



Animal Research
Review Panel
New South Wales



Annual
Report

2004–05



NSW DEPARTMENT OF
PRIMARY INDUSTRIES



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Minister for Primary Industries
Minister for Mineral Resources
Level 33, Governor Macquarie Tower
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Dear Mr Macdonald

In accordance with Section 11 of the *Animal Research Act 1985*, the Animal Research Review Panel presents its annual report covering the period 1 July 2004 to 30 June 2005.

Yours sincerely

MARGARET ROSE
Chair
Animal Research Review Panel

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SUMMARY

The Animal Research Act 1985

The *Animal Research Act 1985* was introduced to protect and enhance the welfare of animals used in research. 'Research' includes teaching, testing, fundamental and applied research, and any other procedure, investigation or study using animals. The Act incorporates a system of enforced self-regulation, with community participation at the institutional and regulatory levels.

The Code of Practice

Ultimate responsibility for animal care and use lies with those who use the animals: the researchers and teachers. This responsibility includes the need to comply with the National Health and Medical Research Council (NHMRC) *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*. This Code is incorporated in the Animal Research Regulation 2005. Adherence to the Code is achieved through a system of enforced self-regulation. Institutions must be accredited and individuals must be authorised to use animals. Failure to comply with the Act, Regulation or Code of Practice results in conditions being imposed on the accreditation or authority. For serious or repeated breaches, the accreditation or authority to conduct research

may be withdrawn. Conducting animal research without appropriate authorisation is an offence with substantial custodial and financial penalties.

The Animal Research Review Panel

The Animal Research Review Panel (ARRP) has responsibility for overseeing the effectiveness and efficiency of the legislation, investigating complaints, and evaluating compliance of individuals and institutions with the legislation. The constitution, membership and mode of operation of the ARRP are set out in the Act. The 12-member Panel has equal representation from industry, government and animal welfare groups. This allows community involvement in regulating the conduct of animal research in New South Wales. Apart from developing overall policy on animal research issues, the ARRP is closely involved in the administration of the legislation. This is achieved through evaluating applications for accreditation and licences, conducting site visits to assess compliance, and investigating complaints. The ARRP also has a role in considering amendments to the Regulation. The NSW Department of Primary Industries Animal Welfare Unit staff provide executive support for the ARRP.

Sheep housed in indoor pens are provided with thick soft bedding and held in groups to meet aspects of their physical and social needs. The insulated building protects them from extremes of heat and cold.



Animal Ethics Committees

Self-regulation operates through institutional Animal Ethics Committees (AECs), which must approve all animal research before it can commence. AECs are also responsible for monitoring research projects and providing recommendations to institutional management on matters relating to animal research. Under the legislation, AEC membership must include a veterinarian, a researcher, an animal welfare representative and an independent community representative. The animal welfare and independent members must be from outside the institution.

Administration and planning

In 2004–05 there were 97 accredited research establishments, 65 accredited schools and 27 holders of animal suppliers' licences.

Inspections

In the 2004–05 year the ARRP carried out 23 inspections of accredited research establishments/animal suppliers and independent researchers. The inspections place a major focus on reviewing the operation of the AECs and ensuring that the AECs, investigators and institutions understand their responsibilities under the legislation and Code of Practice.

Support for Animal Ethics Committees

Support for AECs is provided through site inspections, through publications including policies, guidelines and fact sheets, through maintaining a website dedicated to animal research issues, and through extension activities of Animal Welfare Unit staff and the ARRP. Such activities in the 2004–05 year included holding a meeting for members of AECs, finalising a review of guidelines on wildlife surveys, releasing for comment a draft guideline on rat housing, and publishing two editions of a newsletter for AECs, *Animal Ethics Update*. During the meeting for AEC members a number of interesting papers were presented, covering topics from re-homing of research animals to conscientious objection to the use of animals in teaching. The keynote speaker, Professor Lesley Rogers, gave a highly entertaining and informative talk on the ability of animals to think. The release of the rat housing guidelines was part the ARRP's ongoing plan

to develop evidence-based guidelines for the housing of animals in scientific establishments. Guidelines on the housing of dogs and rabbits have already been published.

Complaints

The Animal Research Act establishes a mechanism for lodging formal complaints against institutions and individuals. The mechanism includes the proviso that these complaints must be referred to the ARRP. No formal complaints were received in 2004–05.

PART ONE: ORGANISATION

1.1 The Animal Research Act 1985

The NSW *Animal Research Act 1985* was the first piece of self-contained animal research legislation introduced in Australia. In introducing the legislation in 1985, the Hon. Kevin Stewart, Minister for Local Government, said that it was based on 'the twin tenets of ... enforced self-regulation and public participation in the decision-making process'. It received bipartisan support in the Parliament when it was introduced in 1985 and continues to do so.

The primary aim of the legislation was to protect the welfare of animals used in teaching and research by ensuring that their use was justified, humane and considerate of their needs. The Act introduced a system of accreditation, licensing and authorisation of organisations and individual researchers, and established the Animal Research Review Panel (ARRP) to provide a mechanism for representatives of government, scientific and animal welfare groups to participate jointly in monitoring the effectiveness of the legislation.

The Act came fully into force in 1990, when the Animal Research Regulation was gazetted. This Regulation was repealed under the requirements of the Subordinate Legislation Act, and a new Regulation was gazetted on 1 September 1995. The *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* is included in the Animal Research Regulation. The Code provides guidance on day-to-day operations within research institutions.

The Act has been amended twice, first in 1989 and again in 1997. It was amended in 1989 to prohibit the use of certain toxicity tests, except with the permission of the Minister. The 1997 amendments were designed to maintain the licensing scheme for animal research but to reduce adverse impacts on competition¹ to a minimum level commensurate with achieving the welfare objectives of the Act.

The majority of the 1997 amendments could not commence until amendments were made to the Animal Research Regulation. These amendments to the Regulation came into effect in July 1999. The amendments affected the areas of licensing, fees, lethality testing, AEC procedures,

schools, and wildlife studies. A later amendment to the Act also allowed for the appointment by the Minister of a Deputy Chairperson to the ARRP.

The Regulation again underwent review in 2005. This was because, under the Subordinate Legislation Act, it was due to be automatically repealed on 1 September 2005. A Regulatory Impact Statement (RIS) was prepared and circulated widely for comment. Proposals in the RIS included:

- changes necessary to update references to the revised seventh edition of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*
- changes necessary as a result of the amalgamation of NSW Agriculture into the NSW Department of Primary Industries
- changes to streamline administration
- changes to fee structures to allow AECs to charge higher fees for applications to carry out research.

Comments on the RIS were due by 1 July 2005.

1.2 The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes

The *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (the Code of Practice) is a nationally accepted code and is included in NSW animal research legislation as part of the Animal Research Regulation. The Code is reviewed regularly by the Code Liaison Group, which includes representatives from the National Health and Medical Research Council (NHMRC), the Commonwealth Scientific and Industrial Research Organisation, the Australian Research Council, the Australian Vice-Chancellors' Committee, the State Government Ministries with responsibility for animal welfare, the RSPCA and Animals Australia. Members of the ARRP and the Animal Welfare Unit of the NSW Department of Primary Industries are represented on the Code Liaison Group.

The ARRP has had significant input into successive revisions of the Code. A review of the sixth edition of the Code was initiated by



Wallabies such as this, housed in a free-range enclosure, are used for a range of behavioural and reproductive studies.

the NHMRC in August 2001. In the course of this review, a number of meetings of the Code Liaison Group and of its working groups have been held. A draft seventh edition of the Code was developed by the Code Liaison Group and released for comment in March 2003. In NSW, information was circulated widely to Animal Ethics Committees, animal welfare groups, scientific groups and independent researchers to alert them to the fact that the Code was being reviewed and thus enable them to comment.

In response to the comments received, the NHMRC released a revised draft in October 2003 that was again circulated widely in NSW for comment.

The ARRP (as well as the Animal Welfare Unit) submitted detailed comments during both rounds of public consultation.

Meetings of the Code Liaison Group were held in early 2004 to revise the draft on the basis of the comments received. A seventh edition of the Code was released in late 2004.

Changes from the previous edition included sections on:

- assessing proposals
- reporting on projects
- projects involving more than one AEC

- responsibilities of the AEC Chairperson
- external triennial reviews of institutions
- use of genetically modified animals.

In addition, the reference section was significantly revised and expanded.

1.3 The Animal Research Review Panel

1.3.1 Mission Statement

- To protect and enhance the welfare of animals used in scientific research, testing and teaching in New South Wales.
- To promote an understanding within the New South Wales community of the ethical and technical issues involved in the use of animals for scientific purposes.

The Animal Research Review Panel (ARRP) was created by the Act to provide a mechanism for representatives of the scientific and broader communities to participate in monitoring the self-regulatory process, which is established within institutions by the Act.

The strength of the ARRP lies in the diversity of expertise, opinions and ethical perspectives of its members. The development of cohesive and progressive policies has occurred as a result of this diversity. All members are employed in other fields and participate on a largely voluntary basis. Non-government members are paid fees for attending formal meetings and conducting site inspections. Members are not paid for time spent preparing for meetings and inspections, for considering applications for accreditation or licenses, or for drafting discussion papers.

1.3.2 Functions of the ARRP

Section 9 of the Act defines the functions of the ARRP as:

- the investigation of matters relating to the conduct of animal research and the supply of animals for use in connection with animal research
- the investigation and evaluation of the efficacy of the Code of Practice in regulating the conduct of animal research and the supply of animals for use in connection with animal research
- the investigation of applications and complaints referred to it under the Act

- such other functions as the Minister may from time to time confer or impose on it.

In November 1998, the then Minister, the Hon. Richard Amery MP, conferred the following additional function on to the ARRP, pursuant to section 9(d) of the Act:

The consideration and comment on proposals referred to the Animal Research Review Panel which relate to the making, amendment or review of the regulations under the *Animal Research Act 1985*.

There have been no other functions formally conferred on the ARRP under section 9(d) of the Act since it commenced.

1.3.3 Membership

The ARRP consists of 12 members appointed by the Minister on the basis of nominations received from industry, government and animal welfare groups. The nominating organisations are:

- New South Wales Vice-Chancellors' Committee: three nominees
- Medicines Australia Inc: one nominee
- New South Wales Minister for Health: one nominee
- New South Wales Minister for Education: one nominee
- New South Wales Minister for Primary Industries: one nominee
- New South Wales Minister for the Environment (National Parks and Wildlife Service): one nominee
- Animal Societies' Federation (New South Wales): two nominees
- Royal Society for the Prevention of Cruelty to Animals (New South Wales): two nominees.

All members of the ARRP are part-time and are normally appointed for a term of 3 years.

The 3-year term of ARRP expired during the 2004–05 period and the Minister appointed a revised membership for the new term.

The revised membership of the ARRP was:

- Associate Professor Margaret Rose (Chair) (nominated by Vice-Chancellors' Committee)
- Dr Regina Fogarty (Deputy Chair) (nominated by Minister for Primary Industries)
- Dr Barry Lowe (nominated by Medicines Australia)

- Ms Stephanie Abbott (nominated by Animal Societies' Federation)
- Ms Siobhan O'Sullivan (nominated by Animal Societies' Federation)
- Mr Mark Lawrie (nominated by RSPCA NSW)
- Mr David O'Shannessy (nominated by RSPCA NSW)
- Associate Professor Ron Pirola (nominated by the Minister for Health)
- Dr Jack Baker (nominated by the Minister for the Environment)
- Ms Julie Buckley (nominated by the Minister for Education)
- Mr Stephen Atkinson (nominated by Vice-Chancellors' Committee)
- Dr Philip Towers (nominated by Vice-Chancellors' Committee)

Members who departed at the end of the 3-year term were:

Flying foxes provided with coarse netting from which to hang. Enrichments to the housing include bags for hanging in, and hanging objects and fruit to manipulate.



- Associate Professor Rosemarie Einstein (Deputy Chair) (nominee of Vice Chancellors' Committee)
- Professor Lesley Rogers (nominee of Vice Chancellors' Committee)
- Mr Don Robinson (nominee of RSPCA NSW)
- Mr Ron Haering (nominee of the Minister for the Environment).

Members of the Animal Research Review Panel in 2004–05 were:

Associate Professor Margaret ROSE (Chair), BVSc (University of Sydney); PhD (University of New South Wales). Professor Rose has had a long-standing interest in the welfare of animals used in research and teaching. She chaired the committee of the Australian Veterinary Association, which developed the proposal for the Animal Research Act, and since 1990 she has been closely involved in the revisions of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*. She was responsible for the development of the proposal to establish ANZCCART (Australian and New Zealand Council for the Care of Animals in Research and Teaching) and, as a member of the Board until 1994, was actively involved in its establishment. She is a member of the editorial board of three international journals devoted to the welfare of laboratory animals: *ATLA (Alternatives to Laboratory Animals)*, *Laboratory Animals* and the *Journal of Applied Animal Welfare Science*.

She has been involved in the development, delivery and assessment of courses on animal care and ethics in both the university and TAFE systems. Professor Rose holds the position of Area Director of Research Management in South Eastern Sydney Area Health Service and is a conjoint Associate Professor at the University of New South Wales. She has been a member of the NSW Government's Animal Welfare Advisory Council since 1981 and in 2002 was appointed to that government's Bioethics Advisory Committee.

Professor Rose joined the ARRP in 1986 as a nominee of the NSW Vice-Chancellors' Committee and has served as the ARRP's Chairman since that time.

Associate Professor Rosemarie EINSTEIN (Deputy Chair), BSc (Hons), PhD (University of Sydney). Associate Professor Einstein was a nominee of the New South Wales Vice Chancellors' Committee. She was appointed to the ARRP in October 1998. She is an Honorary

Associate Professor in Pharmacology at the University of Sydney. Her research interests are in cardiovascular and autonomic pharmacology, especially the effects of stress in laboratory animals. She was Chairman of the University of Sydney Animal Ethics Committee from 1991 to 1996 and is also a member of the Westmead Hospital Animal Ethics Committee (appointed 1991). She was a member of the NHMRC Animal Welfare Committee from 1993–96. Associate Professor Einstein was appointed Deputy Chair of ARRP in October 2001.

Dr Regina FOGARTY (Deputy Chair), BVSc, PhD (University of Queensland). Dr Fogarty is the Director, Extensive Industries Development, at NSW Department of Primary Industries. Dr Fogarty has been actively involved in animal welfare issues in previous positions with the Department as Manager of NSW Agriculture's Animal Welfare Unit; as Program Leader, Intensive Livestock Products; and as Veterinary Officer (Pig Health). Before joining the Department in 1991, Dr Fogarty worked at the University of Queensland's Faculty of Veterinary Science in research, teaching and clinical veterinary practice. Dr Fogarty joined the ARRP in 2003 as the nominee of the then Minister for Agriculture.

Ms Stephanie ABBOTT BA, LLB (University of Sydney). Ms Abbott joined ARRP in March 2004. She is a nominee of the Animal Societies Federation (NSW). She is also the Vice Chair of the NSW Young Lawyers Animal Rights Committee, which she joined in 2002. Ms Abbott has a keen interest in animal law as well as in animal rights and welfare issues generally, and seeks to apply her legal skills to improve the lives of animals. Ms Abbott is the Manager of Knowledge, Learning and Development at Gilbert and Tobin.

Mr Steve ATKINSON BVSc, MACVSc, DipContEd, CMAVA. Mr Atkinson is a nominee of the New South Wales Vice Chancellors' Committee and was appointed to the ARRP in 2005. He has a long-standing interest in the welfare of animals used in research and teaching. Over time he has been a member of four AECs. He edited the *Guidelines for the Use of Animals in NSW TAFE*. He has developed training programs for TAFE teachers who use animals in the delivery of their courses and has delivered training programs to managers within NSW TAFE to help them identify their responsibilities under the NSW Animal Research Act. He worked

as Animal Welfare Manager at the CSIRO McMaster Laboratory in Armidale and at the University of New England, caring for animals being used in research and assisting and training researchers in aspects of the care and welfare of research animals. He is currently setting up a veterinary consultancy practice in animal welfare and animal research ethics.

Mr Atkinson chairs the NSW Government's Animal Welfare Advisory Council after previously being a member of that Council for 5 years. He is a member of the Australian Veterinary Association's Animal Welfare Advisory Committee and chairs their Animal Welfare Trust. He has been appointed to provide animal welfare advice to the national Technical Working Group advising the Committee developing the Australian Standards for the export of live animals from Australia. He is a member of the Animal Research and Teaching Working Group within the Australian Animal Welfare Strategy Implementation process, and is undertaking several projects within that implementation program.

Dr Jack BAKER BSc, GradDipEd, BAppSc, PhD, JP. Dr Baker was the nominee of the Minister for the Environment in 2004. He is an employee of the Department of Environment and Conservation, where he manages the Biodiversity Conservation Science Section. He has expertise in wildlife management and research.

Ms Julie BUCKLEY PSM, BEd (Syd). Ms Buckley was a nominee of the NSW Minister for Education and Training. Ms Buckley is Associate

Director, TAFE NSW Primary Industries and Natural Resources Curriculum Centre, and Executive Member of the TAFE NSW Animal Ethics Board.

Mr Ron HAERING BSc (Hons) MSc.

Mr Haering was a nominee of the Minister for the Environment and is an employee of the Department of Environment and Conservation with expertise in wildlife research.

Mr Mark LAWRIE, BVSc (University of Sydney), MACVSc (Animal Welfare), Grad. Cert. Man. (University of Western Sydney), Chief Veterinarian, RSPCA. Mr Mark Lawrie was a member of the ARRP from July 1993 to August 1996. He was nominated by his employer, the RSPCA NSW, and rejoined the ARRP in August 2000. Mr Lawrie has been a member of three major institutional AECs. He has been a practising veterinarian in Australia and the United Kingdom and has worked as a volunteer in India, Nepal and Rarotonga. He is responsible for four veterinary clinics and 80 staff that provide shelter, welfare and private veterinary services. In July 2002 he assisted the RSPCA Papua New Guinea in restarting its veterinary clinic in Port Moresby. He worked as a veterinary consultant with the International Fund for Animal Welfare (IFAW) on projects in the South Pacific and South Korea for 6 months in 2003–04. He was the President of the NSW Division of the Australian Veterinary Association (AVA) in 2005.

He has particular interests in:

- the link between cruelty to animals and humans
- animal hoarders

Tooth filing, necessary for the dental health of horses, being conducted as part of an equine dentistry school.



- international animal welfare, especially companion animal population control
- the behaviour and training of dogs.

Dr Barry LOWE, BSc (University of Melbourne), BEd (University of Melbourne), PhD (University of Sydney). Dr Lowe currently holds an international position as Director of Research and Development with Elanco Animal Health, the animal health division of Eli Lilly and Company. His field of research is in external parasitology of farm and companion animals and intra-ruminal controlled release of drugs in sheep and cattle. He has been involved in research into the health and nutrition of farm animals for 25 years with the same company and has been Chairman of the Elanco Animal Ethics Committee for 8 years. Dr Lowe was appointed to the ARRP in 2002 after being nominated by Medicines Australia Inc.

Mr David O'SHANNESY, BS Agr. Mr O'Shannessy is the nominee of the RSPCA (NSW). Since completing an Agricultural Science Degree he has been employed as an inspector with the RSPCA NSW and for a period of time was a sales representative for a veterinary pharmaceutical company. He was appointed RSPCA Chief Inspector in May 2005 and was appointed as a member of the ARRP in January 2005

Ms Siobhan O'SULLIVAN, BA (Hons). Ms O'Sullivan began working for animals as a volunteer with Animal Liberation NSW. She has since worked full time with the World League for Protection of Animals and is a former director of the Australian and New Zealand Federation of Animal Societies (ANZFAS). She is also a member of a number of animal protection agencies, including the RSPCA NSW and the NSW Animal Welfare League. Ms O'Sullivan is currently writing a PhD thesis under the Discipline of Government and International Relations at the University of Sydney, where she is focusing on the structure of animal legislation. She also teaches animal welfare and animal rights to ethics, law, veterinary and research students. Ms O'Sullivan was appointed to the ARRP in 2002. She is a nominee of the NSW Animal Societies Federation.

Conjoint Associate Professor Romano (Ron) PIROLA, OAM, MB BS (University of Sydney), MD (University of New South Wales), FRACP. Associate Professor Pirola is the nominee of the Minister for Health and was appointed to the ARRP in May 2002. He has extensive experience in biomedical animal research. He is a consultant in Gastroenterology at the Prince of Wales

Hospital, Randwick. He was formerly the elected staff representative on the Board of the Eastern Area Health Service and the Chairman of the Research Ethics Committee of the South-Eastern Area Health Service – Eastern Division.

Mr Don ROBINSON, Justice of the Peace. Mr Robinson was a nominee of the RSPCA (NSW). He served in rural areas with the NSW Police for 23 years before becoming the Chief Inspector for the RSPCA from 1994 to 1997. During that period he was a member of the Animal Research Review Panel. After a period in the hotel industry, he was re-employed by the RSPCA as Chief Inspector in December 2001. He rejoined the ARRP in February 2002.

Professor Lesley ROGERS, BSc (Hons) (Adelaide University), DPhil, DSc (University of Sussex), FAA. Professor Rogers was a nominee of the New South Wales Vice Chancellors' Committee. She was appointed to the ARRP in October 1998. She holds a Chair in Neuroscience and Animal Behaviour at the University of New England. For many years she served as a member and then Chair of her university's Animal Ethics Committee and held a number of other senior positions at her university. She has been President of the Australian Society for the Study of Animal Behaviour and the International Society of Comparative Psychology. She is a Fellow of the Australian Academy of Science and a recipient of the Clarke Medal.

Professor Rogers is author and co-author of several books related to animal welfare (including *Minds of Their Own: Thinking and Awareness in Animals*; *Songs, Roars and Rituals: Communication in Birds, Mammals and Other Animals*; *Birds: Their Habits and Skills* and *Comparative Vertebrate Cognition*). She has a strong international reputation for her research on brain development and lateralization, funded by the Australian Research Council. Her research includes study of the behaviour of marmosets, chicks, magpies and a number of other species.

Her research publications include over 200 papers in leading international journals and 14 books.

Dr Philip A TOWERS BSc(Hons) MAppSc PhD. Dr Towers was a 2004 nominee of the New South Wales Vice Chancellors' Committee. Dr Towers is a Senior Lecturer in Physiology at Charles Sturt University. He is an academic staff member of the University Council and has chaired the CSU Animal Care and Ethics Committee since 1997. Dr Towers has research



Rabbits housed in floor pens with room to hop, and with adjoining companions.

interests in dietary effects on reproduction and reproduction in Australian wildlife.

1.4 Animal Ethics Committees

At the institutional level, Animal Ethics Committees (AECs) provide avenues for public participation in the regulation of animal research.

AECs are responsible for monitoring research within institutions, including inspections of animals and facilities. They must consider and evaluate applications to conduct research on the basis of the researchers' responses to a comprehensive set of questions, including their justification for the research, its likely impact on the animals, and procedures for preventing or alleviating pain or distress. On behalf of the institution, AECs have the power to stop inappropriate research and to discipline researchers by withdrawing their research approvals. They can require that adequate care, including emergency care, is provided for animals. They also provide guidance and support to researchers on matters relevant to animal welfare, through means such as the preparation of guidelines and dissemination of relevant scientific literature. They are responsible for advising institutions on the changes to physical facilities that should be made to provide for the needs of the animals used.

The membership and duties of AECs are laid down in the NSW legislation and in the Code of Practice, which also provides guidance on how AECs should operate.

Committee membership must be as follows:

- Category A: a veterinarian

- Category B: an animal researcher
- Category C: a person with a demonstrated commitment to animal welfare who is not involved with the institution, animal research or the supply of animals for research
- Category D: an independent person who does not fit the requirements of the other categories and is not associated with the institution.

The Code of Practice states that more than one person may be appointed to each category and, if a Committee has more than four members, categories C plus D should represent no less than one-third of the members.

The criteria used by the ARRPP for assessment of AEC membership were clarified in an ARRPP policy document, *Policy 9: Criteria for the Assessment of Animal Ethics Committee Membership* (<http://www.animaethics.org.au/reader/operation-aecs>). In examining applications from institutions for accreditation as animal research establishments, the membership of the AEC is assessed to ensure it is of acceptable composition and size. During audit inspections, the ARRPP assesses the operation of the AEC.

1.5 Accreditation and licensing

The legislation requires that all applications for accreditation and animal supply licences be referred to the ARRPP for consideration. The ARRPP has established procedures to deal with the considerable workload this entails and has regularly reviewed and updated these procedures to take account of changes in needs and resources.

The application forms for accreditation and licence were extensively revised in 2000–01 to



Cats held long term for non-invasive parasite and nutrition trials are provided with access to an outdoor run with scratching, hiding and climbing areas.

take into account changes to the legislation and to meet evolving needs for particular information.

There are two components in the assessment of applicants by the ARRPP:

- the consideration of a written application to determine whether the applicant is complying with a limited number of fundamental requirements of the legislation
- the evaluation of the applicant at a site inspection, when a much broader approach is taken.

The recommendations of the ARRPP are referred to the Director-General of NSW Department of Primary Industries, who has statutory authority for the issue of accreditation and licences and for imposing, altering or removing conditions of accreditation or licence.

Accreditation and licences are usually issued subject to the condition that a site inspection is satisfactory and are subject to the reporting of changes in AEC membership to the Director-General of NSW Department of Primary Industries for approval. Other conditions may also be stipulated, as relevant to the operation of each institution. (See Appendix M for standard conditions on accreditation and licences).

1.5.1 Evaluation of written applications

The ARRPP has appointed an applications subcommittee to facilitate the assessment of applications. New applications for accreditation or licences are assessed by ARRPP executive

staff, according to criteria developed by the ARRPP. These applications and assessments are then referred to the applications subcommittee, which makes recommendations to the full ARRPP. Recommendations on the applications are then made by the ARRPP to the Director-General of NSW Department of Primary Industries.

A small number of applications are also viewed directly and considered by the full ARRPP. These include applications from individuals or organisations about which the ARRPP has particular concerns, or situations where the application is sufficiently different from the norm to raise policy implications.

Routine applications for renewal of accreditation or supply licences are assessed by ARRPP executive staff, and the ARRPP considers the recommendations arising from these assessments.

The criteria against which the ARRPP assesses written applications are drawn from the legislation. Considerations include whether the AEC is properly constituted, whether its procedures are adequate, whether it is meeting sufficiently frequently to deal with the volume of work, and whether it is conducting inspections of the animals and facilities it supervises. The types and numbers of animals held and their accommodation are also checked, and likely problem areas are flagged for follow-up at site inspection. Similarly, numbers and qualifications of animal care staff are assessed for adequacy.

Monitoring of animal care and use by the AEC and researchers is another vital area of assessment. Details of the type of monitoring undertaken must be provided. Questions on the source and destination of animals allow the ARRPP to double-check compliance with the Act's provisions relating to animal supply.

1.5.2 Conduct of site inspections

Following the evaluation of written applications, the second phase of the process of assessing establishments is the site inspection. The aim of site inspections is to determine whether institutions and individuals are complying with the legislation. The Code of Practice provides the criteria against which institutions are assessed. The range of items assessed includes: the membership, procedures and activities of the AEC; animal care procedures; animal research procedures; and the physical facilities for housing and using animals. An evaluation is also made of the wellbeing of the research or breeding animals.

Audit visits are arranged in advance and usually take from 1 to 4 days per site. Large establishments with multiple sites can take up to 2 weeks to inspect. Information about inspections conducted in the 2004–05 year is provided in Appendixes C and D. The dates provided represent days on site and do not include preparation and follow-up time, which is often considerable.

Assessment begins before site inspection with an examination of written material provided by the institution or individual. This includes lists of the research applications considered by the AEC and people issued with Animal Research Authorities; AEC minutes; the AEC annual report; and records of inspections conducted, together with information about the procedures of the committee and the institutional policy on the committee's operation and decisions.

The examination is carried out by an Animal Welfare Unit Veterinary Inspector and the ARRPP members who have been nominated to participate in the inspection. This pre-inspection evaluation allows likely problem areas to be identified and a general idea to be gained of how the establishment is operating.

On the day(s) of the inspection the inspection team looks at the animals and the facilities and talks with researchers before meeting with the AEC. The team sits in on a scheduled meeting of the AEC, which allows it to view the operation of the AEC and the interaction of its members. At the end of the meeting, time is taken to discuss with the AEC issues arising from the inspection and to solicit feedback from AEC members. Additional important considerations are how the committee liaises with researchers and whether it has developed its own policies or guidelines for procedures of particular concern, such as blood collection techniques, methodology for monoclonal antibody production, and standards for wildlife transportation and the recognition and relief of pain.

A meeting is usually held with the head of the institution at the beginning or end of the inspection. Any serious concerns are immediately referred to the institution at the appropriate level. A letter is usually sent to the institution within a week of the visit, providing the general impressions of the site visit team and reinforcing the need to deal with any serious problems that may have been identified during the visit.

As soon as possible after the inspection, a

detailed report is prepared. The report covers an evaluation of the AEC and an assessment of the animals' wellbeing, housing and holding, and their care and monitoring. Once the ARRPP has considered the report, recommendations may arise that will alter the terms of accreditation or licence. Conditions of an earlier accreditation may have been met, or the ARRPP may feel that additional conditions should be imposed. For example, a condition may be that appropriate post-operative procedures must be implemented.

In addition to conditions for accreditation or licence (which are mandatory and must be implemented), the ARRPP report usually contains a number of recommendations—for example, for more effective operation of the AEC, for improvement of the management of research within the institution, or for improvement of the animal facilities. Implementation of recommendations is not mandatory, but the institution is required to advise on how it has responded to the recommendations. If the recommendations have not been implemented, then the reasons for this must be explained.

Inspection reports also provide an opportunity for the ARRPP to commend the institution, individual researchers or animal attendants for initiatives that raise the standards of the overall operation of the research facility or for techniques or facilities that enhance the welfare of research animals.

The ARRPP also conducts revisits to institutions (and individuals) that have been inspected previously and where particular concerns were raised during the inspection. The primary purpose of these revisits is to evaluate the responses to the recommendations and conditions imposed.

The ARRPP aims to carry out full audit visits for all institutions every 3 years, as well as unannounced visits by inspectors to follow up problems. In formulating its 2004–05 operational plan, the ARRPP recognised that staff reductions within the Animal Welfare Unit would necessitate a reduction in inspections conducted, and the plan reflected this in aiming for inspections to be conducted on a 3- to 4-yearly basis. Re-inspections concentrate more on procedures rather than facilities, unless new facilities have been built. Announced and unannounced spot checks and visits to look at specific aspects of operation may be carried out between full visits.

1.6 The Animal Research Act in schools and TAFE

The Animal Research Act allows the use of animals for educational purposes when there is a demonstrated educational benefit, when there is no suitable alternative, and when the least number of animals is used, with the least impact on their wellbeing. Although animals are used for educational purposes in many situations, their use in schools and TAFE colleges presents special issues, such as mechanisms for approval and monitoring of animal use across the State. Their use also presents opportunities to promote in students an understanding of the ethical and technical issues involved with the use of animals.

1.6.1 The Animal Research Act in schools

The use of animals in teaching activities in schools is governed by the Animal Research Act. Schools that use animals are required to be accredited, and each teacher who uses animals must hold an animal research authority issued by an AEC. Animal use in schools must be conducted in accordance with the requirements of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*, which devotes a section to such use. The Schools Animal Ethics Committee (SAEC) oversees the use of animals in schools. Each school overseen by the SAEC appoints an Animal Welfare Liaison Officer to communicate with the committee.

Most of the teaching activities that use animals and are carried out in schools are described in a list approved by the ARRPP. Teachers wishing to undertake an activity on the approved list may do so, provided that they follow the comprehensive guidelines developed and published by the SAEC. These guidelines have ARRPP approval and set the parameters for the conduct of approved activities. Approved activities include observation; measurement of weight and growth rates; collection of samples such as urine and faeces; and the teaching of normal husbandry procedures. Any teacher wishing to carry out activities that are not on the approved list, or activities that are in higher categories on the approved list, must submit a detailed proposal to the SAEC for approval. A major review of the guidelines was undertaken with detailed input from the ARRPP, and a significantly revised document was released in 2001. The guidelines can be accessed at: <http://www.schools.nsw.edu.au/animalsinschools/>.

The ARRPP liaises regularly with the SAEC. In general, complaints received by the ARRPP about the use of animals in schools are referred to the SAEC and the relevant school system. In this way, prompt and effective action can be taken without unnecessary interference by the ARRPP. If necessary, as in the case of serious complaints, the ARRPP may initiate its own investigation into the matter.

Meetings by the ARRPP with the SAEC and Schools sector, as part of the inspection process and to address specific issues, have proved productive. For example, as a result of a meeting to review teaching application forms, new forms were developed that were better tailored to obtaining the information required by the SAEC.

1.6.2 The Animal Research Act in TAFE

The wide variety of animal use within the extensive TAFE system prompted the development of a special administrative structure. Over 50 per cent of TAFE institutes within NSW use animals, in some 20 different courses. These range from courses teaching normal stock husbandry procedures (such as shearing sheep and drenching cattle), to more specialised areas such as training laboratory animal attendants, research technicians, veterinary nurses and zoo keepers.

With approval from the ARRPP, TAFE established a two-tiered structure to approve and monitor the different types of activities carried out in each institute. Regional AECs were put in place in TAFE institutes. These AECs approved and monitored those teaching activities that were conducted at the institutes and used animals. The AECs were overseen by the TAFE Animal Care and Ethics Board (ACEB).

To monitor the implementation of this system first-hand, the ARRPP met with representatives of TAFE and its ACEB twice in the 2000–01 reporting period and undertook an intensive program of inspections of TAFE AECs and facilities. Early results of these activities included revision of the membership and procedures of some regional AECs.

Early in 2003, TAFE presented the ARRPP with a revised system of management for implementing the Animal Research Act. This system centred around the disbanding of regional AECs and expansion of the role of the ACEB in approving and monitoring animal use activities. Discussions were held to finalise this new system to ensure its compliance with the animal research

legislation. The ARRPP intendeds to continue to @ monitor the activities of, and liaise with, TAFE to @ help it to maintain high standards of animal care @ and management under the Animal Research Act. @

1.7 Administration

The Animal Welfare Unit was established @ in October 1993 as an independent program @ within NSW Agriculture, reporting directly to @ the Director-General of NSW Agriculture. A @ permanent subsection of the Unit is maintained @ in the inspectorial office in Sydney. In July 2004 @ the Departments of Agriculture, Fisheries, Forests @ and Mineral Resources were amalgamated into a @ new Department of Primary Industries. @

The functions of the Animal Welfare Unit @ cover: @

- animal research issues under the *Animal Research Act 1985*, including providing @ Executive services to the ARRPP; @
- general animal care and cruelty issues under @ the *Prevention of Cruelty to Animals Act 1979* (POCTAA), including the operation of the @ Animal Welfare Advisory Council (AWAC) @ under the Minister for Primary Industries @
- animal display issues under the *Exhibited Animals Protection Act 1986* (EAPA), @ including the operation of the Exhibited @ Animals Advisory Committee @
- Departmental animal welfare activities. @

The Animal Welfare Unit can be contacted at: @

Animal Welfare Inspectorial Office @
NSW Department of Primary Industries @
95 Castle Hill Road @
WEST PENNANT HILLS NSW 2125 @
Phone (02) 9872 0570 @
Fax (02) 9871 6938 @
PO Box 100 @
BEECROFT NSW 2119 @

or at the NSW Department of Primary Industries' @
Head Office: @

Animal Welfare Unit @
NSW Department of Primary Industries @
161 Kite Street @
Locked Bag 21 @
ORANGE NSW 2800 @
Phone (02) 6391 3715 @
Fax (02) 6391 3570 @
E-mail: animal.welfare@agric.nsw.gov.au @



Mice benefit from an area to hide within their cages (such as this 'igloo'), especially when the cage sides are transparent.

In financial year 2004–05 the following staff @ were assigned to provide inspectorial and/or @ executive support to the ARRPP. @

Orange:

Ross Burton, BVSc, MVSc, Manager @
Amanda Paul, BVSc, MACVSc (Animal @
Welfare), Veterinary Officer (part-time) @
Len Cantrill, BVM&S, MACVSc (Animal @
Welfare), Veterinary Officer @
Tammy Kirby, Clerical Officer / Acting @
Licensing Clerk @
Rebecca Hutchinson, Clerical Officer @

Sydney:

Lynette Chave, BVSc, Senior Veterinary @
Officer @
Peter Johnson, BVSc, PhD, Veterinary Officer. @
Ann Sullivan, Clerical Officer @

PART 2: REPORT ON WORK AND ACTIVITIES

2.1 Administration and planning

Administrative functions have varied from activities such as assessments of licensing and accreditation to formulating the ARRPs strategic plan for 2005–08. The appendixes to this annual report contain details of many of the operational and strategic functions of the ARRPs. These include the dates of, and attendance at, ARRPs meetings (Appendixes A and B); dates and attendance of ARRPs members at inspections of accredited research establishments and animal supply licence holders (Appendixes C and D); the ARRPs Strategic Plan 2005–08 (Appendix E) and Operational Plan for 2004–05 (Appendix F); and ARRPs operating expenses (Appendix I).

2.1.1 Strategic Plan 2005–08

During 2005 the ARRPs developed a new 3-year strategic plan. The plan identifies the primary goals of the ARRPs and strategies for achieving these goals. In developing the plan the ARRPs identified four priority areas:

- training of Animal Ethics Committee members
- promoting education of researchers and teachers
- ongoing review and maintenance of the ARRPs website ‘Animal Ethics Infolink’ (<http://animaletics.org.au>)
- promoting alternatives to the use of animals in research and teaching.

Details of the Plan are given in Appendix E.

2.1.2 Operational Plan for 2004–05

The ARRPs Operational Plan, including a performance review of each activity, is provided in Appendix F.

2.1.3 Liaison with organisations, accredited institutions and authority holders

The ARRPs liaised with several organisations, accredited institutions and research authority holders to offer advice and to facilitate the implementation of legislative requirements and adherence to replacement, reduction and refinement principles. (See examples of activities under ‘1.6.1 The Animal Research Act in Schools’ and ‘2.6 Support for Animal Ethics Committees’.)

2.2 Assessment of applications

New applications for accreditation and/or licensing were reviewed by an applications subcommittee of Ms Stephanie Abbott, Dr Barry Lowe and Mr Mark Lawrie. The subcommittee discussed applications via teleconference and made recommendations to the ARRPs.

During 2004–05 the ARRPs considered:

- nine new applications for accreditation
- 34 renewal applications for accreditation
- three new applications for school accreditation
- 25 renewal applications for school accreditation
- two new applications for animal suppliers’ licences
- 20 renewal applications for animal suppliers’ licences.

2.2.1 LD50 testing and regulatory product testing

LD50 is a toxicity test used to determine the dose or concentration of a test substance—that is, the lethal dose—that is expected to kill 50 per cent of the animals to which it is administered. For the purposes of the *NSW Animal Research Act 1985* the definition of LD50 has been broadened. Included are all tests in which a potentially lethal dose of a substance will be administered and is expected to kill a proportion of the individuals in any group of animals to which it is given. In NSW such tests may be undertaken only under the approval of a properly constituted Animal Ethics Committee, with the agreement of the Minister for Primary Industries. Applications for permission to conduct LD50 tests are evaluated by an ARRPs subcommittee. Members of the subcommittee in 2004–05 were Associate Professor Einstein, Dr Fogarty and Dr Lowe. The subcommittee makes recommendations to the ARRPs, which in turn advises the Minister.

In 2004–05 the subcommittee considered one application from an Accredited Animal Research Establishment. The testing was required as part of the registration process for biological agents. The ARRPs recommended to the Minister that he approve the applications on the conditions that



Dogs used for serum production making full use of their daily paddock run.

the organisation report to the ARRП progress with the development of replacement in vitro tests, and provide annual statistics for the numbers of animals used in each test. (One ARRП member did not approve the recommendation because of fundamental objections to the use of animals for research.)

A paper discussing issues in achieving the 3Rs in the manufacture and testing of veterinary vaccines was co-authored with Associate Professor Einstein and staff from the Animal Welfare Unit and presented by Associate Professor Rose at the 5th World Congress on Alternatives to Animals in the Life Sciences (Berlin, August 2005).

A meeting was held between DPI staff and representatives of the Australian Pesticides and Veterinary Medicines Authority in November 2004 to discuss some of issues affecting the development and adoption of alternative tests.

The ARRП continues to support an intergovernmental, inter-agency approach in cooperation with industry to develop a practical policy that will bring significant animal welfare benefits, together with efficiencies for industry, through the phase-out of large-scale animal-based tests and replacement with non-animal alternatives.

2.3 Subcommittees

The ARRП appoints subcommittees to deal with particular issues. They explore issues in depth, including discussions with relevant members of the scientific and broader communities. Subcommittees provide reports and recommendations to the full ARRП for

consideration. There are standing subcommittees that make recommendations on licensing, accreditation, and LD50 testing. Membership of subcommittees is largely drawn from the ARRП. External members of subcommittees are occasionally co-opted on a voluntary basis. Issues considered by subcommittees in the past year include:

- the hosting of a meeting to be held in 2006 for members and executive officers of AECs (Associate Professor Rose, Mr Lawrie and Ms Abbott)
- applications for accreditation and licences (Dr Lowe, Ms Abbott and Mr Lawrie)
- applications for LD50 testing (Associate Professor Einstein, Dr Fogarty and Dr Lowe).

2.4 Legislation

2.4.1 Review of the Animal Research Act

A review of the *Animal Research Act 1985* began in November 1998 to meet the Government's obligations under the Competition Principles Agreement. A Review Group was established to conduct the review, and its report was completed and forwarded to the Minister for Primary Industries in 2002.

2.4.2 Review of the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes

The *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* is incorporated into the NSW animal research

legislation. A review of the Code was undertaken, and a revised draft seventh edition was released for comment in March 2003. In recognition of the importance of the Code as central to the conduct of animal research in NSW, the ARRП held a special meeting to discuss this revised draft and to formulate comments to be sent to the Code Liaison Group. As a result of the meeting a detailed submission was developed.

In response to the comments received, in October 2003 the NHMRC released a revised draft, which was again circulated widely in NSW for comment. The ARRП again held a special meeting to formulate a submission to the Code review.

Meetings of the Code Liaison Group (which includes members of the ARRП and Animal Welfare Unit) were held in early 2004 to revise the draft on the basis of the comments received. A seventh edition of the Code was released in late 2004.

Changes from the previous Code include:

- assessing proposals (Clauses 2.2.18–2.2.25)
- reporting on projects (Clauses 2.2.37–2.2.39)
- projects involving more than one AEC (Clauses 2.2.41–2.2.42)
- responsibilities of the AEC Chairperson (Clause 2.2.9)
- external triennial reviews of institutions (Clause 2.1.2 and Appendix 1)
- use of genetically modified animals (Clauses 3.3.56–3.3.63)
- a significantly revised reference section (Appendixes 2–5).

2.5 Statistics on animal use

The Animal Research Regulation 1995 requires accredited research establishments (other than schools) and animal research authority holders to record and submit information on the number of animals used in research each year.

The requirements for reporting on animal use provide data on the numbers of animals used in all research protocols in NSW, reported against the purpose of the research and the types of procedures in which they were involved. The aim of collecting these statistics is to give some indication of the level of ‘invasiveness’ of the procedures on the animals and to provide data for inclusion in national statistics on the use of animals in research. The system for the collection

of statistics was revised in 2001. Advantages of this new system over the previous one include:

1. the recording of an animal in all protocols in which it is used
2.) the recording of animals for each year in which they are held in long-term protocols
3.) the recording of the types of procedures used, combined with the recording of the purpose of the research
4.) the ability to collate and submit statistics electronically.

The categories used are based on those planned to be used in a future national database. Figures relate to the calendar, rather than to the financial, year.

Appendix G of this report provides a summary of animal usage in 2004.

2.5.1 Lethality testing

Accredited research establishments must keep figures on lethality testing and submit these to the ARRП. Lethality testing is defined as ‘any animal research procedure in which any material or substance is administered to animals for the purpose of determining whether any animals will die or how many animals will die’.

Approved forms for the recording of these figures were sent to all accredited research establishments, with a deadline for submission of completed forms to the ARRП of 31 March 2005.

2.6 Support for Animal Ethics Committees

The ARRП and the Animal Welfare Unit continue to use various means to support AECs in performing their duties. These means include the conducting of site inspections; the writing of policies, guidelines and fact sheets where a need is identified; the holding of meetings for AEC members; and the supply of advice over the telephone or by correspondence.

The ARRП is used as a reference source by the State’s AECs, for example as a source of information on successful policies developed at other institutions.

All establishments are required to advise the Director-General of NSW Department of Primary Industries of changes to AEC membership. The ARRП advises the Director-General on the suitability of the qualifications of the new members for the categories of membership to which they are nominated.

The following are examples of ARRП activities related to support for AECs:

- Two issues of a newsletter for AECs, *Animal Ethics Update*, were published in the 2004–05 reporting period. The newsletters are designed to provide information and updates on topics relevant to AECs, as well as to provide a forum for AEC members to share experiences. The newsletters were published electronically and can be accessed at the ‘Animal Ethics Infolink’ website at <http://www.animaletics.org.au>.
- An ongoing issue related to the management of a dog colony was addressed. The AEC concerned had experienced difficulties in obtaining adequate plans of management for the care and use of the dogs concerned. After a condition had been imposed on the establishment requiring the development of a plan of management for the dogs, the ARRП took the matter up with the establishment’s Executive, organising a meeting attended by Associate Professor Rose and Mr Lawrie (accompanied by an Inspector). A plan of management was subsequently developed. Owing to ongoing issues related to the care and management of these dogs, the ARRП has maintained liaison with the establishment.

2.6.1 Register of candidates for AEC membership

Finding interested and suitable members has been a problem experienced by a number of AECs. Categories A, C and D have presented the most difficulty. To help AECs to maintain the required membership, the ARRП suggested

the establishment of a register of AEC members interested in joining other AECs. The Animal Welfare Unit has established a list of names, contact details and the categories that individuals believe they can represent. This list is available to all NSW AECs.

2.6.2 Meeting for members and executive officers of AECs

In July 2004 a meeting for members and Executive Officers of AECs was held by the ARRП in conjunction with the Animal Welfare Unit.

In an effort to ensure that the program for the meeting met the needs of AECs, comment was sought from all NSW AECs on topics they wished to discuss and the format for conducting the meeting. Valuable feedback was provided, and a program was structured accordingly. The members of the ARRП subcommittee that worked on this project (in the 2003–04 year) were Associate Professor Margaret Rose, Associate Professor Rosemarie Einstein and Ms Siobhan O’Sullivan. The meeting was well attended.

A session on ‘3Rs—Implementation and Opportunities’ included an enlightening presentation by Mr Darek Figa on enriching the environment of laboratory rats. Also in this session, Ms Rebecca Robey gave a comprehensive explanation of the re-homing strategy for animals used at her employer’s establishment.

During a session looking at alternatives to animals in teaching, Dr Sue Dodds outlined a policy developed by a teaching establishment on conscientious objection to the use of animals in teaching. Of particular interest was the

Rats exhibiting stretching and climbing behaviours. Note that the ‘low top’ cage on the left would not allow the rat to fully stretch upright, whereas the ‘high top’ cage on the right accommodates this behaviour. (Photos courtesy of Darek Figa)



involvement of students in the development of this policy. Dr Robert Dixon gave a presentation on replacing live animals in veterinary teaching.

The keynote speaker was Professor Lesley Rogers (a member of the ARRPP). Professor Rogers has extensive credentials in animal behaviour and gave a lively and thought provoking talk on 'Can Animals Think? – Implications for Animal Welfare'. The feedback from meeting participants was that this presentation was exceptionally well received and sparked a high degree of interest.

Participants broke up into groups for a workshop session discussing the topic of what Animal Ethics Committee members expect from each other.

Indications from participants were that there was a desire for these meetings for members of AECs to be held on a regular basis.

2.7 Website: Animal Ethics Infolink

Development and maintenance of a website by the ARRPP ('Animal Ethics Infolink') was identified as an important project aimed at providing educational material for those involved in the care and use of animals for research and teaching in NSW. The site is designed to provide an opportunity for interchange with animal research entities worldwide, and to give the general community access to information about animal use for research and teaching in NSW. It is intended to enhance channels of communication and make information more accessible. The website has been developed and is maintained in conjunction with the Animal Welfare Unit. The Animal Ethics Infolink site is accessible at www.animaletics.org.au.

2.8 Site inspections

A list of site inspections undertaken in 2004–05 is provided in Appendix C, and a list of ARRPP members attending is given in Appendix D. There were 23 inspections conducted over a period of 26 working days. The length of these inspections ranged from half a day to 3 days for larger institutions. The inspections included AECs and the facilities of 22 accredited institutions/licensed animal suppliers and independent researchers.

The ARRPP aims to carry out a routine inspection of each accredited animal research institution approximately every 3 years to maintain personal contact with institutions, AECs

and researchers, and to carry out a complete audit of institutional operation under the *Animal Research Act 1985*.

The ARRPP places a major focus on reviewing the operation of AECs, to ensure that AECs, investigators and institutions understand their responsibilities under the Animal Research Act and the Code of Practice. The conduct of research procedures and the conditions in which animals are held also receive close scrutiny during site visits.

2.9 Policies, guidelines and fact sheets

The ARRPP and Animal Welfare Unit produce policies, guidelines and fact sheets to aid researchers, AECs, research establishments, animal suppliers and members of the broader community to understand and comply with the requirements of the animal research legislation. These documents are available from the Animal Welfare Unit and can also be found by following the links from the ARRPP's website www.animaletics.org.au (see Appendix K for a list of guidelines and policies).

New policies, guidelines and fact sheets are produced to fill needs identified by the ARRPP.

When first published, guidelines and policies are sent out to AECs and other groups as appropriate (such as user groups and animal welfare organisations) for comment. The documents are then reviewed in the light of the comments received. The ARRPP also has a policy of actively reviewing older guidelines and policies to ensure they are up to date. The following guidelines and policies were developed or reviewed in 2004–05:

- *ARRP Guideline 10: Wildlife Surveys*. A comprehensive review was finalised after extensive consultation and revised version published.
- *Draft ARRPP Guideline 20: Guidelines for the Housing of Rats in Scientific Institutions*. The drafting of an extensive guideline on rat housing, based on evidence from the scientific literature, was finalised and sent out for comment. Review was also sought from international experts in the field of laboratory rat housing and behaviour (such as from the Canadian Council on Animal Welfare and the Universities Federation for Animal Welfare). Very favourable responses were received, including from the international reviewers,

and the guidelines are to be revised on the basis of the comments received.

2.10 Initiatives in replacement, reduction and refinement

Information collected from the 'Annual Return on Animal Use' submitted by each research establishment and independent researcher includes information on techniques developed or used by the establishment to replace, reduce and refine animal use in research and teaching. The adoption of such techniques is actively encouraged by the ARR. A list of some of the initiatives can be found in Appendix H.

2.11 Complaints

A formal process for making specific complaints about animal research is set out in sections 22, 28 and 42 of the *Animal Research Act 1985*. The process allows any person to make such a formal complaint. The complaint must be made in writing to the Director-General of NSW Department of Primary Industries, who refers the complaint to the ARR for investigation. The ARR is bound to investigate formal complaints and to make recommendations to the Director-General for disciplinary action (if it is considered warranted) or dismissal of the complaint. Both the complainant and the individual or institution being investigated have a right of appeal. There were no complaints received in the 2004–05 reporting period.

The ARR also has a policy of responding to

informal complaints. These may involve varying degrees of investigation, from formal interviews to requests for documents or unannounced visits to animal holding facilities. Complaints may arrive from a variety of sources: the RSPCA may refer matters that fall outside its jurisdiction; ARR members may raise matters brought to their attention by members of the community; public concern may be expressed in the media; and complaints may be raised in direct correspondence to the Minister for Primary Industries, the ARR, or the Animal Welfare Unit. Five informal complaints were received in the 2004–05 reporting period; all of them were satisfactorily resolved.

APPENDIXES

Appendix A: Dates of ARRP meetings 2004–05

Meeting number	Date of meeting
153	7 July 2004
154	25 August 2004
155	13 October 2004
156	7 December 2004
157	23 March 2005
158	11 May 2005

Appendix B: Members' attendance at ARRP meetings N 2004–05N

Member	Meeting number					
	153	154	155	156	157	158
A/Professor M Rose (Chair)	*	*	*	*	*	*
Ms S Abbott	*	*	*	*	A	*
Mr S Atkinson	—	—	—	—	A	*
Dr J Baker	—	—	—	—	*	*
Ms J Buckley	—	—	—	—	A	A
A/Professor R Einstein	*	A	*	*	—	—
Dr R Fogarty	*	*	*	*	*	*
Mr R Haering	*	*	*	*	—	—
Mr M Lawrie	*	*	*	*	*	*
Dr B Lowe	*	*	*	*	*	A
Mr D O'Shannessy	—	—	—	—	*	*
Ms S O'Sullivan	*	*	*	*	A	*
A/Professor R Pirola	*	A	*	*	A	*
Mr D Robinson	*	*	*	*	—	—
Professor L Rogers	*	A	*	A	—	—
Dr P Towers	—	—	—	—	*	*

* = Present
A = Absent
— = Not Applicable

Appendix C: Inspections July 2004 – June 2005C

Establishment	Date
Murray Darling Freshwater Research Centre	21/7/2004
NSW Fisheries – Inland Saline Aquaculture Research Centre	22/7/2004
CSAHS (RPA / Concord / Camperdown / Wallacia)	27/7/2004
	29/7/2004
	30/7/2004
Sydney Water	29/7/2004
Agrisearch (facilities only)	16/8/2004
Supercoat	27/8/2004
Hanrob (ASL)	27/8/2004
State Forests	2/9/2004
Department of Infrastructure, Planning and Natural Resources	2/9/2004
NSW DPI – Cowra	14/9/2004
NSW DPI – Trangie	14/9/2004
Bioproperties	23/9/2004
University of New England	28/9/2004
	29/9/2004
Vision CRC	22/10/2004
Jurox	25/11/2004
National Parks Association	7/12/2004
Warringah Council	8/12/2004
Australian Sciences	14/2/2005
NSW DPI – Orange	25/2/2005
Shore School	31/3/05
	8/4/05
University of Wollongong	22/6/2005
	23/6/2005
Hamilton Paul	2/5/2005
UTS (Kuringai)	19/5/2005
ICP Firefly (facilities)	28/4/2005

Appendix D: Attendance of ARRP members at site inspections 2004–05

Member	Number of days spent on site inspection
A/Professor M Rose	3
Ms S Abbott	3
Mr S Atkinson	0
Dr J Baker	0
Ms J Buckley	0
A/Professor R Einstein	1
Dr R Fogarty	1
Mr R Haering	2
Mr M Lawrie	2
Dr B Lowe	2
Mr D O'Shannessy	0
Ms S O'Sullivan	3
A/Professor R Pirola	0
Mr D Robinson	1
Prof. L Rogers	0
Dr P Towers	2

Appendix E: NSW Animal Research Review Panel N

Strategic Plan July 2005 – June 2008N

Priority items are numbers 2.5, 3.1, 3.2, 4.2 and 9.3.

Goals and strategies

- 1. Effective and efficient implementation of the statutory requirements of the Animal Research Act 1985, the Animal Research Regulation 1995 and the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes.**
 - 1.1 Maintain a system to accredit all establishments and individuals in NSW conducting research and teaching using animals.
 - 1.2 Maintain a program of site visits to effectively monitor compliance with the legislation.
 - 1.3 Review the methods of conducting site visits and the documentation of these methods on a regular basis to help ensure high standards of efficiency, effectiveness and consistency.
 - 1.4 Identify and implement adjuncts to inspections to better ensure compliance with the legislation.
 - 1.5 Monitor compliance with the Act, Regulations and the Code with respect to the conduct of animal research and teaching and the supply of animals for research and teaching.
 - 1.6 Active participation in national reviews of the Code to ensure that it is effective in regulating the conduct of animal research and teaching and the supply of animals for research and teaching.
 - 1.7 Prepare an annual report to Parliament on the operations and achievements of the Animal Research Review Panel.
 - 1.8 Maintain and review the system for collection and analysis of statistics on animal use for research and teaching; to ensure that it provides useful information which accurately reflects the use of animals, without imposing an undue administrative burden on institutions or Government.
 - 1.9 Maintain a system for receiving and investigating complaints relating to the requirements of the legislation.
 - 1.10 Provide opportunities to the research, teaching, veterinary, animal welfare and lay communities to provide feedback on the activities of the Animal Research Review Panel and respond appropriately.
 - 1.11 Maintain a system to consider and make recommendations on applications for permission to carry out LD50 tests.
- 2. The principles, processes and responsibilities in the Code are actively embraced wherever animals are used, principally through Animal Ethics Committees**
 - 2.1 Ensure there is effective participation by researchers and teachers, veterinarians, animal welfare representatives and independent representatives in a formal review of the justification and merit for all proposals for the use of animals for scientific purposes.
 - 2.2 Promote support for AECs within institutions.
 - 2.3 Promote and foster interaction between AECs and researchers/teachers.
 - 2.4 Promote an appreciation of the ethos underpinning the Code through visits and all communications from the Animal Research Review Panel to institutions, AECs, researchers/teachers and animal care staff.
 - 2.5 Promote an understanding of the roles and responsibilities of AECs through encouraging participation in AEC training programs. *(Priority item)*
 - 2.6 By identifying problems and suggesting remedies, provide assistance to institutions, AECs and researchers/teachers to ensure that the principles, processes and responsibilities in the Code are actively embraced.
 - 2.7 Promote discussion and understanding of key technical and ethical issues and foster interaction between AECs by maintaining a program of meetings of Chairs of AECs and participating in AEC meetings during site inspections.
 - 2.8 Review the membership and operation of individual AECs during site visits to ensure that all categories of membership are able to contribute effectively to discussions, decisions and activities of the AEC.
 - 2.9 Develop and promulgate guidelines to assist AECs to evaluate protocols effectively.
 - 2.10 Conduct ongoing monitoring of TAFE, Schools and Director-General's AECs to identify any special needs.
 - 2.11 Promote a critical review of the operation of AECs with a view to maximising their effectiveness.

3.) **Researchers and teachers using animals actively support the principles set out in the Act, Regulation and Australian Code of Practice for the Care and Use of Animals for Scientific Purposes.**
 - 3.1) Promote an understanding of the roles and responsibilities of researchers/teachers through encouraging participation in education programs, to foster an awareness of ethical and scientific issues and the implementation of the 3Rs. *(Priority item)*
 - 3.2) Maintain the 'Animal Ethics Infolink' website as a resource for AECs, researchers and teachers and members of the community. *(Priority item)*
4.) **Methods that complement or replace animal use are used wherever possible.**
 - 4.1 Encourage AECs critically to assess the adequacy of researchers'/teachers' attempts to identify alternatives to animal use.
 - 4.2 Encourage greater awareness of the use of alternatives to animals in research and teaching. *(Priority item)*
 - 4.3 Collate and disseminate information on alternatives to animal use.
5.) **Procedures involving animals are regularly reviewed and refined to minimise the number of animals required and to reduce the impact on individual animals.**
 - 5.1 Encourage a critical review of the design of experiments before protocols are submitted to AECs.
 - 5.2 Ensure close scrutiny by AECs of breeding programs to minimise overproduction of animals.
 - 5.3 Ensure close scrutiny by AECs of the competence of researchers to carry out specific procedures.
 - 5.4 Promote the critical evaluation of the monitoring of animals being used in procedures.
 - 5.5 Promote the critical evaluation by AECs and researchers of the impact of the type of housing / holding on experimental animals and awareness of its implications for experimental results.
6.) **Pain or distress in animals used in research and teaching is anticipated, promptly recognised and relieved.**
 - 6.1) Promote the use of appropriate analgesia and anaesthesia by facilitating access by researchers/teachers to information resources.
 - 6.2) Ensure that AECs and researchers/teachers focus on the possible impact of procedures at the planning stage and implement appropriate strategies for monitoring and alleviation.
 - 6.3) Promote awareness by researchers/teachers and animal care staff of signs of pain or distress in animals.
 - 6.4) Promote awareness of the effects of handling and other interactions with humans on levels of pain and distress and the use of strategies to minimise adverse impacts.
 - 6.5) Monitor and identify deficiencies in anticipation, recognition and relief of pain and distress during site visits and ensure deficiencies are rectified, including by provision of pre-operative analgesia where appropriate.
7.) **High standards of housing and routine care are established for animals used in research and teaching.**
 - 7.1 Evaluate housing and routine care through the ongoing site visit program.
 - 7.2 Develop and disseminate policies and/or guidelines for housing and routine care.
 - 7.3 Actively participate in the development and review of appropriate national standards for housing and routine care.
8.) **Animals used are supplied in accord with the legislation.**
 - 8.1) Identify areas of non-compliance through scrutiny of records during site visits and investigation of complaints.
 - 8.2) Develop and disseminate appropriate educational material.
9.) **The community (research, teaching, veterinary, animal welfare and lay) has access to information about animal use for research and teaching in NSW.**
 - 9.1) Provide information in the annual report on ARRPs activities and achievements, areas of concern to the Animal Research Review Panel and statistics on animal use.
 - 9.2) Identify options for disseminating information about specific issues of interest and concern both broadly and to specific groups (researchers, teachers, veterinarians, animal welfare, lay).

- 9.3 Review and maintain a web site for the dissemination of information (including the publication of a newsletter). (*Priority item*)
- 9.4 Provide opportunities for and encourage the community (researchers, teachers, veterinarians, animal welfare, lay) to have an input into legislative review, development of standards for housing and care, and policy development.
- 9.5 Ensure that information about animal use provided by the Animal Research Review Panel is in lay terms where appropriate.
- 9.6 Encourage institutions to provide information about their animal use direct to the general community.
- 10. The approach to administration of animal research is harmonised between State and Territory regulatory and funding bodies.
- 10.1 Promote interaction between State and Territory regulatory and funding bodies as issues are identified.

Appendix F: Animal Research Operational Plan July 2004 – June 2005

Activity	Measure of Performance	Time frame	Status
1. Mandatory			
1.1 Review incoming applications for accreditation and licence	Recommendation to Director-General	3 months (new) 2 months (renewal)	All applications processed and recommendations made to the Director-General
1.2 Investigate formal and informal complaints	Recommendation to Director-General	Interim or final recommendations within 3 months	Five informal complaints considered.
1.3 Review incoming applications to conduct LD50 tests	Recommendations to Minister	3 months	All applications reviewed and recommendations sent to the Minister.
1.4 Prepare annual report for 2003–04	Report submitted to Minister	December 2004	Report submitted.
1.5 Prepare statistics on animal use for 2003	Statistics collated	December 2004	Statistics collated.
2. Inspections			
2.1) Conduct site visits of all accredited establishments on a 3- to 4-yearly basis	Number of establishments inspected	Ongoing	21 establishments inspected (23 inspections conducted).
	Number of days for inspections		26 days of inspections.
	Total number of establishments not inspected within the last 4 years		Two establishments (active over the last 4 years and with own AEC) not inspected. (Note: These were out-of State).
2.2 Inspect new establishments applying for accreditation before, or within 2 months of, accreditation	Number of new establishments inspected	Ongoing	Three
	Number of new establishments not inspected		0 (with own AEC)
2.3 Conduct site visits of selected independent researchers with animal-holding facilities	Number visited	Ongoing	One
2.4 Review and send inspection reports	Reports sent	Within 3 months of inspection	Reports sent.

Activity	Measure of Performance	Time frame	Status
2.5 Follow up 'problems' identified at inspection or on review of applications for accreditation or licence	Problems rectified	Within 12 months	Problems followed up as per 'Accreditation / Site Inspection Responses' section of ARRP agendas.
2.6 Review inspection procedures	Review commenced	June 2005	Review not commenced.
3. Education			
3.1 Maintain ARRP website	Site maintained	Ongoing	Website maintained.
3.2 Publish 6-monthly newsletter via website	Editions published	Ongoing	Two editions published
3.3 Develop learning guide to accompany AEC learning package	Investigate funding sources	June 2005	Funding for writing of reference document being progressed.
3.4 Meeting for members of AECs	Meeting held	July 2004	Meeting held July 2004.
3.5 Hold meeting on revised Code of Practice	Meeting held	June 2005	Meeting not held.
4. Policies and guidelines			
4.1 Standards linked to performance criteria for rats, mice, guinea pigs and farm animals (sheep, cattle, pigs)	Collate comments on rat document	June 2005	Collation in progress.
	Draft of mouse document edited	June 2005	Draft not edited.
	Draft of guinea pig document commenced	June 2005	Draft commenced.
	Draft of sheep document progressed	June 2005	Draft not progressed.
4.2 Develop policies/ guidelines where strong need identified (maximum of two)	Developed as need identified	Ongoing	One new guideline
4.8 Revise current policies and guidelines	Policies and guidelines revised	June 2004	One guideline revised.
5. Legislation			
5.1 Assess results of revised statistics package	Results assessed	June 2005	Results considered.
5.2 Assess lethality statistics for publication	Statistics assessed	June 2005	Statistics received.
6. Subcommittees			
6.1 Activate wildlife advisory group (WAG) if special wildlife issues arise	WAG activated where issues identified	Low priority	No need for activation.
6.2 Activate Toxicology Technical Advisory Group (TTAG) for special toxicology issues	TTAG activated where issues identified	Low priority	No need for activation.

Activity	Measure of Performance	Time frame	Status
7. Additional			
7.1 Continue liaison with NHMRC	Meeting held	Ongoing	Liaison via comments on publications.
7.2 Continue liaison with APVMA	Contact with APVMA maintained	Ongoing	Meeting held November 2004.
7.3 Develop strategic plan for July 2005 – June 2008	Plan developed	June 2005	Plan developed.

Appendix G: Animal use statistics 2004

Note: Statistics on animal use are collected on a calendar year basis.

The following graphs, one for each **purpose** (see table on next page) show the numbers of animals used against category of **procedure** (1–9 see below). The categorisation of procedures aims to give some indication of the ‘invasiveness’ or ‘impact’ of the work on the animals involved. **Species** are grouped as indicated below.

Some animals are used in a number of projects, for example those used to teach animal handling techniques. Animals that are re-used are counted in each project for which they are used. In welfare terms, this gives a more meaningful indication of animal use.

The system includes obtaining statistics on observation of free-living animals. This causes a large number of animals to be recorded in procedure category 1 (‘observation involving minor interference’). For example, an aerial survey of birds can include many hundreds of thousands of individual animals.

Animal species categories used for collection of data

Group	Comprises
Aquatic vertebrates	Fish, amphibians and other aquatic vertebrates
Birds	All birds except poultry
Domestic animals	Dogs and cats
Laboratory mammals	Mice, rats, guinea pigs, rabbits
Native mammals	Macropods, possums/gliders, native rodents, dasyurids, wombats, koalas
Primates	All non-human primates
Reptiles	All reptiles
Stock animals	Sheep, horses, goats, pigs, cattle, poultry
Feral	Exotic animals in the wild
Other	Any not categorised above

Purposes

Stock breeding

Breeding protocols to produce new teaching or research stock. Include the animals used to produce progeny and any breeders or progeny culled in the process, NOT the final progeny themselves (as these will be counted under the protocol in which they go on to be used).

Stock maintenance

Holding protocols for animals maintained for use in other protocols. These animals may be maintained under an ethics authority because they require special management. If they are not held under an authority (e.g. normal stock animals kept mainly for commercial production, but occasionally used in research), then they are counted in the protocol only where they are used for teaching/research.

Examples:

Fistulated ruminants that are maintained under a holding protocol, for use in other short-term feeding trial protocols.

Non-breeding colony of diabetic rats held for research in other protocols

Education

Protocols carried out for the achievement of educational objectives. The purpose of the protocol is not to acquire new knowledge, rather to pass on established knowledge to others. This would include interactive or demonstration classes in methods of animal husbandry, management, examination and treatment.

Examples

Animals used by veterinary schools to teach examination procedures such as pregnancy diagnosis

Research: human or animal biology

Research protocols that aim to increase the basic understanding of the structure, function and behaviour of animals, including humans, and processes involved in physiology, biochemistry and pathology.

Research: human or animal health and welfare

Research protocols that aim to produce improvements in the health and welfare of animals, including humans.

Research: animal management or production

Research protocols that aim to produce improvements in domestic or captive animal management or production.

Research: environmental study

Research protocols that aim to increase the understanding of the animals' environment or its role in it, or aim to manage wild or feral populations. These will include studies to determine population levels and diversity and may involve techniques such as observation, radio tracking or capture and release.

Examples

Pre-logging or pre-development fauna surveys

Production of biological products

Using animals to produce products other than milk, meat, eggs, leather, fur, etc.

Examples

Use of a sheep flock to donate blood to produce microbiological media

Production of commercial antiserum

Production of products, such as hormones or drugs, in milk or eggs from genetically modified animals

Quality assurance testing of drugs

Diagnostic procedures

Using animals directly as part of a diagnostic process.

Examples

Inoculation of day-old chicks with Newcastle Disease virus to determine virulence

Blue-green algae toxicity testing

Water supply testing using fish

Regulatory product testing

Protocols for the testing of products required by regulatory authorities, such as the National Registration Authority. **If the product testing is not a regulatory requirement (e.g. if it is part of a Quality Assurance system only), those animals should be included in the appropriate category selected from above.** (This would be normally be category 8 in the case of QA testing.)

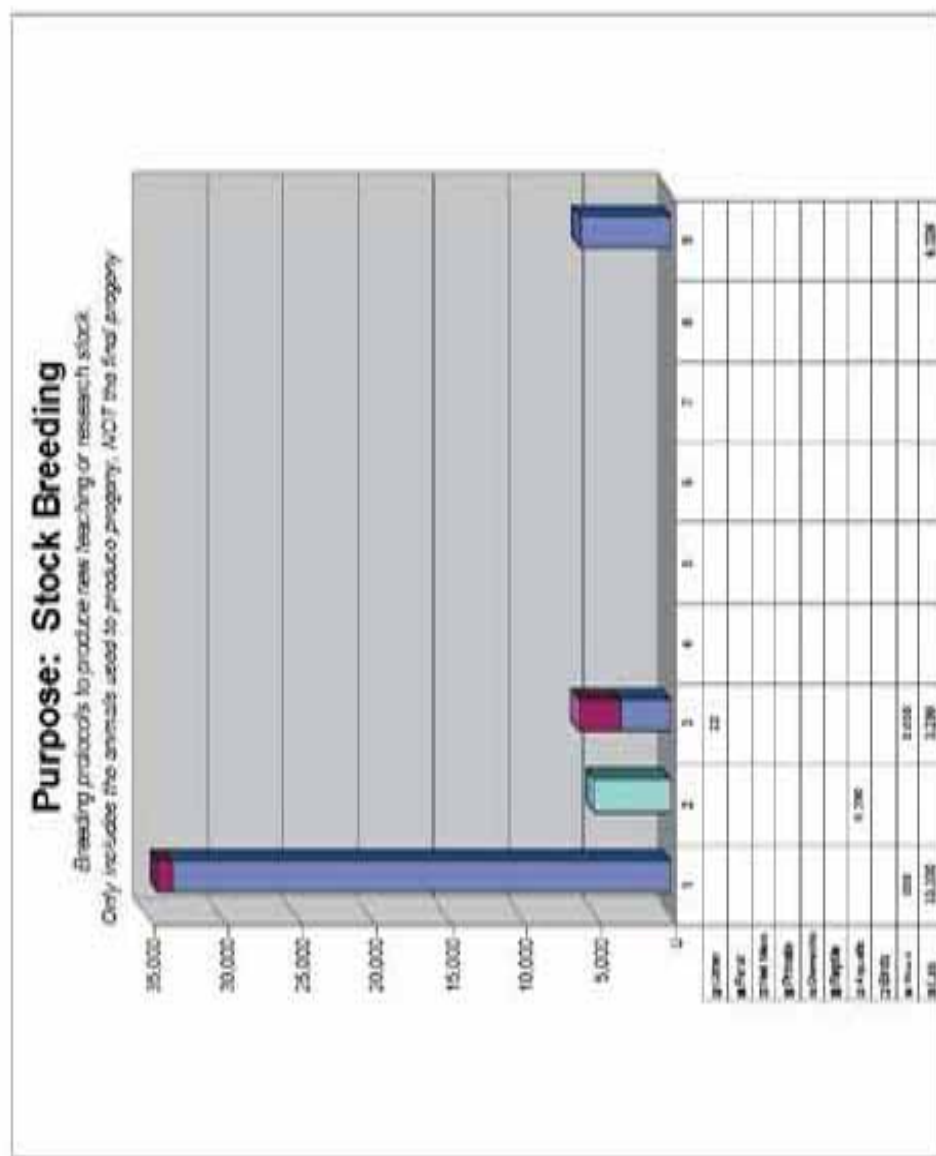
Examples

Pre-registration efficacy or toxicity testing of drugs and vaccines

Data collection: procedure categories and guidelines used for classification

1: Observation involving minor interference	5: Major surgery with recovery
Animals are not interacted with or (where there is interaction) it would not be expected to compromise the animal's welfare any more than normal handling, feeding, etc. There is no pain or suffering involved.	Animal is rendered unconscious with as little pain or distress as possible. A major procedure such as abdominal or orthopaedic surgery is carried out and the animal allowed to recover. Post-operative pain is usually considerable and at a level requiring analgesia.
2: Animal unconscious without recovery	6: Minor physiological challenge
Animal is rendered unconscious under controlled circumstances (i.e. not in a field situation) with as little pain or distress as possible. Capture methods are not required. Any pain is minor and brief and does not require analgesia. Procedures are carried out on the unconscious animal, which is then killed without regaining consciousness.	Animal remains conscious for some, or all, of the procedure. There is interference with the animal's physiological or psychological processes. The challenge may cause only a small degree of pain/distress, or any pain/distress is quickly and effectively alleviated.
3: Minor conscious intervention	7: Major physiological challenge
Animal is subjected to minor procedures that would normally not require anaesthesia or analgesia. Any pain is minor and analgesia usually unnecessary, although some distress may occur as a result of trapping or handling.	Animal remains conscious for some, or all, of the procedure. There is interference with the animal's physiological or psychological processes. The challenge causes a moderate or large degree of pain/distress that is not quickly or effectively alleviated.
4: Minor surgery with recovery	8: Death as an endpoint
Animal is rendered unconscious with as little pain or distress as possible. A minor procedure such as cannulation or skin biopsy is carried out and the animal allowed to recover. Depending on the procedure, pain may be minor or moderate and postoperative analgesia may be appropriate. Field capture using chemical restraint methods is also included here.	This category applies only in those rare cases where the death of the animal is a planned part of the procedures. Where predictive signs of death have been determined and euthanasia is carried out before significant suffering occurs, the procedure may be placed in category 6 or 7.
9: Production of genetically modified animals	
This category is intended to allow for the variety of procedures that occur during the production of genetically modified animals. As animals in this category may be subjected to both minor and major physiological challenges and surgical procedures, this category reflects the varied nature of the procedures carried out. It effectively includes all animals used in GM production, other than the final progeny, which are used in a different category of procedure.	

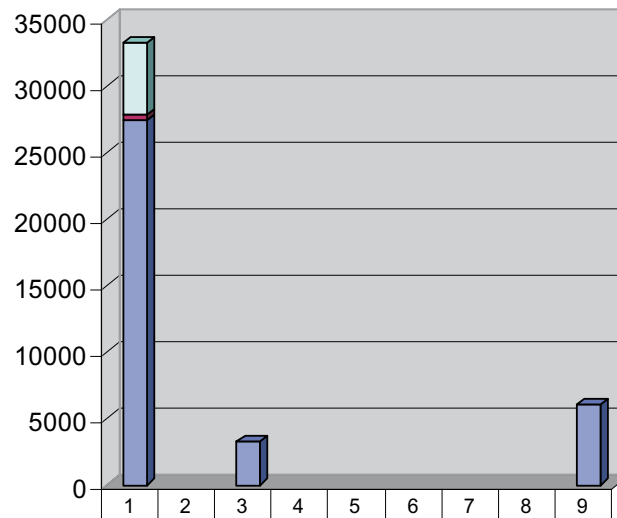
The following graphs for each purpose show the numbers of animals used against the category of procedure (Categories 1 to 9).



Refer to following page for a further breakdown of Laboratory Mammals and Stock Species.

Purpose: Stock Breeding

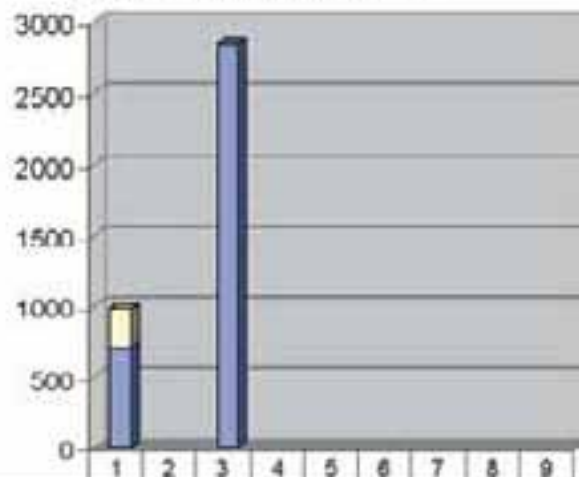
Breakdown of Laboratory Mammals Species



Other									
Ferret									
Hamster									
Rabbit	5400								
Guinea Pig	5								
Rat	504								
Mouse	27391		3298						6024

Purpose: Stock Breeding

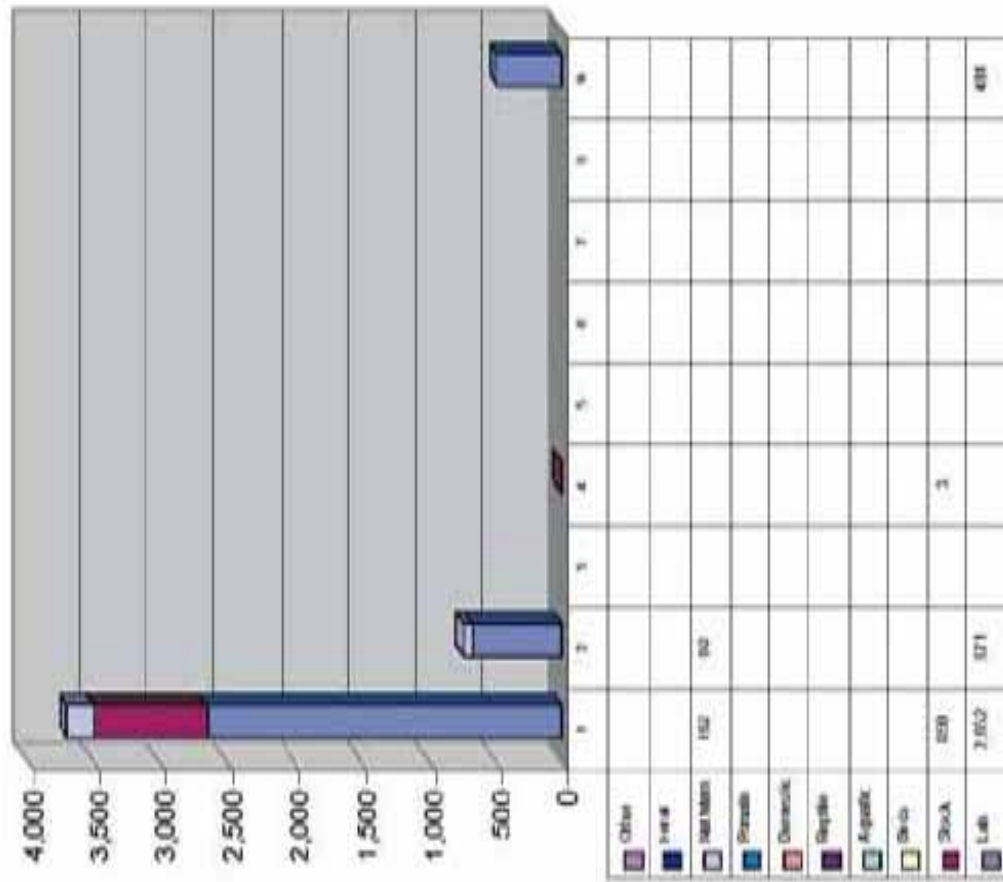
Breakdown of Stock Species



Other									
Deer									
Dom. Poultry									
Goats									
Horses									
Pigs	284								
Cattle									
Sheep	706		2850						

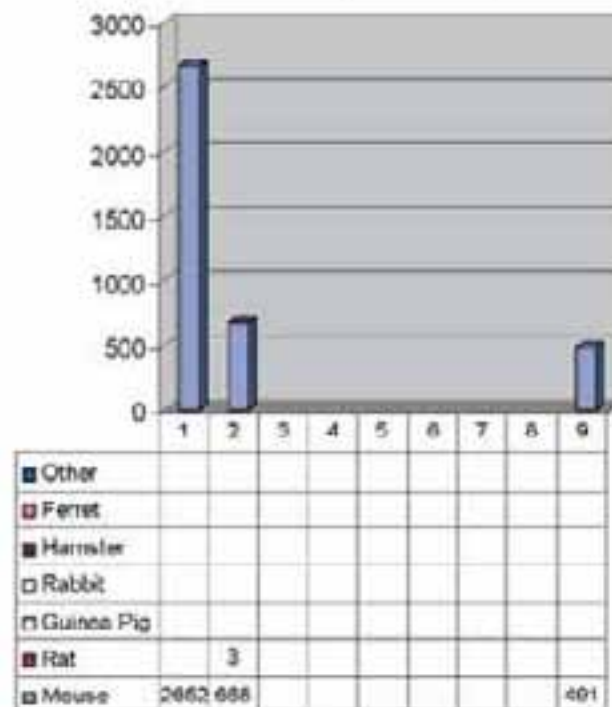
Purpose: Stock Maintenance

Holding Protocols for animals maintained for use in other protocols

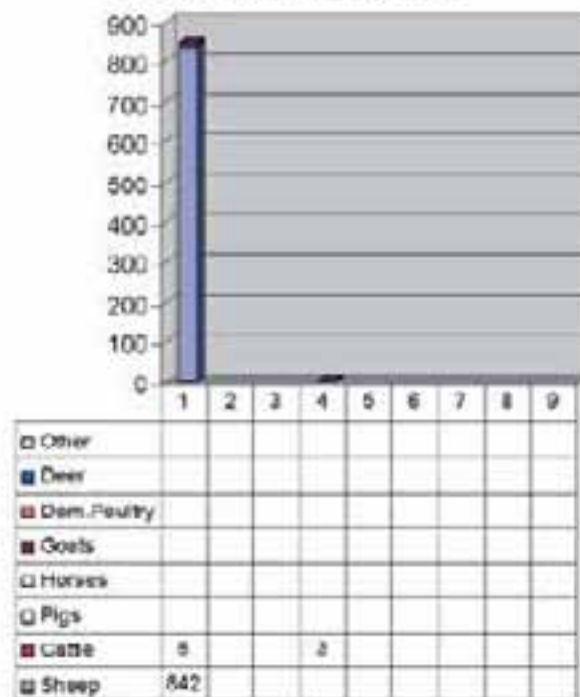


Refer to following page for a further breakdown of Laboratory Mammals and Stock Species.

Purpose: Stock Maintenance
Breakdown of Laboratory Mammals Species

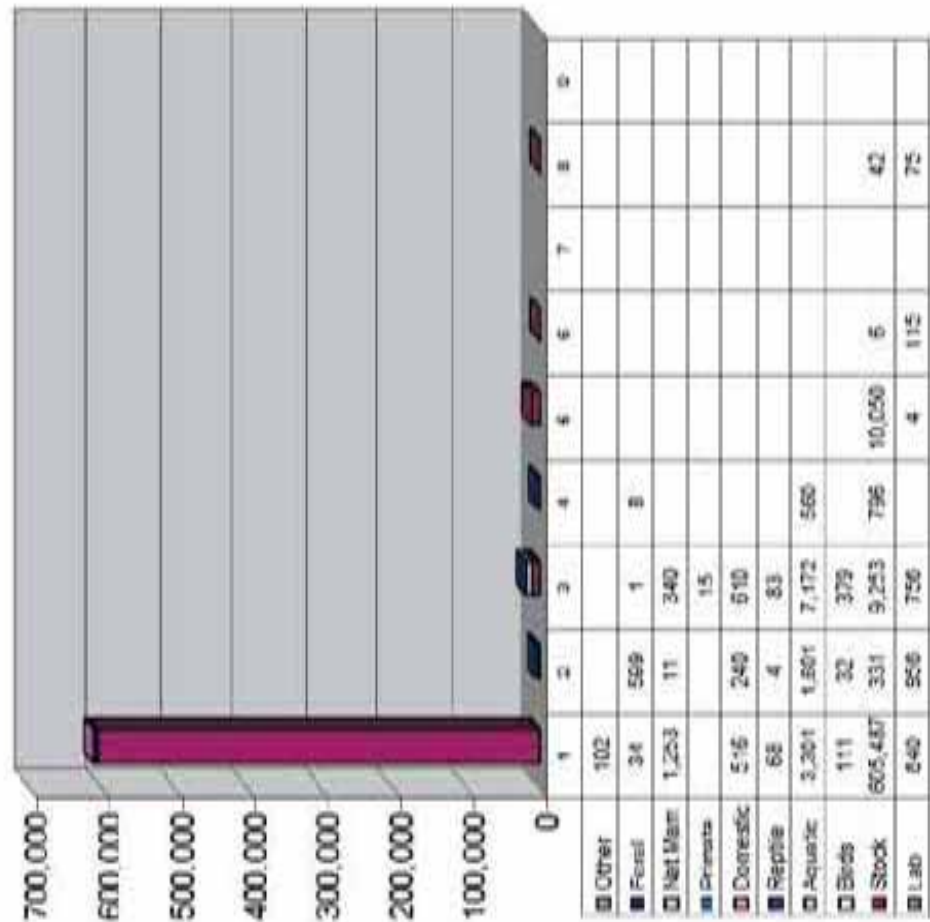


Purpose: Stock Maintenance
Breakdown of Stock Species



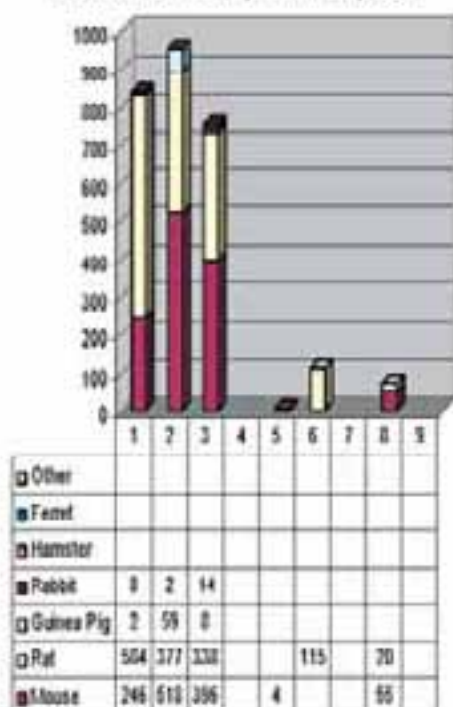
Purpose: Education

Protocols carried out for the achievement of educational objectives, including interactive or demonstration classes in methods of animal husbandry, management, examination and treatment



Refer to following page for a further breakdown of Laboratory Mammals, Stock, and Domestic and Primate Species.

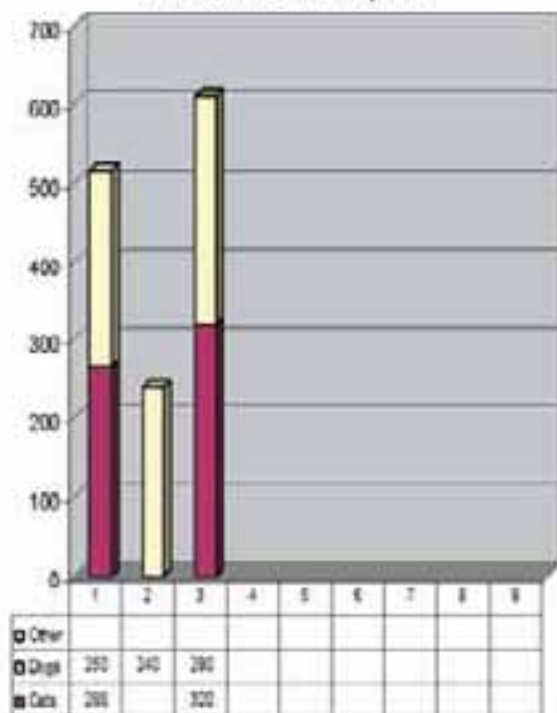
Purpose: Education
Breakdown of Laboratory Mammals Species



Purpose: Education
Breakdown of Stock Species



Purpose: Education
Breakdown of Domestic Species

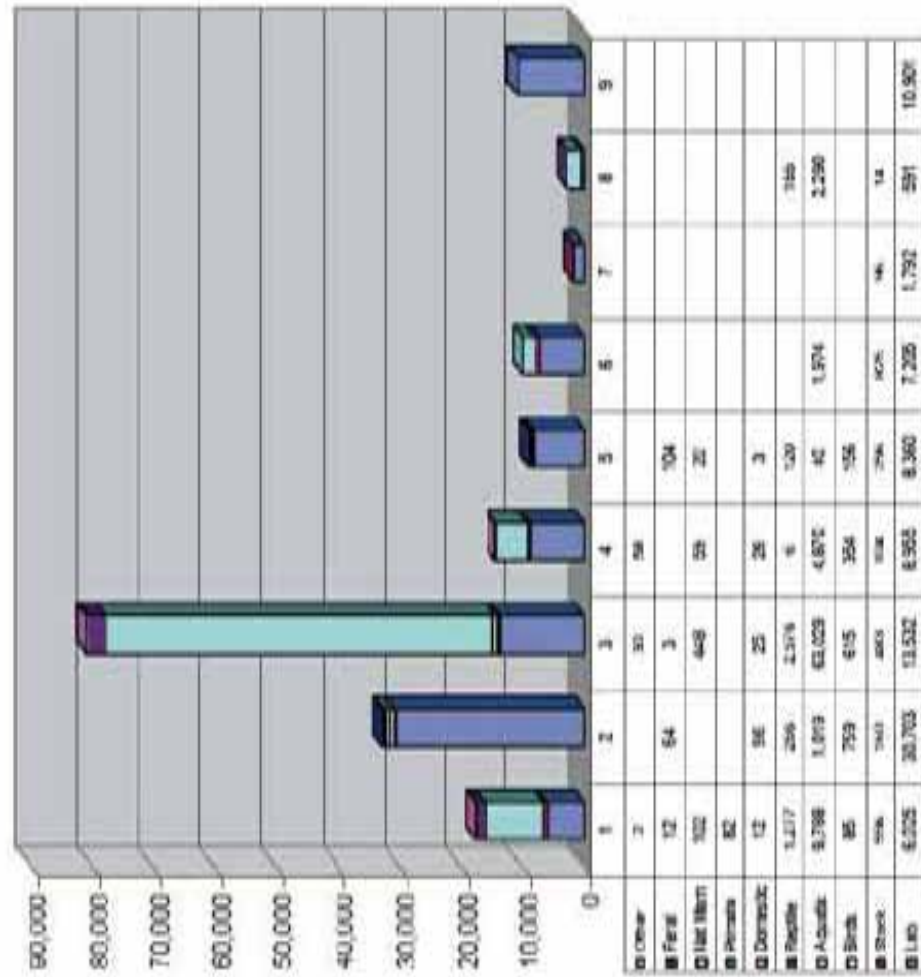


Purpose: Education
Breakdown of Primate Species



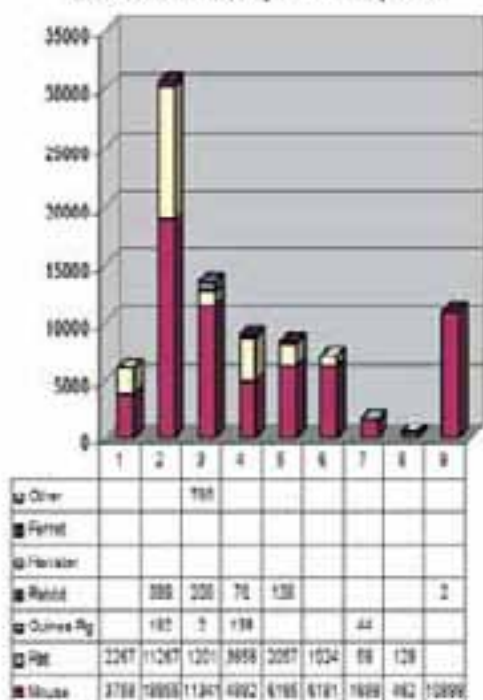
Purpose: Research - Human or Animal Biology

Research protocols which aim to increase the basic understanding of the structure, function and behaviour of animals, including humans, and processes involved in physiology, biochemistry and pathology.

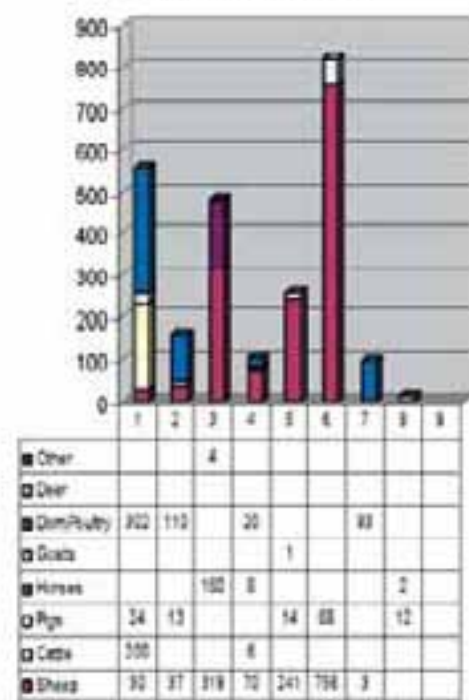


Refer to following page for a further breakdown of Laboratory Mammals, Stock, and Domestic and Primate Species.

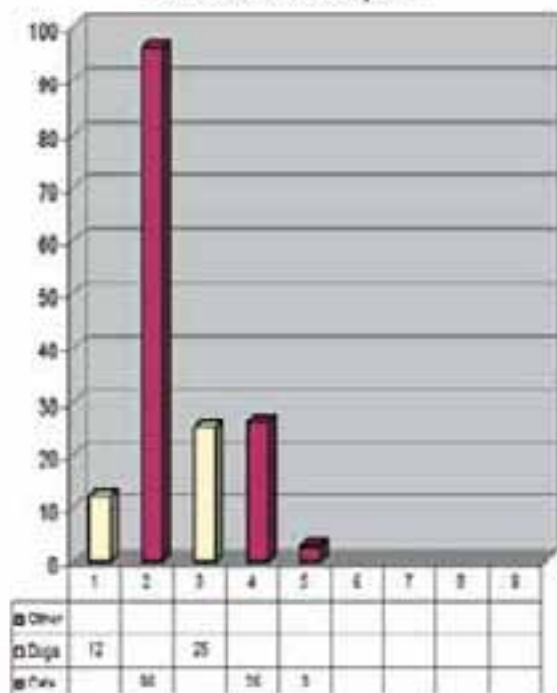
Purpose: Research - Human or Animal Biology
Breakdown of Laboratory Mammals Species



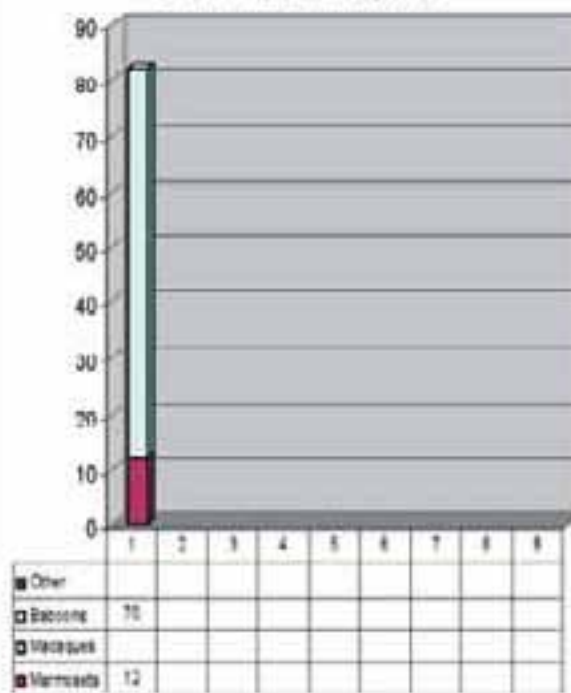
Purpose: Research - Human or Animal Biology
Breakdown of Stock Species



Purpose: Research - Human or Animal Biology
Breakdown of Domestic Species

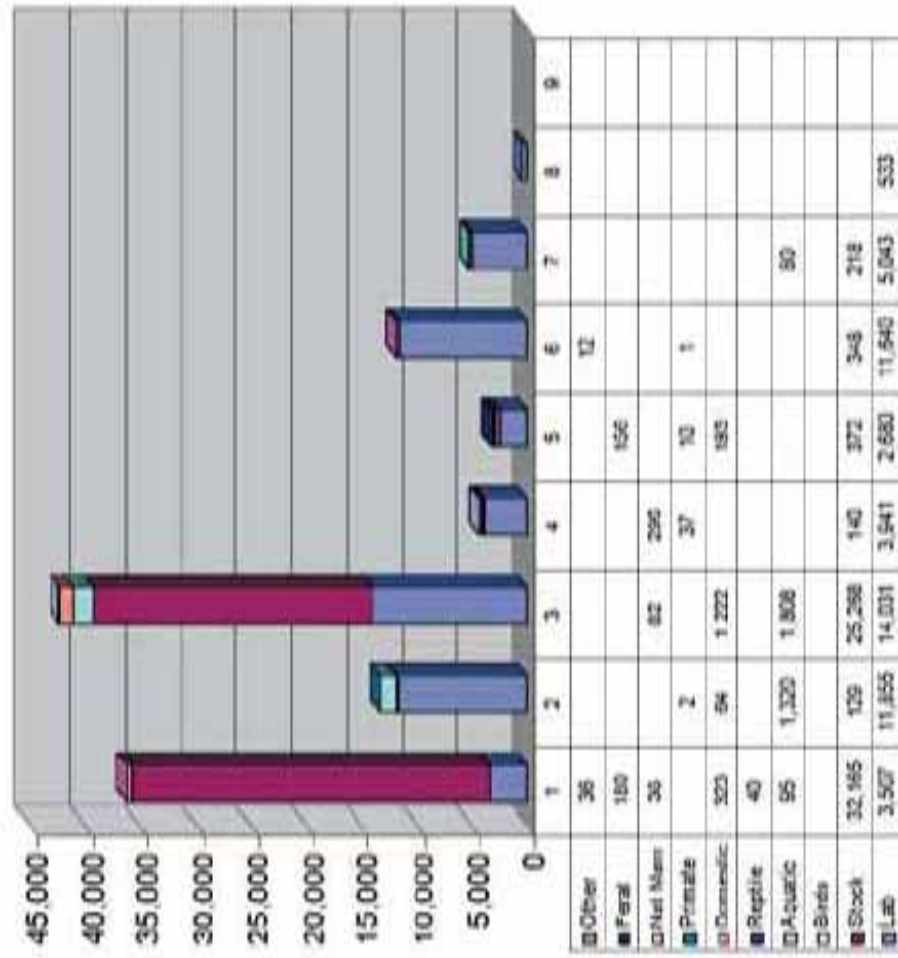


Purpose: Research - Human or Animal Biology
Breakdown of Primate Species



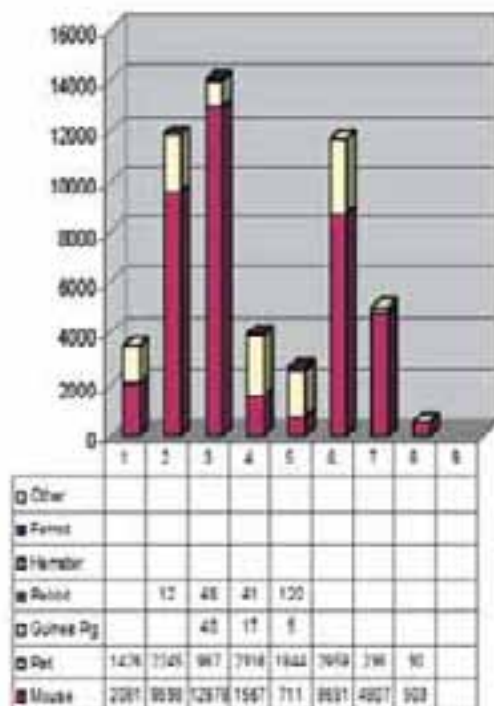
Purpose: Research - Human or Animal Health & Welfare

Research Protocols which aim to produce improvements in the health and welfare of animals, including humans

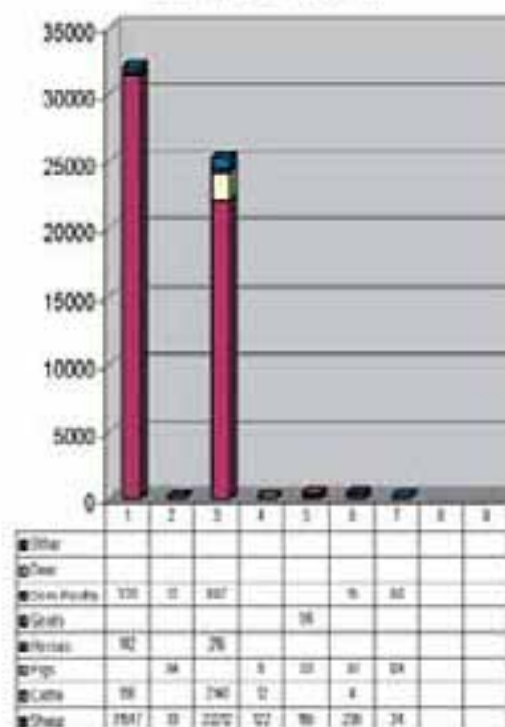


Refer to following page for a further breakdown of Laboratory Mammals, Stock, and Domestic and Primate Species.

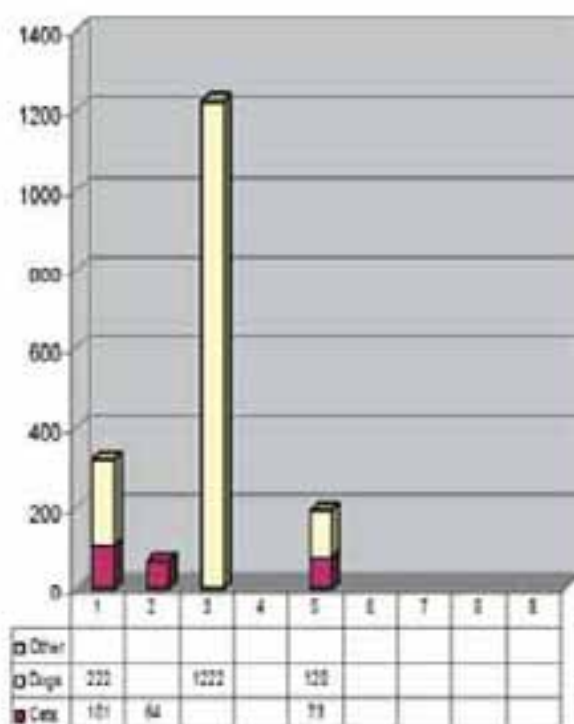
Purpose: Research - Human or Animal Health & Welfare
Breakdown of Laboratory Mammals Species



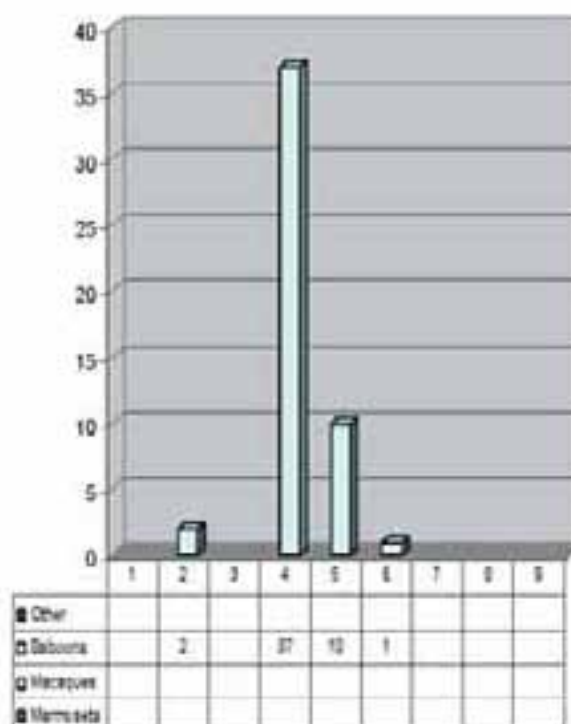
Purpose: Research - Human or Animal Health & Welfare
Breakdown of Stock Species



Purpose: Research - Human or Animal Health & Welfare
Breakdown of Domestic Species

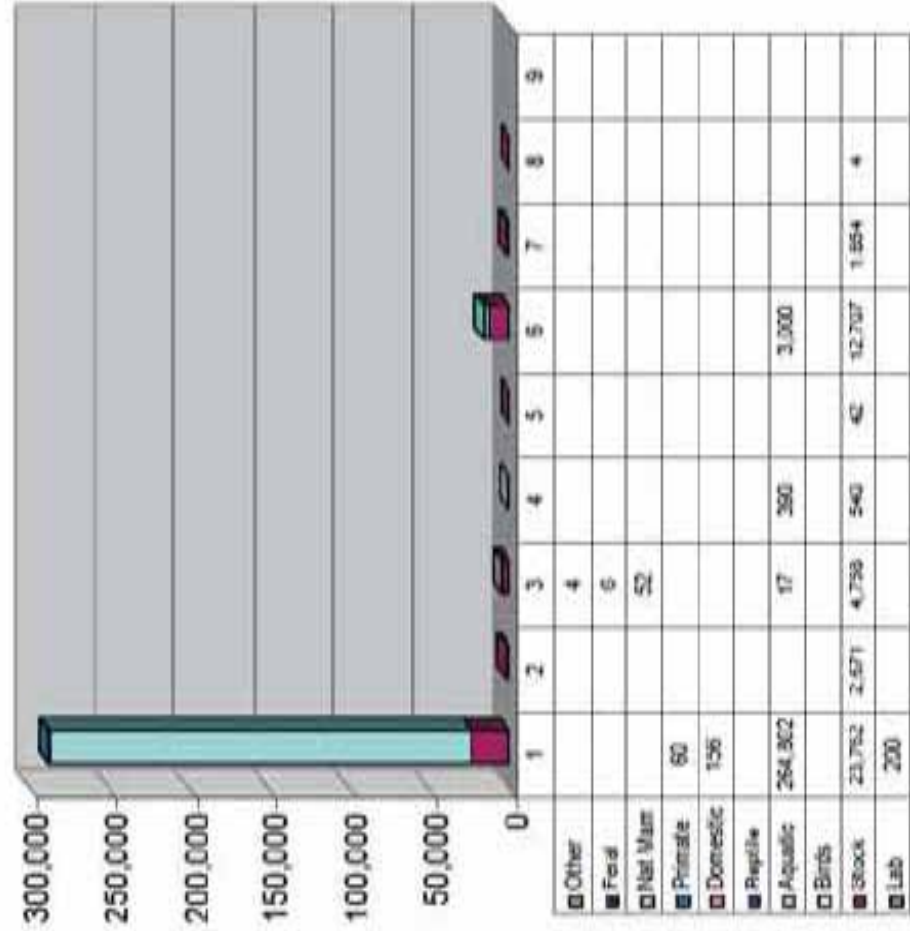


Purpose: Research - Human or Animal Health & Welfare
Breakdown of Primate Species



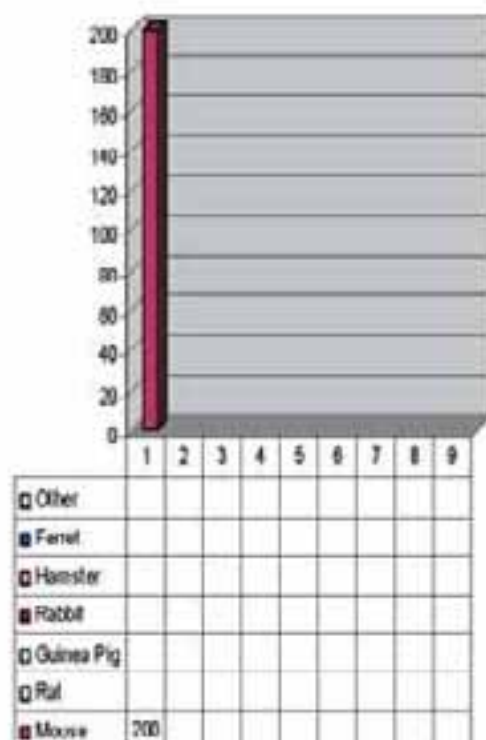
Purpose: Research - Animal Management or Production

Research protocols which aim to produce improvements in domestic or captive animal management or production

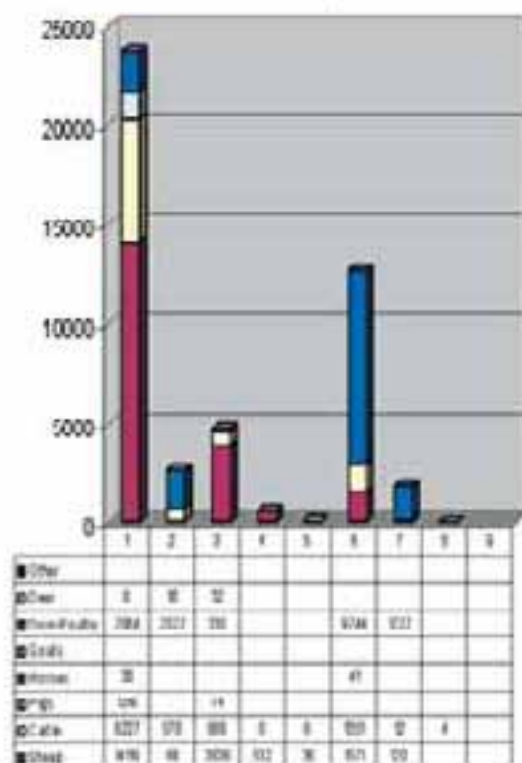


Refer to following page for a further breakdown of Laboratory Mammals, Stock, and Domestic and Primate Species.

Purpose: Research - Animal Management or Production
Breakdown of Laboratory Mammals Species



Purpose: Research - Animal Management or Production
Breakdown of Stock Species



Purpose: Research - Animal Management or Production
Breakdown of Domestic Species

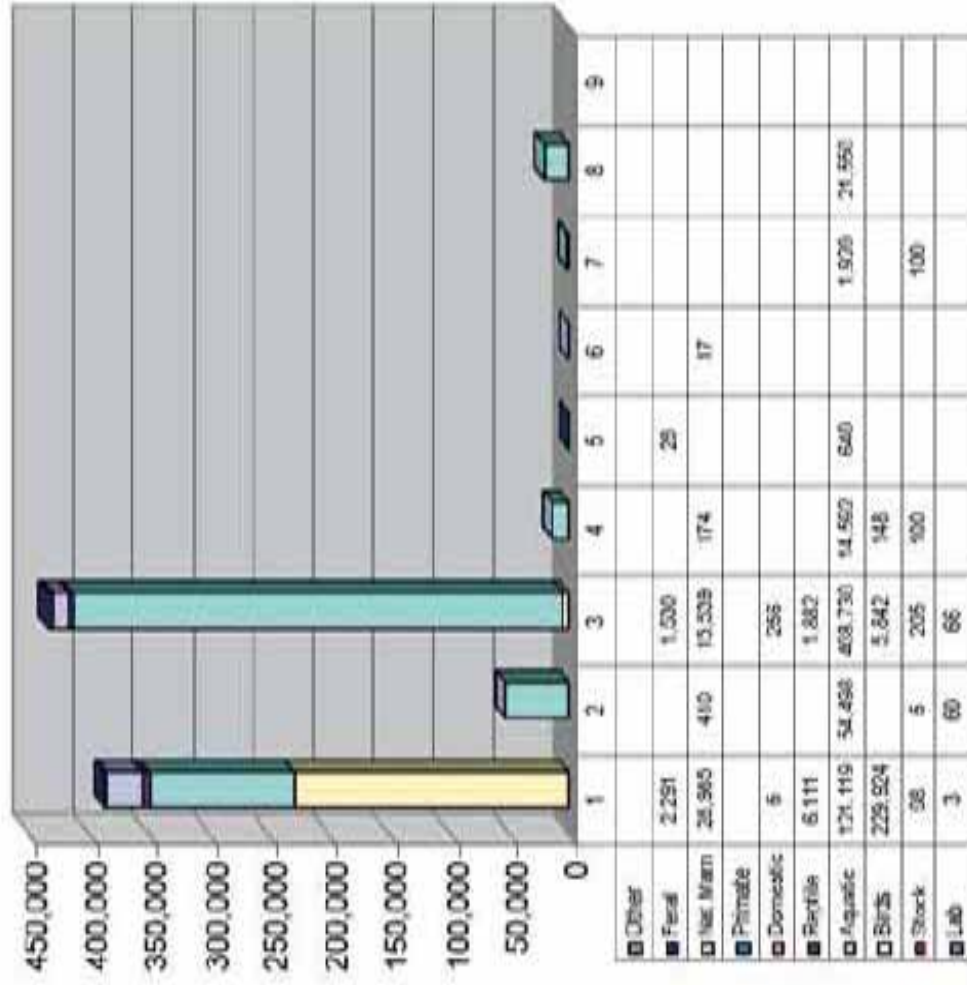


Purpose: Research - Animal Management or Production
Breakdown of Primate Species



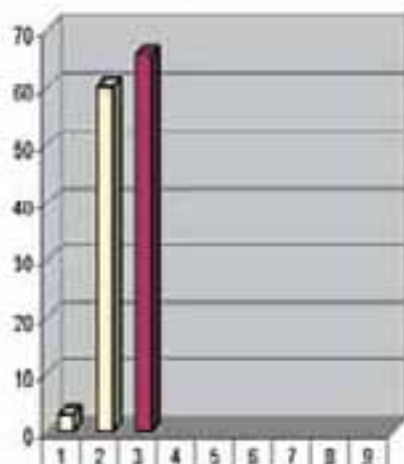
Purpose: Research - Environmental Studies

Research Protocols which aim to increase the understanding of the animals' environment or its role in it, or that aim to manage wild or feral populations



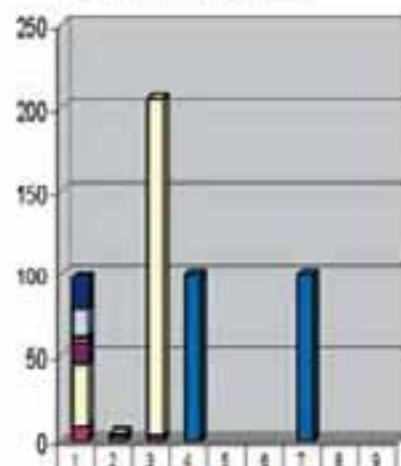
Refer to following page for a further breakdown of Laboratory Mammals, Stock and Domestic Species.

Purpose: Research - Environmental Study
Breakdown of Laboratory Mammals Species



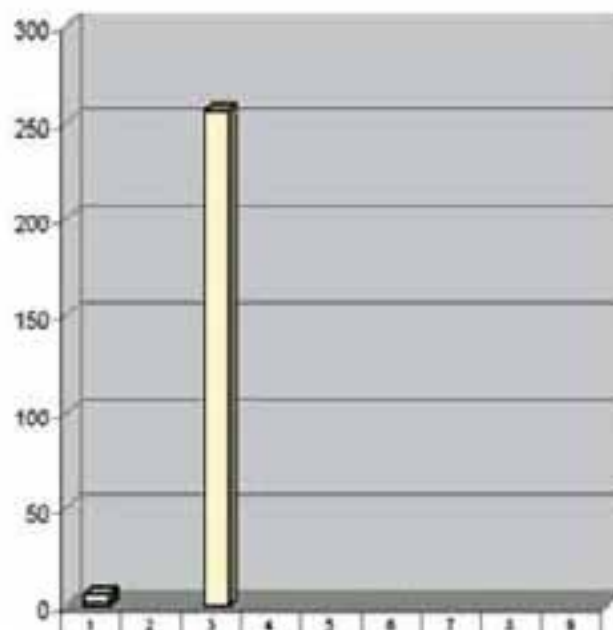
Other									
Ferret									
Hamster									
Rabbit									
Guinea Pig									
Rat	3	60							
Mouse			68						

Purpose: Research - Environmental Study
Breakdown of Stock Species



Other	18								
Pigeon	15								
Dom. Poultry	2		100			100			
Goats	9								
Horses	10								
Pigs	2								
Cattle	27	2	202						
Sheep	9	9	9						

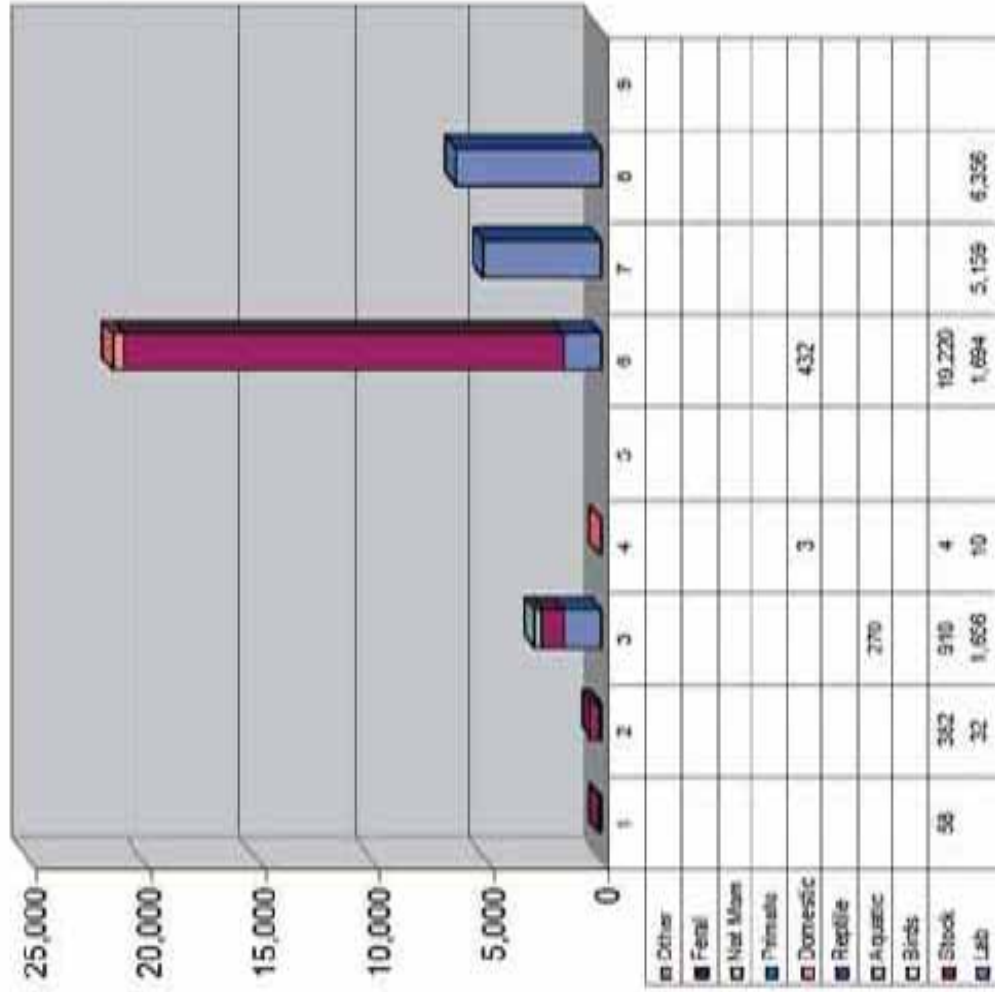
Purpose: Research - Environmental Study
Breakdown of Domestic Species



Other	3								
Dogs	2		254						
Cats									

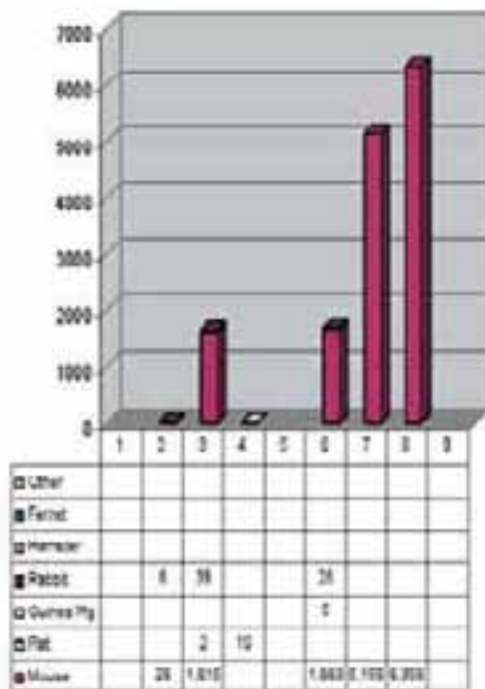
Purpose: Production of Biological Products

Use of animals to produce products (other than normal milk/meat/egg, etc)

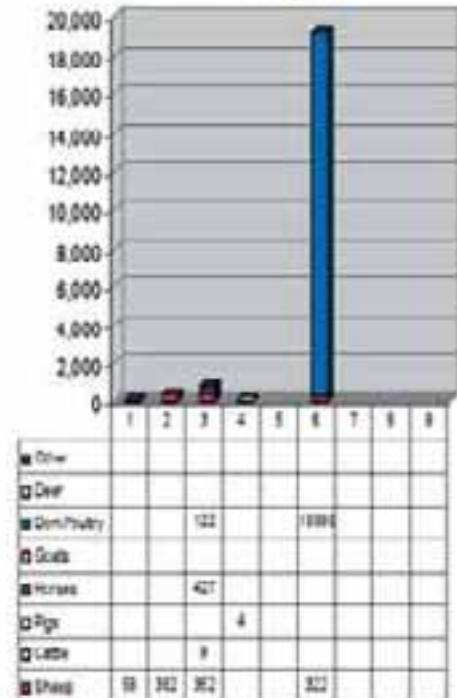


Refer to following page for a further breakdown of Laboratory Mammals, Stock and Domestic Species.

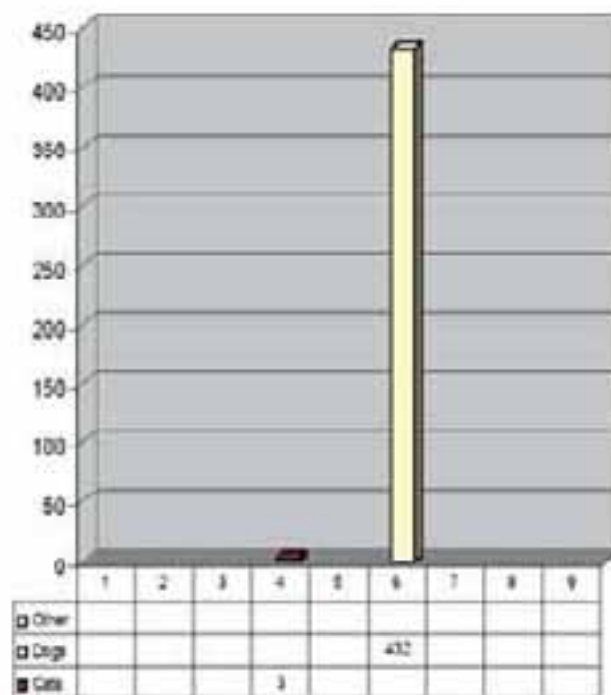
Purpose: Production of Biological Products
Breakdown of Laboratory Mammals Species



Purpose: Production of Biological Products
Breakdown of Stock Species

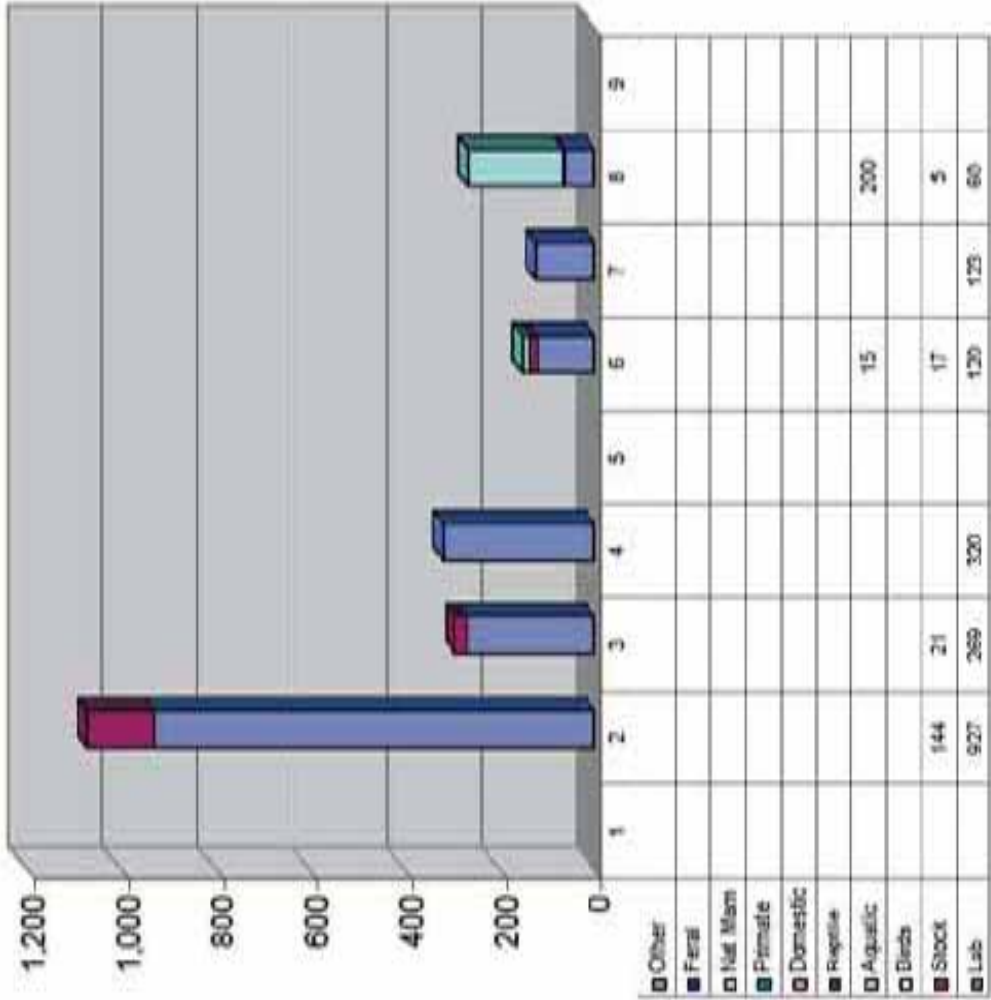


Purpose: Production of Biological Products
Breakdown of Domestic Species



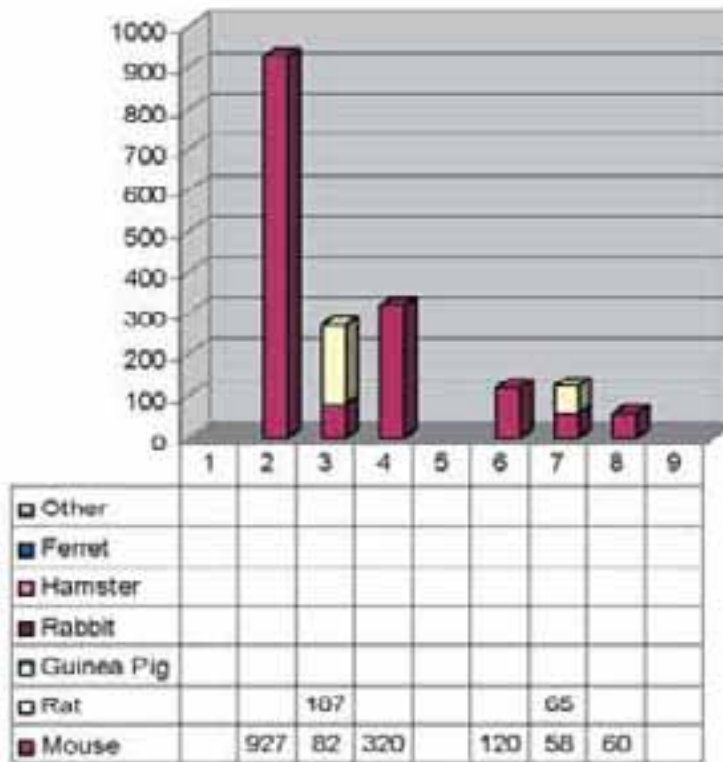
Purpose: Diagnostic Procedures

Using animals directly as part of a diagnostic process

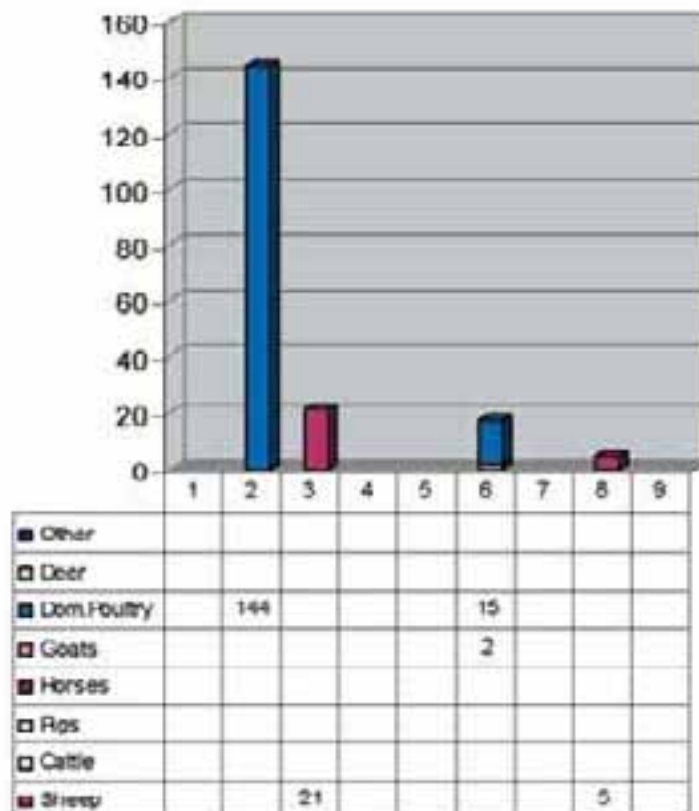


Refer to following page for a further breakdown of Laboratory Mammals and Stock Species.

Purpose: Diagnostic Procedures
Breakdown of Laboratory Mammals Species

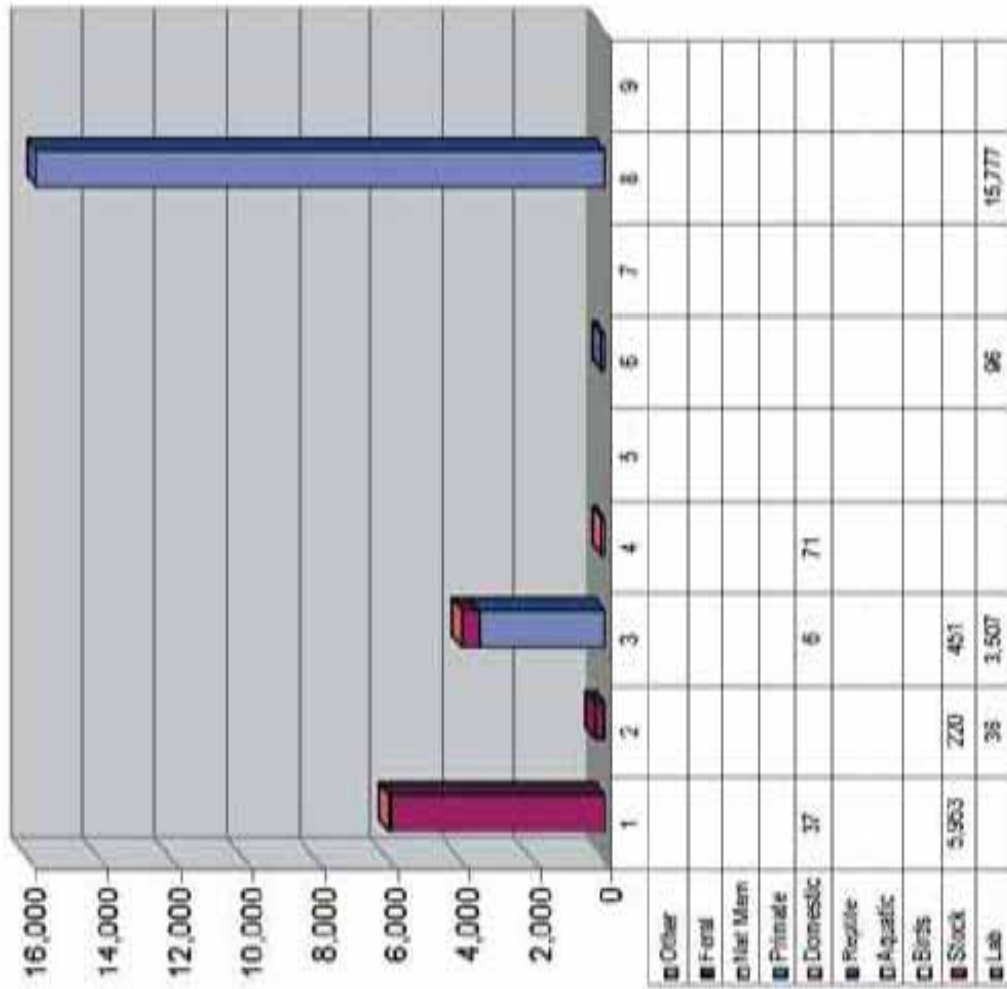


Purpose: Diagnostic Procedures
Breakdown of Stock Species



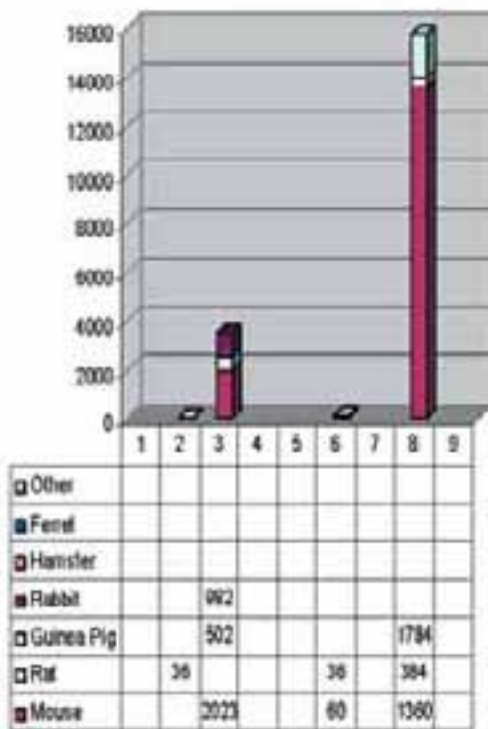
Purpose: Regulatory Product Testing

Protocols for the testing of products required by regulatory authorities

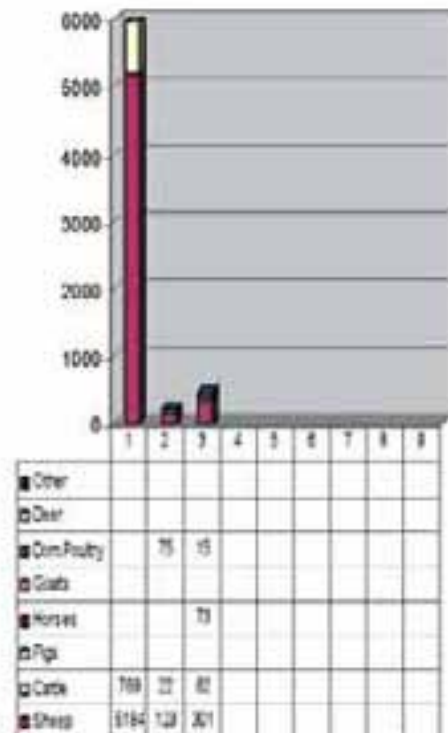


Refer to following page for a further breakdown of Laboratory Mammals, Stock and Domestic Species.

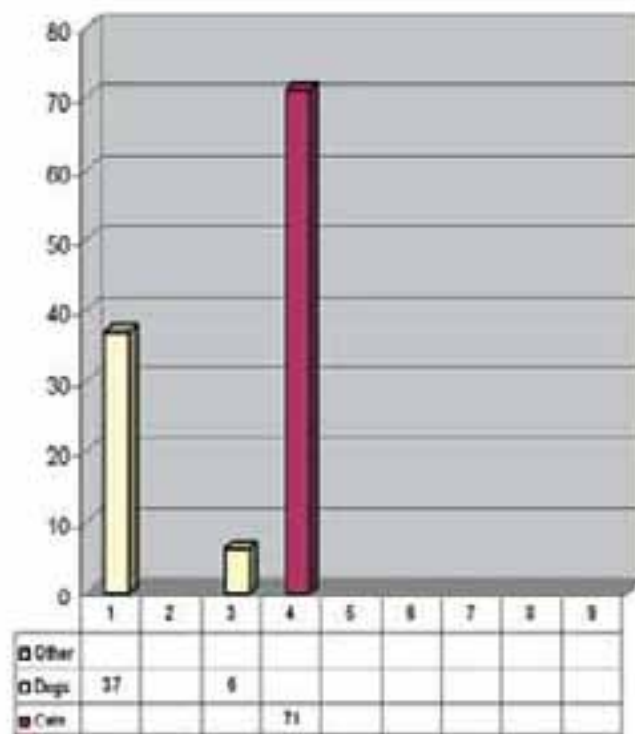
Purpose: Regulatory Product Testing
Breakdown of Laboratory Mammals Species



Purpose: Regulatory Product Testing
Breakdown of Stock Species



Purpose: Regulatory Product Testing
Breakdown of Domestic Species



Appendix H: Examples of methods used to implement the ‘3Rs’

The following are practical examples of strategies used to implement the ‘3Rs’ (Replacement, Reduction and Refinement in animal use). These examples have all been reported by accredited establishments. They are under the headings of ‘Replacement’ (of animals with other methods), ‘Reduction’ (in the number of animals used in specific protocols) and ‘Refinement’ (of techniques used to reduce the impact on animals).

Category	Comments
Replacement	<ul style="list-style-type: none"> Models or artificial animals are used wherever possible to reduce the number of live animals used, and also when a technique that is too stressful for a live animal is demonstrated. Videos and cadavers are also used. Development of in-vitro systems as an alternative to using animals. Education of committee members on available alternatives to the use of animals. Use of commercially available tissue cultures or antibodies in all or part of the study. Use of audio-visual material such as videos, slides, interactive computer programs. Use of plant tissue as a replacement for animal tissue for certain enzymatic assays. In-vitro monoclonal antibody production Potential development of a cellular model for functional studies in neurons. Development of an in-vitro potency assay for evaluation of vaccine batches; this is being tested alongside the in-vivo assay and may eventually replace the in-vivo assay. Extensive use of cell lines and in-vitro systems before use of animals.
Reduction in numbers	<ul style="list-style-type: none"> Hair and scat analysis has been improved and has led to a reduction in the need to trap during wildlife surveys. The techniques adopted have been more productive and less invasive than trapping. Reduction of number of specimens collected, by using photographs and feather samples (for DNA analysis) rather than collection of entire specimens. Majority of trials conducted according to Good Clinical Practice or Good Laboratory Practice guidelines to ensure quality of data and minimise number of animals required for trials. Full statistical assessment of projects to ensure adequate power in results and appropriate animal numbers to achieve this. Utilisation of blood samples previously collected as part of industry drug control program for the purpose of population survey of antibodies to a viral disease. Sharing of animal tissues between members of research groups and centres. Use of new analysis methods such that fewer animals are required as sources of tissues (e.g. numbers of ovaries from live animals necessary for RNA collection). Testing program reviewed, resulting in a reduction in overall testing requirement per unit of production output. Certain tests have been refined to reduce animal numbers used per test. Development of at least three models to reduce the total numbers of animals used in future research. Animal use minimised by careful scrutiny of numbers of animals requested, approval of new techniques for embryo freezing rather than continuous breeding to maintain lines, re-use of animals where appropriate after extended recovery interval, and making surplus tissue available through a tissue availability database and seeking prior agreement from investigators to make surplus tissue available. The committee has instigated the consolidation of breeding protocols to ensure there is no overbreeding; this in turn reduces the need for culling.

Refinement of techniques	<ul style="list-style-type: none"> • Use of gaseous anaesthesia for potentially painful procedures, rather than using simple restraint (e.g. for cell injection). • Use of adjuvants known not to produce adverse reactions. • A dog study that was designed so that dogs remained in their home environment to reduce stress. • Earlier endpoints of animal xenograft studies have been implemented. • Ongoing mentoring/training of animal-handling staff implemented to ensure their handling techniques remain current. • Additional enrichment of mouse environment, i.e. by using autoclaved cardboard tubing that is replaced at each weekly cage clean. • Monitoring improved. After the finding that mice in a study developed proteinuria at 6 to 8 months of age, their urine was checked once a week from 6 months of age. • Frequent monitoring implemented to ensure that if animals experience discomfort, the surgeon can act quickly to reverse the discomfort. • Continuation of program providing companions for animals. • Introduction of formal postoperative monitoring checklist with all protocols. • Trials of chocolate hazelnut spread and peanut butter to combat postoperative weight loss (short term). • Continuation of supply of cardboard toys and 'houses' in rat cages. • Increase in variety of forage foods in bedding. • Spontaneous collection of naturally voided urine from horses. • Application of new or modified analgesic protocols for surgery. • Increased awareness and use of environmental enrichment. • Use of the saphenous vein method as the standard technique for blood collection in rodents. • Use of monitoring checklists developed specifically for each project, and documented welfare intervention points and endpoints. • Requirement for the use of analgesia in all recovery surgical procedures. • Group housing of animals wherever possible, with separation of animals only when required and for the minimal period of time. • Refinement of surgical techniques to reduce the number of postoperative problems. • Refinement of anaesthetic regimes to methods that place less stress on the animals and lead to fewer mortalities and improved recovery. • Polyclonal antibody production: use of adjuvants that are less likely to result in granulomas, and use of chicken eggs whenever possible. • Use of low infection doses and short infection times. • Evaluation of equipment on humans before use on animals to allow elimination of potential pinch-points or protrusions, and choice of a material that optimised
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Appendix I: ARRP expenses

Note: The following figures do not include the time and costs incurred by individual ARRP members, and met at their own expense, for work such as maintenance of the Animal Ethics Infolink website, planning for the AEC members' meeting, and input into the development of guidelines. In addition, support for members provided by their employing establishments (e.g. salaries paid by government departments for their employees' time spent on ARRP business) is not included in the figures.

Fees and retainers	\$11,088
Travel and subsistence	\$8,241
Stores and printing	\$1,673
Freight and postage	\$1,151
TOTAL	\$22,153

Appendix J: Abbreviations

ACEB	Animal Care and Ethics Board
AEC	Animal Ethics Committee
APVMA	Australian Pesticides Veterinary Medicines Authority
ARRP	Animal Research Review Panel
ATLA	Alternatives to Laboratory Animals
AWAC	Animal Welfare Advisory Council
CSIRO	Commonwealth Scientific and Industrial Research Organisation
EAPA	<i>Exhibited Animals Protection Act 1986</i>
NHMRC	National Health and Medical Research Council
NPWS	National Parks and Wildlife Service
POCTAA	Prevention of Cruelty to Animals Act
RSPCA	Royal Society for the Prevention of Cruelty to Animals
SAEC	Schools Animal Ethics Committee
TAFE	Technical and Further Education
'3Rs'	Replacement, Reduction and Refinement in animal use

Appendix K: ARRP policies and guidelines

(Available from <http://www.animaethics.org.au>)

Policies

2. Payment of External Members of Animal Ethics Committees
3. Procedures Prohibited under POCTAA
4. Non-Research Animals on Designated Land
5. Accredited Establishment Policy on the Operations of Animal Ethics Committees and Annual Reporting
6. Differentiation Between Acts of Animal Research and Acts of Veterinary Treatment
7. Relationships Between Accredited Research Establishments and Licence Holders
8. Establishment of Protocols for Grievance Procedures
9. Criteria for Assessment of Animal Ethics Committee Membership
10. Emergency Procedures
11. Formal agreements between accredited research establishments sharing Animal Ethics Committees
12. Frequency of Animal Ethics Committee meetings
13. Inspections by Animal Ethics Committees
14. Acts of Veterinary Science and the Use of S4 and S8 Drugs
15. Orientation of New Members of Animal Ethics Committees
16. Conflict of Interest with Membership of Animal Ethics Committees
17. Training Personnel

Guidelines

1. Opportunistic Research on Free-Living Wildlife
2. Specific to Animal Ethics Committees Supervising Research on Captive Wildlife (additional to 1)
3. Individuals and Institutions Engaged in Collaborative Research
4. Animal Ethics Committees Considering the Use of Animals for Post-graduate Surgical Workshops
5. Collection of Voucher Specimens
6. Use of Pitfall Traps
7. The Use of Feral Animals in Research
8. Welfare Guidelines for Teaching Artificial Insemination and Pregnancy Testing in Cattle
9. Radio Tracking in Wildlife Research
10. Animal Care Guidelines for Wildlife Surveys
11. Guidelines for Tick Serum Producers
12. Animal Research Model Application Form
13. Guidelines for the Production of Monoclonal Antibodies
14. Guidelines for the Care and Housing of Dogs in Scientific Institutions
15. Blood Collection
16. Supervision of Animal Supply by Animal Ethics Committees
17. Training Personnel Involved in the Care and Use of Animals for Scientific Purposes
18. Guidelines for the Housing of Rabbits in Scientific Institutions
19. Teaching Cervical or Vaginal Artificial Insemination of Sheep
20. Guidelines for the Housing of Rats in Scientific Institutions

Appendix L: Animal Welfare Unit fact sheets

(Available from <http://www.agric.nsw.gov.au/Aw/index.html>)

- Fact Sheet 1: The *Animal Research Act 1985*
- Fact Sheet 2: Applying for accreditation as a animal research establishment
- Fact Sheet 3: Animal Ethics Committees (AECs)
- Fact Sheet 4: Application for accreditation as an Animal Research Establishment (Schools) Form D
- Fact Sheet 5: Animal Research Authorities
- Fact Sheet 6: Application—Animal Supplier's Licence (Form J)
- Fact Sheet 7: The Animal Research Review Panel
- Fact Sheet 8: The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes
- Fact Sheet 9: Inspections under the Animal Research Act
- Fact Sheet 10: Draize tests, LD50 tests and lethality tests requiring death as an endpoint
- Fact Sheet 11: Independent and welfare members of Animal Ethics Committees frequently asked questions
- Fact Sheet 12: Staff of the Animal Welfare Unit
- Fact Sheet 13: Publications available from the Animal Welfare Unit
- Fact Sheet 14: Animal Research Review Panel policy statements and guidelines
- Fact Sheet 15: Example of fauna emergency procedures for wildlife researchers
- Fact Sheet 16: Guidelines for minimum standards for keeping horses in urban areas
- Fact Sheet 17: Summary of amendments to the Animal Research Act made in 1997
- Fact Sheet 19: Summary of amendments to the Animal Research Act and Regulations made in 1999
- Fact Sheet 20: Protecting the welfare of horses competing in bush races in NSW
- Fact Sheet 21: Supply of dogs and cats for use in research

Appendix M: Standard conditions for accreditation and Animal Supply Licences

The following are standard conditions that are placed on establishments seeking accreditation as animal research establishments and licences as animal suppliers. Additional conditions are added on a case-by-case basis.

Accreditation

1.) That any site inspection is satisfactory.
2.) Details of changes to Animal Ethics Committee membership (including the qualifications of new members and the categories to which they are appointed) must be provided to the Director-General of NSW Department of Primary Industries within 30 days of membership changes. The revised composition of the AEC must meet the approval of the Director-General.
3. Rabbits should be housed in groups in pens. Rabbits may be housed in cages only with the express permission of the AEC on the basis of compelling evidence for the need to use such housing. Lack of space or facilities for pens should not be considered sufficient justification for the use of cages. Where rabbits are held in cages, these cages should be enriched by methods such as pair housing in double cages. (Australian Code of Practice for the Care and Use of Animals for Scientific Purposes Clause 4.4.22)

(For establishments housing rabbits)

4.) It is essential that the AEC members are provided with a copy of the inspection report of {date} and that the AEC is involved in the assessment of, and provision of responses to, the conditions, recommendations and observations contained in this report.

(Added after inspection)

5.) A response to conditions {xx} of the inspection report of {date} must be provided to the Director-General of NSW Department of Primary Industries by {date—within 2 months of inspection report being sent}.

(Added after inspection)

Animal Supply Licence

1.) That any site inspection is satisfactory.
2.) The documented procedures and methods of record keeping, as required under Clauses 4.5.7 and 4.5.8 of the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, must be submitted by the supply unit to the AEC for approval.
3.) To assist in monitoring the management of breeding colonies, the supply unit must provide regular reports to the AEC, for review, on the fertility, fecundity, morbidity and mortality of all breeding colonies. The frequency of such reports should be at least 6 monthly and more often if determined necessary by the AEC.
4.) To help ensure that overproduction is avoided, the supply unit must provide regular reports to the AEC, for review, on the number of animals culled and the reasons for these numbers. The frequency of such reports should be at least 6 monthly and more often if determined necessary by the AEC.
5.) Any breeding that involves animals that have been the subject of genetic modification (involving the introduction of foreign DNA into cells or whole animals) must comply with Clauses 3.3.54 to 3.3.57 of the Code of Practice for the Care and Use of Animals for Scientific Purposes.