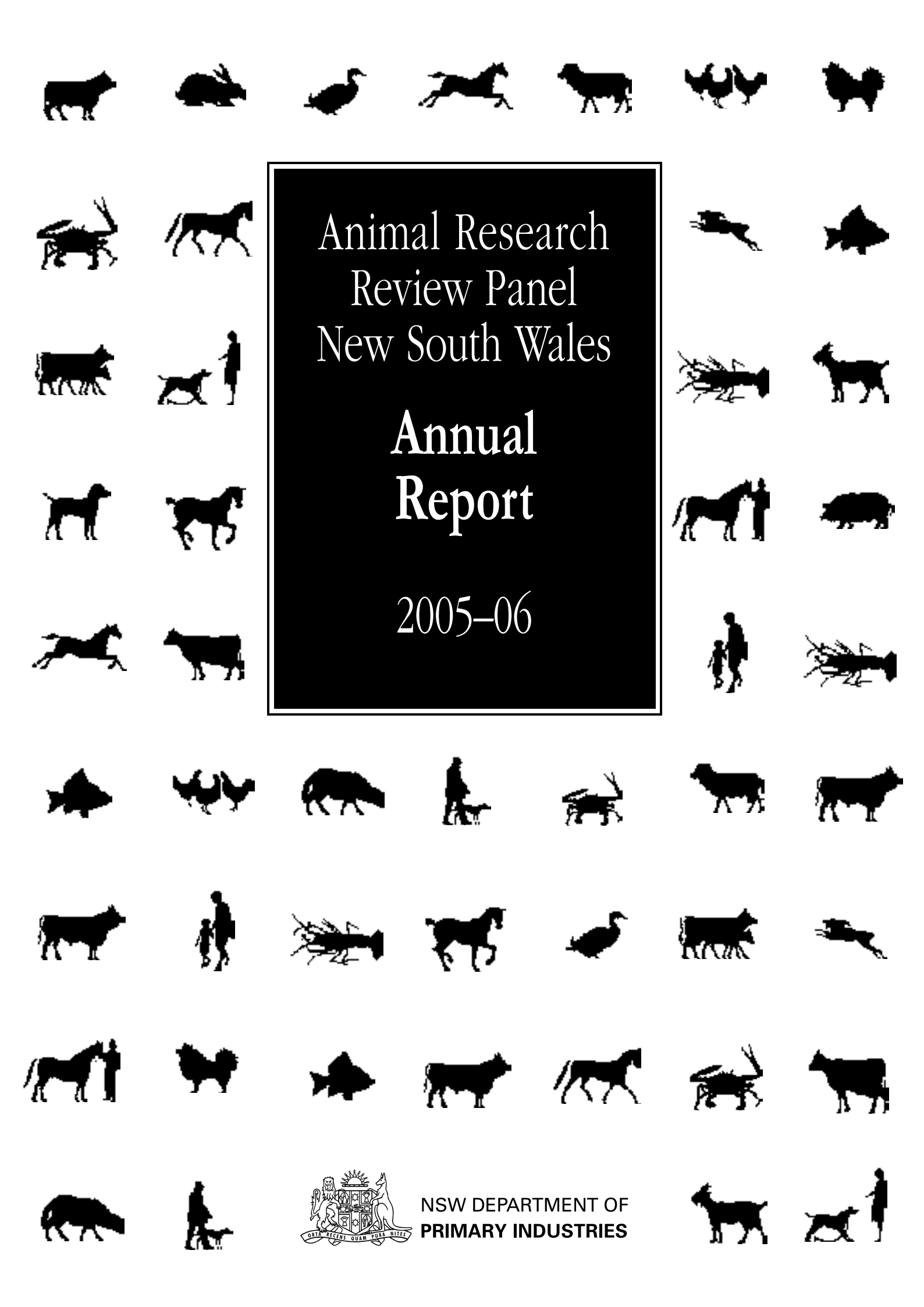

Animal Research Review Panel New South Wales

Annual Report

2005–06

NSW DEPARTMENT OF
PRIMARY INDUSTRIES

DISCLAIMERS

The information contained in this publication is based on knowledge and understanding at the time of writing (February 2007). However, because of advances in knowledge, users are reminded of the need to ensure that information upon which they rely is up to date and to check currency of the information with the appropriate officer of New South Wales Department of Primary Industries or the user's independent adviser.

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ISSN 0139-9402
Prepared by Lynette Chave
Edited by Ann Munroe
Orange, March 2007

NSW DEPARTMENT OF
PRIMARY INDUSTRIES

Animal Research Review Panel

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The Hon Ian Michael Macdonald, MLC
Minister for Natural Resources
Minister for Primary Industries
Minister for Mineral Resources
Level 33, Governor Macquarie Tower
1 Farrer Place
SYDNEY NSW 2000

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 2005 to 30 June 2006.

Yours sincerely

Margaret Rose

MARGARET ROSE
Chair
Animal Research Review Panel

CONTENTS

SUMMARY AND HIGHLIGHTS

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

Well socialised dogs approaching visitors for attention.

considering amendments to the Regulation. NSW Department of Primary Industries Animal Welfare Branch staff provide executive support for the ARRP.

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 2005–06 there were 103 accredited research establishments, 75 accredited schools and 24 holders of animal suppliers' licences.

Inspections

In the 2005–06 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 2005–06 year included holding a meeting for members of AECs and releasing for comment a draft evidence-based guideline on guinea pig housing. During the meeting for AEC members a number of interesting papers were presented, covering topics from genetic modification to the Australian Animal Welfare Strategy and a training package for AEC members. The release of the guinea pig 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, rabbits and rats 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 2005–06.

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 competition[1] 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.

As a result of the review the Regulation was remade with:

- 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.

A summary of the changes can be found at: http://www.animalethics.org.au.

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.

1 The Competition Principles Agreement requires that legislation should not restrict competition unless it can be demonstrated that the benefits to the community as a whole outweigh the costs, and that the objectives of the legislation can be achieved only by restricting competition.

Cats in an enclosure are provided with items, such as trays of grass, which are used for chewing, playing and resting.

The ARRP has had significant input into successive revisions of the Code.

The Chairman of the ARRP attended a meeting of the Code Liaison Group in May 2006 to discuss matters related to the most recent (7th) edition of the Code of Practice.

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.

During the 2005–06 period the membership of the ARRP was:

- 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) (resigned in December 2005)
- 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) (resigned January 2006)
- Mr Stephen Atkinson (nominated by Vice-Chancellors' Committee)
- Dr Philip Towers (nominated by Vice-Chancellors' Committee)

Information on members of the Animal Research Review Panel in 2005–06 is as follows:

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 that 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 and Illawarra Area Health Service and is a conjoint Professor at the University of New South Wales.

Dr Regina Fogarty (facing camera) in conversation during an inspection of a mouse room.

Dr Barry Lowe and Dr Philip Towers during an inspection of an accredited animal research establishment.

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

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 she seeks to apply her legal skills to improving 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 was an Executive Member of the TAFE NSW Animal Ethics Board.

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 for 6 months in 2003–04 as a veterinary consultant with the International Fund for Animal Welfare (IFAW) on projects in the South Pacific and South Korea. 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
- 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 worked for Elanco Animal Health for 34 years until his recent retirement. He currently holds an international position as Emeritus Director of Research and Development with Elanco Animal Health, the animal health division of Eli Lilly and Company. His fields of research are the external parasitology of farm and companion animals and the 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 30 years with the same company and has been Chairman of the Elanco Animal Ethics Committee for 10 years.

Dr Lowe was appointed to the ARRP in 2002 after being nominated by Medicines Australia Inc.

Mr David O'SHANNESSY, BSAgr. 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 was a nominee of the NSW Animal Societies Federation.

Mr David O'Shannessy inspecting a facility for dogs and cats.

Conjoint Associate Professor Romano (Ron) PIROLA, OAM, MBBS (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.

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 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 ARRP for assessment of AEC membership were clarified in an

Enriched housing for rats, including nesting material, a running wheel and a raised level. Rats can be seen resting in nesting material on the raised level.

ARRP policy document, *Policy 9: Criteria for the Assessment of Animal Ethics Committee Membership* (http://www.animalethics.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 ARRP 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 ARRP for consideration. The ARRP 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.

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

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

The recommendations of the ARRP 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 ARRP has appointed an applications subcommittee to facilitate the assessment of applications. New applications for accreditation or licences are assessed by ARRP executive staff, according to criteria developed by the ARRP. These applications and assessments are then referred to the applications subcommittee, which makes recommendations to the full ARRP. Recommendations on the applications are then made by the ARRP to the Director-General of NSW Department of Primary Industries.

A small number of applications are also viewed directly and considered by the full ARRP. These include applications from individuals or organisations about which the ARRP 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 ARRP executive staff, and the ARRP considers the recommendations arising from these assessments.

The criteria against which the ARRP 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 ARRP 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 2005–06 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 ARRP 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 initially looks at the animals and the facilities and talks with researchers. This examination includes assessing a broad range of items such as the physical condition of animals, animal care and management, and records related to the animals held. After examining animals and facilities, the inspection 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 ARRP 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 ARRP may feel that additional conditions should be imposed. For example, a condition may be that appropriate post-operative procedures must be implemented.

Rabbits that need to be confined on trial are kept in a small enclosure within an enriched pen that houses a familiar companion. This avoids the stress of isolation of a social animal.

In addition to conditions for accreditation or licence (which are mandatory and must be implemented), the ARRP 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 ARRP 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 ARRP 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 ARRP 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 2005–06 operational plan, the ARRP 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. Reinspections 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.

1.7 Administration

The Animal Welfare Branch 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 Branch 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 Branch cover:

- animal research issues under the *Animal Research Act 1985*, including providing executive services to the ARRP
- 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
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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

In the 2005–06 financial year the following staff were assigned to provide inspectorial and/or executive support to the ARRP.

Orange:
Ross Burton, BVSc, MVSc, Director, Animal Welfare
Amanda Paul, BVSc, MACVSc (Animal Welfare), Veterinary Officer (part-time)
Tammy Kirby, Clerical Officer / Acting Licensing Clerk

Sydney:
Lynette Chave, BVSc, Leader, Animal Research
Peter Johnson, BVSc, PhD, Veterinary Officer
Janelle Townsend, Clerical Officer (part-time)

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 ARRP's operational plan for 2005–06. The appendixes to this annual report contain details of many of the operational and strategic functions of the ARRP. These include the dates of, and attendance at, ARRP meetings (Appendixes A and B); dates and attendance of ARRP members at inspections of accredited research establishments and animal supply licence holders (Appendixes C and D); the ARRP Strategic Plan 2005–08 (Appendix E) and Operational Plan for 2005–06 (Appendix F); and ARRP operating expenses (Appendix I).

2.1.1 Strategic Plan 2005–08

During 2005 the ARRP revised its 3-year strategic plan. The plan identifies the primary goals of the ARRP and strategies for achieving these goals. In developing the plan the ARRP identified four priority areas:

- training of Animal Ethics Committee members
- promoting education of researchers and teachers
- ongoing review and maintenance of the ARRP website 'Animal Ethics Infolink' (http://www.animalethics.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 2005–06

The ARRP 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 ARRP 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 '2.6 Support for Animal Ethics Committees'.)

2.2 Assessment of applications

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

During 2005–06 the ARRP considered:

- nine new applications for accreditation
- 27 renewal applications for accreditation
- 12 new applications for school accreditation
- 19 renewal applications for school accreditation
- two new applications for animal suppliers' licences
- 22 renewal applications for animal suppliers' licences.

2.2.1 LD50 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% 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 concurrence of the Minister for Primary Industries. Applications for permission to conduct LD50 tests are evaluated by an ARRP subcommittee. Members of the subcommittee in 2005–06 were Dr Fogarty and Dr Lowe. The subcommittee makes recommendations to the ARRP, which in turn advises the Minister.

In 2005–06 the subcommittee considered one application from an Accredited Research Establishment. The testing was required as part of the registration process for biological agents. The ARRP recommended to the Minister that he approve the applications on the conditions that the organisation report to the ARRP on its progress in developing replacement in vitro tests, reducing

the numbers of animals used in testing, and refining the testing procedures, and that it provide annual statistics for the numbers of animals used in each test. (One ARRP member did not approve the recommendation because of fundamental objections to the use of animals for research.)

In making its recommendation for approval, the ARRP noted the significant progress made by the establishment in the areas of reduction and refinement. These included:

- the introduction of an earlier endpoint in a test, thus reducing the impacts on the animals
- progress with the development of a single strain of rabbit that would reduce the number of rabbits needed for testing
- improvement of the methods used to increase the yield of product per batch, thus reducing the number of animal tests required.

The ARRP 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 their replacement with non-animal alternatives.

2.3 Subcommittees

The ARRP appoints subcommittees to deal with particular issues. They explore issues in depth and have discussions with relevant members of the scientific and broader communities. Subcommittees provide reports and recommendations to the full ARRP for consideration. There are standing subcommittees that make recommendations on licensing, accreditation and LD50 testing. Membership of subcommittees is largely drawn from the ARRP. External members of subcommittees are occasionally co-opted on a voluntary basis. Activities of subcommittees in the 2005–06 year include:

- hosting of a meeting to be held in 2006 for members and executive officers of AECs (Associate Professor Rose, Mr Lawrie and Ms Abbott)
- hosting of a meeting to be held in 2007 for members and executive officers of AECs (Dr Baker, Dr Fogarty and Mr Atkinson)
- applications for accreditation and licences (Dr Lowe, Ms Abbott and Mr Lawrie)
- applications for LD50 testing (Dr Fogarty and Dr Lowe)
- meeting with the Australian Association for Humane Research and sponsored UK scientists (Dr Fogarty and Mr Lawrie).

2.4 Legislation

2.4.1 Review of the Animal Research Regulation

A review of the Animal Research Regulation 1995 was undertaken in 2005. This was because, under the Subordinate Legislation Act, it was due to be automatically repealed on 1 September 2005. The ARRP considered the Regulatory Impact Statement and provided a detailed submission on the review. (See Item 1.1 The *Animal Research Act 1985*).

A Maremma sheepdog is successfully used to guard sheep from predators at a teaching establishment.

2.5 Statistics on animal use

The Animal Research Regulation 2005 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. Aspects of the system 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 (giving an indication of the impact of procedures), combined with the recording of the purpose of the research.

The categories used are based on those planned to be used in a future national database. Figures are collected on a calendar year basis rather than by financial year.

Appendix G of this report summarises animal usage in 2005.

2.5.1 Lethality testing

Accredited research establishments must keep figures on lethality testing and submit these to the ARRP. 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'. Figures on lethality testing are included in Appendix G of this report.

2.6 Support for Animal Ethics Committees

The ARRP and the Animal Welfare Branch 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 ARRP 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 ARRP 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 is an example of ARRP activities related to support for AECs:

- Funding was obtained by the ARRP from the Department of Primary Industries to further the development of a training package for AEC members. A consultant with a background in education was engaged to develop the content and method of delivery of the course, the framework of which had already been created. Feedback from AECs was sought during the meeting held for members of AECs in April 2005. Subsequent to this, the consultant attended an ARRP meeting to obtain further input from the ARRP members. It is intended that a self-directed, web-based package will be developed.

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 ARRP has suggested the establishment of a register of AEC members interested in joining other AECs. The Animal Welfare Branch 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 April 2006 a meeting for members and Executive Officers of AECs was held by the ARRP in conjunction with the Animal Welfare Branch.

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

Tammar wallabies provided with structures for shelter and a solid fence lining as a sight screen to prevent their being startled.

wished to discuss and the format for conducting the meeting. Valuable feedback was provided, and a program was structured accordingly. The members of the ARRP subcommittee that worked on this project were Associate Professor Rose, Mr Lawrie and Ms Abbott.

Approximately 90 AEC members attended the meeting, kindly hosted by the Australian Catholic University at its MacKillop Campus. The format for the day was a mixture of presentations and audience interaction. The program included an overview of the Australian Animal Welfare Strategy as it relates to animals used in research, information on revision of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*, and an interactive session on the development of a training package for AEC members. A presentation was given on genetic modification and cloning in livestock and the implications for animal welfare. The afternoon interactive sessions centered around short talks from AEC members on hot topics of interest; these talks were designed to stimulate discussion amongst participants and allow the sharing of experiences between AEC members. The interactive sessions proved to be very popular.

The success of the day can be attributed to many factors, including the quality of the speakers who volunteered to present information on a variety of topics, and the attendance of members of AECs and their contributions to the discussions.

2.7 Website: Animal Ethics Infolink

Development and maintenance of a website by the ARRP ('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 Branch. The Animal Ethics Infolink site is accessible at www.animalethics.org.au.

2.8 Site inspections

A list of site inspections undertaken in 2005–06 is provided in Appendix C, and a list of ARRP 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 5 days for larger institutions. The inspections included AECs and the facilities of 27 accredited institutions/licensed animal suppliers and independent researchers.

The ARRP 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 ARRP 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 ARRP 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 ARRP's website www.animalethics.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 ARRP.

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 ARRP also has a policy of actively reviewing older guidelines and policies to ensure they are up to date.

As a measure of the importance of the documents being produced, an approach was made by the Canadian Council on Animal Care (CCAC) about the possibility of adopting for its own use ARRP Guideline 20: *Guidelines for the Housing of Rats in Scientific Institutions* for its own use. In addition, the CCAC suggested the possibility of collaboration in the development of further laboratory animal housing guidelines. The CCAC is the organisation responsible for setting and maintaining standards for the care of animals in research, teaching and testing throughout Canada. It is internationally respected as a leader in the area of the care and management of animals used in research and the ARRP has been pleased to co-operate with the CCAC in these endeavours.

The following guideline was developed in 2005–06:

- *Draft ARRP Guideline 21: Guidelines for the Housing of Guinea Pigs in Scientific Institutions.* The drafting of an extensive guideline on guinea pig 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 guinea pig 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

Sheep held in an indoor–outdoor facility for external parasite trials.

Housing for a stripe-faced Dunnart includes paper to create a hiding place.

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 ARRP. 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 ARRP for investigation. The ARRP 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 formal complaints received in the 2005–06 reporting period.

The ARRP 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; ARRP 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 ARRP, or the Animal Welfare Unit. Two informal complaints were received in the 2005–06 reporting period, both of which were satisfactorily resolved.

2.12 World Congress on Alternatives

Professor Rose attended the World Congress on Alternatives in Berlin in August 2005 (personally funded). She submitted two papers and two posters on behalf of the ARRP and the Animal Welfare Branch. The first paper looked at the development and implementation of public policies on the use of animals in research and teaching, with a focus on the development and implementation of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*. The second paper dealt with achieving the '3Rs' in the manufacture and testing of veterinary vaccines. The posters provided information on the development of the ARRP's evidence-based guidelines for the housing of laboratory animals and on the Animal Ethics Infolink website.

Subsequent to the conference, Professor Rose also attended, by invitation, a workshop on the international harmonisation of guidelines on the care, housing and use of animals used for scientific purposes. It was noted at this workshop that the ARRP's evidence-based guidelines on the housing of laboratory animals were of international standing.

2.13 Comments on documents

The ARRP provided comments on documents received for review as follows:

OGTR (Office of the Gene Technology Regulator):

Draft National Framework for the Development of Ethical Principles in Gene Technology

NHMRC:

Draft Guidelines on the Creation, Breeding, Care and Use of Genetically Modified and Cloned Animals for Scientific Purposes

NHMRC:

Draft Guidelines on Minimising Pain, Distress and Suffering in Animals in Research

NHMRC:

Draft Non-Compliance Flow Chart

NSW DPI (Department of Primary Industries):

Emergency Management Planning for Animal Holding Establishments

APPENDIXES

Appendix A: Dates of ARRP meetings 2005–06

Meeting number	Date of meeting
159	6 July 2005
160	24 August 2005
161	12 October 2005
162	14 December 2005
163	15 February 2006
164	22 March 2006
165	10 May 2006

Appendix B: Members' attendances at ARRP meetings 2005–06

	Meeting number						
Member	**159**	**160**	**161**	**162**	**163**	**164**	**165**
A/Professor M Rose (Chair)	*	A	*	*	*	*	*
Dr R Fogarty (Deputy Chair)	*	*	A	*	*	*	*
Ms S Abbott	*	A	*	*	A	*	*
Mr S Atkinson	*	*	*	*	*	*	*
Dr J Baker	A	*	A	*	*	*	*
Ms J Buckley	A	A	A	A	–	–	–
Mr M Lawrie	A	*	*	*	*	*	*
Dr B Lowe	*	*	*	*	*	*	A
Mr D O'Shannessy	*	*	*	*	*	*	A
Ms S O'Sullivan	*	*	*	*	–	–	–
A/Professor R Pirola	*	*	*	*	*	*	A
Dr P Towers	*	*	*	*	*	*	*

* = Present
A = Absent
– = Not applicable

Appendix C: Inspections July 2005 – June 2006

Establishment	Date
Australian Sciences	14/2/2005
NSW DPI, Orange	25/2/2005
Shore School	31/3/05
	8/4/05
ICP Firefly (facilities)	28/4/2005
University of Wollongong	22/6/2005
	23/6/2005
Hamilton Paul	2/5/2005
UTS, Kuring-gai	19/5/2005
CSIRO, Armidale	20/7/2005
	21/7/2005
Chemicon	20/7/2005
The Cicerone Project	21/7/2005
Tecra	22/7/2005
Agrisearch (facilities)	16/8/2005
Serum Australis	4/8/2005
NSW DPI, Wagga Wagga	30/8/2005
UTS	17/8/2005
North Shore Hospital	18/8/2005
University of NSW	17/10/2005
	18/10/2005
	19/10/2005
	20/10/2005
	4/11/2005
South Eastern Sydney Area Health Service	19/11/2005
Bioquiv	30/1/2006
College of Equine Dentistry Australia	7/2/2006
Cobbett	20/2/2006
Vision CRC	2/3/2006
Armidale Dumaresq Council	13/3/2006
Sydney West Area Health Service (Springer Spaniels)	28/3/2006
Children's Hospital Westmead (new facility)	28/3/2006
Northern Serums (Ross Sillar)	29/3/2006
Warne and Webster Serum	29/3/2006
Keith Curtin	30/3/2006
David Jones (independent)	30/3/2006
Novogen	14/6/2006
Charles Sturt University	20/6/2006
	12/7/2006
Liverpool Hospital (SSWAHS)	23/6/2006
Garvan	28/6/2006

Appendix D: Attendance of ARRP members at site inspections 2005–06

Member	Number of days spent on site inspection
A/Professor M Rose	1
Ms S Abbott	0
Mr S Atkinson	0
Dr J Baker	0
Ms J Buckley	0
Dr R Fogarty	7
Mr M Lawrie	2
Dr B Lowe	2
Mr D O’Shannessy	1
Ms S O’Sullivan	6
A/Professor R Pirola	0
Dr P Towers	7

Appendix E: NSW Animal Research Review Panel Strategic Plan July 2005 – June 2008

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 ARRP 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 2005 – June 2006

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	Two 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 2004–05	Report submitted to Minister	December 2005	Report prepared.
1.5	Prepare statistics on animal use for 2004	Statistics collated	December 2005	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	27
		Number of days inspections were conducted		26
		Total number of establishments not inspected within the last 4 years		4 (establishments that were in NSW, active and with their own AEC)
2.2	Inspect new establishments applying for accreditation before or within 2 months of accreditation	Number of new establishments inspected	Ongoing	N/A (No new establishments that were in NSW, active and with their own AEC)
		Number of new establishments not inspected		N/A (No new establishments that were in NSW, active and with their own AEC)
2.3	Conduct site visits of selected independent researchers with animal-holding facilities	Number visited	Ongoing	2
2.4	Review and send inspection reports	Reports sent	Within 3 months of inspection	Reports sent
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’ section of ARRP agendas.
2.6	Review inspection procedures, including consideration of annual reporting by establishments	Review commenced	September 2005	Review commenced.

Activity		Measure of performance	Time frame	Status
2.7	Assess means to conduct a general review of the operation of AECs	Assessment carried out	December 2005	Assessment not carried out.
3.	**Education**			
3.1	Maintain ARRP website	Site maintained	Ongoing	Website maintained.
3.2	Develop learning guide to accompany AEC learning package	Investigate funding sources	December 2005	Funding located. Development of learning guide in progress.
3.3	Meeting for members of AECs	Meeting held	December 2005	Meeting held April 2006.
3.4	Hold meeting on revised Code of Practice	Meeting held	December 2005	Meeting held with AEC members meeting.
3.5	Assess means to facilitate access to education programs by researchers and teachers	Assessment carried out	June 2006	Assessment not carried out.
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	September 2005	Comments collated.
		Draft of mouse document edited	December 2005	Draft not edited.
		Draft of guinea pig document presented to ARRP	December 2005	Draft presented to ARRP. Draft published for comment.
		Draft of sheep document progressed	December 2005	References assessment in progress.
4.2	Develop policies/guidelines where strong need identified (maximum of two)	Developed as need identified	Ongoing	1
4.8	Revise current policies and guidelines	Policies and guidelines revised	December 2005	0
5.	**Legislation**			
5.1	Assess results of revised statistics package	Results assessed	December 2005	Results considered.
5.2	Assess lethality statistics for publication	Statistics assessed	Low priority	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.
7.	**Additional**			
7.1	Continue liaison with NHMRC	Meeting held	Ongoing	Liaison via comments on publications ; Code Liaison Group meeting attended.
7.2	Continue liaison with (APVMA)	Contact with APVMA maintained	Ongoing	Correspondence with APVMA.

Appendix G: Animal use statistics 2005

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 the category of **procedure** (1–9; see overleaf). 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 (e.g. those used to teach animal-handling techniques) are used in a number of projects. 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 the collection of statistics on the 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.

Statistics are also given on the lethality testing performed in 2005.

Animal species categories used for collection of data

Laboratory mammals	Mouse
	Rat
	Guinea pig
	Rabbit
	Hamster
	Ferret
	Other
Stock animals	Sheep
	Cattle
	Pigs
	Horses
	Goats
	Domestic poultry
	Deer
	Other
Birds	Exotic captive
	Exotic wild
	Native captive
	Native non-endemic
	Native wild
	Other
Aquatic animals	Fish
	Amphibians
	Other
Reptiles	Lizards
	Snakes
	Tortoises
	Other
Zoo animals	Zoo animals

Domestic animals	Cats
	Dogs
	Other
Primates	Marmosets
	Macaques
	Baboons
	Other
Native mammals	Macropods
	Possums, gliders
	Native rats, mice
	Dasyurids
	Wombats
	Koalas
	Monotremes
	Bandicoots
	Bats
	Other
Exotic feral animals	Camels
	Cats
	Cattle
	Goats
	Hares
	Horses
	Mice
	Pigs
	Rabbits
	Rats
	Dingoes/wild dogs
	Fox
	Other

Purpose

1. 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).

2. 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

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

3. Education

Protocols carried out for the achievement of educational objectives. The purpose of the protocol is not to acquire new knowledge but 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

4. 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.

5. Research: human or animal health and welfare

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

6. Research: animal management or production

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

7. 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

8. Production of biological products

Using animals to produce products other than e.g. milk, meat, eggs, leather or fur.

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

9. 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

10. Regulatory product testing

Protocols for the testing of products required by regulatory authorities, such as the APVMA. **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 Purpose category selected from above.** (This would normally be Purpose Category 8 in the case of QA testing.)

Examples:

Pre-registration efficacy or toxicity testing of drugs and vaccines

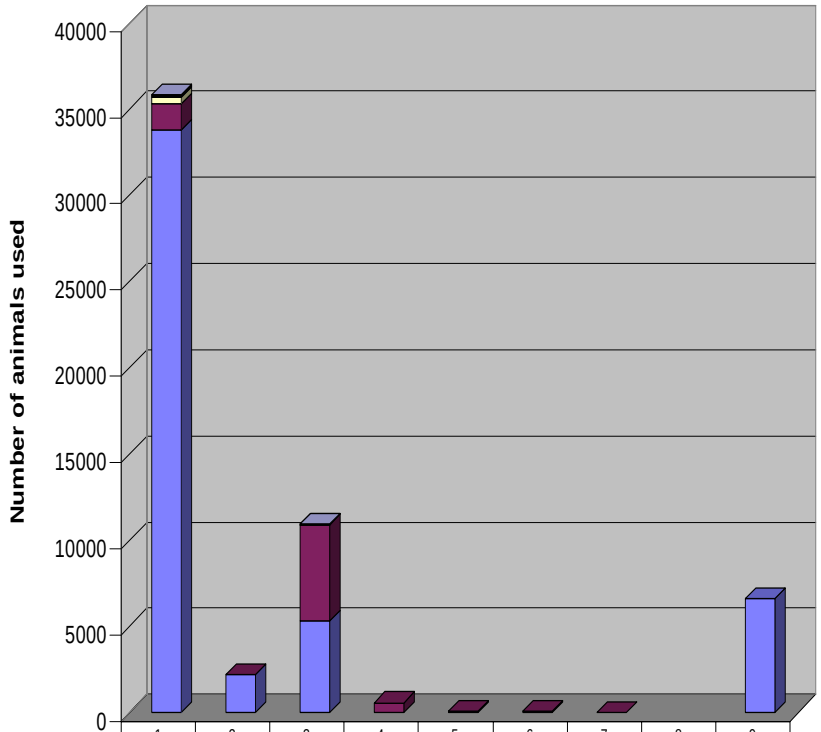
Data collection: procedure categories and guidelines used for classification

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. Postoperative 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 by 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 (GM) 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 (one for each purpose) show the numbers of animals used against the category of procedure (Categories 1 to 9).

Purpose: Stock Breeding

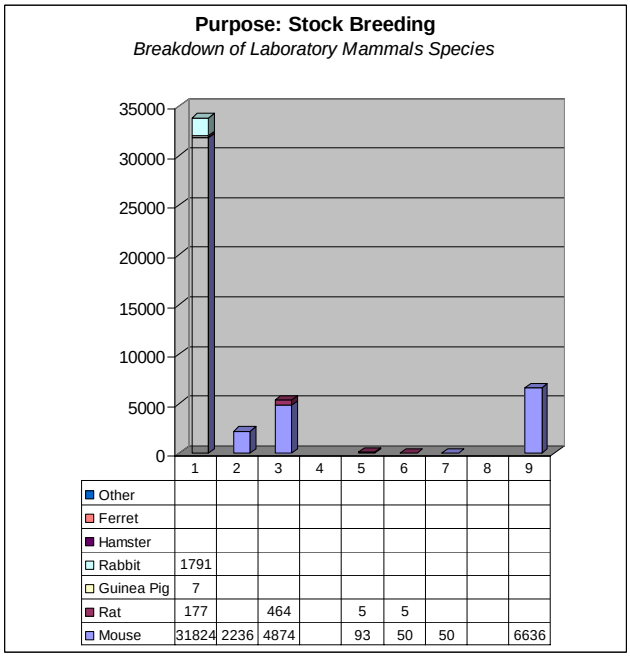
Breeding protocols to produce new teaching or research stock.
Only includes the animals used to produce progeny, NOT the final progeny

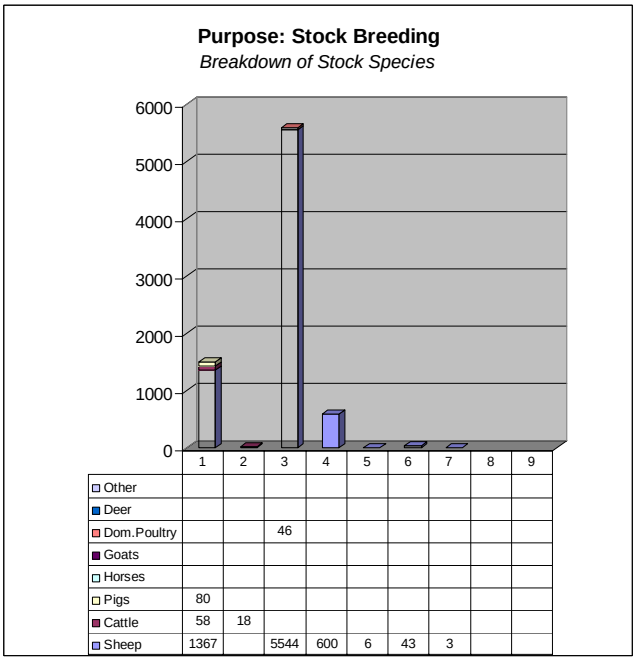


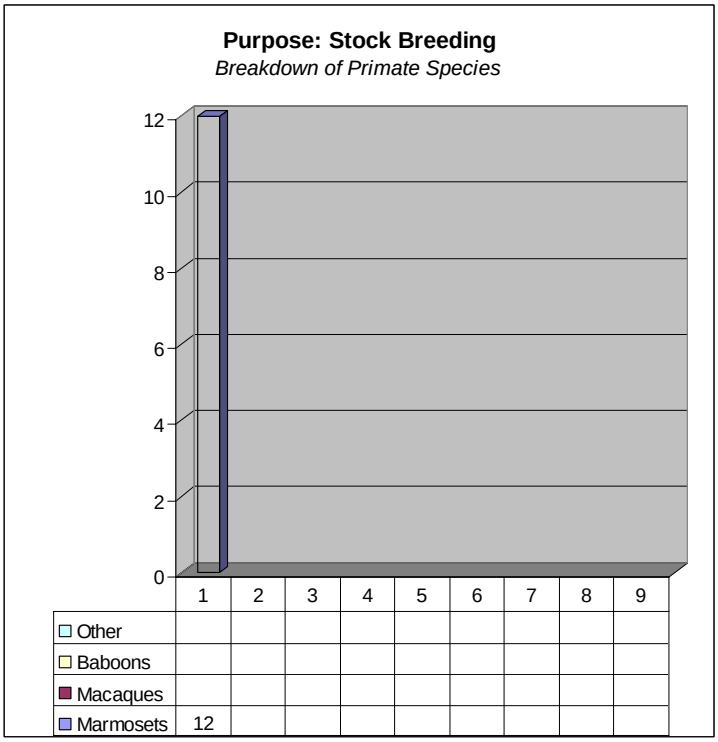
	1	2	3	4	5	6	7	8	9
Other									
Feral									
Nat Mam	118		30						
Primate	12								
Domestic									
Reptile									
Aquatic	30								
Birds	437								
Stock	1505	18	5590	600	6	43	3		
Lab	33799	2236	5338		98	55	50		6636

Procedure category

Refer to following page for a further breakdown of species.

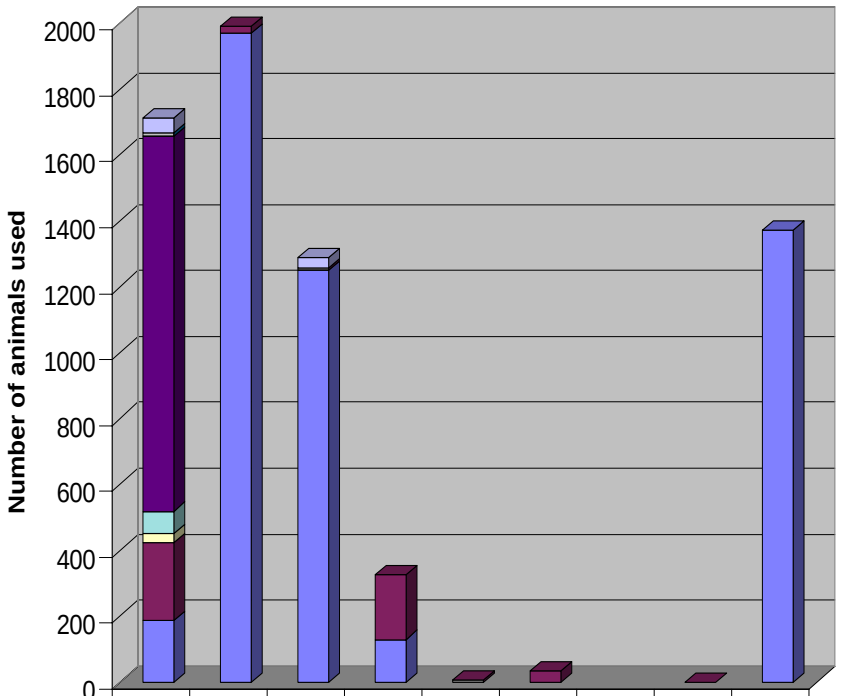

Purpose: Stock Breeding
Breakdown of Laboratory Mammals Species
35000
30000
25000
20000
15000
10000
5000
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit 1791
Guinea Pig 7
Rat 177 464 5 5
Mouse 31824 2236 4874 93 50 50 6636


Purpose: Stock Breeding
Breakdown of Stock Species
6000
5000
4000
3000
2000
1000
0
1 2 3 4 5 6 7 8 9
Other
Deer
Dom.Poultry 46
Goats
Horses
Pigs 80
Cattle 58 18
Sheep 1367 5544 600 6 43 3


Purpose: Stock Breeding
Breakdown of Primate Species
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9
Other
Baboons
Macaques
Marmosets 12

Purpose: Stock Maintenance

Holding Protocols for animals maintained for use in other protocols



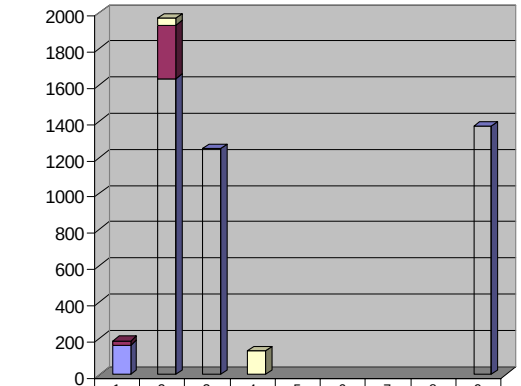
	1	2	3	4	5	6	7	8	9
Other									
Feral									
Nat Mam	45		30						
Primate	12								
Domestic									
Reptile	1137								
Aquatic	67								
Birds	30								
Stock	236	20	7	195	8	34		1	
Lab	186	1969	1250	130					1371

Procedure category

Refer to following page for a further breakdown of species.

Purpose: Stock Maintenance

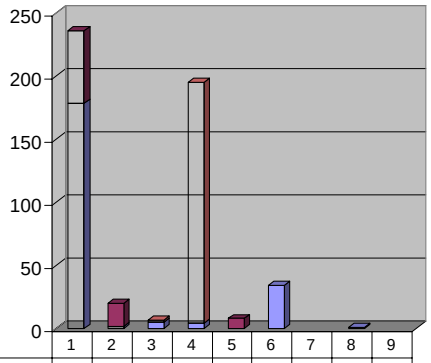
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit									
Guinea Pig		37		130					
Rat	23	295							
Mouse	163	1637	1250						1371

Purpose: Stock Maintenance

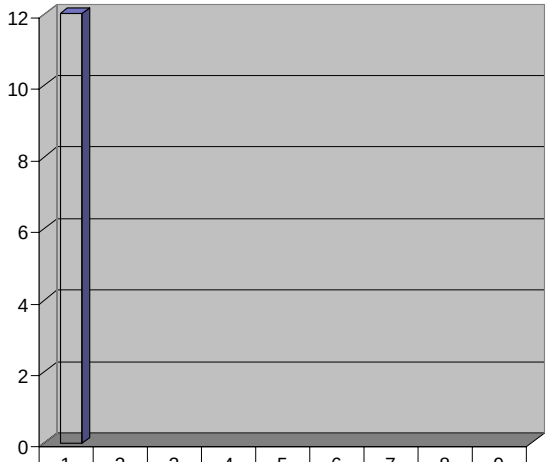
Breakdown of Stock Species



	1	2	3	4	5	6	7	8	9
Other									
Deer									
Dom.Poultry			2	191					
Goats									
Horses									
Pigs									
Cattle	58	18			8				
Sheep	178	2	5	4		34		1	

Purpose: Stock Maintenance

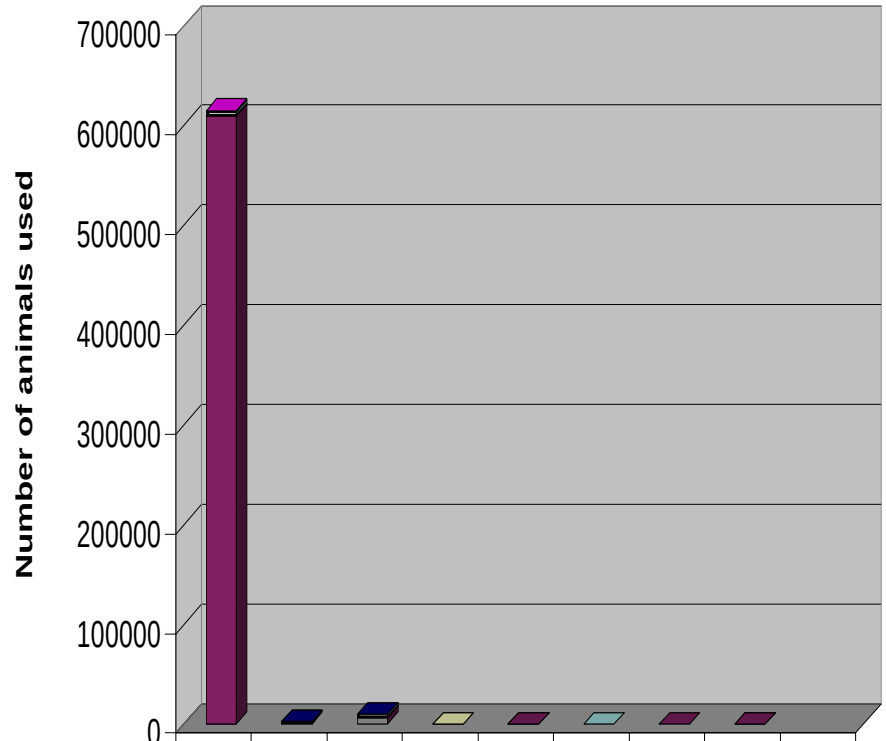
Breakdown of Primate Species



	1	2	3	4	5	6	7	8	9
Other									
Baboons									
Macaques									
Marmosets	12								

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



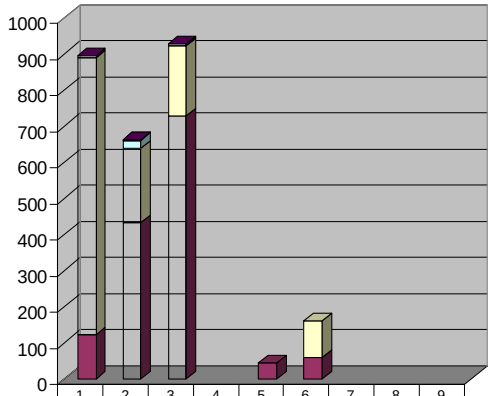
	1	2	3	4	5	6	7	8	9
Other	200								
Feral	25	259	18						
Nat Mam	877	5	132					1	
Primate									
Domestic	54	373							
Reptile	224	3	74						
Aquatic	3096	1003	2659			23			
Birds	161	24	136	18					
Stock	609628	462	6439	155	2	44	4	2	
Lab	896	662	928		45	161			

Procedure category

Refer to following page for a further breakdown of species.

Purpose: Education

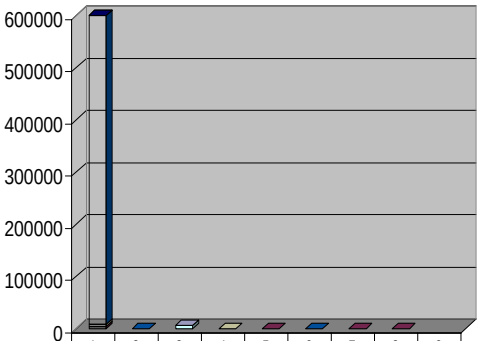
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit	6	1	6						
Guinea Pig		21							
Rat	766	206	193			100			
Mouse	124	434	729		45	61			

Purpose: Education

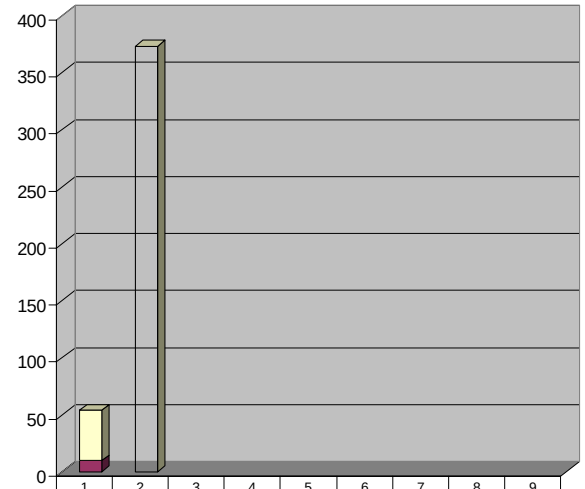
Breakdown of Stock Species



	1	2	3	4	5	6	7	8	9
Other	133								
Deer			50						
Dom.Poultry	600996	165	63			18			
Goats	20	4							
Horses	294	30	97						
Pigs	58	28	5446						
Cattle	4390		201	149					
Sheep	3737	235	582	6	2	26	4	2	

Purpose: Education

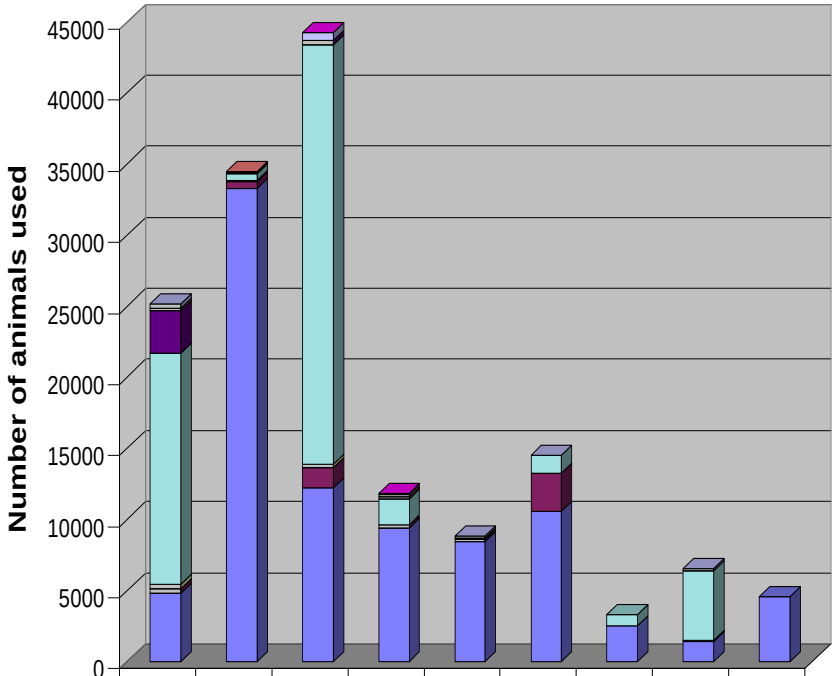
Breakdown of Domestic Species



	1	2	3	4	5	6	7	8	9
Other									
Dogs	44	373							
Cats	10								

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.



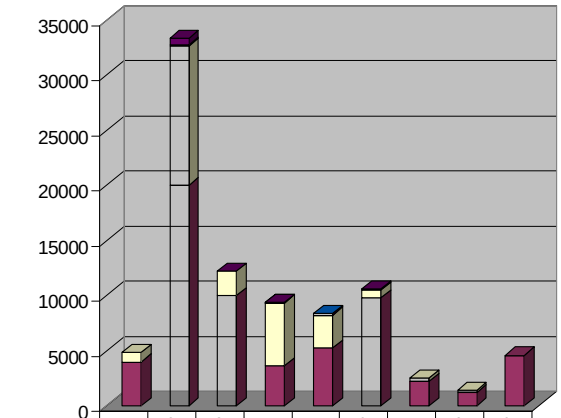
	1	2	3	4	5	6	7	8	9
Other			5	88					
Feral			3						
Nat Mam	329		546	188	24	17		117	
Primate									
Domestic	109	57	33	157					
Reptile	3034	95	343					3	
Aquatic	16209	482	29510	1789	120	1291	712	4921	
Birds	328	70	210	33	88				
Stock	303	478	1377	185	186	2644	4	26	
Lab	4824	33280	12238	9381	8385	10554	2540	1428	4574

Procedure category

Refer to following page for a further breakdown of species.

Purpose: Research - Human or Animal Biology

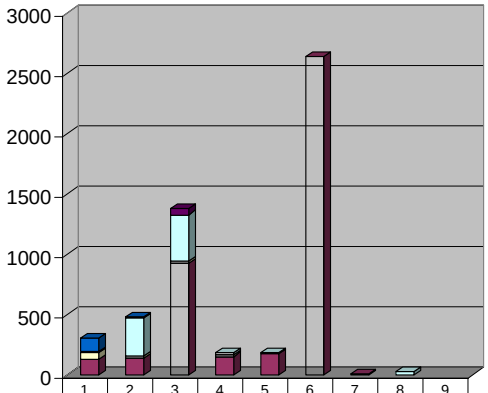
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret					3				
Hamster									
Rabbit		610	4	62	155	32			
Guinea Pig		115	5			8			
Rat	845	12611	2235	5710	2960	716	336	259	
Mouse	3979	19944	9994	3609	5267	9798	2204	1169	4574

Purpose: Research - Human or Animal Biology

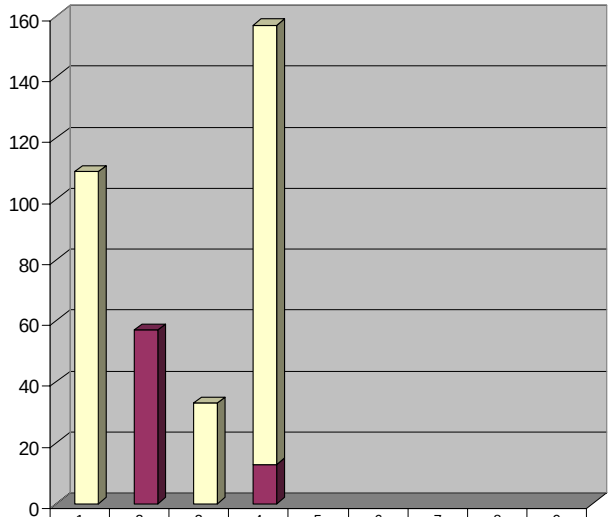
Breakdown of Stock Species



	1	2	3	4	5	6	7	8	9
Other									
Deer									
Dom.Poultry	110	4							
Goats									
Horses	6		48						
Pigs		316	383	17	14			26	
Cattle	58	18	20	17					
Sheep	129	140	926	151	172	2644	4		

Purpose: Research - Human or Animal Biology

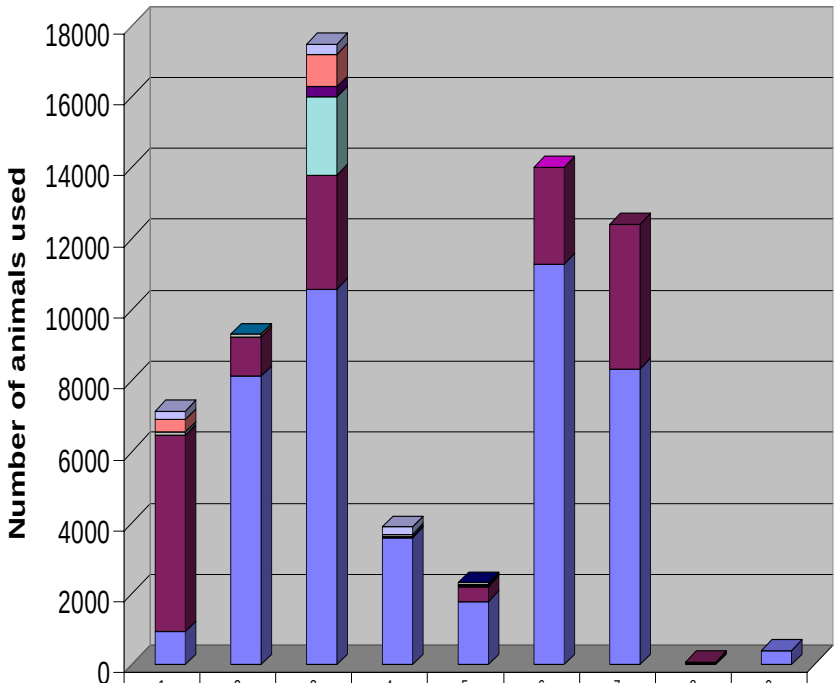
Breakdown of Domestic Species



	1	2	3	4	5	6	7	8	9
Other									
Dogs	109		33	144					
Cats		57		13					

Purpose: Research - Human or Animal Health & Welfare

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



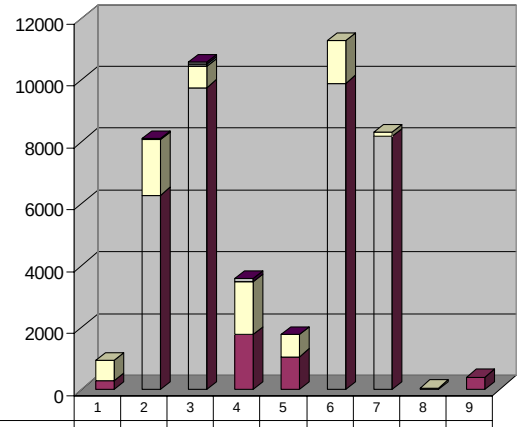
	1	2	3	4	5	6	7	8	9
Other						12			
Feral					40				
Nat Mam	235		277	202					
Primate		1		70	8				
Domestic	361	84	918	1	22				
Reptile			293						
Aquatic	80		2197		39				
Birds	12								
Stock	5526	1104	3208	24	420	2714	4083	27	
Lab	924	8113	10573	3580	1779	11271	8323	47	398

Procedure category

Refer to following page for a further breakdown of species.

Purpose: Research - Human or Animal Health & Welfare

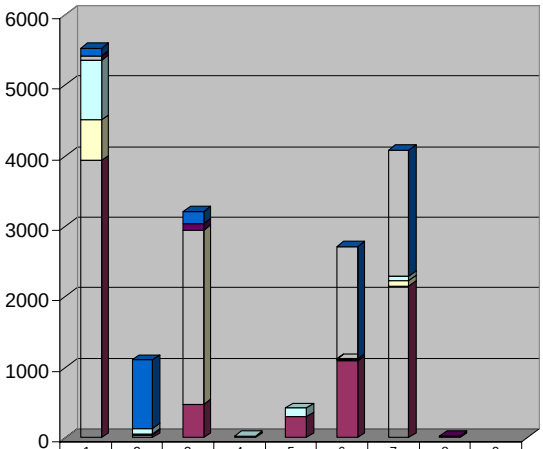
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit		37	67	107	18				
Guinea Pig			56	3					
Rat	654	1801	695	1688	701	1375	142	47	
Mouse	270	6275	9755	1782	1060	9896	8181		398

Purpose: Research - Human or Animal Health & Welfare

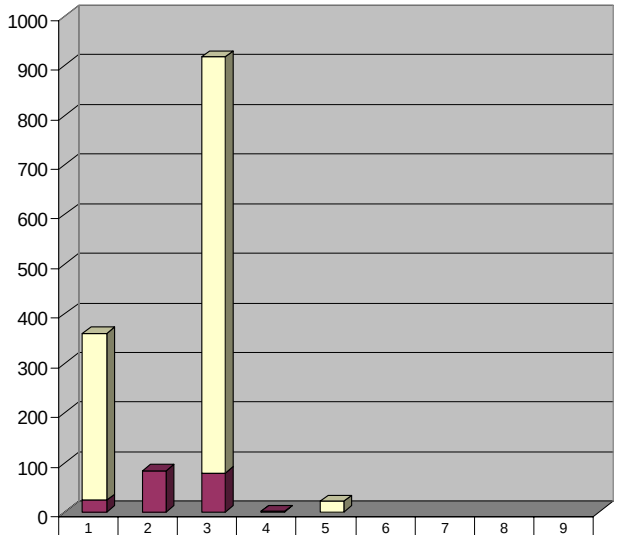
Breakdown of Stock Species



	1	2	3	4	5	6	7	8	9
Other									
Deer									
Dom.Poultry	107	975	170			1595	1788		
Goats									
Horses	66		88					27	
Pigs	846	75		10	126	8	62		
Cattle	575	18	2481			23	83		
Sheep	3932	36	469	14	294	1088	2150		

Purpose: Research - Human or Animal Health & Welfare

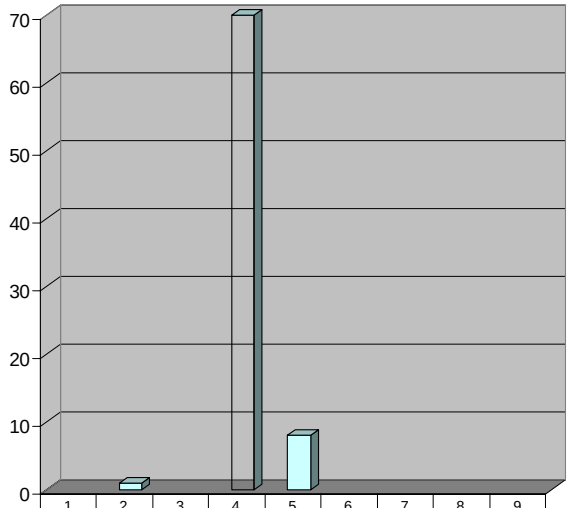
Breakdown of Domestic Species



	1	2	3	4	5	6	7	8	9
Other									
Dogs	337		839		22				
Cats	24	84	79	1					

Purpose: Research - Human or Animal Health & Welfare

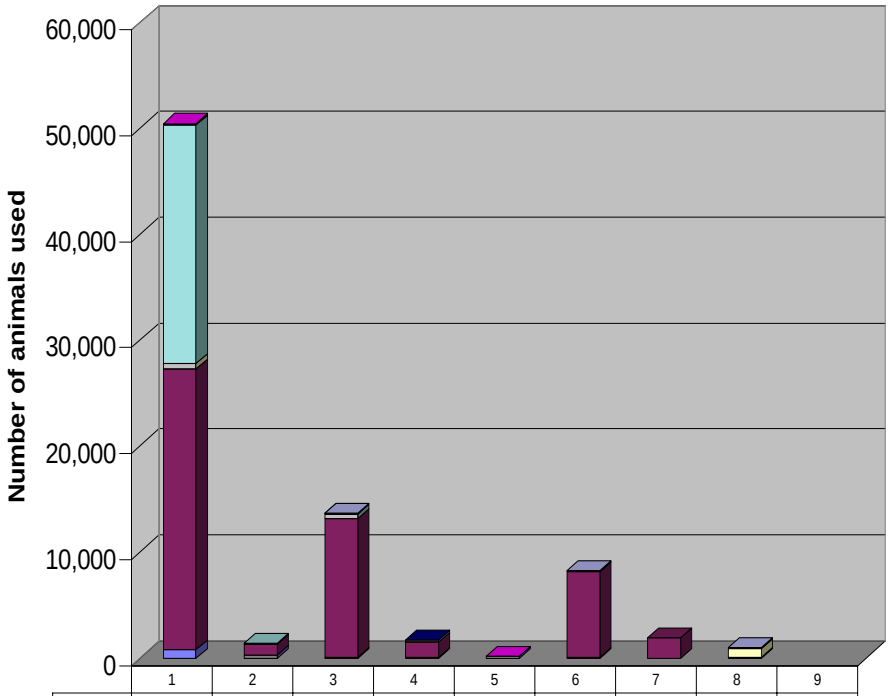
Breakdown of Primate Species



	1	2	3	4	5	6	7	8	9
Other									
Baboons		1		70	8				
Macaques									
Marmosets									

Purpose: Research - Animal Management or Production

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



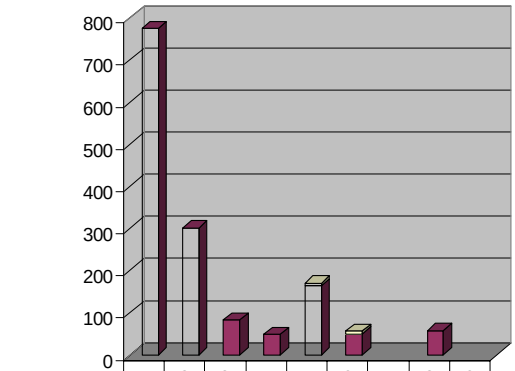
	1	2	3	4	5	6	7	8	9
Other	18				1				
Feral				50					
Nat Mam			3			3		118	
Primate	55		27						
Domestic	37		13						
Reptile									
Aquatic	22,559	126	410	142		89			
Birds	513							826	
Stock	26,508	1,005	13,123	1,492	31	8,117	1,886	2	
Lab	775	302	83	48	171	56		58	

Procedure category

Refer to following page for a further breakdown of species.

Purpose: Research - Animal Management or Production

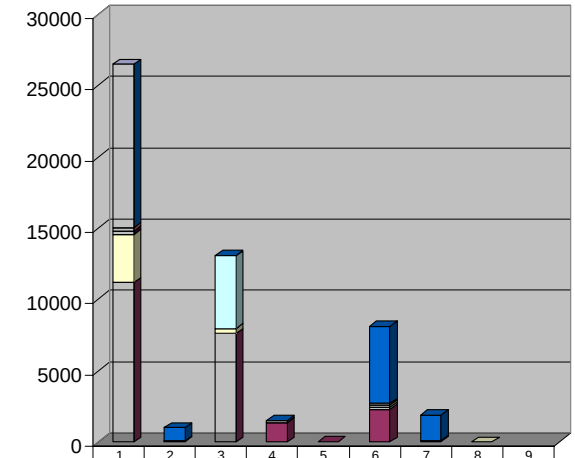
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit									
Guinea Pig									
Rat					6	6			
Mouse	775	302	83	48	165	50		58	

Purpose: Research - Animal Management or Production

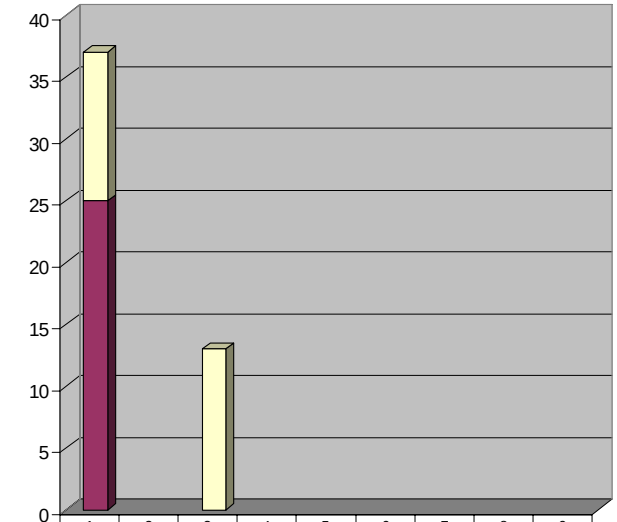
Breakdown of Stock Species



	1	2	3	4	5	6	7	8	9
Other									
Deer	6								
Dom.Poultry	11489	919	40	150		5400	1788		
Goats	205					108			
Horses	210		17			18			
Pigs	12		5124			125			
Cattle	3391	18	322			183	49	2	
Sheep	11195	68	7620	1342	31	2283	49		

Purpose: Research - Animal Management or Production

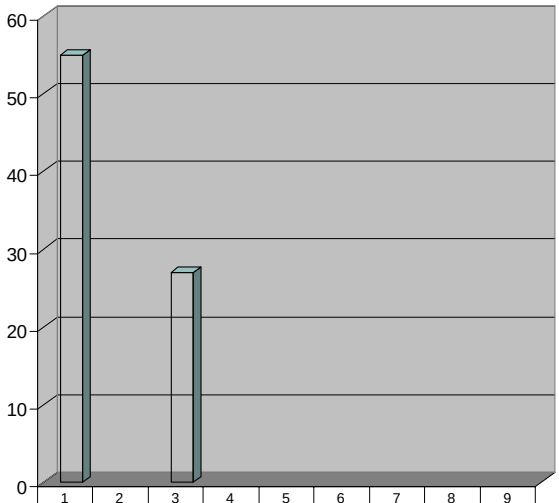
Breakdown of Domestic Species



	1	2	3	4	5	6	7	8	9
Other									
Dogs	12		13						
Cats	25								

Purpose: Research - Animal Management or Production

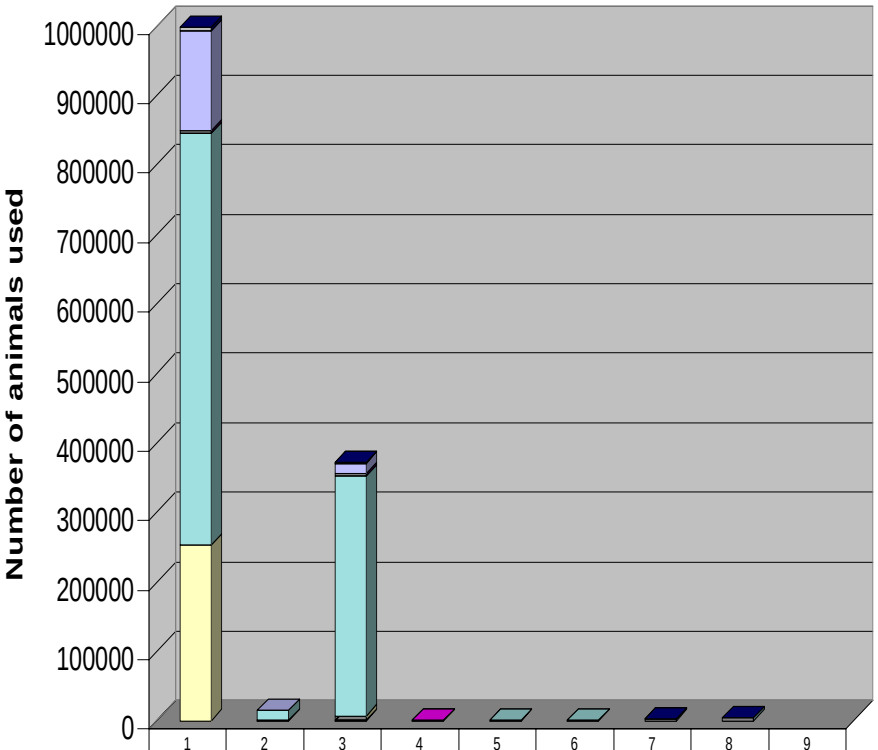
Breakdown of Primate Species



	1	2	3	4	5	6	7	8	9
Other									
Baboons	55		27						
Macaques									
Marmosets									

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



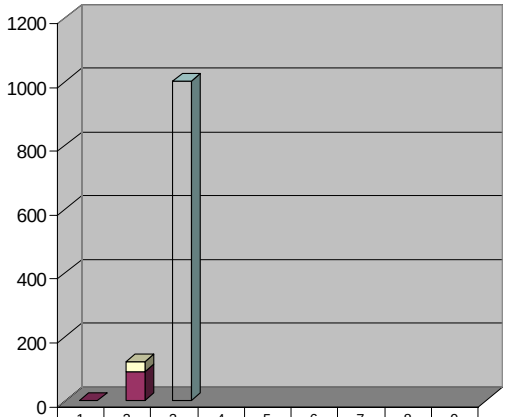
	1	2	3	4	5	6	7	8	9
Other				14					
Feral	4640		1396				3	100	
Nat Mam	143767	74	15707	492				118	
Primate	6								
Domestic	4								
Reptile	3840		3241				8		
Aquatic	592788	15093	344617	566	765	1290	1921	4317	
Birds	252114	144	5914			3			
Stock	48		90						
Lab	1	121	1001						

Procedure category

Refer to following page for a further breakdown of species.

Purpose: Research - Environmental Study

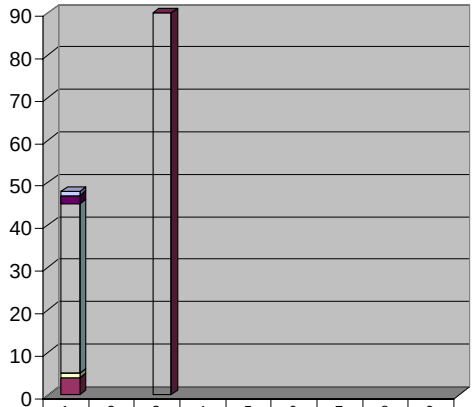
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit									
Guinea Pig			1000						
Rat		30							
Mouse	1	91	1						

Purpose: Research - Environmental Study

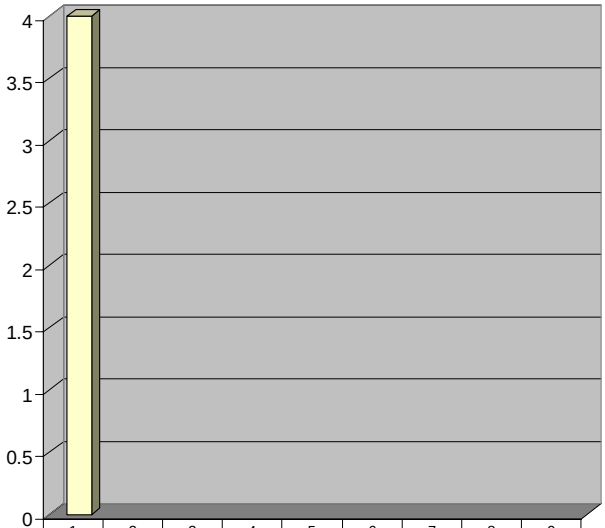
Breakdown of Stock Species



	1	2	3	4	5	6	7	8	9
Other									
Deer	1								
Dom.Poultry									
Goats									
Horses	2								
Pigs	40								
Cattle	1								
Sheep	4		90						

Purpose: Research - Environmental Study

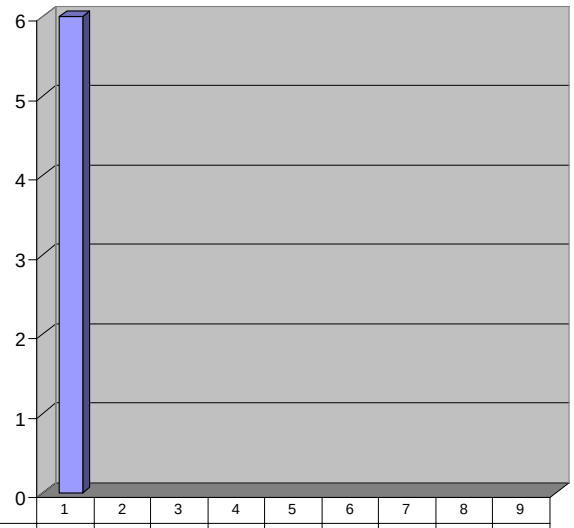
Breakdown of Domestic Species



	1	2	3	4	5	6	7	8	9
Other									
Dogs	4								
Cats									

Purpose: Research - Environmental Study

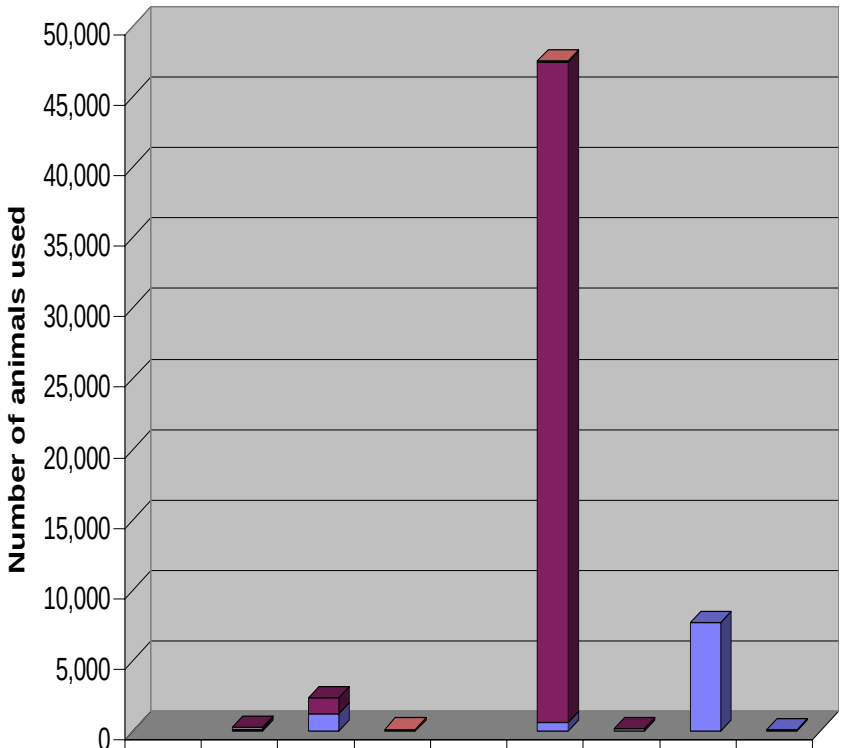
Breakdown of Primate Species



	1	2	3	4	5	6	7	8	9
Other	6								
Baboons									
Macaques									
Marmosets									

Purpose: Production of Biological Products

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



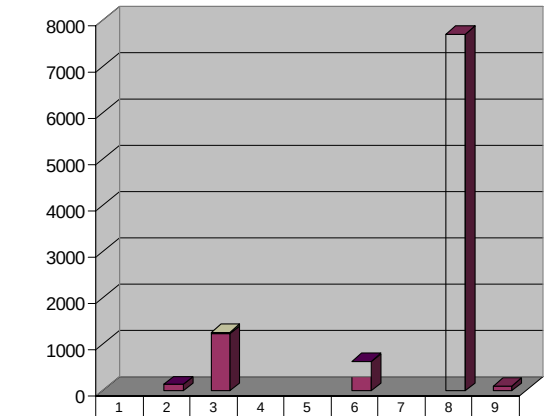
	1	2	3	4	5	6	7	8	9
Other									
Feral									
Nat Mam									
Primate									
Domestic				137		116			
Reptile									
Aquatic									
Birds									
Stock		152	1,106			46,802	152		
Lab		141	1,262			632		7,695	100

Procedure category

Refer to following page for a further breakdown of species.

Purpose: Production of Biological Products

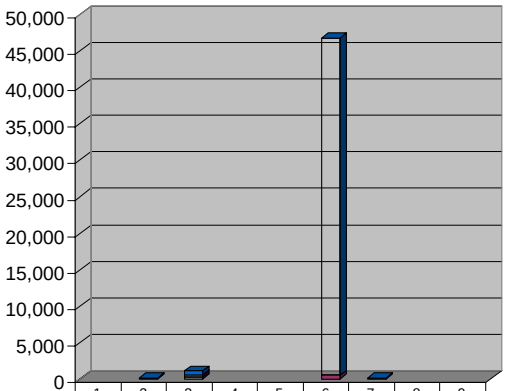
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit		4				4			
Guinea Pig									
Rat			37						
Mouse		137	1,225			628		7,695	100

Purpose: Production of Biological Products

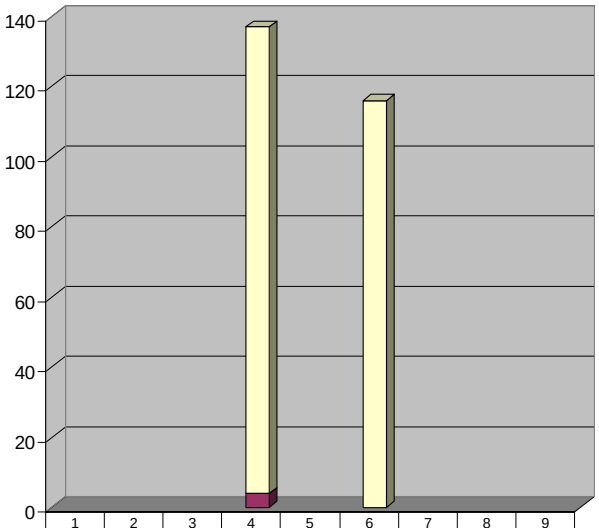
Breakdown of Stock Species



	1	2	3	4	5	6	7	8	9
Other									
Deer									
Dom.Poultry		152	499			46287	152		
Goats									
Horses			416						
Pigs									
Cattle			13			36			
Sheep			178			479			

Purpose: Production of Biological Products

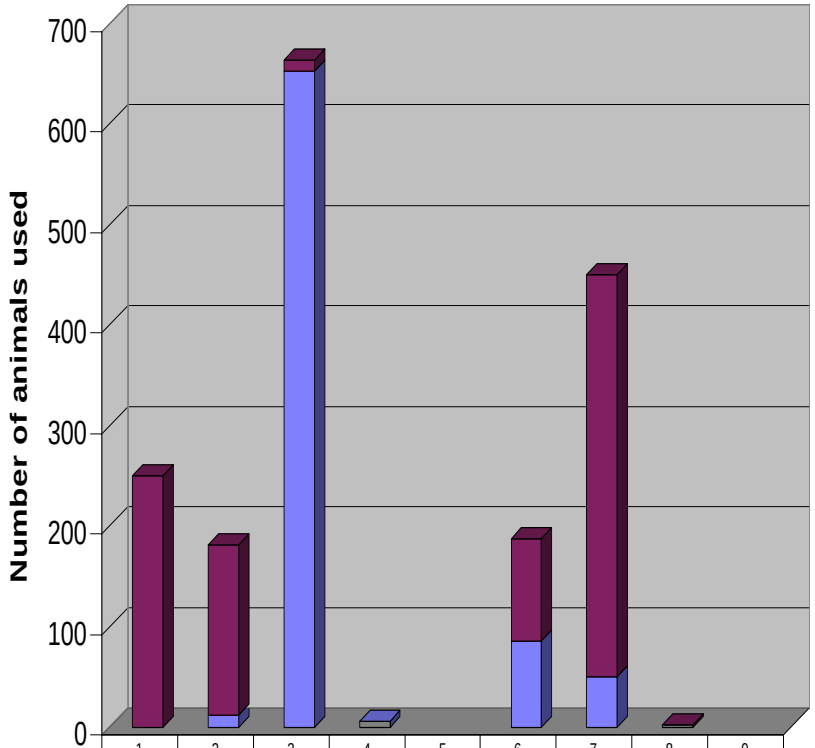
Breakdown of Domestic Species



	1	2	3	4	5	6	7	8	9
Other									
Dogs				133		116			
Cats				4					

Purpose: Diagnostic Procedures

Using animals directly as part of a diagnostic process



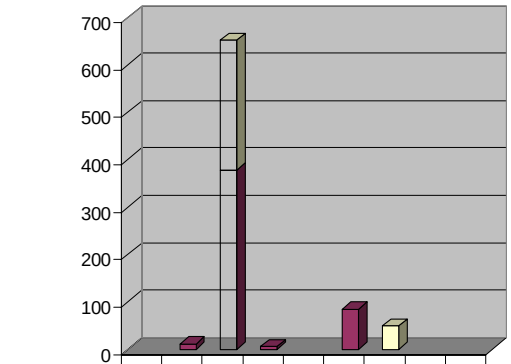
	1	2	3	4	5	6	7	8	9
Other									
Feral									
Nat Mam									
Primate									
Domestic									
Reptile									
Aquatic									
Birds									
Stock	250	169	11			102	400	2	
Lab		12	652	6		85	50		

Procedure category

Refer to following page for a further breakdown of species.

Purpose: Diagnostic Procedures

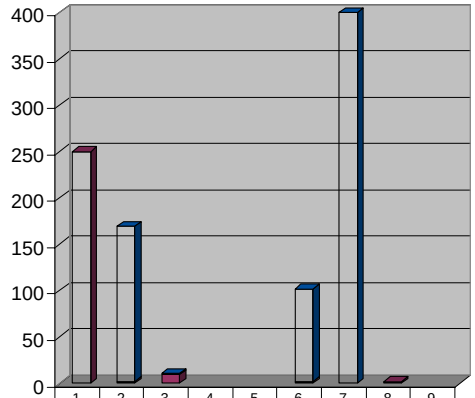
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit									
Guinea Pig									
Rat			273				50		
Mouse		12	379	6		85			

Purpose: Diagnostic Procedures

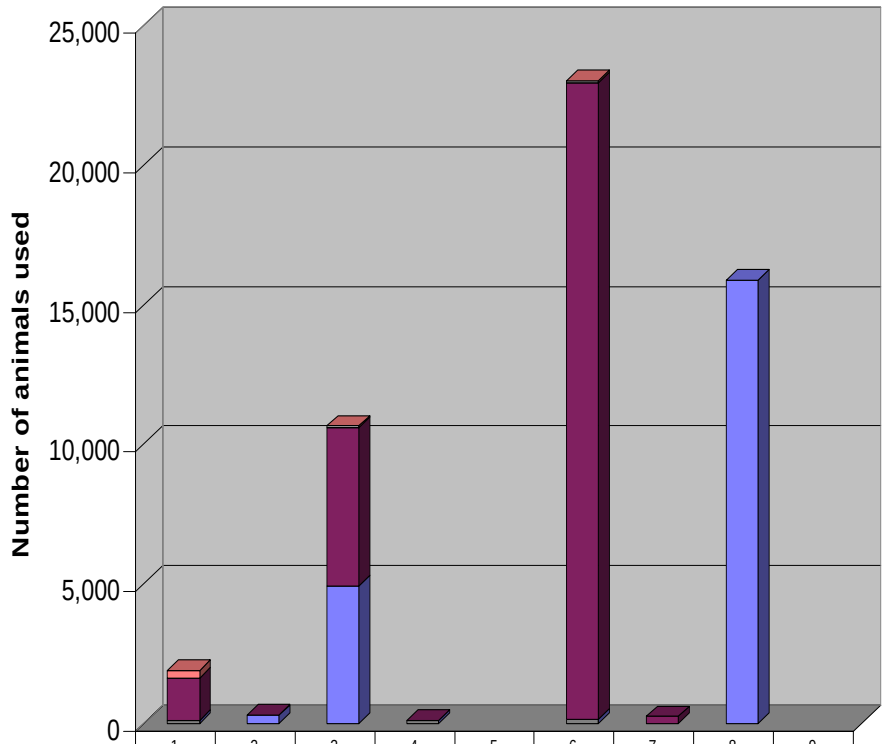
Breakdown of Stock Species



	1	2	3	4	5	6	7	8	9
Other									
Deer									
Dom.Poultry		167	1			100	400		
Goats						2			
Horses									
Pigs									
Cattle									
Sheep	250	2	10					2	

Purpose: Regulatory Product Testing

Protocols for the testing of products required by regulatory authorities



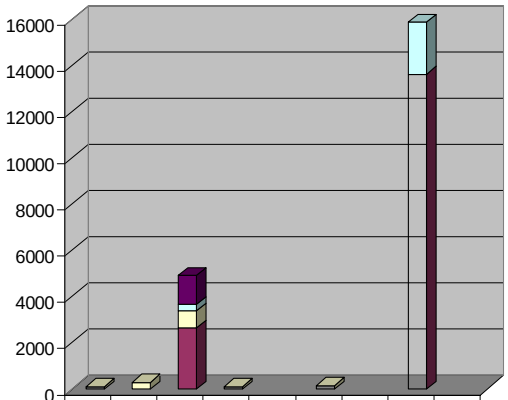
	1	2	3	4	5	6	7	8	9
Other									
Feral									
Nat Mam									
Primate									
Domestic	259		74			65			
Reptile									
Aquatic									
Birds									
Stock	1,530	16	5,663	4		22,800	248		
Lab	108	294	4,926	108		153		15,876	

Procedure category

Refer to following page for a further breakdown of species.

Purpose: Regulatory Product Testing

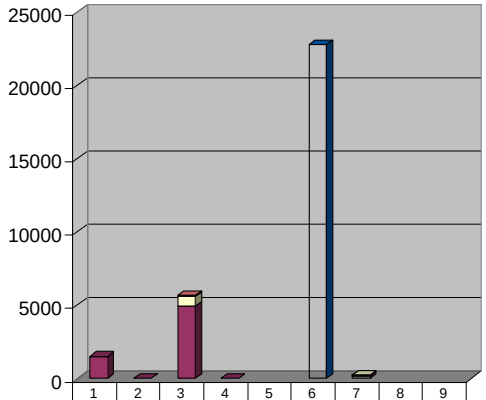
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit			1253						
Guinea Pig			300					2263	
Rat	108	294	739	108		153			
Mouse			2634					13613	

Purpose: Regulatory Product Testing

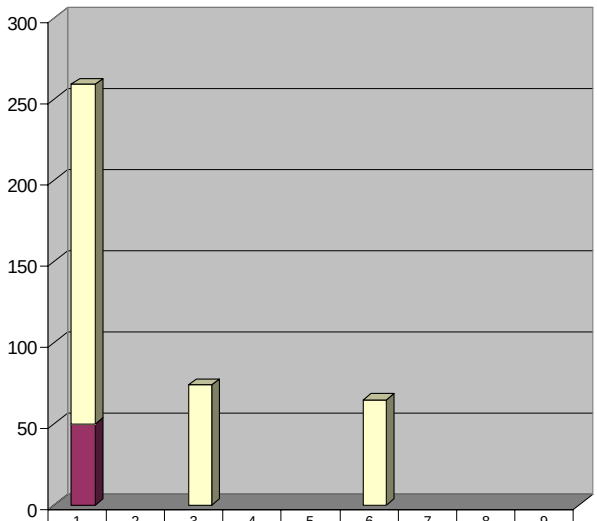
Breakdown of Stock Species



	1	2	3	4	5	6	7	8	9
Other									
Deer									
Dom.Poultry						22800			
Goats			16						
Horses			61						
Pigs									
Cattle			634				42		
Sheep	1530	16	4952	4			206		

Purpose: Regulatory Product Testing

Breakdown of Domestic Species



	1	2	3	4	5	6	7	8	9
Other									
Dogs	209		74			65			
Cats	50								

Lethality testing 2005

The *Animal Research Act 1985* defines a 'lethality test' as 'an 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'.

The following are the figures reported on animal use for lethality testing in 2005.

Species	Number used	Number died/ euthanased	Procedure	Justification	Alternatives
Mice	6285	2018	Serum neutralisation test	Regulatory testing for vaccines	None available
Mice	120	71	Vaccine efficacy test	Regulatory testing for vaccines	None available
Mice	830	468	Determination of antigen potency	In-process testing of antigen growths	None available The testing process has been reviewed, resulting in a reduction in overall testing required per unit. Test has been refined to reduce animal numbers used per test.
Mice	4348	1768	Determine potency of antigen preparations	Test to allow evaluation of vaccine suitability for further manufacture	None available
Guinea pigs	910	337	Vaccine efficacy test	Regulatory testing for vaccine potency	None available
Guinea pigs	1353	446	Vaccine efficacy test	Regulatory testing for vaccine potency	None available
Mice	7208	2314	Serum neutralisation test	Regulatory testing for vaccine potency	None available
Mice	1556	633	Antigen potency test	In-process vaccine testing	None available
Mice	951	537	Determination of antigen potency	In-process testing of antigen growths	None available

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	• Education of Committee members of available alternatives to the use of animals. • Promotion of alternatives to animals in teaching (e.g. 'Muscle Physiology' CD-ROM). • Testing of an *in vitro* assay in parallel with the *in vivo* assay. Although the *in vitro* assay gives similar results in some areas, further optimisation and testing of the *in vitro* assay is required before it can replace the *in vivo* assay. • Mathematical modelling experiments that will augment physiology experiments (just commenced). • Rather than measure adherence in mice, tissue culture models are used and the antisera used to measure adhesion *in vitro.* The tissue-culture models are currently being established and will be more representative of the *in vivo* conditions. • Use of audiovisual material such as videos, slides and interactive computer programs. • Use of plant tissue as a replacement for animal tissue for certain enzymatic assays. • Development of a computer model to predict potential worm burdens in sheep. • In applications submitted to the AEC, researchers are increasingly adopting *in vitro* techniques or using the results of *in vitro* studies by others to identify the elements involved in the physiological and pathophysiological states under study. This has the benefit of reducing subsequent experiments on animals.
Reduction in numbers	• Sharing of animal tissues between members of research groups and centres. • Use of new analytical methods such that fewer animals are required as sources of tissues. • Close scrutiny of the number of animals requested in applications to the Committee. • Number of animals always determined by statistical analysis or minimum number required to satisfy regulatory authority for new drug products. • Use of biometricians' comments before approval by AEC. • Limiting the number of birds used to the minimum required for statistical outcomes at defined confidence and power levels (reduced in one experiment from a proposed 200 birds down to 180). • In-vitro testing efficacy of the test product before its use of animals. These techniques allowed us to reduce the number of animals used. • Implementation of new oral toxicity guidelines by the Organisation for Economic Cooperation and Development that use fewer animals. • Application of compounds to skin explants rather than mice. This reduced the number of animals required and removed the pain induced from UV exposure, as the UV was applied to skin explants instead. • Testing program was reviewed, resulting in a reduction in overall testing requirements per unit of production output. Certain tests have been refined to reduce the animal numbers used per test. • Use of abattoir specimens and cadavers. • Development of new computer software that can simulate breeding strategies for any species to improve commercial livestock breeding and reduce experimentation on animals.

Category	Comments
	• Animal use has been minimised by careful scrutiny of numbers of animals requested; approval of new techniques for embryo freezing rather than continuous breeding to maintain lines' reuse of animals, where appropriate, after an extended recovery interval; 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 that there is no overbreeding; this, in turn, reduces the need for culling.
Refinement of techniques	• Promotion of adequate training of researchers in research methods and procedures. • AEC is now requiring video evidence of the processes used in undeveloped techniques. • Development of endpoints in protocols, so that animals are euthanased before they are exposed to unnecessary pain and suffering. • All personnel have been going through training in techniques such as blood sampling, faecal sampling and ear tagging. • Use of the saphenous vein method as the standard technique for blood collection in rodents. • Use of monitoring checklists developed specifically for each project, as well as 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 achieve a reduction in the incidence of post-operative problems. • Refinement of anaesthetic regimes to methods that cause less stress in the animals, with fewer mortalities and improved recovery. • Improved peri-and-post operative analgesia to reduce pain from surgery. • In polyclonal antibody production, the use of adjuvants that are less likely to result in granulomas, and the use of chick eggs whenever possible. • Use of adjuvants known not to produce adverse reactions. • In the case of infection models, the use of low infective doses and short infection times to minimise the impact on animals. • The use of visible implant elastomer (VIE) tags for the identification of amphibians < 50 mm long. Microchips are used for larger amphibians. • Use of a material bag (pillow slip) when weighing animals after removal from the Elliott trap. • Placement of a heat source in a box taken to the trapping site for use on animals suffering hypothermia. • Attempt to establish paracetamol in jelly cubes as an analgesic protocol for rats. Although these were consumed preoperatively they were rarely consumed postoperatively. Paracetamol in drinking water appeared more effective, although no measures of analgesic effect were made. • Use of xylazine and ketamine in low doses in adult female macropods for the collection of milk and reattachment of the pouch young. This procedure not only reduced pain and distress, it also minimised the killing of pouch young. • Placement of blood flow measuring probes on the femoral artery. Because these probes are outside the abdominal cavity, the rabbits make a speedy recovery from surgery. The mask system for delivery of gas mixtures and measurement of ventilation is a major advance. It is non-invasive, non-harmful, and well tolerated by most rabbits.

Category	Comments
Refinement of techniques	• Transcutaneous immunisation rather than immunisation via injection. • We have established collaborations with other investigators in Australia who are also using the mouse model of allergic airway inflammation. This has given us the opportunity to compare our particular experimental model, and its impact on the mice, with that used in other labs. In fact, our current set up is very comparable to that used by other researchers, but we are continuing discussions to try to identify refinements. • Operative technique involved a learning curve as shown by the improvement in the mortality figures. As well as technical improvements, we have changed ventilation techniques to reduce pulmonary trauma and are now using low-volume ventilators. Additional staff have been recruited to assist in surgery and to enable better monitoring of the mice post-operatively. • To prevent death due to anaphylactic shock as a consequence of virus injection an improved regime of pre-injection steroids and anti-histamines was administered. • We have reduced the number of animals used as a result of prioritising experimental groups and restricting our present studies to one strain of mouse. • The monitoring form has been amended to include observation for skin ulceration, which was observed to be an infrequent complication of the immunisation procedure. • We upgraded our aerosol apparatus and this led to improved reproducibility. This means that we are able to obtain better-quality data using fewer mice. • Increased awareness and use of environmental enrichment. • The project developed a non-invasive technique for accessing the reproductive status, population, stress and health of great whales by using ‘blow’ samples. • Morphometric data and a small amount of blood were collected from Little Penguins as part of the project. The penguins are handled only once, as briefly as possible. Genetic analysis of the blood provides information on the sex of the penguin and some information about the movements and therefore population structure of the Little Penguins. Historically, banding was used to obtain movement data from penguins. It is no longer used, as it was found to increase mortality rates. Bands stay on the penguin for its lifetime and have been found to hamper swimming ability. Often the penguin has to be recaptured to read the band. • Relocation of research horses to a farm setting where horses were free to roam in a large, well-grassed paddock with other horses. • Spontaneous collection of naturally voided urine in both equines and bovines. • Indirect methods such as plot tracking to assess animal presence; giving-up densities (GUD) to assess feeding activity in the presence or absence of predators; and non-lethal uptake as a substitute measure for fox predation activity were used to minimise the impact of research on small native mammals. • Use of raked sand-plots instead of cage traps for surveying quolls. • Hair and scat analysis has been improved, and this 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. • Wildlife study: anaesthetic regimes in the field (e.g. portable isoflurane administration). • Wildlife study: veterinarian included for anaesthetic administration and any necessary veterinary interventions. • Wildlife study: edible bait to provide sustenance for animals after capture. • Wildlife study: trapping only when weather conditions are optimal. • Wildlife study: to reduce the risk of pathogen transfer between frogs disposable latex gloves and sterilisation of instruments were used.

Category	Comments
Refinement of techniques	• Use of GPS (global positioning system) collars for collecting continuous data on large mammals reduces the need for frequent recapture. • All housed cattle have access to a bedded area. • Housed sheep in trials have access to a bedded area when protocol allows. • Housed breeder ewes and lambs have access to hay. • Sheep and cattle rations include pellets/nuts, thus reducing the amount of dust. • Earlier endpoints of animal xenograft studies have been implemented. • Additional mouse enrichment is being utilised (i.e. autoclaved cardboard tubing that is replaced at each weekly cage clean). • Traps are cleared no later than 2 hours after sunrise. • Competency-based training has been implemented for all techniques used by research staff. Certificates of competence are issued only after competency has been established against a written competency standard. With the growth of research in the last 2 years this has been a critical strategy in ensuring ongoing animal wellbeing. Key to the minimising of distress to animals used is regular review of handling and restraint techniques. • Use of microimaging for detection of abdominal tumours has been introduced, and further training by experienced collaborators is to occur this year. • Determination of analgesic drug effects that can be used to refine experimental procedures in sheep. • Convention of two continuing education workshops for staff involved in research with animals to improve Animal Ethics procedures and handling and care of experimental animals. • Development of electronic sensing program for fly strike in sheep. • Development of a computer-based experimental animal tracking system to monitor animal use and animal reuse with a view to reducing individual animal exposure to experimental procedures and to monitor animal status within the research flock at any time. • Investigation of methods for environmental enrichment for long-term housed sheep. • Application of a process of using artificial windbreaks to reduce lamb losses during inclement weather. • The AEC has paid particular attention to anaesthetic doses and analgesia doses to minimise pain, and a number of modified procedures have been adopted by researchers on the basis of the experience of other researchers with these techniques. • The AEC has distributed the publication by DB Morton (1999), Humane Endpoints in AnimalExperimentation for Biomedical Research: Ethical, Legal and Practical Aspects, which gives researchers and animal house managers criteria for decision-making in the euthanasia of unwell animals.

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 provided to members 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	$12,537
Travel and subsistence	$9,199
Stores and printing	$5,057
Freight and postage	$2,251
TOTAL	**$29,044**

Appendix J: Abbreviations

ACEB	Animal Care and Ethics Board
AEC	Animal Ethics Committee
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARRP	Animal Research Review Panel
ATLA	Alternatives to Laboratory Animals
AWAC	Animal Welfare Advisory Council
CCAC	Canadian Council on Animal Care
CSIRO	Commonwealth Scientific and Industrial Research Organisation
EAPA	*Exhibited Animals Protection Act 1986*
OGTR	Office of the Gene Technology Regulator
NHMRC	National Health and Medical Research Council
NSW DPI	New South Wales Department of Primary Industries
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.animalethics.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. Annual Reporting by Animal Ethics Committees to Accredited Establishments

5a. Institutional Support for Animal Ethics Committees

6. Differentiation Between Acts of Animal Research and Acts of Veterinary Treatment
7. Relationships Between Accredited Research Establishments and Licence Holders WITHDRAWN
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 Restricted 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
21. Guidelines for the Housing of Guinea Pigs in Scientific Institutions

Appendix L: Animal Welfare Branch 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*.