



**FIFTH REPORT OF
THE ANIMAL WELFARE
ADVISORY COMMITTEE**

November 2000

ANIMAL WELFARE ADVISORY COMMITTEE

Introduction

1. This is the fifth report of the Animal Welfare Advisory Committee (AWAC) established in July 1996. The terms of reference ([Appendix A](#)) are those approved at the outset by the Ministry of Defence (MOD). The Committee has set its own objectives: to consult, inspect and make all necessary enquiries into all aspects of animal care and their use in Defence Evaluation and Research Agency (DERA) establishments in order to advise senior management and report directly to the MOD Chief Scientific Adviser.

2. As an advisory non-departmental public body (NDPB) the Committee is an independent group of specialist advisers acting in the public interest. The Committee's findings are published in order to inform Parliament and the public. Publication is subject to the constraints of national security. There is also no intention of compromising the personal safety of individuals in DERA establishments.

3. The fourth report was submitted in November 1999 and published in response to a parliamentary question in September 2000. The fifth report covers the period from 31st October 1999 to 1st November 2000. The report is being circulated to a list of interested individuals and organisations as well as being placed in the libraries of the House of Commons and House of Lords. It is also available at the MOD website at <http://www.mod.uk/>

4. The following points have been made in previous reports but merit emphasis by repetition. There is a continuing public concern over the use of animals in scientific research - in particular, defence research. Having made specific enquiries in previous years, the Committee can give an assurance that animals used in defence research programmes in the UK are regulated under the Animals (Scientific Procedures) Act 1986. No special exemptions apply. Animals used in all DERA establishments are subject to the same Home Office regulation and inspection as applies elsewhere. In accordance with its terms of reference, the Committee does not monitor compliance with the 1986 Act, that is the role of the Home Office Inspectorate.

Matters raised by the public

5. Matters raised by the public and through parliamentary questions are drawn to the attention of the Committee. These can provide a useful basis for the Committee to make its enquiries. The Committee has noted a National Anti-Vivisection Society article published in 'The Campaigner', May-August 2000, which makes some specific criticisms regarding a Chemical and Biological Defence Sector (CBD) Porton paper published in the open scientific literature. We have also noted some publications in 'The People' relating to a published paper on dermabrasion as a treatment for sulphur mustard injuries. The Committee will be raising selected issues arising from these articles with DERA staff in the coming year. It should be noted, however, that the Committee exercises its own discretion in its choice of matters to raise with DERA.

Meetings and Operation of the Committee

6. The full Committee has met 3 times during the reporting period CBD Porton in November 1999 and September 2000, and a meeting in Guildford in July 2000. In order to ensure the best use of time and resources individual members of the Committee make visits to observe or attend specific events. Members of the Committee have observed two simulated dives at the Centre for Human Sciences (CHS) Alverstoke, and attended two Ethical Review Process (ERP) meetings and one Licensee training day at Porton.

7. The Committee's full visits usually comprise a briefing from DERA staff on recent activities and management structures, as well as visits to the animal accommodation and laboratories. In some instances, the Committee has been present during the carrying out of licensed procedures. However, it is important to understand that the Committee does not have a regulatory function and is not involved in a programme of inspection to ensure compliance with UK or European legislation. The Committee's role is to provide advice to the Chief Scientific Adviser (Ministry of Defence). In addition, the Committee provides advice and feedback to DERA management, scientists and animal care staff during site visits.

8. The 3 Rs principles (that is, to adopt wherever possible measures for the Reduction of animal numbers in experiments, Refinement of procedures and husbandry and Replacement with non-animal alternatives) were first formulated by Russell and Burch (1959). The 3 Rs are now well accepted as a framework to improve laboratory animal welfare, and the Committee uses the principles as a basis for its enquiries at DERA establishments.

Number of Animals used in Research

9. Corrigendum to reports 1-4. The Committee is provided with statistics of animal use at CBD Porton and CHS Alverstoke. In all previous reports these have been inaccurately labelled as referring to the numbers of animals being used in research. The Committee has now been informed that the figures provided to them represent the numbers of procedures carried out using each species. In this and future reports the committee will present figures both for the number of procedures and the numbers of animals used for the first time (as defined in the returns to the Home Office) in those procedures. It is worth noting here that special permission from the Secretary of State is required for reuse. This is usually only granted if the animal has suffered no significant ill effects as a consequence of its first use, and if the first use has not compromised the animal's suitability for its use in a subsequent procedure. Given these precautions, reuse - of animals such as primates, can be a humane way of reducing the numbers of animals used in research. The vast majority of animals, almost all mice for example, are used in only one procedure.

10. The total number of procedures carried out at CBD Porton increased from 11,091 in 1998 to 11,501 in 1999, an increase of 3.7%. The increase was accounted for by a rise in the numbers of procedures on mice, however the use by CBD of all other species declined. There was no reuse of animals in 1999 so the numbers of animals used for the first time was also 11,501. The breakdown of these figures by animal species during the last 5 years is shown in the table below. The table also shows the numbers of procedures carried out on goats at CHS.

Numbers of procedures on animals carried out in 1999 at DERA establishments

	1995	1996	1997	1998	1999
Goat (CBD)*	0	0	2	22	0
Goat (CHS)**	153	124	127	124	149
Guinea pig	495	792	1,109	1,039	636
Hamster	0	42	396	222	144
Macaque	0	4	16	17	8
Marmoset	17	10	14	111	52
Mouse	6,706	7,701	8,569	7,477	10,144
Pig	48	48	85	96	84
Rabbit	39	19	31	48	10
Rat	1,406	2,428	717	1,999	410
Sheep	36	53	17	30	13
Ferret	0	0	0	30	0
Total	8,900	11,221	11,083	11,215	11,650

*CBD Chemical and Biological Defence Sector Porton

**CHS Centre for Human Sciences, Alverstoke

(N.B. Goats are the only species used at CHS Alverstoke. In 1999 60 goats were used in procedures for the first time.)

11. The types of procedures in which animals were used in 1999 are summarised in the following paragraphs:

12. **Mice.** The mouse continues to be the most commonly used species and there has been a 36% increase in the number of procedures in 1999 compared to 1998. Mice are used in studies of the safety and efficacy of vaccines and other treatments, one aspect of which is to continue to investigate alternative routes for treatment such as oral and nasal routes. Mice are also used in research to study disease progression.

13. **Rats.** Rat use decreased by 79%. Most of these rats were used in two programmes to develop therapeutic regimen against poisoning by chemical warfare agents. One of these programmes was to develop protection against lung injuries. In the other, the rats were humanely killed, and their tissue used to study the effects of nerve agents on brain function.

14. **Guinea pigs.** Guinea pig use decreased by 39%. The majority of procedures on these animals were toxicity tests of agents that have been identified as a risk to servicemen, and programmes to improve pretreatment and therapy for nerve agent poisoning. A small number of guinea pigs were used in microbiological programmes.

15. **Hamsters.** Hamster use fell by 35% as CBD has been moving from hamsters to mice as models of certain infectious diseases. Hamsters will, however, continue to be used in programmes for the development of prophylaxis and treatment of microbial infections.

16. **Rabbits.** Rabbit usage decreased by 79%. Approximately half the rabbits were used for the identification and detection of microbiological agents, the remainder being used in programmes investigating the pathogenesis and treatment of viral infections.

17. **Pigs and sheep.** The majority of these animals were used in the trauma and surgery programme in which the animals were anaesthetised throughout the procedure and killed at the end of the experiment before regaining consciousness. The number of pigs used overall showed a decrease of 12%. Most of these animals were used in studies to develop enhanced blast protection for military personnel and the treatment of hypovolaemic shock. However, there has been an increase in the numbers of pigs used to investigate wound healing following chemical injury to the skin or lungs. Sheep use fell by 57%. All the sheep were used in a study to develop improved orthopaedic techniques for the management of long bone fractures in battlefield casualties.

18. **Non-human primates.** The total number of procedures on primates decreased by 53%. Marmosets continue to be used in investigations of alternative treatments for nerve agent poisoning and to investigate the physiological and behavioural effects of organophosphorus compounds such as sheep dip. Eight macaques were used in minor procedures, specifically to provide blood samples, after which they were returned to the breeding colony.

19. **Ferrets.** A small number of ferrets were used in 1998 for procedures to study emesis. No procedures were carried out in 1999.

20. **Goats.** No goats were used at CBD in 1999. Goats were used at CHS Alverstoke to investigate the effects of decompression after a simulated dive, in order to develop safe escape protocols and treatments for submariners trapped in disabled submarines. The number of procedures on goats increased in 1999 by 20%. As previously described, the Home Office normally allows animals only to be used in a single procedure. Nonetheless, it has been agreed that, because of the mild nature of most of the procedures in the programme conducted at Alverstoke, animals can undergo more than one, and therefore, only 60 animals were used for the first time. However, it was a licence condition for one programme of work aimed at developing procedures to rescue submariners from pressurised disabled submarines, that the goats in this programme (60 in 1999) should be humanely killed after a single procedure.

Non-human Primate Breeding

21. In its 4th report, the Committee presented its findings on animal breeding, the reasons for the need to cull surplus animals and measures taken to match supply and demand. Whilst animal overproduction of any species should be avoided, there is particular public concern about any overbreeding of primates. With this in mind, the Committee enquired into the rationale for breeding primates at CBD Porton, and on the operational mechanisms to prevent or minimise overbreeding of primate species.

22. Two primate species are maintained in breeding colonies at Porton: rhesus macaques (*Macaca mulatta*) and the common marmoset (*Callithrix jacchus*). Cynomolgus or long-tailed macaques (*Macaca fascicularis*) have become the most commonly used macaque species in the UK, since the Indian ban on the export of rhesus macaques in the 1970s. However most cynomolgus macaques are imported into the UK and there is public concern about the welfare implications of importing primates for experimental use and in particular long transport times from breeding sites.

23. CBD Porton continues to have a need for rhesus macaques, as there is a large body of knowledge on their use within CBD programmes (background data). Moreover, if CBD were to change to cynomolgus macaques, then there would almost certainly be a temporary increase in macaque use, to validate and interpret experimental outcomes. Therefore, CBD maintains a breeding colony in order to guarantee rhesus macaque availability, health standards and to obviate potential welfare implications of importation/transport.

24. Matching supply and demand is important in order to minimise animal wastage. The Committee noted that Porton are increasing macaque production in the expectation of increased future experimental demand. The Committee was assured that there was no current overproduction of macaques, or intent to produce a surplus, but that there are mechanisms in place to sell any surplus to other institutions. The Committee's view is that matching supply and demand between different UK users is good practice and helps to minimise overproduction throughout the research community.

25. At present there is no surplus of marmosets at CBD. However, marmosets breed relatively rapidly and there is considerable fluctuation in the external research community's demand for marmosets. Therefore, the possibility of a surplus of marmosets at CBD, due to unforeseen circumstances coinciding with a general surplus at other Home Office Designated Establishments, needs to be considered.

26. Marmoset colony management methods, including birth control measures, can be instituted to control production and allow young animals to be kept in the breeding colony for longer than usual. However, there are potential welfare problems when holding a large number of sexually mature marmosets for a prolonged period in a restricted space. If it appears likely that the animals would be under an unacceptable level of social stress then it is possible that euthanasia may be the best option. It is important to emphasise that such circumstances are expected to be rare. Marmoset breeding will be kept under review by the Committee in future.

Animal Care and Husbandry

27. **New Buildings.** The Committee has visited the new buildings housing animals used in scientific procedures, which was opened in December 1999. The Committee was pleased to note that the macaque housing included both internal and external runs and provided a spacious socially and physically enriched environment. The Committee also visited a new semi-barrier unit that has been developed to house scrapie-free sheep. Again, the Committee was impressed by the thought for the welfare of the sheep that had gone into the unit, in particular to enable good handling of the animals and to provide them with an interesting and comfortable environment.

28. **Veterinary Staff.** Both the Senior Manager of Animal Services and the breeding facility and the Named Veterinary Surgeon retired in 2000. These positions are critical in terms of ensuring that there is a good culture of animal care and to act as first ports of call for any staff who might have concerns about animal welfare. The Committee has met their successors (recruited externally) and will maintain an interest in their progress and activities as they settle into their new jobs.

29. **Animal care during procedures.** Animal experiments sometimes produce unexpected results in which animals may suffer unexpected adverse consequences as a result of the procedure. Members of the Committee observed two simulated dives at Alverstoke. During one of these the goat showed mild symptoms of the 'bends', characterised by discomfort in a limb. The symptoms were picked up very early during routine monitoring of the goat after the simulation, and the goat was effectively treated by recompression within the pressure vessel attended by two members of the research team.

30. The Committee was also informed of a subsequent incident raised at an ERP meeting in which a goat suffered more severe effects of barotrauma. It is understood that the symptoms were identified early, that the goat was promptly and humanely killed as required by the Home Office Licence, and that measures were in place to identify the possible causes of the incident.

31. The Committee was satisfied with the actions taken in both these instances to minimise the suffering of the animals involved and with the mechanisms in place to cope with unexpected adverse effects.

Animal Training.

32. In 1998 the Committee suggested that an expert (Dr Viktor Reinhardt) should be invited from the USA to provide advice on training macaques to cooperate in routine handling and procedures. This resulted in a very useful visit that was combined with a meeting open to other UK primate users. Such training can dramatically reduce stress to the animals involved.

33. The Committee was provided with a very impressive demonstration of the results of the CBD macaque training programme and was informed that CBD was investigating the potential of training for other species. We hope that progress in this area will be maintained and that information will continue to be disseminated to other research organisations.

Internal Regulation and the Ethical Review Process

34. **Ethical Review Process (ERP).** The Committee has attended a number of ERP meetings at Porton. These have been well attended and achieve the goals for ERPs set out by the Home Office. The Committee continues to be impressed by the standard of critical review and by the input from the lay persons on the ERP Committee.

35. **3Rs Audit trail.** In last year's report, the committee identified the importance of instituting a 3Rs Audit trail to identify and assess improvements in the Reduction and Refinement of animal use and their Replacement by non-animal alternatives where possible.

36. CBD Porton currently uses the ERP meeting as a focus for the 3Rs Audit. Each applicant making a project proposal is required to specifically address these issues during the ERP. This meets the aims of ensuring that the 3Rs have been considered at an early stage, but the Committee feels that there are additional benefits to be gained by recording and assessing achievements throughout the life of the project. The Committee will, therefore, be making further enquiries, in the coming year, as to how the Audit trail can be refined in order to monitor progress.

External Peer Review.

37. Effective peer review is essential in order to ensure that science being carried out is high quality. In last year's report the Committee described the extent of peer review in DERA facilities which include contacts at the experimental design phase and publication where appropriate in the open scientific literature. In some cases it is necessary that work should remain classified for reasons of national security, however, in many instances it is possible to publish the work.

38. The Committee has been informed that 75-80% of biomedical work carried out at CBD is published in open peer reviewed scientific journals, and has been provided with a list of 28 papers published in the open literature. In addition 23 oral papers have been presented at scientific conferences. The Committee remains satisfied that there is adequate peer review.

LD50 Tests and their Use at CBD

39. For many years there has been considerable public concern about toxicity testing, and in particular the LD50 test. The LD50 test procedure involves exposing groups of animals to varying doses of a compound, so that the dose that is lethal to 50% of them can be calculated. LD50 tests are currently becoming superseded by more humane techniques in civilian regulatory toxicity, and in October 1999, the Home Office announced that it would no longer grant licences for the so called classical LD50 test if a suitable alternative test were available. Moreover, the organisation for Economic Co-Operation and Development (OECD) announced on 4 December 2000 that it would delete the LD50 test, after a phasing out period of one year, from its manual of internationally accepted test guidelines. The regulatory community will then reject the test.

40. CBD continues to occasionally seek permission from the Home Office to carry out LD50 tests. In view of the apparent changes in attitude of the scientific community to this test, the Committee sought clarification from CBD for their continuing need for this test.

41. The Committee was informed that there are fundamental differences between the requirements of a research programme aimed at defending military personnel, where it is necessary to determine the lethal dose of extremely toxic chemicals, compared to the more modest requirements of regulatory toxicity. CBD requires a thorough understanding of the toxicity of potential chemical and biological agents, and may also need information on the biological impact of exposure over a wide range of doses.

42. The position of CBD regarding obtaining permission from the Home Office to carry out these tests, is no different to that of any other research organisation. In each case, CBD has to specifically justify the need to carry out a LD50 to the Home Office. All project licences for this type of work include the requirement to try to identify humane endpoints which could be used in future work. CBD will continue to review its requirements for information on the toxicology of materials of concern and will continue to keep the Committee informed on its progress in these areas.

CBD Staff Training Policy

43. It is a Home Office requirement that new licence holders should receive training on an accredited course. CBD provides a series of courses accredited by the Institute of Biology (IOB) for new licence holders that are tailored to meet the needs of the prospective licence holder. These courses provide a general introduction to the practical and ethical issues of caring for animals and carrying out procedures. The courses are run for MOD staff only with the exception of a course on primates that is open to outsiders. The numbers of persons attending each course are kept small to allow plenty of practical hands-on training and attention.

44. All personal licensee applicants attend a basic animal handling course. The course is also attended by people who will be handling animals as part of their work but will not necessarily go on to hold a licence as it covers euthanasia and CBD in-house rules and procedures. The duration of the course is 1 day plus as much time as each individual needs to handle the various animal species with confidence. Anyone needing re-training or training in a new species is encouraged to re-attend this course.

45. Applicants for a Home Office personal licence must have successfully completed Modules 1-3 of an accredited training programme ([see Appendix B](#)). Having completed this, they take additional courses (see below) depending on the types of procedure they will be carrying out or the species with which they will be working:

- primate course,
- farm animal course,
- module 4 surgery (general principles) for existing licence holders.

46. It is a minimum requirement that all CBD animal technicians attend the Institute of Animal Technology Certificate Level Animal Technology Course (part A). Dependent on individual ability they are encouraged to take further courses and exams up to Fellow of the Institute of Animal Technologists and Masters degree level. Many of the courses are held on site and the Committee was pleased to note that technicians from other animal units also attend. This can be a valuable method of spreading best practice in animal care and husbandry.

47. In addition, animal services technologists undergo an internal on-the job training scheme to ensure that they are trained in the full range of duties in all the different buildings and are competent in the care of all the different species.

48. During the reporting year, members of the AWAC Committee attended a licensee training seminar. This meeting provided an opportunity for licensees to meet the Named Animal Care Welfare Officers (NACWOs) and the new Named Veterinary Surgeon. The meeting also featured a presentation by a member of a pharmaceutical company on methods of enriching rodent housing that had been demonstrated to meet regulatory toxicology requirements. The meeting was well attended and there was a lively question and answer session afterwards.

DERA Private/Public split Programme

49. The Committee has been informed that, as a result of the Public Private Partnership initiative, some three quarters of DERA, including the Directorate of Corporate Affairs, which has until now provided the Secretary to AWAC, and CHS Alverstoke, is to be privatised. CBD Porton Down, however, will remain in the Ministry of Defence as part of the newly created Defence Science and Technology Laboratory (DSTL). DSTL will be responsible for providing the Secretary to the committee. Contact details are given below. It is encouraging to note that it is the intention that the work at CHS Alverstoke will remain within the remit of the AWAC committee.

Future activities

In the coming year the Committee will continue to follow up current lines of enquiry including:

- Numbers of animals bred and used;
- Animal care and husbandry;
- Evaluation of the new animal accommodation;
- Animal training;
- 3Rs audit;
- Toxicology testing policy.

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ANIMAL WELFARE ADVISORY COMMITTEE

TERMS OF REFERENCE

General

1. The Committee will review animal care and welfare arrangements within the Defence Evaluation and Research Agency.

Conditions

2. It will advise the relevant Managing Directors within DERA, but will be appointed by, and report annually, or more frequently if necessary, to the Chief Scientific Adviser, MOD.

Specific Guidance

3. The Committee will review:

3.1 How effectively the DERA Animal Care and Use Committees operate;

3.2 The mechanism of the Ethical Review Process for projected scientific work involving the use of live animals;

3.3 Evidence of how Reduction, Refinement and Replacement are being encouraged and promoted. (As defined by W.M.S. Russell and R.L. Burch in 'The Principles of Humane Experimental Technique 1959', Methuen and Co London);

3.4 The degree of external peer review of the results of scientific work involving animals;

3.5 Broad trends in the numbers of animals used under the Animals (Scientific Procedures) Act annually;

3.6 Local control over any procedures on live animals not covered by the Animals (Scientific Procedures) Act, eg Euthanasia;

3.7 Training and education programmes for all DERA personnel relevant to the use or care of animals;

3.8 Initiatives to ensure the maintenance of a high standard of animal welfare within

DERA.

4. The function of the Committee is not to monitor compliance with the Animals (Scientific Procedures) Act. This is the duty of the Home Office.

MODULE 1

1. **Historical background**
Legislation and attitudes to animals and animal welfare in the United Kingdom.
2. **An introduction to ethical aspects of the use of animals in scientific procedures**
3. **The Animals (Scientific Procedures) Act 1986**
The Certificate of Designation
The Project Licence
The Personal licence
Schedule 1
Schedule 2
Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act, 1986 (ISBN 0 10 218290-6 from HMSO)
Home Office Code of Practice for the Housing and Care of animals used in Scientific Procedures (ISBN 0 10 2107890 from HMSO)
Other Codes of Practice and Guidelines.
4. **Other relevant legislation**

MODULE 2

1. **Recognition of well-being, pain, suffering or distress in the relevant species.**
2. **Handling and restraint** of relevant species.
3. **Humane methods of killing** appropriate to the relevant species
4. **Local procedures**
Security
Administration
Supply of animals and disposal of animals
5. **Personal Health and Safety**

MODULE 3Elements

1. **Biology and husbandry** of relevant species
2. **Common diseases and recognition** in the relevant species
3. **Health monitoring and disease prevention or control**
General principles
Principles of gnotobiology
Local practices and procedures
4. **Introduction to anaesthesia and analgesia** in the relevant species
5. **Conduct of minor procedures** in the relevant species
Common methods of dosing
Common methods of sampling
Minor procedures not requiring sedation, analgesia or general anaesthesia
Other minor procedures involving sedation, analgesia or brief anaesthesia

MODULE 4

Elements

- 1. Surgical anaesthesia and analgesia in the relevant species**
- 2. Conduct of surgical procedures**
 - Principles of surgery
 - Common surgical procedures
 - Post-surgical care and monitoring

MODULE 5

- 1. Ethical aspects of the use of live animals**
- 2. Analysis of the literature**
 - Critical appraisal
 - Literature searches
- 3. Alternatives**
 - Refinement
 - Reduction
 - Replacement
- 4. Project design**
 - Plan of work
 - Good laboratory practice
 - Appropriate laboratory methods
 - Selection of appropriate animal models
 - Appropriate statistical methods
- 5. Project licence management**
 - Responsibilities
 - Supervision of personnel and programme of work
 - Record keeping requirements
 - Annual return of procedures
- 6. Legal aspects - the European and wider**
 - International context