of all types of animal listed on Schedule 2 imported for use in scientific procedures in

³ Home Office Statistics of Scientific Procedures on Living Animals Great Britain 2005 Table 2).

⁴ <http://www.apc.gov.uk/reference/primate-sources-report.pdf> Acceptance of overseas centres supplying non-human primates to UK laboratories: a report by the Primates Sub-Committee of the Animals Procedures Committee.

the UK. In our enquiries, we have, for practical reasons, restricted our consideration to Schedule 2 animals⁵, as the sources of these are subject to regulatory approval by the Home Office. Our purpose in this document is to clarify and review the processes by which the Inspectorate and users obtain information and make decisions with respect to housing standards for Schedule 2 animals imported for scientific purposes.

Current system for ensuring standards for overseas suppliers

The Housing and Husbandry Sub-Committee has inquired into the current system adopted by the Inspectorate for ensuring standards for overseas suppliers. Most users of laboratory animals are likely to be highly motivated to ensure that the quality of the animals that they import is high, not least for ethical reasons, but also because it impacts on the quality of the science that they carry out, the management of the animals with respect to health status, and their reputation. In some cases, they visit their suppliers to inspect the animals and the conditions under which they are kept, and the Inspectorate collates feedback it obtains from UK users about welfare and suitability of animals from various sources. In the broadest terms, the Inspectorate uses a hierarchy of risk assessment to target their resources to best effect as outlined below, based on species, number of animals being supplied, their protection under the Act⁶, the ability of the Inspectorate to exert an influence in different source countries, and resource issues.

1. Non-Human Primates

The importation and use of primates in scientific procedures is of particular public concern and this is reflected in the provisions made in the Act. The process by which overseas suppliers of primates are authorized has recently been reviewed by the Primates Sub-Committee in a report which notes that:

“Project licences, which require the use of primates, are subject to a series of conditions on the licence which require authorisation of each consignment of animals from a centre considered acceptable to the Home Office. Each consignment of primates to be acquired from an overseas source requires separate authorisation prior to their acquisition, and this is given only if the conditions at the breeding or supplying centre are acceptable to the Home Office. If a centre is not considered acceptable, then the Home Office can refuse to allow it to be used as a source of animals.

Centres are currently assessed on the basis of a Home Office form⁷. Additional information is gathered from visits to centres by the Inspectorate and user-establishment staff. The information is scrutinised by at least two members of the Home Office Inspectorate and a recommendation made to the Animals Scientific Procedures Division (ASPD) of the Home Office. If ASPD consider that further consultation is advisable, the opinion of the PSC “may be sought”, although in practice the PSC is asked for a view on all applications. ASPD can choose not to accept the advice of the PSC and has done so on one occasion.

All centres are informed of the Home Office decision on whether and on what terms they have been accepted. If judged to meet the expected standards, a centre will be accepted

⁵ Schedule 2 to ASPA lists types of animal, which may be obtained only from a designated breeding establishment, unless an official exemption is granted.

⁶ Special provisions are made for non-human primates, cats dogs and equidae under the Animals (Scientific Procedures) Act 1986

⁷ Home Office pro forma are available from the Home Office Animals in Scientific Procedures website: <http://scienceandresearch.homeoffice.gov.uk/animal-research>

typically for periods of 2 years. If not, it is advised of the action necessary to achieve acceptance with re-consideration being conditional on appropriate action being taken. Current and prospective customers are informed of the decision promptly in any event.”

The Primates Sub-Committee report made a number of suggestions to refine the process and identified criteria it considered important in the assessment of overseas sites. Nonetheless, it did not propose that these criteria should always be treated as absolute standards below which sites would automatically be rejected. This pragmatic approach allows an overall assessment of the institution rather than focussing on what might be a minor deviation from UK standards.

2. Dogs and cats

Requests to import dogs and cats are also given particular attention by the Inspectorate. While visits to the major overseas breeders of dogs and cats have not been as regular as for primate sources, informal visits have been made. These are often made jointly with the national responsible authority, such as the USDA in the USA. The Inspectorate has produced a form,⁸ to be filled in by someone in a position of authority at the overseas breeding centre that provides a snapshot of dog or cat colony management and structure and of any likely welfare issues. The Inspectorate assesses requests for importation of these animals by considering the overseas institution’s national standards, the information gathered during informal visits by the Inspectorate, and information gained through its links with other national authorities. In addition users/purchasers visit suppliers and provide feedback to the Inspectorate. All of this information can then be used to provide an informed decision on suitability.

3) Other species e.g. rodents, rabbits.

As for non-human primates, dogs and cats, the Inspectorate advises the Secretary of State on requests to use rodents and rabbits from overseas suppliers. However, in contrast to the situation with primates, cats and dogs, the number of potential suppliers is much greater. Conventional animals almost always come from well-known commercial overseas breeders with whom the Inspectorate will have had previous contact, will usually be aware of the standards in operation and, will have discussed variations between the supplier’s national standards and those of the UK. However, the rapid development of genetic technology has resulted in the production of many new genetically altered mouse strains, many of which come from a few large scale producers but which may also come from a variety of academic sources (Universities, NGOs etc.), where the import is likely to be a “one-off”. It would be a great strain on current resources, and so currently impracticable for the Inspectorate to visit all these sites before importation. Decisions are, therefore, made taking into account: past experience, if any, with the importer; the institution’s national standards, independent accreditation schemes, such as AAALAC International (Association for Assessment and Accreditation of Laboratory Animal Care) or ISO (International Standards Association), and evidence regarding the health status and quality of the animals supplied by those wishing to purchase them. Health status is here used as just one indicator of welfare. If the Inspectorate have any concerns over the information provided in the Transfer of Animals request they will ask for supplementary information before coming to a decision.

Conclusion

The current system implements a performance standard that utilises the professional judgement of the Inspectorate. In our view, this is a flexible system, within which there can be continual

⁸ Home Office pro forma are available from the Home Office Animals in Scientific Procedures website: <http://scienceandresearch.homeoffice.gov.uk/animal-research>

improvement. While, in general, prescriptive standards are not set we consider that the Inspectorate are applying standards that are based on their perception of best current practice and a holistic view of the information gained regarding: the importer, the national standards in the source country, additional standards adopted by the supplier, health status, visits made by the Inspectorate, past experience, etc.

The system could be criticised on the grounds that there are differences in the type and extent of the checks carried out for different types of animals. The sub-committee is aware that there are considerable differences in standards between different overseas suppliers, which suggests that the welfare of at least some imported animals could be improved. We do not wish to make recommendations that might have negligible animal welfare benefits but which would have substantial resource implications for the Inspectorate or users. Nonetheless, we consider that the current approaches for collecting data on the welfare of species other than non-human primates, cats and dogs could usefully be enhanced in ways which have minimal impact on cost and bureaucracy. We believe that a more structured approach which ensured that establishments and scientists involved in the use of animals are well informed of health, husbandry, care and transport issues prior to import would enable them to minimise change and stressors on the incoming animals. This would have benefits for animal welfare, the quality of science obtained from these animals and would draw the attention of overseas establishments to UK standards.

This report should be viewed as an advice paper that advocates best practice in terms of animal health and welfare reporting for those intending to purchase overseas supplies of animals for scientific procedures.

Recommendations

Importing animals for use in studies in the UK inevitably involves some risk regarding the health and welfare status of the animals. To help reduce this risk it appears that some users, in addition to the regulatory requirements already described in this document, obtain information from overseas breeders on the welfare and husbandry conditions for species other than primates, cats and dogs. To reduce unnecessary bureaucracy this process may be carried out in conjunction with a risk analysis that takes into account additional factors including the country of importation, the supplier and whether animals have been previously from this source. Hence, wider ranging, and more detailed questions might be asked from a small previously unused supplier, whilst a major breeder might be visited once every few years in conjunction with ongoing liaison between the two institution's veterinary teams. Similarly, institutions with little or no systems of over-view (regulatory or voluntary) would require a more detailed assessment.

We believe that this risk-analysis based approach to seeking information is good practice, as it enables importers to satisfy themselves with respect to the quality of the animals (which impacts on the quality of the science) and helps them to ensure that they are importing from an ethically acceptable source. A secondary benefit of asking such questions is that it can help to disseminate information regarding the standards expected in the UK. In the long term this may contribute towards raising global standards of welfare.

We therefore recommend that, in addition to collecting data on the health of imported animals, establishments should seek information from their supplier regarding the welfare and standards of housing and husbandry for all Schedule 2 imported species. This should form part of the responsibilities of the Ethical Review Process, which is responsible for "considering the care and

accommodation standards applied to all animals in the establishment, including breeding stock.⁹. This approach avoids prescribing how any institution might organise itself, but encourages good oversight of the welfare of imported animals.

We do not wish to be prescriptive as to how this information would be obtained or on the detail to be provided. Health and welfare issues vary by species, strain and genetic status, and should be assessed in the light of current knowledge and research. For genetically modified mice an expert working group set up as a response to the 2001 Animal Procedures Committee (APC) report on biotechnology has drafted a passport scheme¹⁰, which could form part of this process. As a minimum, the purchaser should obtain from the supplier information regarding health issues/status, whether animals are housed in appropriate social groups, what enrichment is provided, and whether the supplying institution meets or exceeds any national or professional standards relating to housing. Welfare information should be judged in the light of current UK standards for Breeders¹¹, and the recent revision of Appendix A to Europe Convention ETS 123¹²

In some cases, purchaser/user visits may be appropriate, and these are likely to be the best way to obtain accurate health and welfare information. Where this is not possible, plans, photographs or videos of the housing conditions can be valuable.

Summary

In order to encourage and enhance good practice with respect to importing animals of the types listed in Schedule 2, other than non-human primates, cats and dogs, we make the following recommendations:

1. It is good practice for the local Ethical Review Process (ERP) to establish a process that allows the institution to monitor and record health and previous housing or husbandry issues that could affect the welfare of imported animals and the quality of science derived from them. Animal suppliers should meet their own national standards, and health and welfare information should be assessed in the light of, current UK standards and the recent revision of Appendix A to Europe Convention ETS 123. Single or periodic communication between purchaser and supplier may be required to obtain this information depending on whether the import is a one-off or repeated. Some of this information might be obtained from a supplier's web site.
2. As such information may periodically be required by the Inspectorate, it is reasonable and prudent for ERPs to ensure that records are kept of the above process.
3. The procedure for obtaining authority to use Schedule 2 animals (currently the application form for authority to transfer schedule 2 animals) should include confirmation by the institution that: its ERP has oversight of enquiries that have been made into the health and

⁹ <http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/publications/guidance/ethical-review-process/chiefsinspector.pdf?view=Standard&pubID=428459>

¹⁰ <http://www.nc3rs.org.uk/page.asp?id=231>

¹¹ <http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/publications/code-of-practice/housing-of-animals-breeding/?version=1>

¹² http://www.coe.int/T/E/Legal_affairs/Legal_co-operation/Biological_safety_use_of_animals/Laboratory_animals/

welfare (including housing conditions) of the animals to be imported; and that the supplier's housing and husbandry conditions meet their national standards;

4. The aggregated information collected by ERPs should be reviewed at a National Level within two years. If deficiencies are identified, they could be used to inform a revision of the process by which requests are made to use protected animals.

Advantages:

- This system would require only minor changes to current forms and procedures by the Home Office.
- Any increase in the quality of animals imported would be likely to enhance science as well as animal welfare.
- Inspectorate load would not be substantially increased.
- Questions from users would bring standards to the attention of supplying establishments.

Disadvantages:

- There would be an increase in bureaucracy for some purchasers/users as they might need to increase the amount of information requested and subsequently maintained from suppliers. However, we understand that this is already current practice for some users.
- Reluctance to seek to use animals from non-compliant suppliers might impede research.
- The lack of defined minima would allow animals to continue to be used from breeders whose standards may in some instances fall below the minima for breeders within the UK.

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The Housing and Husbandry Sub-Committee to the APC April 2007.