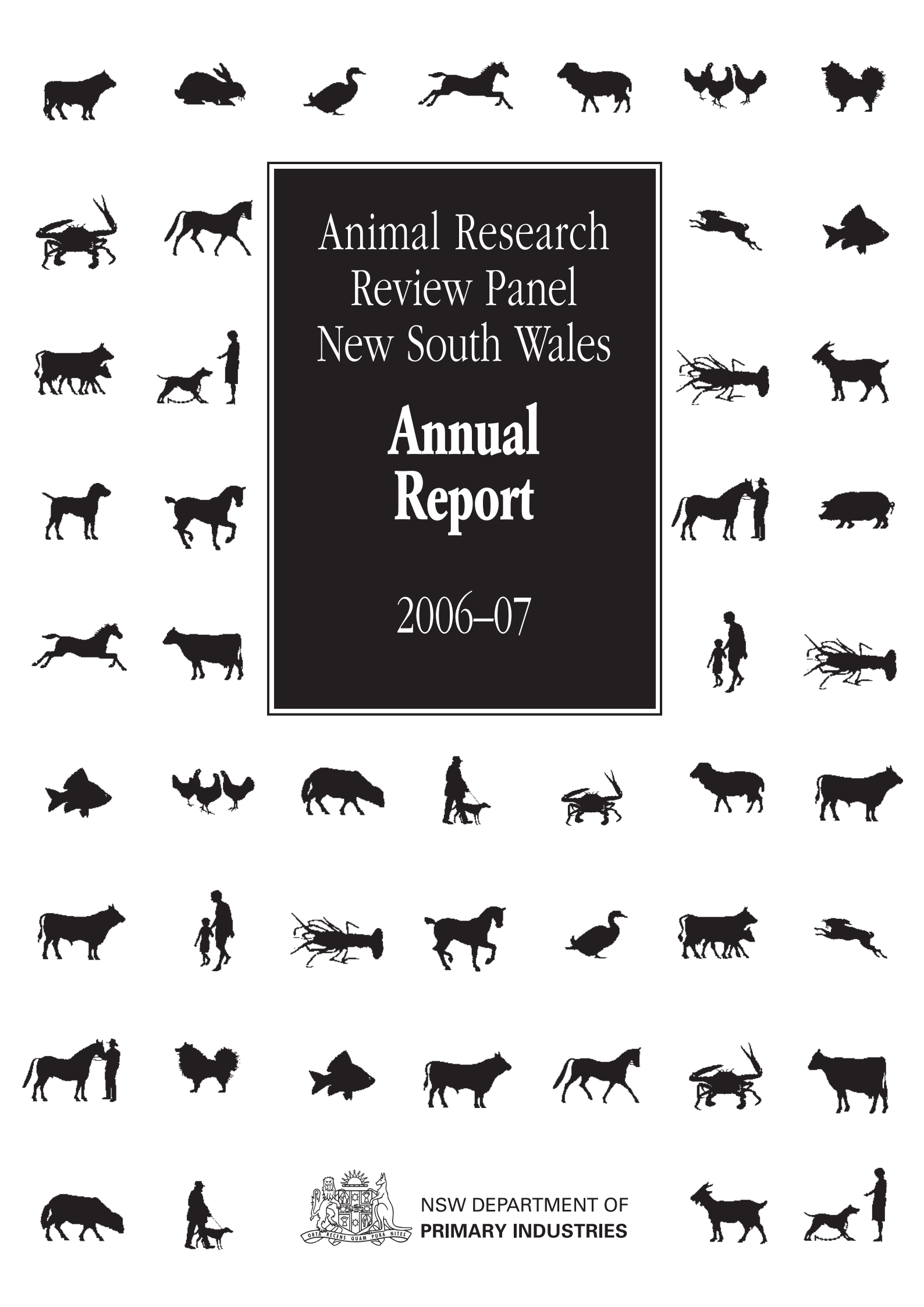
Animal Research Review Panel New South Wales

Annual Report

2006–07

NSW DEPARTMENT OF
PRIMARY INDUSTRIES



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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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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 2006 to 30 June 2007.

Yours sincerely

MARGARET ROSE
Chair
Animal Research Review Panel

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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 considering amendments to the Regulation. NSW Department of Primary Industries Animal Welfare

Deer held in pasture-improved paddocks with special fencing to prevent escape and injury.

Plains rats used in a teaching project to demonstrate handling and husbandry of native mammals. The animals are provided with a shelter, natural sand substrate, and straw bedding material. A varied diet includes seeds and fresh vegetables.

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 2006–07 there were 98 accredited animal research establishments, 68 accredited schools and 27 holders of animal suppliers' licences.

Inspections

In the 2006–07 year the ARRP carried out 19 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 Branch staff and the ARRP. Such activities in the 2006–07 year included holding a meeting for members of AECs and releasing a revised version of evidence-based guidelines on guinea pig housing. The revisions were based on comments received from user groups and people with internationally recognised expertise in guinea pig care and management. The release of the guinea pig housing guidelines was part of 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 2006–07. Five informal complaints were received and dealt with in the 2006–07 reporting period.

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 Branch 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.

Rabbit in a floor pen. Note the clear barrier that allows rabbits in adjoining pens to see, hear and smell each other but keeps them separate when this is needed.

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 March 2007 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 2006–07 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)
- Dr Jason Grossman (nominated by Animal Societies' Federation)
- Dr 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)
- Dr Stephen Atkinson (nominated by Vice-Chancellors' Committee)
- Dr Philip Towers (nominated by Vice-Chancellors' Committee)

The position of the nominee from the Minister for Education was vacant for the 2006–07 period.

Information on members of the Animal Research Review Panel in 2006–07 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.

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.

Nude mice in filter-top boxes with examples of environmental enrichment: cardboard hiding areas, tissue paper for nesting material, and food within the cage to manipulate.

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.

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.

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 was the Vice Chair of the NSW Young Lawyers Animal Rights Committee from 2002–2006. 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 Learning and Development at Gilbert and Tobin.

Dr Jason GROSSMAN, MA (Cantab), MPH (University of Sydney), PhD (University of Sydney). Dr Jason Grossman joined ARRP in August 2006. He is a nominee of the Animal Societies Federation (NSW). Dr Grossman has degrees in mathematics, public health and philosophy. He has been both a public health academic and a public health bureaucrat, and he is now a lecturer in philosophy at the Australian National University and a research fellow in the Centre for Applied Philosophy and Public Ethics. His research is on scientific methodology—especially statistical methodology.

Dr Mark LAWRIE, BVSc (University of Sydney), MACVSc (Animal Welfare), Grad. Cert. Man. (University of Western Sydney), Chief Veterinarian, RSPCA. Dr 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. Dr 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 and the Secretary of Animal Management in Rural and Remote Indigenous Communities (AMRRIC) from 2003–2007. He will be the National President of AVA in 2008.

He has particular interests in:

- the link between cruelty to animals and humans
- animal hoarders
- international animal welfare—especially companion animal population control.

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.

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

Sheep on deep bedding in indoor housing.

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 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 Climate Change, where he manages the Biodiversity Conservation Science Section. He has expertise in wildlife management and research.

Dr Steve ATKINSON, BVSc, MACVSc, DipContEd, CMAVA. Dr 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.

Dr 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 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.

1.3.4 20th Anniversary

The year 2006–07 marked 20 years since the establishment of the Animal Research Review Panel. Some of the initiatives and achievements of the ARRP over this period include:

- strongly influencing the *Australian Code of Practice for the Care and use of Animals for Scientific Purposes*
  - ARRP's revision of an existing Commonwealth code was the catalyst for the revision of this Code, resulting in the development of a nationally accepted Code in 1990 (ARRP's major influence was recognised by a Senate Select Committee in its report on Animal Experimentation).
  - There has been continued major input into the content of the Code via membership of the Code Liaison Group.
- development of accreditation and licensing procedures
- development of a Schools system, guidelines and approved procedures—the first time in Australia that the use of animals in schools was addressed in a comprehensive way.

Ongoing work with the Schools system resulted in outcomes such as improved monitoring by the Schools AEC and improved communication with teachers.

- development of a system for the collection and publication of statistics (later revised to take account of a proposed national system)
- development and implementation of a detailed inspection process for accredited establishments and licence holders
- development of an extensive set of policies and guidelines in consultation with user and interest groups
- development of comprehensive wildlife guidelines well ahead of moves in other States to consider wildlife research
- development of housing guidelines that are evidence based and internationally recognised (rabbits, rats, guinea pigs and dogs)
- development and maintenance of a website—Animal Ethics Infolink—that is a source of very broad-ranging information on the use of animals in research and teaching
- reduction in, and refinement of, LD50 testing, through continued work to encourage establishments carrying out LD50 tests to reduce and refine animal use. Successful replacements, reductions and refinements have been implemented.
- the holding of AEC members meetings, instigated to help provide information for, and contact with, AEC members. These are very valuable resources for AECs.

Children's python used in a study to determine optimum feeding regimes for these animals.

- development of the outline of a training package for AEC members. A consultant is currently developing a delivery package.
- the holding of various workshops and meetings for members of AECs, covering such topics as:
  - alternatives to the use of animals in education
  - Animal Welfare for independent AEC members
  - use of farm animals in research
  - monitoring within research establishments.

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 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

New and renewal applications for accreditation or licences are assessed by Animal Welfare Branch staff, according to criteria developed by the ARRP. Arising from these assessments, recommendations on the applications are made to the ARRP. The ARRP considers the recommendations and then makes recommendations on the applications to the Director-General of NSW Department of Primary Industries.

The ARRP has an Applications Subcommittee to facilitate the assessment of new applications. During the 2006–07 period a decision was made that the subcommittee be convened on a 'needs' basis. Where no need was identified by the Animal Welfare Branch for input by the Applications Subcommittee, recommendations would be made by the Branch directly to the ARRP.

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.

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 2006–07 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 Branch 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.

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 2006–07 operational plan, the ARRP again recognised that staff availability within the Animal Welfare Branch would mean that reinspections would mostly 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.

In September 2006 Professor Rose met with representatives of NSW Department of Primary Industries to discuss issues of resourcing for the ARRP and, in particular, the availability of Animal Welfare Branch staff to help the ARRP in its activities. Discussions also extended to streamlining of the administration of some ARRP activities.

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

In the 2006–07 financial year the following staff were assigned, at various times, to provide inspectorial and/or executive support to the ARRP (amongst their other duties):

Orange:

Ross Burton, BVSc, MVSc, Director, Animal Welfare
Amanda Paul, BVSc, MACVSc (Animal Welfare), Veterinary Officer (part-time)
Angela Thompson, BLMgt, Licensing Clerk
Tammy Kirby, Clerical Officer / Acting Licensing Clerk
Frances Kumbley, Clerical Officer
Natasha Coker, Clerical Officer (part-time)

Sydney:

Lynette Chave, BVSc, Leader, Animal Research
Peter Johnson, BVSc, PhD, Veterinary Officer
Janelle Townsend, Clerical Officer (part-time)
Ann Sullivan, 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 2006–07. 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 2006–07 (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 2006–07

The ARRP Operational Plan for 2006–07, 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

The ARRP has an Applications Subcommittee to facilitate the assessment of new applications. During the 2006–07 period a decision was made that the subcommittee be convened on a 'needs' basis. Where no need was identified by the Animal Welfare Branch for input by the Applications Subcommittee, recommendations would be made by the Branch directly to the ARRP.

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

During 2006–07 the ARRP considered:

- 13 new applications for accreditation
- 51 renewal applications for accreditation
- two new applications for school accreditation*
- 13 renewal applications for school accreditation*
- two new applications for animal suppliers' licences
- 26 renewal applications for animal suppliers' licences.

* **Note:** In April 2007 the Association of Independent Schools obtained accreditation on behalf of independent schools. This meant that independent schools no longer needed individual accreditation, bringing the independent school system into line with the systems in place for public schools (covered by accreditation of the NSW Department of Education and Training) and Catholic schools (covered by accreditation of the Catholic Education Commission NSW).

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

Blood sampling of fish: the fish are captured by lowering the water level in their tank. They are then anaesthetised by placing them in a bucket with water-soluble anaesthetic. Once anaesthetised, the fish are gently placed in a plastic-lined foam holder designed to avoid damage to their scales and slime layers, and the blood is collected. Fish are returned to the main tank for recovery.

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 2006–07 were Dr Fogarty and Dr Lowe. The subcommittee makes recommendations to the ARRP, which in turn advises the Minister.

In 2006–07 the subcommittee considered one application (six tests) 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 application on the following conditions:

- that the establishment provide detailed statistical data comparing numbers of animals used and showing the trends in animal use in the 2005, 2006 and 2007 calendar years
- that the establishment report in detail on the purpose for which animals were used in research and development applications
- that the establishment report on the application, where feasible, of early endpoints in approved tests
- that the organisation continue to identify and implement refinements to lessen the impact of existing approved tests on animals and methods of reducing the numbers of animals used in tests, and report upon these to the ARRP.

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

- reductions achieved in the use of animals in non-lethal testing

- an overall decrease in animal use, brought about by improvements in manufacturing processes.

The ARRP requested that it be kept informed of the technical developments that lead directly to reductions in the need for animal-based tests.

The ARRP continues to support an intergovernmental, inter-agency approach in cooperation with industry to develop policies that encourage the production, validation and implementation of alternative methods that bring significant animal welfare benefits, together with efficiencies for industry, through the phase-out of animal-based tests.

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 2006–07 year included:

- hosting of a meeting held in 2007 for members and executive officers of AECs (Drs Baker, Fogarty and Atkinson)
- evaluation of applications for accreditation and licences (Dr Lowe, Ms Abbott and Dr Lawrie)
- evaluation of applications for LD50 testing (Dr Fogarty and Dr Lowe).

2.4 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 2006.

2.4.1 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.

2.5 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.

Cats in enriched rooms, which include objects to climb on and play with, access to a window so they can see outside, and a skylight for sunbathing.

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

- An AEC wrote to the ARRP expressing concern about applications it was receiving for surgical workshops. In particular, the AEC was concerned about the justification for these workshops and whether viable alternatives to the use of animals were available. These workshops were conducted in NSW at a number of locations under the approval of various AECs. In response to this, the ARRP contacted the AECs and the establishment concerned for advice on the concerns raised. The advice from the AECs was unanimous in its support for the justification for the workshops and the lack of suitable alternatives. A detailed response from the establishment supported this view. The establishment indicated a commitment to the use of non-animal alternatives where these were able to meet the educational aims of the surgical workshops. The information provided was collated and circulated to all the AECs concerned, as well as to the NHMRC Animal Welfare Committee, which had an interest in the conduct of surgical workshops.
- Follow-up was completed on an ongoing matter related to the care and management of dogs at an accredited establishment. The ARRP had helped the AEC to ensure there were adequate procedures for the care and management of the dogs via direct liaison with the head of the establishment.
- An incident of deaths of animals post-surgery was brought to the attention of the ARRP. As this was not the first time such an incident had occurred in the research group concerned, the ARRP convened a meeting with relevant personnel, including the Executive of the establishment and the AEC Chair. The outcome of the meeting included the assessment of the surgical procedures and techniques by an independent veterinary surgical expert. Requirements for additional monitoring and for reporting to the AEC were placed on the research group.
- Representatives of the ARRP and Animal Welfare Branch met with staff from the Department of Education and Training in response to a request from the Schools Animal Ethics Committee on the status of fishing carried out in schools. Discussions included whether the various fishing activities were encompassed by the animal research legislation and how the activities could best be approached by the AEC. Mechanisms for ensuring best practice related to the welfare of fish were developed as a result of this meeting.

2.5.1 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.

Viewing portals in tanks designed to allow the fish to be checked may also be used by the fish to view their visitors: this snapper took more than a passing interest in the inspection team!

2.5.2 Meeting for members and executive officers of AECs

In April 2007 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 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 Dr Baker, Dr Fogarty and Dr Atkinson.

Over 100 AEC members attended the meeting, which was once again kindly hosted by the Australian Catholic University at its MacKillop Campus. The focus of the meeting was to reflect on changes in the conduct of animal research since the introduction of animal research legislation 20 years ago. Presentations were given on changes from the perspectives of the Animal Research Review Panel/ Government, researchers, and AEC members. Interactive sessions were also held on current topics of interest, including the monitoring of transgenic animals, regulatory testing requirements, the effects of patents on information provided to AECs, environmental enrichment for animals, and the use of animals in teaching.

The ARRP was grateful to the speakers who donated their time and expertise and to the audience members who actively participated in discussions; these contributions greatly added to the success of the day.

Analysis of feedback forms indicated that the majority of participants found the meeting very informative and useful for their activities related to AECs.

Reports from the meeting can be found at www.animalethics.org.au.

2.6 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.

2.7 Site inspections

A list of site inspections undertaken in 2006–07 is provided in Appendix C, and a list of ARRP members attending is given in Appendix D. There were 19 inspections conducted over a period of 24 working days. The length of these inspections ranged from 1 day for smaller institutions up to 3 days for larger ones. The inspections included AECs and the facilities of 22 accredited institutions / licensed animal suppliers.

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.

2.8 Policies, guidelines and fact sheets

The ARRP and Animal Welfare Branch produces 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 Branch 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*. 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 finalised in 2006–07:

- *ARRP Guideline 21: Guidelines for the Housing of Guinea Pigs in Scientific Institutions.* The draft 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 Care and the Universities Federation for Animal Welfare). Very favourable responses were received, including from the international reviewers, and the guidelines were revised on the basis of the comments received.

The following policy was revised in 2006–07:

- *ARRP Policy 10: Emergency Procedures.* The document was considerably expanded to encourage establishments to plan for emergencies affecting animals and to provide guidance on the content of such emergency plans.

2.9 Initiatives in replacement, reduction and refinement

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

2.10 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 2006–07 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

Branch. Five informal complaints were received in the 2006–07 reporting period.

The informal complaints are summarized as follows:

Rats not being provided with adequate dark periods in an animal house

The matter had implications both for the welfare of the rats and for the results of the studies in which the rats were being used. The matter was taken up with the Chair of the AEC and was satisfactorily resolved to ensure that adequate dark periods were provided.

Illegal bleeding of sheep

Information was provided to the Animal Welfare Branch about blood allegedly being collected from sheep and the serum being sold by Mr Paul Hamilton of Starrate Australia Limited.

Such collection of blood is encompassed by the Animal Research Act and requires the approval of an Animal Ethics Committee and accreditation of the corporation as an Animal Research Establishment. The bleeding of sheep without the approvals required under the Act leaves the animals unprotected. In particular, where appropriate approvals are not obtained, there is no scrutiny of the procedures used, nor is there monitoring of animal care and use by an AEC, Animal Welfare Branch Veterinary Inspectors or members of the Animal Research Review Panel.

The purpose of the legislation is to protect the welfare of animals used in research. Research cannot be conducted without the approval of the relevant AEC. In assessing an application to carry out research the AEC examines many issues, including the impact of the procedures on the animals and the benefits of the research to be conducted. The AEC also monitors the conduct of approved projects and the care of animals used. In the case of blood collection, specific issues about which the AEC will need to be satisfied include:

- the volume of blood to be collected from each animal (to ensure that not too much blood is collected)
- the frequency of blood collection from individual animals (to ensure that the blood is not collected too frequently)
- the methods used to monitor animals for anaemia
- the method of blood collection (to ensure the least pain and distress for the animals).

Additional factors that would be considered by the AEC as a matter of course would include:

- the qualifications and skill of the people handling animals and collecting blood
- the routine care and management of the animals, including feeding and housing.

Mr Hamilton had approval in the past for bleeding sheep, but the approval had lapsed and, before the illegal collection of blood, he had been advised by NSW Department of Primary Industries that he did not have an authority to collect blood from animals.

The matter was investigated by the Animal Welfare Branch and the Animal and Plant Regulatory Operations Branch of NSW Department of Primary Industries with the assistance of the police.

The NSW Department of Primary Industries prosecuted Mr Hamilton with respect to four offences under the Animal Research Act:

S 46(1) and s 58(1): Director of Corporation that did carry on the business of animal research when not being an accredited research establishment.

S 47(1): Carry out animal research without an Animal Research Authority.

S 47A(1): Keep animals with intention of using them for animal research when not authorised.

S47A(1) and 58(1): Director of Corporation that kept animals with the intention of using them for animal research when not authorised.

The Department prosecuted Starrate Australia Limited with respect to two offences under the Act:

S 46 (1): Corporation did carry on the business of animal research when not being an accredited research establishment.

S 47A(1): Keep animals with intention of using them for animal research when not authorised.

The prosecution was heard by Magistrate Moon before Junee Local Court on 14 August 2007. Mr Hamilton was convicted of the four offences and Starrate Australia Limited was convicted of the two offences.

Fines and costs totalled approximately $14,000. In addition, Mr Hamilton became a disqualified individual and Starrate Australia Limited a disqualified corporation; this prevents Mr Hamilton and Starrate Australia from carrying out animal research in NSW for a period of 3 years.

Out-of-session approval of a project

A complaint was received that a project under consideration by the AEC had been approved by the AEC secretariat. Approval by the AEC had been deferred pending the provision of additional information to the AEC. The matter had animal welfare implications because of the impact on the animals of the procedures that were yet to be approved by the AEC. Approval for projects may be granted only at quorate meetings of AECs.

Investigation involved communication with the AEC about the circumstances leading to the approval. In the course of the investigation it was established that the project was subsequently approved at a quorate AEC meeting.

In response to the information provided, a letter was sent to the head of the establishment to outline the AEC procedures required under the legislation and to note the need for support of the AEC by the establishment. A follow-up inspection was organised at which members of the ARRP and Animal Welfare Branch met with the AEC to assess its operation and to help it to meet its responsibilities under the Animal Research Act.

Use of dogs

Information was received about the use of dogs by an Accredited Animal Research Establishment that did not have approval to obtain and use dogs.

The investigation established that the project involving dogs had been approved by the AEC, but that the dogs had not been obtained from a licensed animal supplier. Inspections by members of ARRP and the Animal Welfare Branch were carried out to assess the operation of the AEC and the dog care and management, and to provide advice on authorisations required under the legislation. The Director-General of NSW Department of Primary Industries cautioned the establishment about its responsibilities. Subsequently appropriate authorisations were obtained.

Conduct of research

A complaint was referred by the RSPCA in relation to the conduct of research. The complainant was contacted to provide information to enable investigation, but no information was provided and the matter could not be followed up.

2.11 International harmonisation on animal care and use guidelines

In April 2007 Professor Rose was invited by the International Council for Laboratory Animal Care (ICLAS) to be a member of the Working Group on the Harmonisation of Guidelines on the Use of Animals in Science.

On its website, ICLAS states:

> The international harmonization of guidelines for the use of animals in research, teaching and testing is an emerging issue in the context of the globalization of research. The International Council for Laboratory Animal Science (ICLAS), as an international umbrella organization, is well situated to act as a facilitator in this area. ICLAS supports the harmonization of animal care and use policies, guidelines and other forms of regulation on a worldwide basis, as a reflection of the globalization of research. This does not mean standardization. ICLAS considers that each country should be able to maintain an animal welfare oversight system that reflects its cultures, traditions, religions, laws and regulations.

Membership of the Working Group is by invitation only, and Professor Rose is the sole representative from Australia. Professor Rose's participation in discussions on animal care guidelines at an international level will be of value to the ARRP in its ongoing program of developing evidence-based guidelines on the housing of animals used for research and teaching. Housing guidelines already developed by the ARRP are being used by the Working Group in the context of its deliberations.

2.12 Comments on documents

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

NSW Department of Primary Industries:

Emergency Management Planning for Animal Holding Establishments

APPENDIXES

Appendix A: Dates of ARRP meetings 2006–07

Meeting number	Date of meeting
166	5 July 2006
167	23 August 2006
168	11 October 2006
169	6 December 2006
170	14 February 2007
171	18 April 2007
172	13 June 2007

Appendix B: Members' attendances at ARRP meetings 2006–07

	Meeting number						
Member	**166**	**167**	**168**	**169**	**170**	**171**	**172**
Professor M Rose (Chair)	*	*	A	*	*	*	A
Dr R Fogarty (Deputy Chair)	*	*	*	A	*	*	*
Ms S Abbott	A	A	*	*	*	A	*
Dr S Atkinson	*	A	*	*	*	*	*
Dr J Baker	*	*	*	*	*	*	*
Dr J Grossman	–	A	*	*	*	A	A
Dr M Lawrie	A	*	*	*	*	A	*
Dr B Lowe	*	*	A	*	*	*	*
Mr D O'Shannessy	*	*	*	*	A	*	*
A/Professor R Pirola	A	*	*	*	*	*	*
Dr P Towers	*	*	*	*	*	*	*

* = Present
A = Absent
– = Not applicable

Appendix C: Inspections July 2006 – June 2007

Establishment	Date
Charles Sturt University	12/7/2006
Bioproperties	2/8/2006
Australian Museum	16/8/2006
University of Technology Sydney (new facility)	7/9/2006
Novartis	21/11/2006
University of Newcastle	22/11/2006
	23/11/2006
	24/11/2006
Hunter New England Health	23/11/2006
	24/11/2006
Wildthing Environmental Consultants	24/11/2006
Avondale	24/11/2006
Children's Cancer Institute	27/11/2006
University of Technology Sydney (new facility)	15/3/2007
	17/5/2007
University of Technology Sydney (new facility)	10/4/2007
Zoological Parks Board	17/4/2007
Apollo Life Sciences	1/5/2007
Sally Colgan	9/5/2007
Director-General's AEC	14/5/2007
Agrisearch	24/5/2007
ICP Firefly	29/5/2007
	14/6/2007
CSIRO – Molecular Science	7/6/2007
Bioquest Pty Ltd	7/6/2007
Department of Environment and Conservation	18/6/2007
University of New England	27/6/2007
	28/6/2007
	29/6/2007
Veterinary Health Research	27/6/2007
Millipore	27/6/2007

Appendix D: Attendance of ARRP members at site inspections 2006–07

Member	Number of days spent on site inspection
A/Professor M Rose	4
Ms S Abbott	1
Dr S Atkinson	–
Dr J Baker	–
Dr R Fogarty	7
Dr J Grossman	3
Mr M Lawrie	–
Dr B Lowe	4
Mr D O'Shannessy	3
A/Professor R Pirola	–
Dr P Towers	4

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 2006 – June 2007

= Priority

	Activity	Measure of performance	Time frame	Status
1.	**Mandatory**			
1.1	Review incoming applications for accreditation and licence	Recommendation to Director-General	3 months (new) 2 months (renewal)	All applications processed and recommendations made to the Director-General.
1.2	Investigate formal and informal complaints	Recommendation to Director-General	Interim or final recommendations within 3 months	Five informal complaints considered.
1.3	Review incoming applications to conduct LD50 tests	Recommendations to Minister	3 months	All applications (six) reviewed and recommendations sent to the Minister.
1.4	Prepare annual report for 2005–06	Report submitted to Minister	December 2006	Report prepared.
1.5	Prepare statistics on animal use for 2005	Statistics collated	December 2006	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	22
		Number of days for inspections		24
		Total number of establishments not inspected within the last 4 years		Six (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	0
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.

	Activity	Measure of performance	Time frame	Status
2.6	Review inspection procedures, including consideration of annual reporting by establishments	Seek input from accredited establishments	September 2006	Input not sought
		Revise procedures after collation of responses	June 2007	Annual reports collected.
2.7	Assess means to conduct a general review of the operation of AECs	Assessment carried out	June 2007	Annual reports to be assessed.
3.	**Education**			
3.1	Maintain ARRP website	Site maintained	Ongoing	Website maintained.
3.2	Finalise learning guide to accompany AEC learning package	Guide finalised	December 2006	Development of learning guide in progress.
3.3	Meeting for members of AECs	Meeting held	June 2007	Meeting held in April 2007.
3.4	Facilitate access to education programs by researchers and teachers (via Code Liaison Group)	Plan to facilitate access developed.	June 2007	Code Liaison Group agenda item on education of researchers and teachers.
4.	**Policies and guidelines**			
4.1	Standards linked to performance criteria for rats, mice, guinea pigs and farm animals (sheep, cattle, pigs)	Finalise revision of rat document	August 2006	Revision in progress
		Draft of mouse document circulated for comment	March 2007	Draft being developed.
		Collate comments on guinea pig document	March 2007	Comments collated Document finalised
		Draft of sheep document progressed	June 2007	Draft in progress
4.2	Develop policies/guidelines where strong need identified (maximum of two)	Developed as need identified	Ongoing	0
4.3	Revise current policies and guidelines	Policies and guidelines revised	December 2006	1
5.	**Legislation**			
5.1	Assess results of revised statistics package	Results assessed	October 2006	Results considered and publication revised.

	Activity	Measure of performance	Time frame	Status
5.2	Assess lethality statistics for publication	Statistics assessed	October 2006	Statistics assessed and published.
6.	**Additional**			
6.1	Continue liaison with NHMRC	Meeting held	Ongoing	Liaison via comments on publications / Code Liaison Group meetings attended.
6.2	Continue liaison with APVMA via the Animal Welfare Working Group	Contact with APVMA maintained	Ongoing	No specific issues to require liaison.
6.3	Establish liaison with AAWS Advisory Committee	Liaison established	December 2006	Refer matters to AAWS as relevant.

Appendix G: Animal use statistics 2006

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 2006.

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

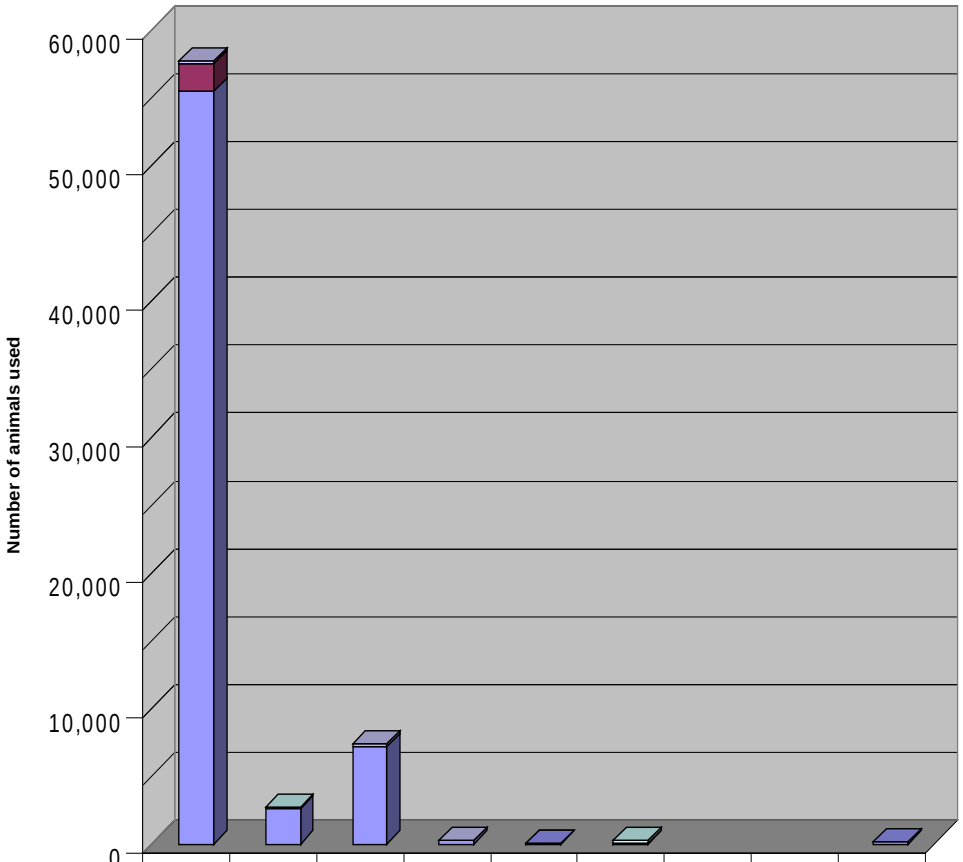
Data collection: procedure categories and guidelines used for classification

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

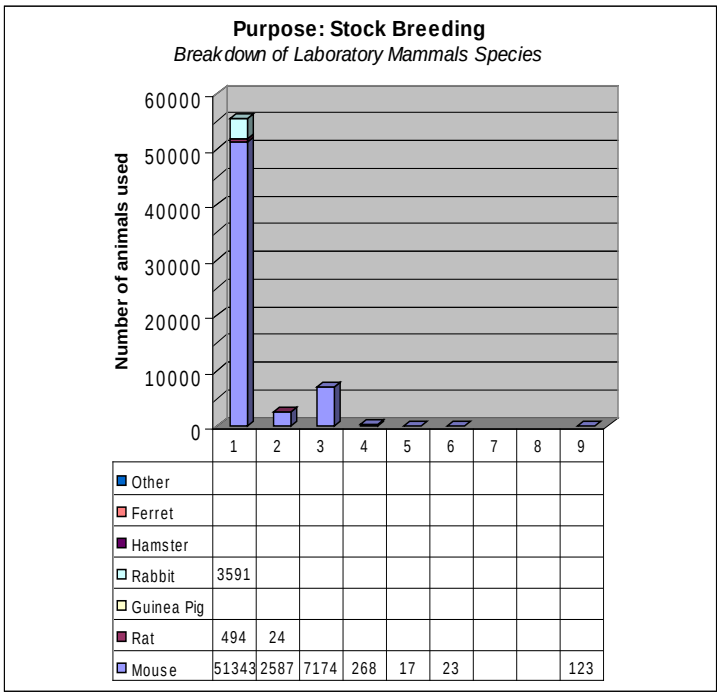
Breeding protocols to produce new teaching or research stock.
Only includes the animals used to produce progeny, NOT the final progeny.

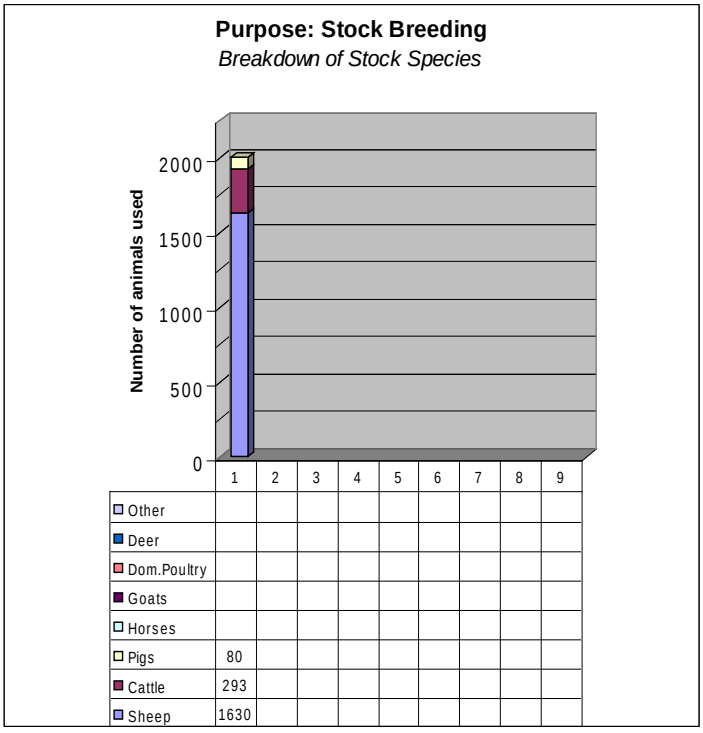


	1	2	3	4	5	6	7	8	9
Other									
Exotic Feral									
Nat Mam	174		142	16					
Primates									
Domestic									
Reptiles									
Aquatic		94	8			240			
Birds	36								
Stock	2003								
Lab Mam	55428	2611	7174	268	17	23			123

Procedure

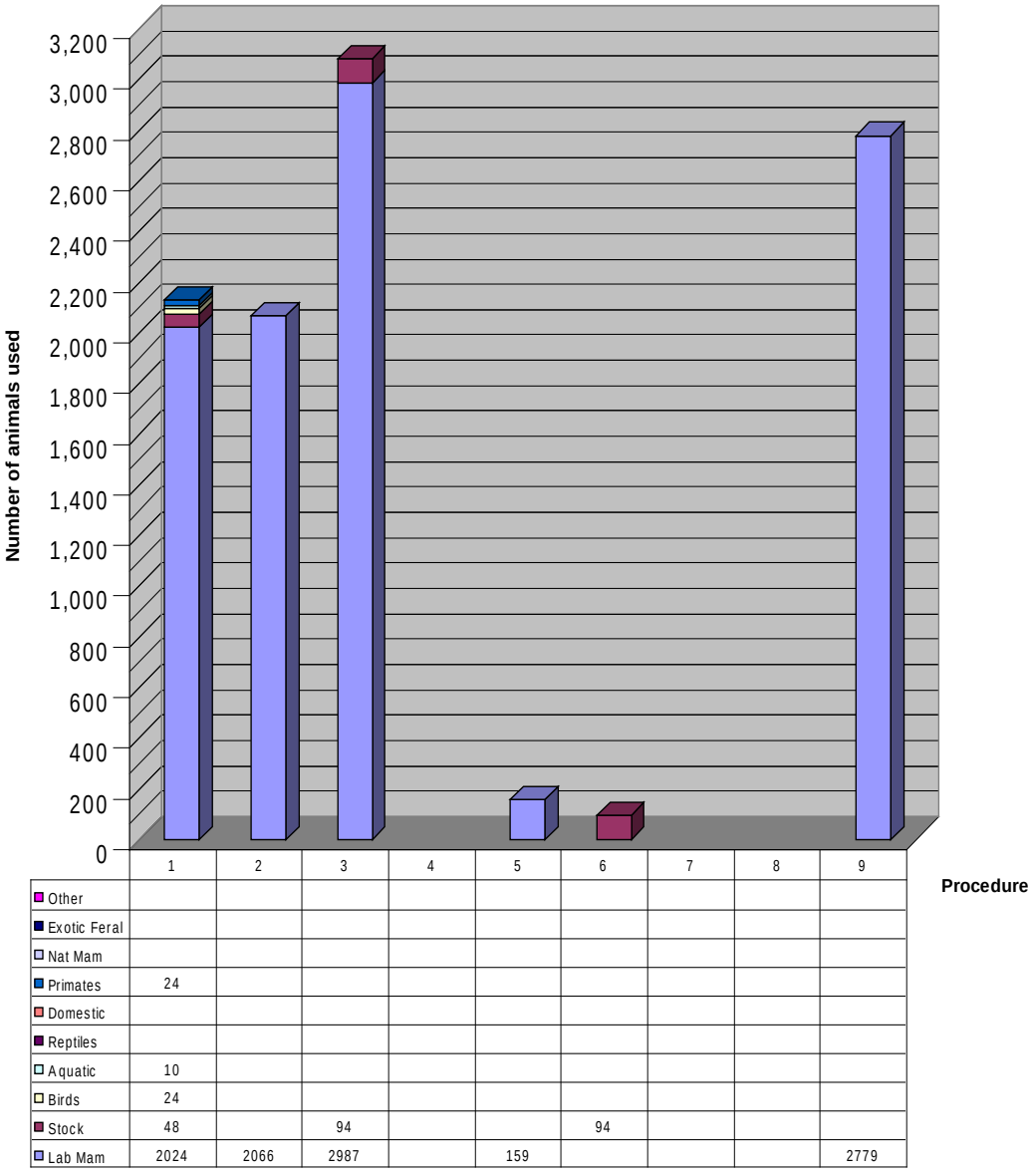
Refer to following page for a further breakdown of species.


Purpose: Stock Breeding
Breakdown of Laboratory Mammals Species
Number of animals used
60000
50000
40000
30000
20000
10000
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit 3591
Guinea Pig
Rat 494 24
Mouse 51343 2587 7174 268 17 23 123


Purpose: Stock Breeding
Breakdown of Stock Species
Number of animals used
2000
1500
1000
500
0
1 2 3 4 5 6 7 8 9
Other
Deer
Dom.Poultry
Goats
Horses
Pigs 80
Cattle 293
Sheep 1630

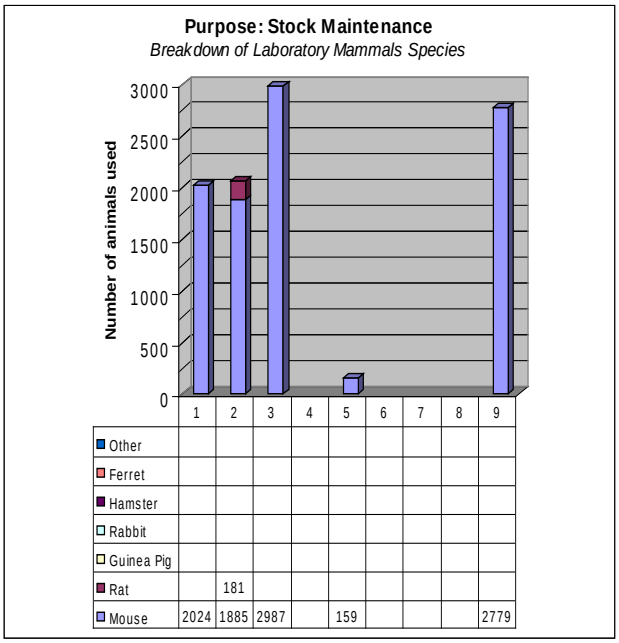
Purpose: Stock Maintenance

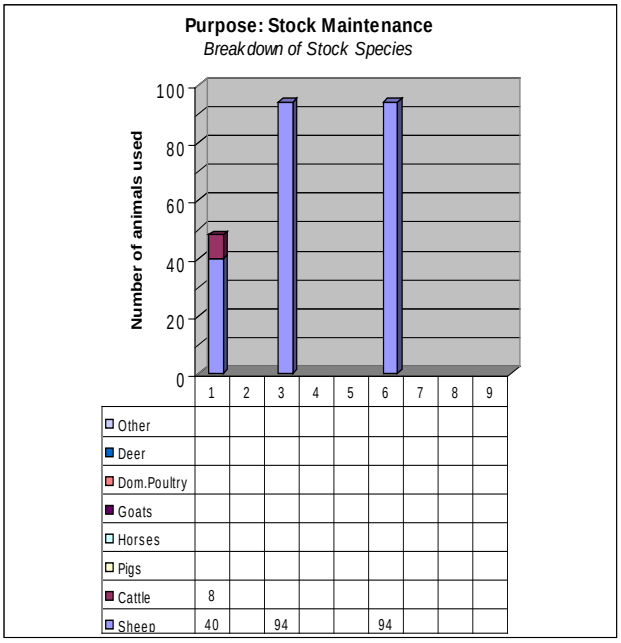
Holding Protocols for animals maintained for use in other protocols .

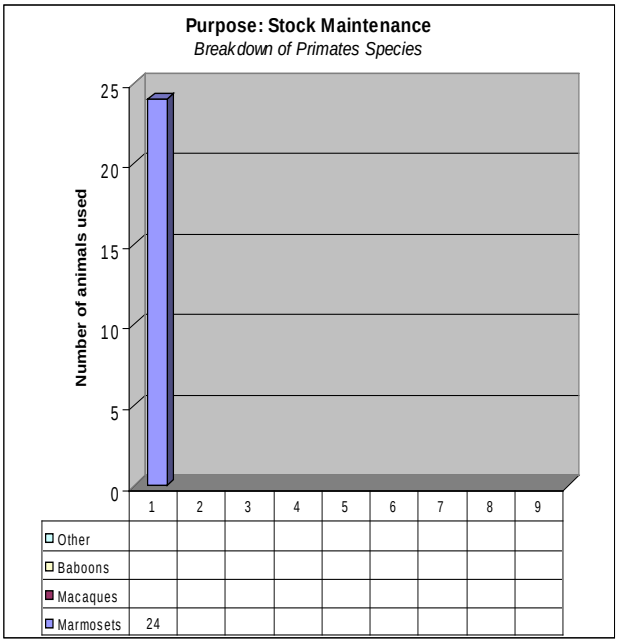


	1	2	3	4	5	6	7	8	9
Other									
Exotic Feral									
Nat Mam									
Primates	24								
Domestic									
Reptiles									
Aquatic	10								
Birds	24								
Stock	48		94			94			
Lab Mam	2024	2066	2987		159				2779

Refer to following page for a further breakdown of species.

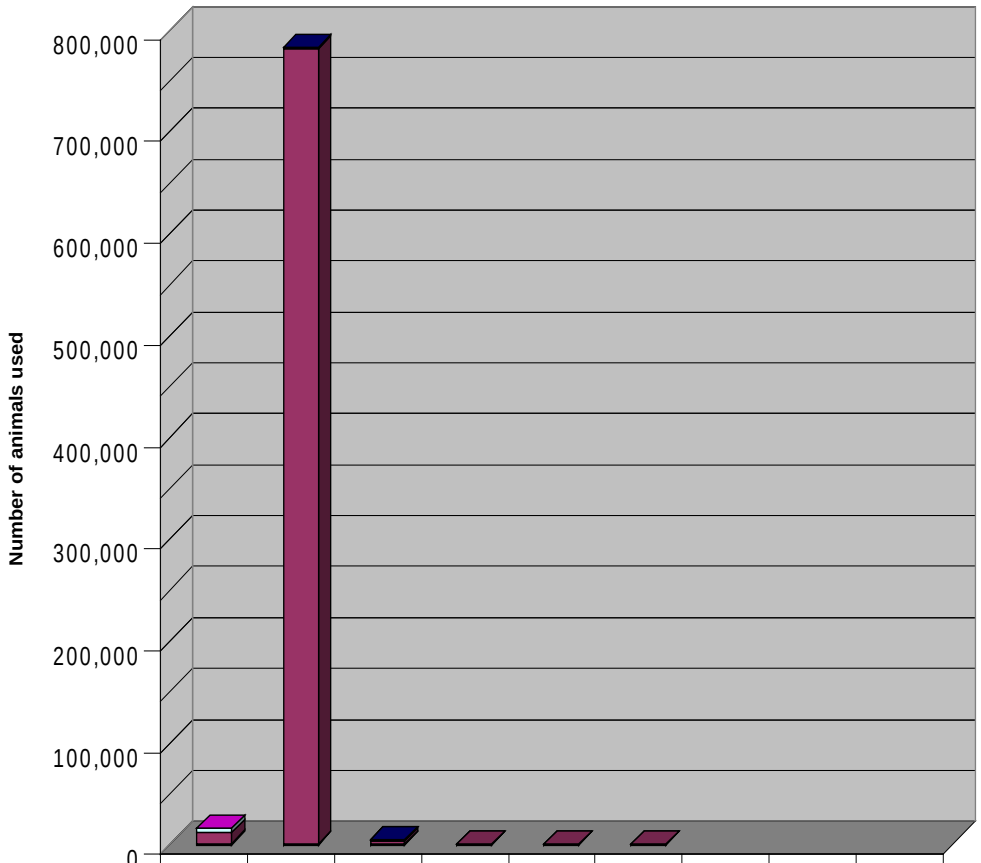

Purpose: Stock Maintenance
Breakdown of Laboratory Mammals Species
Number of animals used
3000
2500
2000
1500
1000
500
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit
Guinea Pig
Rat 181
Mouse 2024 1885 2987 159 2779


Purpose: Stock Maintenance
Breakdown of Stock Species
Number of animals used
100
80
60
40
20
0
1 2 3 4 5 6 7 8 9
Other
Deer
Dom.Poultry
Goats
Horses
Pigs
Cattle 8
Sheep 40 94 94


Purpose: Stock Maintenance
Breakdown of Primates Species
Number of animals used
25
20
15
10
5
0
1 2 3 4 5 6 7 8 9
Other
Baboons
Macaques
Marmosets 24

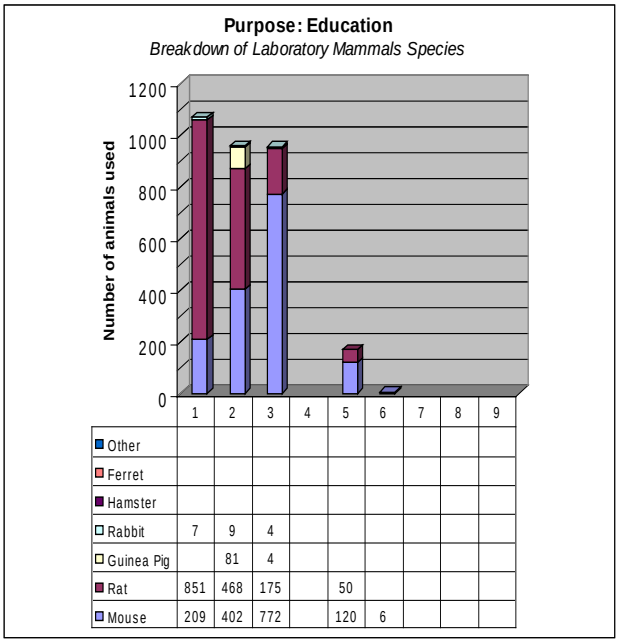
Purpose: Education

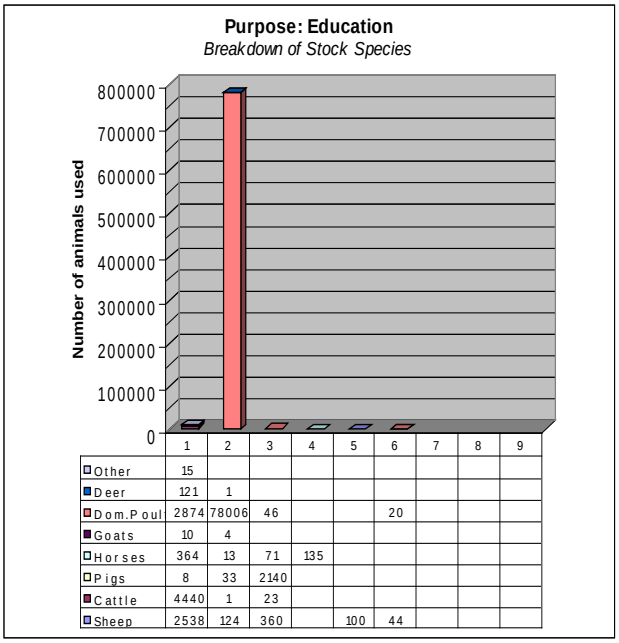
Protocols carried out for the achievement of educational objectives, including interactive or demonstration classes in methods of animal husbandry, management, examination and treatment .

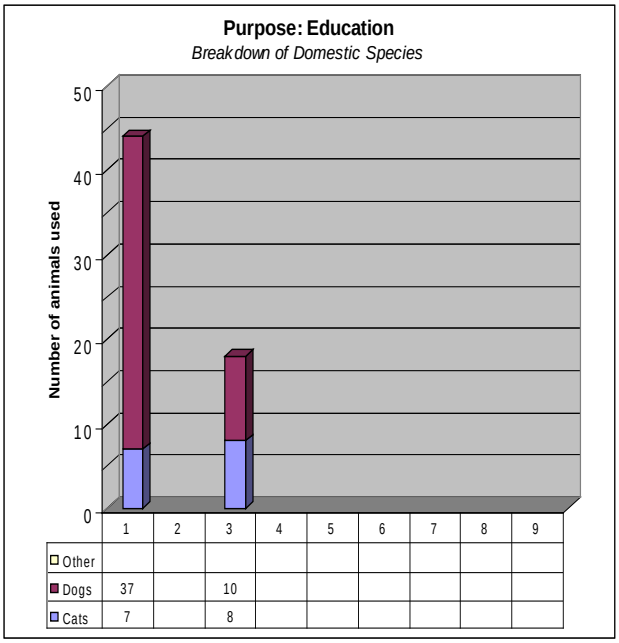


	1	2	3	4	5	6	7	8	9
Other	162								
Exotic Feral	1	122	5						
Nat Mam	185	46	253						
Primates									
Domestic	44		18						
Reptiles	52	4	25						
Aquatic	4309	1472	456						
Birds	148	103	50						
Stock	10370	780242	2640	135	100	64			
Lab Mam	1067	960	955		170	6			

Refer to following page for a further breakdown of species.

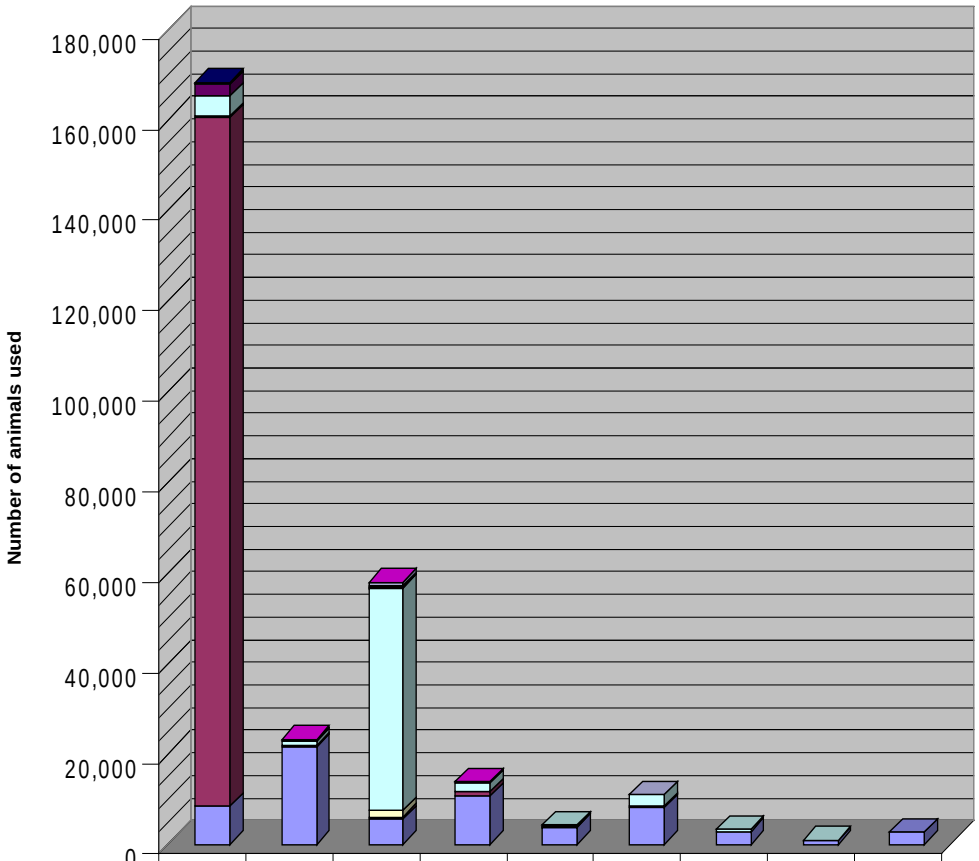

Purpose: Education
Breakdown of Laboratory Mammals Species
Number of animals used
1200
1000
800
600
400
200
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit 7 9 4
Guinea Pig 81 4
Rat 851 468 175 50
Mouse 209 402 772 120 6


Purpose: Education
Breakdown of Stock Species
Number of animals used
800000
700000
600000
500000
400000
300000
200000
100000
0
1 2 3 4 5 6 7 8 9
Other 15
Deer 121 1
Dom.Poul 2874 78006 46 20
Goats 10 4
Horses 364 13 71 135
Pigs 8 33 2140
Cattle 4440 1 23
Sheep 2538 124 360 100 44


Purpose: Education
Breakdown of Domestic Species
Number of animals used
50
40
30
20
10
0
1 2 3 4 5 6 7 8 9
Other
Dogs 37 10
Cats 7 8

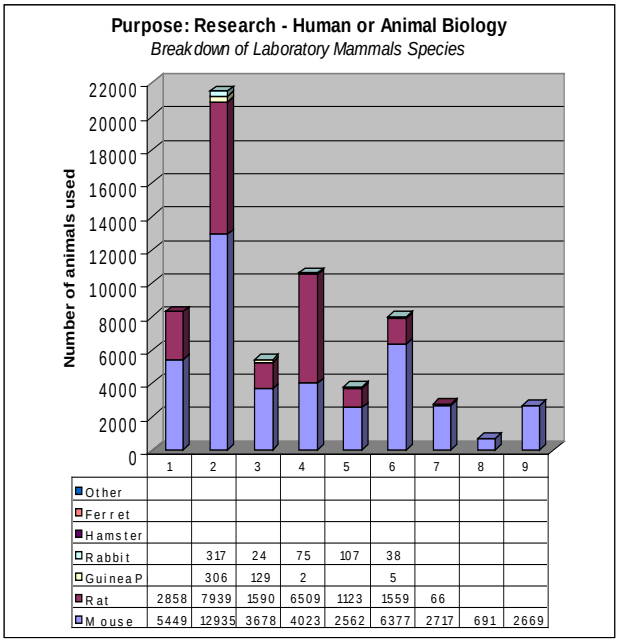
Purpose: Research - Human or Animal Biology

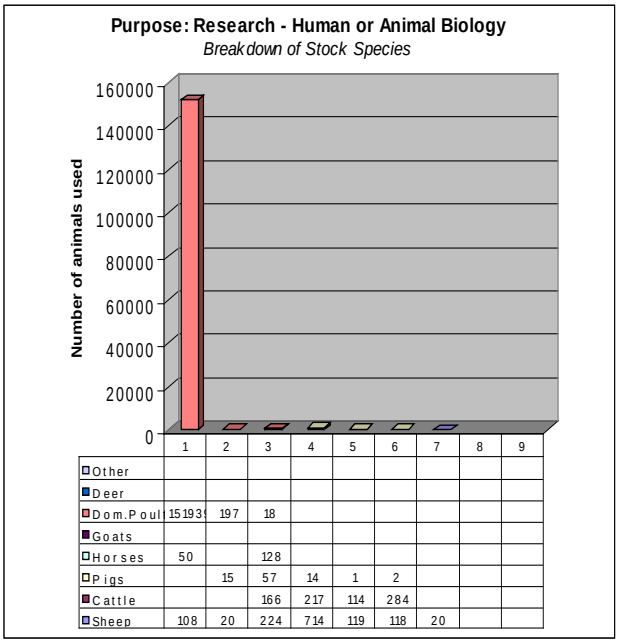
Research protocols which aim to increase the basic understanding of the structure, function and behaviour of animals, including humans, and processes involoved in physiology, biochemistry and pathology .

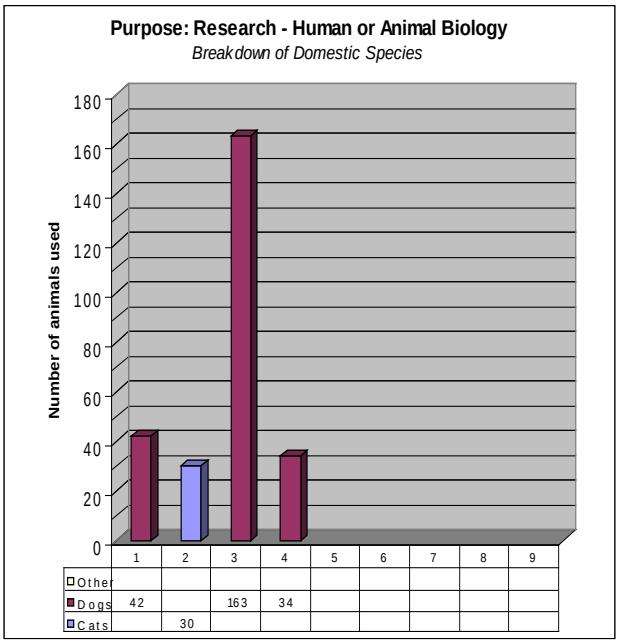


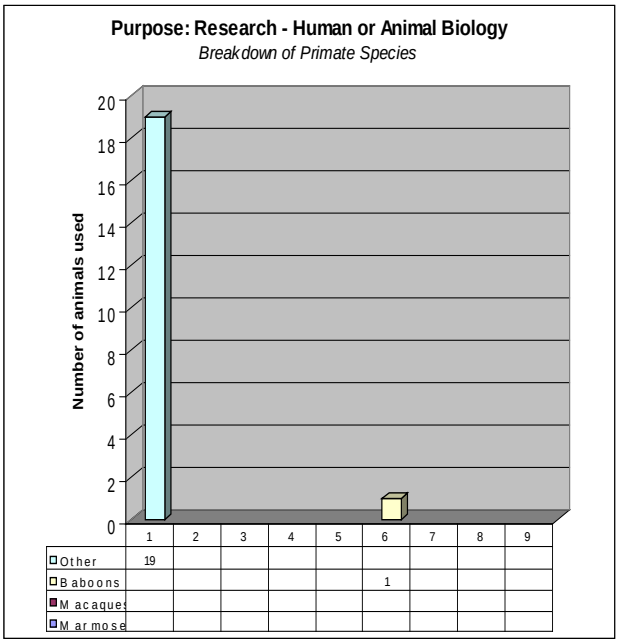
	1	2	3	4	5	6	7	8	9
Other		49	5	13					
Exotic Feral	111								
Nat Mam	244	132	900	246		78			
Primates	19					1			
Domestic	42	30	163	34					
Reptiles	2701	286	204	1		10			
Aquatic	4287	939	49129	1931	192	2480	500	260	
Birds	447	29	1488			71		11	
Stock	152097	232	593	945	234	404	20		
Lab Mam	8307	21497	5421	10609	3792	7979	2783	691	2669

Refer to following page for a further breakdown of species.


Purpose: Research - Human or Animal Biology
Breakdown of Laboratory Mammals Species
Number of animals used
22000
20000
18000
16000
14000
12000
10000
8000
6000
4000
2000
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit 317 24 75 107 38
GuineaP 306 129 2 5
Rat 2858 7939 1590 6509 1123 1559 66
Mouse 5449 12935 3678 4023 2562 6377 2717 691 2669

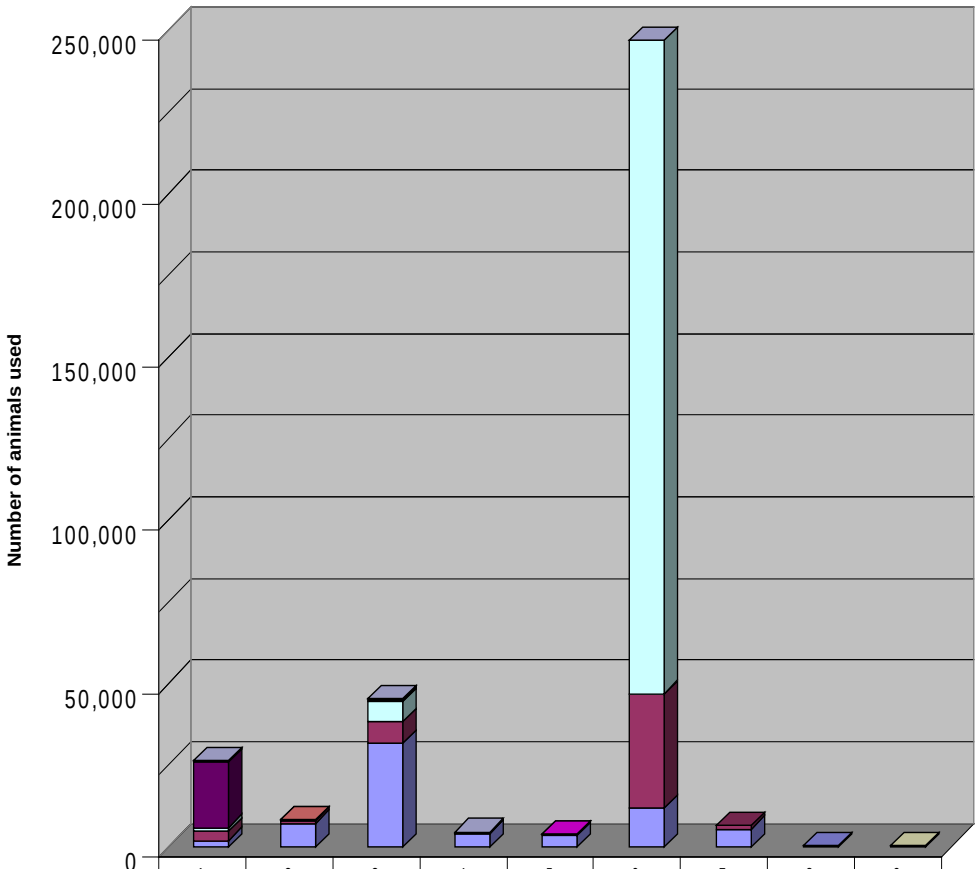

Purpose: Research - Human or Animal Biology
Breakdown of Stock Species
Number of animals used
160000
140000
120000
100000
80000
60000
40000
20000
0
1 2 3 4 5 6 7 8 9
Other
Deer
Dom.Poul 197 18
Goats
Horses 50 128
Pigs 15 57 14 1 2
Cattle 166 217 114 284
Sheep 108 20 224 714 119 118 20


Purpose: Research - Human or Animal Biology
Breakdown of Domestic Species
Number of animals used
180
160
140
120
100
80
60
40
20
0
1 2 3 4 5 6 7 8 9
Other
Dogs 42 163 34
Cats 30


Purpose: Research - Human or Animal Biology
Breakdown of Primate Species
Number of animals used
20
18
16
14
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9
Other 19
Baboons 1
Macaques
Marmose

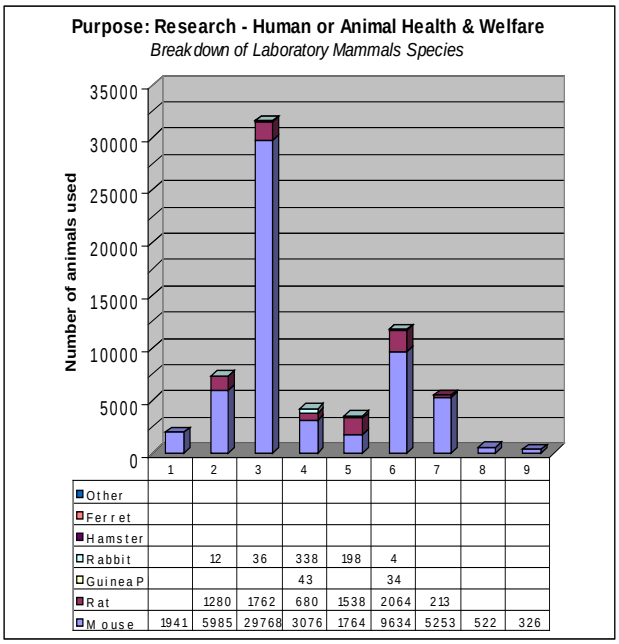
Purpose: Research - Human or Animal Health & Welfare

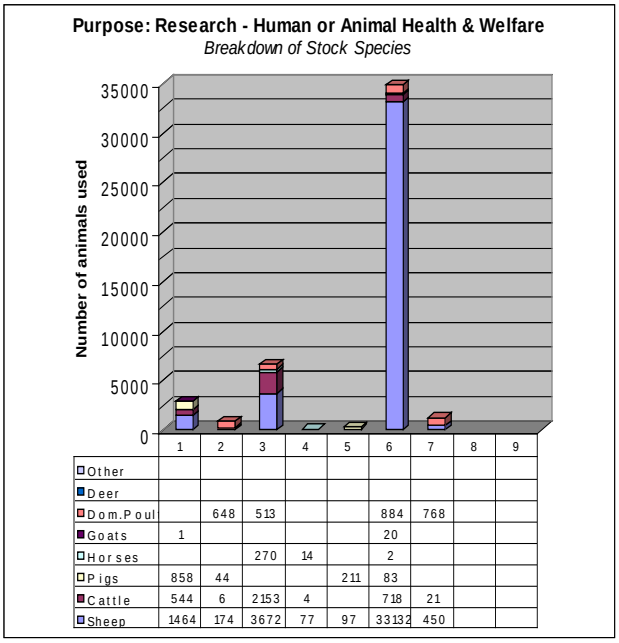
Research protocols which aim to produce improvements in the health and welfare of animals, including humans .

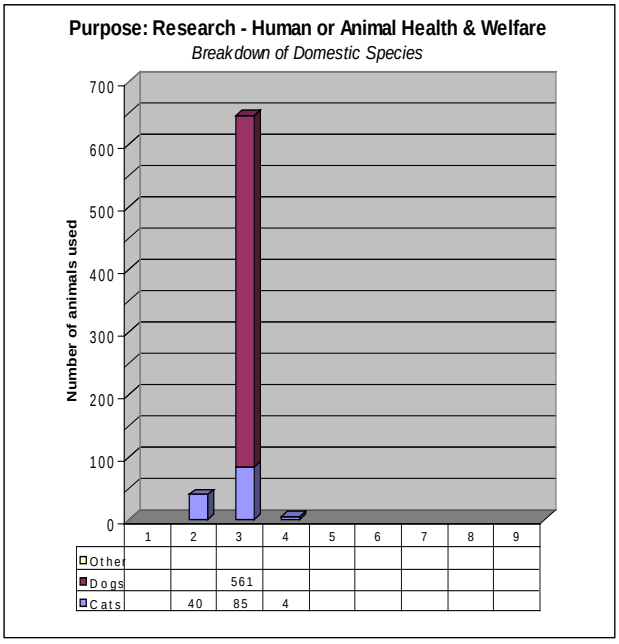


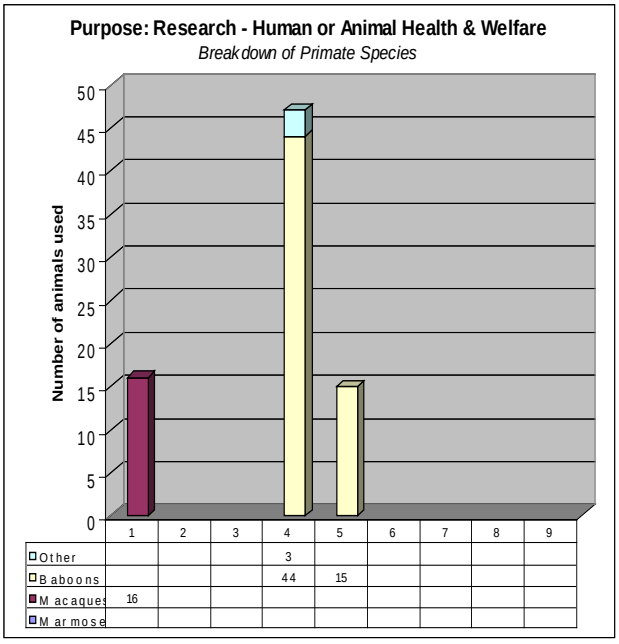
	1	2	3	4	5	6	7	8	9
Other					5				
Exotic Feral									
Nat Mam	611		298	280	22	16			
Primates	16			47	15				
Domestic		40	646	4					
Reptiles	20000								
Aquatic	1035		6211			200000			
Birds			36		1	288			28
Stock	2867	872	6608	95	308	34839	1239		
Lab Mam	1941	7277	31566	4137	3500	11736	5466	522	326

Refer to following page for a further breakdown of species.


Purpose: Research - Human or Animal Health & Welfare
Breakdown of Laboratory Mammals Species
Number of animals used
35000
30000
25000
20000
15000
10000
5000
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit 12 36 338 198 4
GuineaP 43 34
Rat 1280 1762 680 1538 2064 213
Mouse 1941 5985 29768 3076 1764 9634 5253 522 326

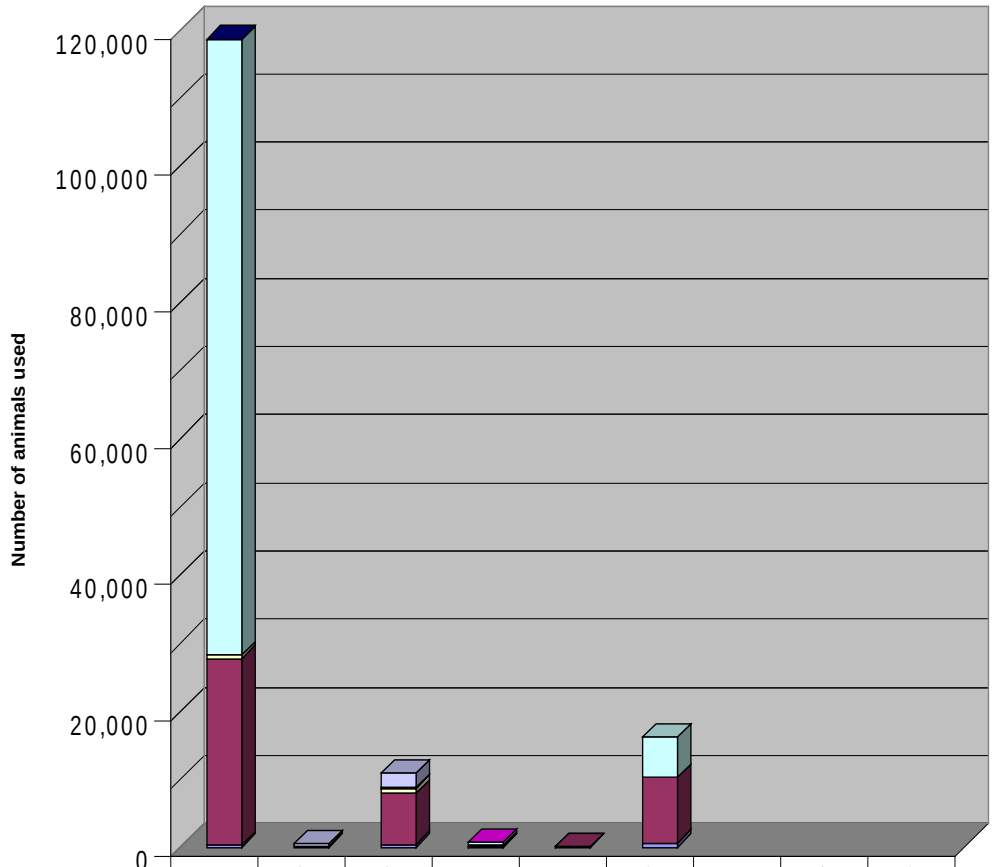

Purpose: Research - Human or Animal Health & Welfare
Breakdown of Stock Species
Number of animals used
35000
30000
25000
20000
15000
10000
5000
0
1 2 3 4 5 6 7 8 9
Other
Deer
Dom.Poul 648 513 884 768
Goats 1 20
Horses 270 14 2
Pigs 858 44 211 83
Cattle 544 6 2153 4 718 21
Sheep 1464 174 3672 77 97 33132 450


Purpose: Research - Human or Animal Health & Welfare
Breakdown of Domestic Species
Number of animals used
700
600
500
400
300
200
100
0
1 2 3 4 5 6 7 8 9
Other
Dogs 561
Cats 40 85 4


Purpose: Research - Human or Animal Health & Welfare
Breakdown of Primate Species
Number of animals used
50
45
40
35
30
25
20
15
10
5
0
1 2 3 4 5 6 7 8 9
Other 3
Baboons 44 15
Macaques 16
Marmose

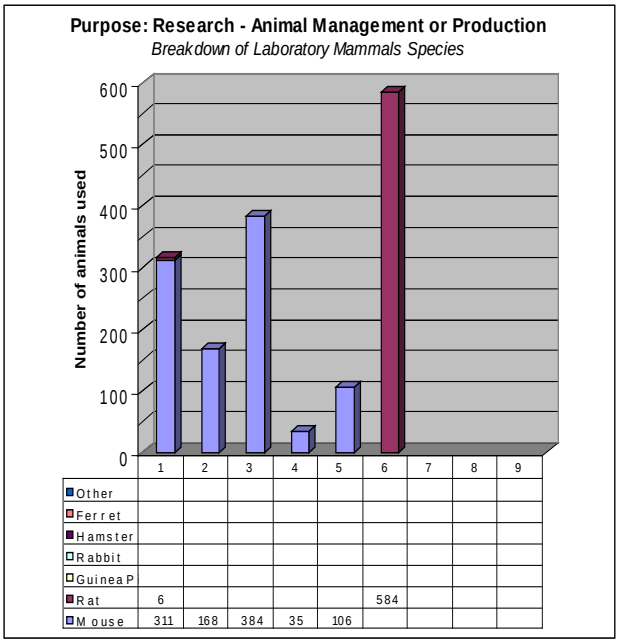
Purpose: Research - Animal Management or Production

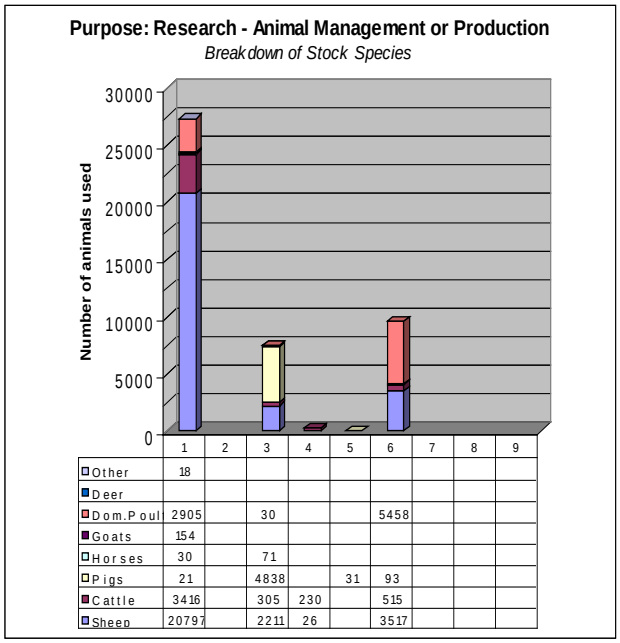
Research protocols which aim to produce improvements in domestic or captive animal management or production .

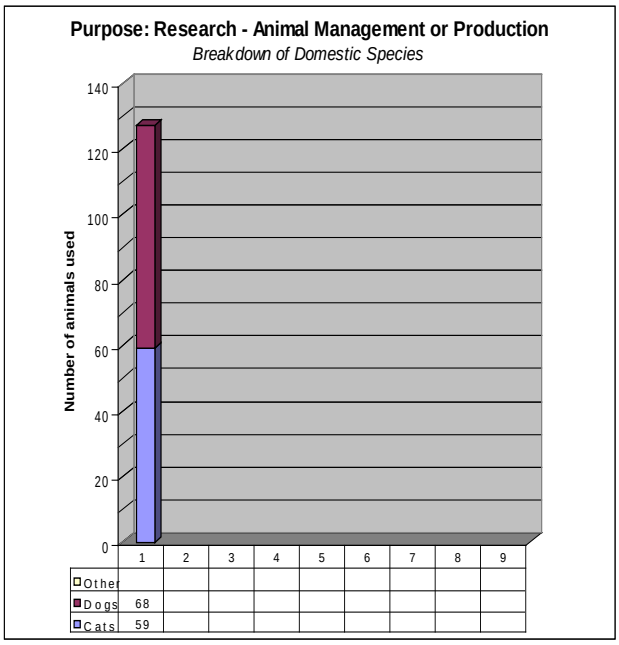


	1	2	3	4	5	6	7	8	9
Other				7					
Exotic Feral	4								
Nat Mam	16	318	2173						
Primates									
Domestic	127								
Reptiles			70						
Aquatic	90210			439		6000			
Birds	511		826						
Stock	27341		7455	256	31	9583			
Lab Mam	317	168	384	35	106	584			

Refer to following page for a further breakdown of species.

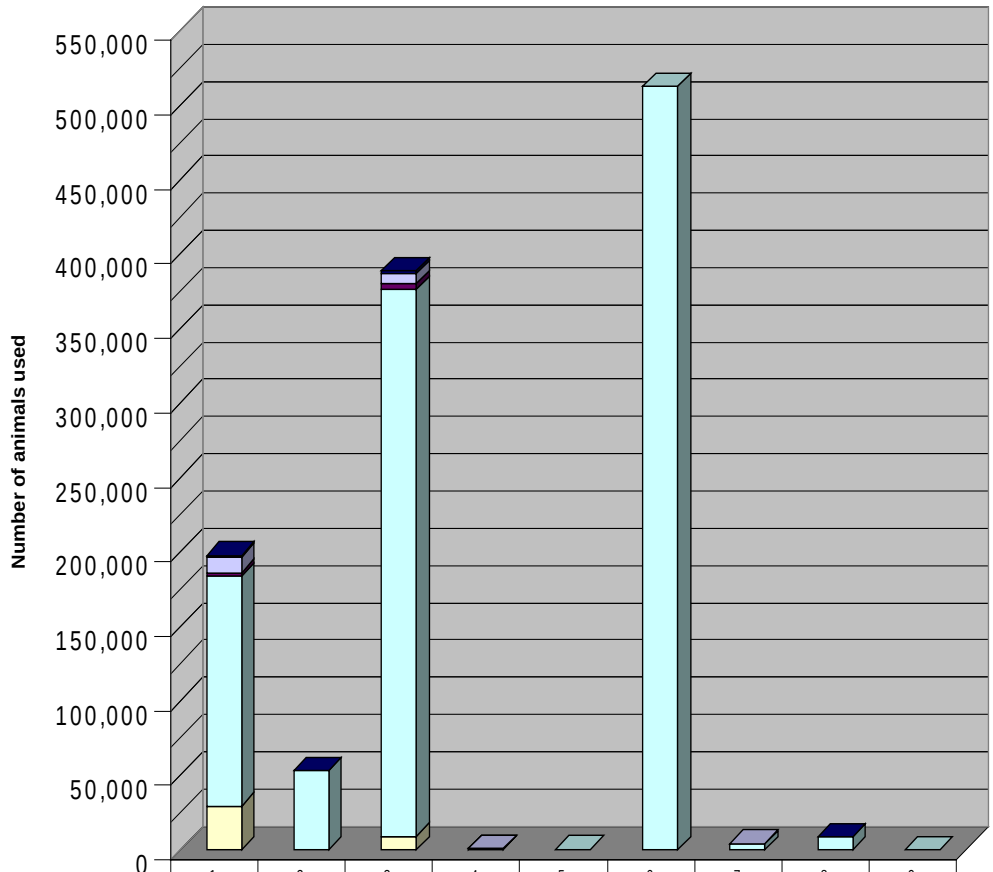

Purpose: Research - Animal Management or Production
Breakdown of Laboratory Mammals Species
Number of animals used
600
500
400
300
200
100
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit
GuineaP
Rat 6 584
Mouse 311 168 384 35 106


Purpose: Research - Animal Management or Production
Breakdown of Stock Species
Number of animals used
30000
25000
20000
15000
10000
5000
0
1 2 3 4 5 6 7 8 9
Other 18
Deer
Dom.Poul 2905 30 5458
Goats 154
Horses 30 71
Pigs 21 4838 31 93
Cattle 3416 305 230 515
Sheep 20797 2211 26 3517


Purpose: Research - Animal Management or Production
Breakdown of Domestic Species
Number of animals used
140
120
100
80
60
40
20
0
1 2 3 4 5 6 7 8 9
Other
Dogs 68
Cats 59

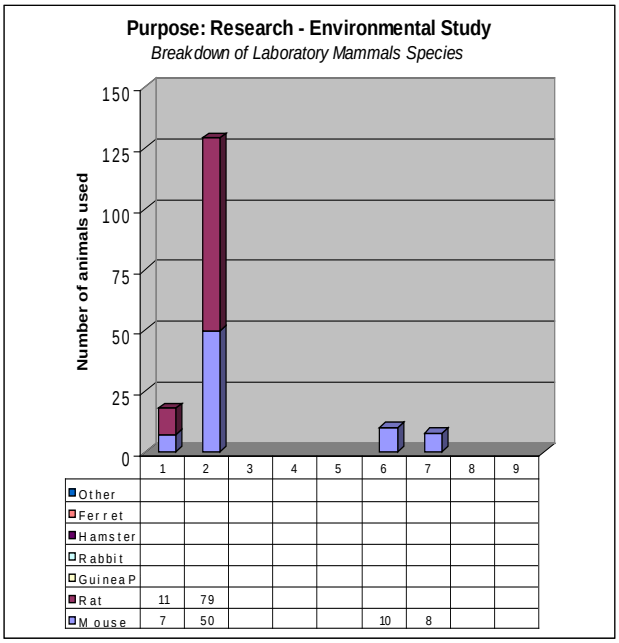
Purpose: Research - Environmental Study

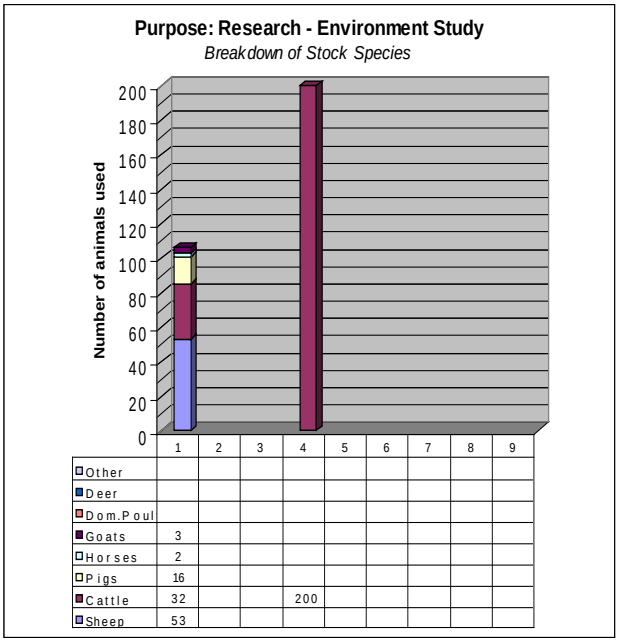
Research protocols which aim to increase the understanding of the animals' environment or its role in it, or that aim to manage wild or feral populations .

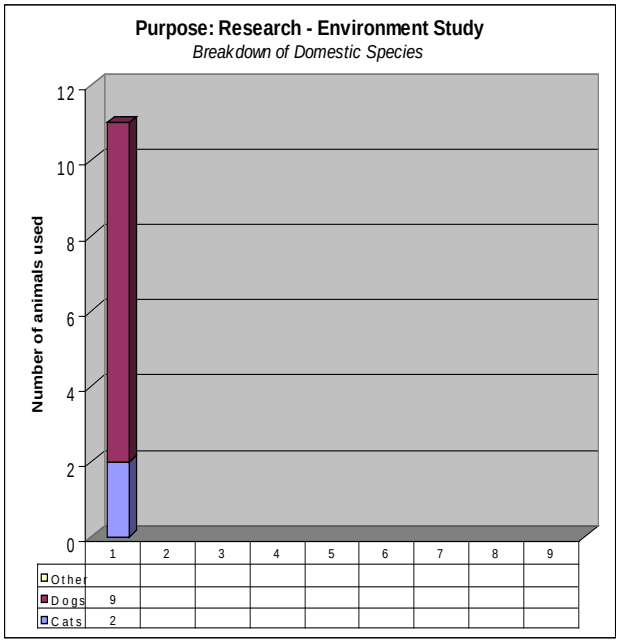


	1	2	3	4	5	6	7	8	9
Other									
Exotic Feral	1140	77	1909					100	
Nat Mam	10468	7	6822	822			102		
Primates									
Domestic	11								
Reptiles	2534	2	4016	1			578		
Aquatic	154157	53033	366934	3	319	512676	3660	8632	59
Birds	29228		8873						
Stock	106			200					
Lab Mam	18	129				10	8		

Refer to following page for a further breakdown of species.

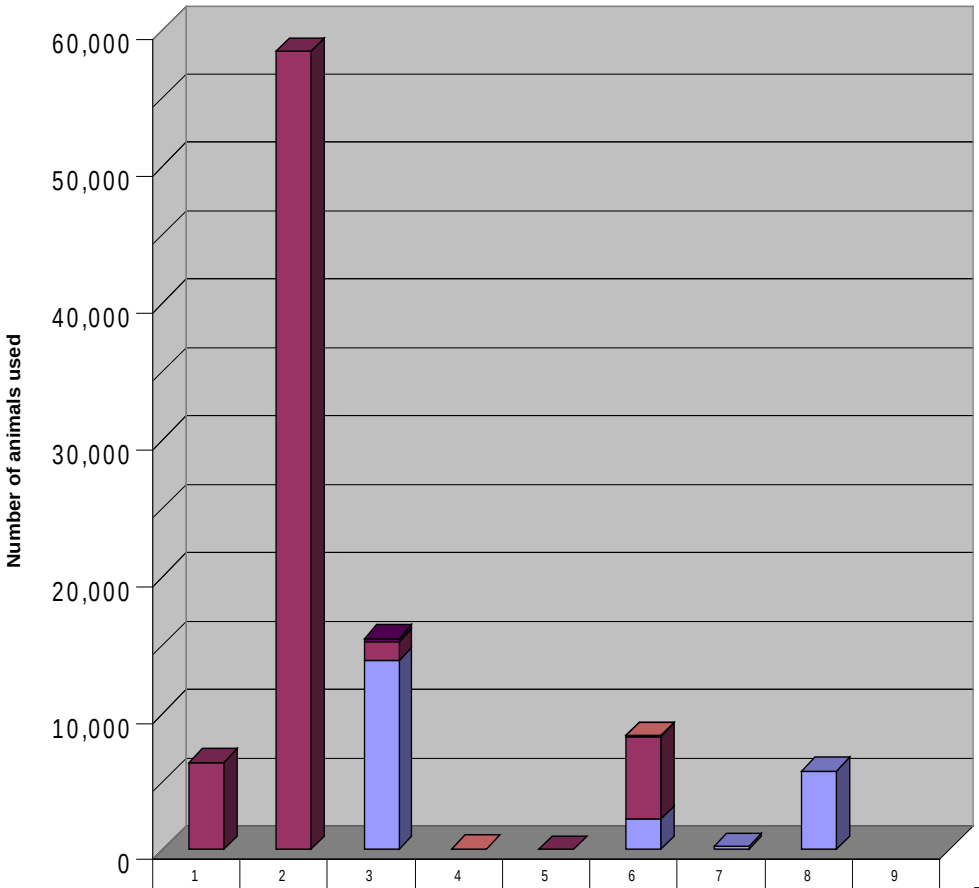

Purpose: Research - Environmental Study
Breakdown of Laboratory Mammals Species
Number of animals used
150
125
100
75
50
25
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit
GuineaP
Rat 11 79 10 8
Mouse 7 50


Purpose: Research - Environment Study
Breakdown of Stock Species
Number of animals used
200
180
160
140
120
100
80
60
40
20
0
1 2 3 4 5 6 7 8 9
Other
Deer
Dom.Poul
Goats 3
Horses 2
Pigs 16
Cattle 32 200
Sheep 53


Purpose: Research - Environment Study
Breakdown of Domestic Species
Number of animals used
12
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9
Other
Dogs 9
Cats 2

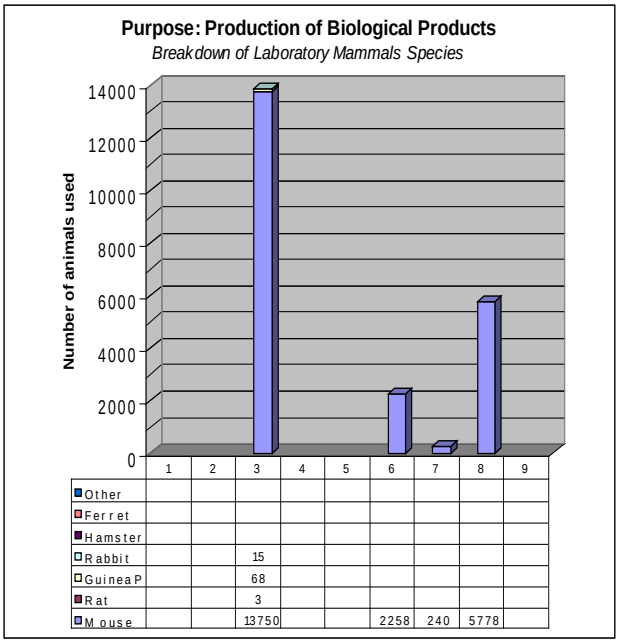
Purpose: Production of Biological Products

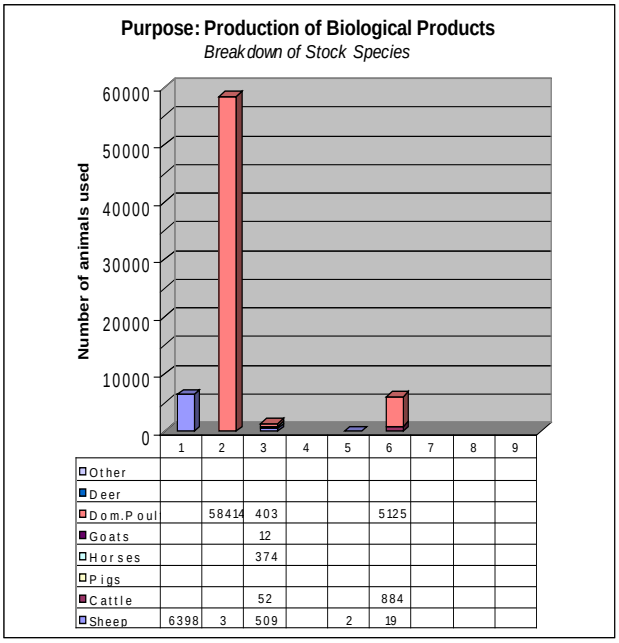
Use of animals to produce products (other than normal milk/meat/egg, etc).

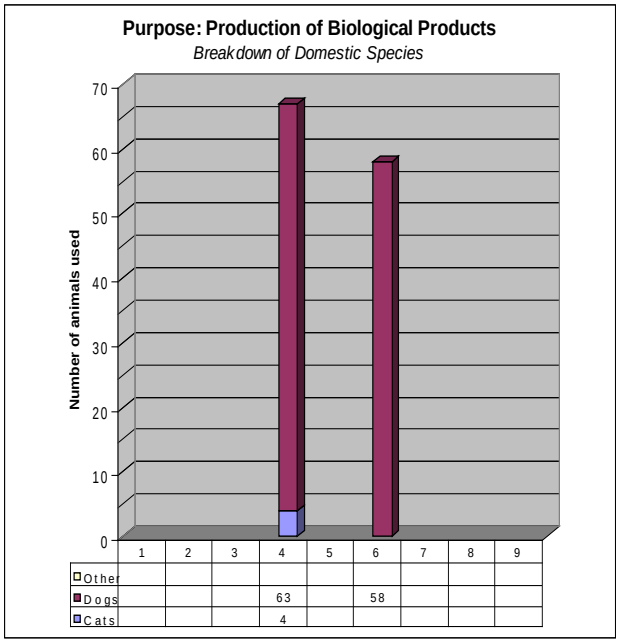


	1	2	3	4	5	6	7	8	9
Other									
Exotic Feral									
Nat Mam									
Primates									
Domestic				67		58			
Reptiles			293						
Aquatic									
Birds									
Stock	6398	58417	1350		2	6028			
Lab Mam			13836			2258	240	5778	

Refer to following page for a further breakdown of species.

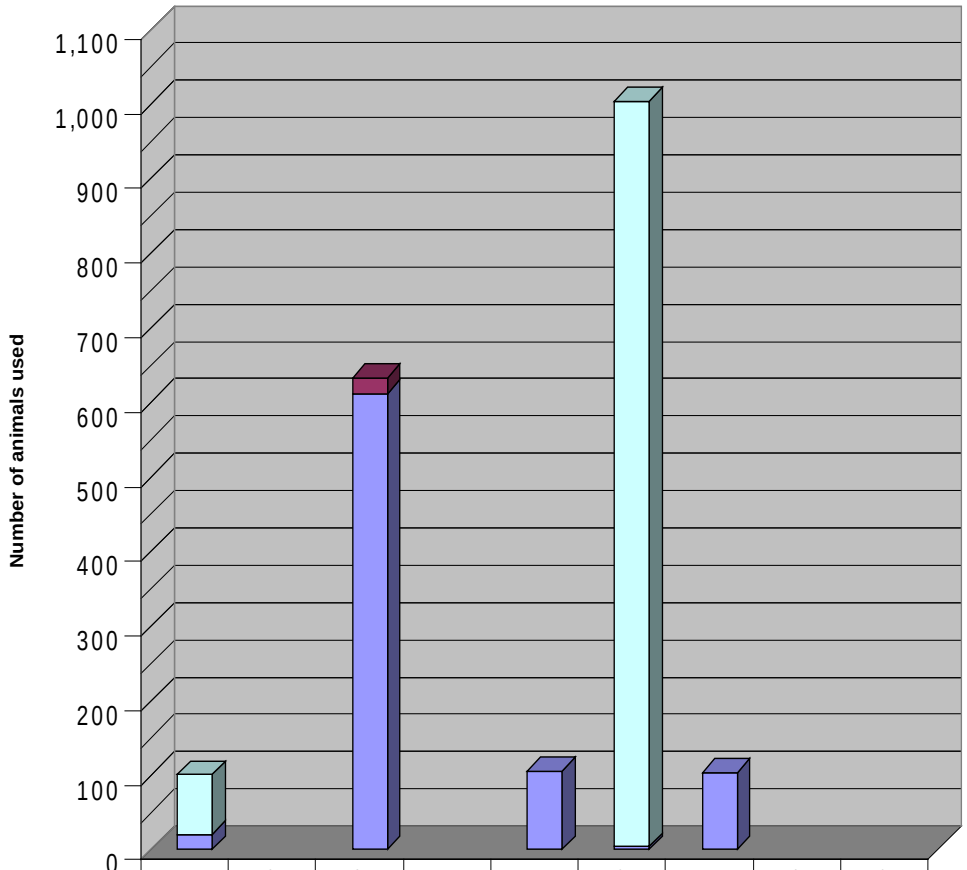

Purpose: Production of Biological Products
Breakdown of Laboratory Mammals Species
Number of animals used
14000
12000
10000
8000
6000
4000
2000
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit 15
GuineaP 68
Rat 3
Mouse 13750 2258 240 5778


Purpose: Production of Biological Products
Breakdown of Stock Species
Number of animals used
60000
50000
40000
30000
20000
10000
0
1 2 3 4 5 6 7 8 9
Other
Deer
Dom.Poul 58414 403 5125
Goats 12
Horses 374
Pigs
Cattle 52 884
Sheep 6398 3 509 2 19


Purpose: Production of Biological Products
Breakdown of Domestic Species
Number of animals used
70
60
50
40
30
20
10
0
1 2 3 4 5 6 7 8 9
Other
Dogs 63 58
Cats 4

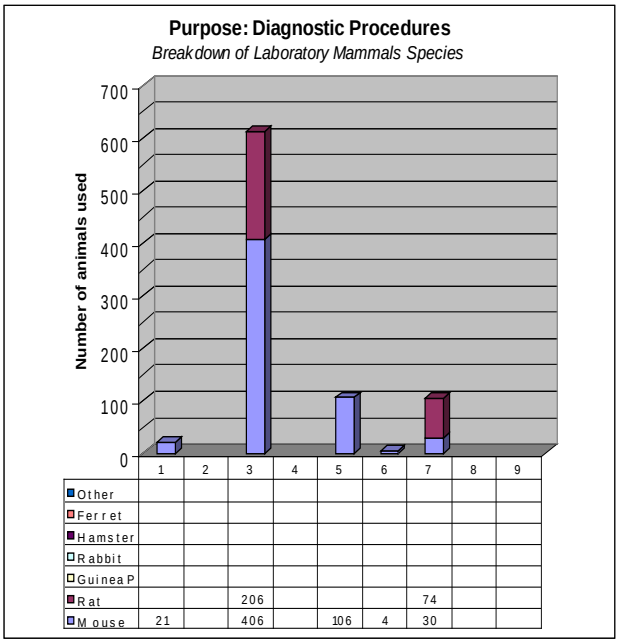
Purpose: Diagnostic Procedures

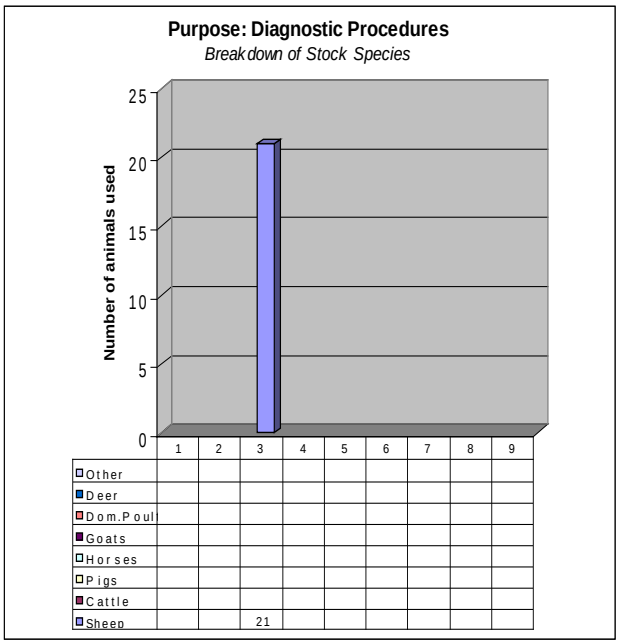
Using animals directly as part of a diagnostic process.



	1	2	3	4	5	6	7	8	9
Other									
Exotic Feral									
Nat Mam									
Primates									
Domestic									
Reptiles									
Aquatic	80					1000			
Birds									
Stock			21						
Lab Mam	21		612		106	4	104		

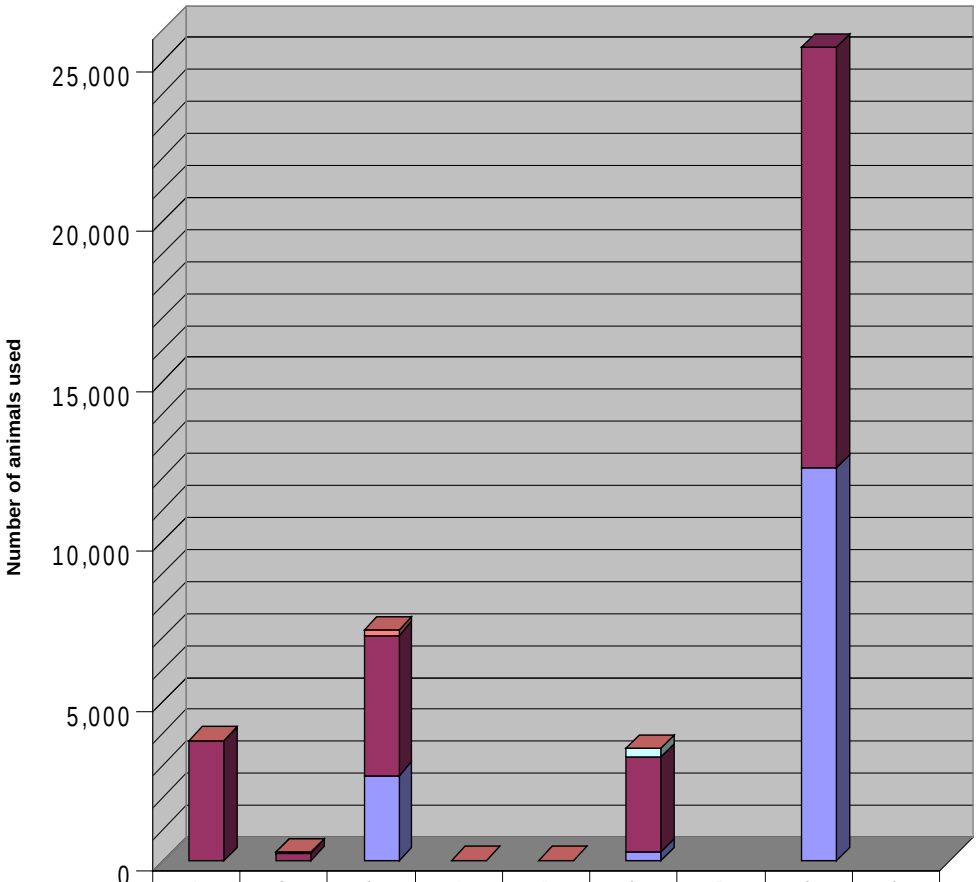
Refer to following page for a further breakdown of species.


Purpose: Diagnostic Procedures
Breakdown of Laboratory Mammals Species
Number of animals used
700
600
500
400
300
200
100
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit
GuineaP
Rat 206 74
Mouse 21 406 106 4 30


Purpose: Diagnostic Procedures
Breakdown of Stock Species
Number of animals used
25
20
15
10
5
0
1 2 3 4 5 6 7 8 9
Other
Deer
Dom.Poult
Goats
Horses
Pigs
Cattle
Sheep 21

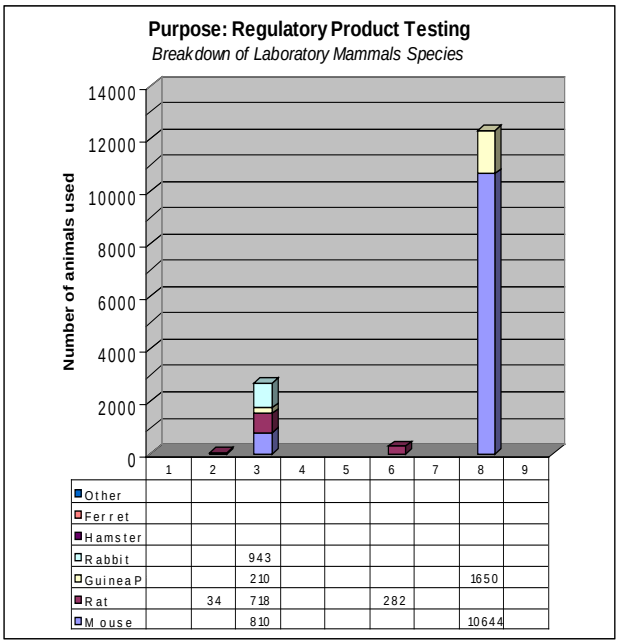
Purpose: Regulatory Product Testing

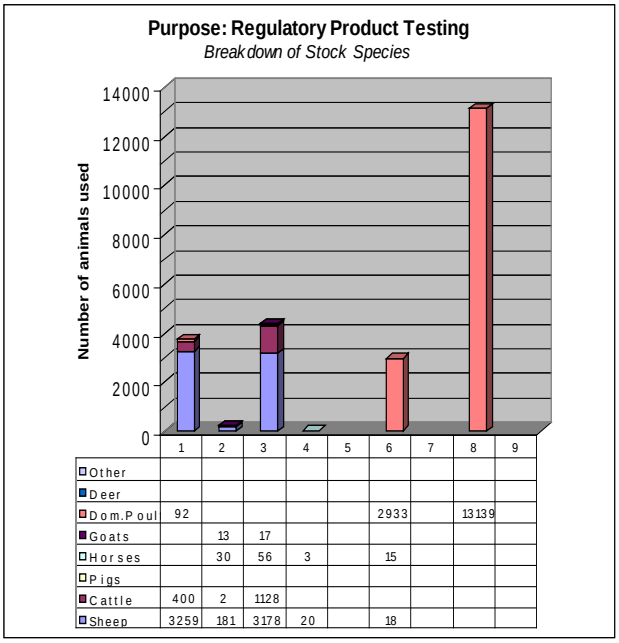
Protocols for the testing of products required by regulatory authorities.

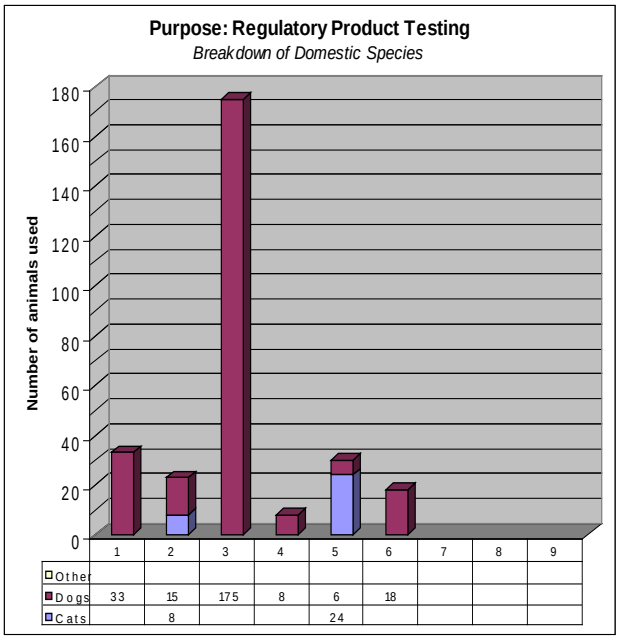


	1	2	3	4	5	6	7	8	9
Other									
Exotic Feral									
Nat Mam									
Primates									
Domestic	33	23	175	8	30	18			
Reptiles									
Aquatic						270			
Birds									
Stock	3751	226	4379	23		2966		13139	
Lab Mam		34	2681			282		12294	

Refer to following page for a further breakdown of species.


Purpose: Regulatory Product Testing
Breakdown of Laboratory Mammals Species
Number of animals used
14000
12000
10000
8000
6000
4000
2000
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit 943
GuineaP 210 1650
Rat 34 718 282
Mouse 810 10644


Purpose: Regulatory Product Testing
Breakdown of Stock Species
Number of animals used
14000
12000
10000
8000
6000
4000
2000
0
1 2 3 4 5 6 7 8 9
Other
Deer
Dom.Poul 92 2933 13139
Goats 13 17
Horses 30 56 3 15
Pigs
Cattle 400 2 1128
Sheep 3259 181 3178 20 18


Purpose: Regulatory Product Testing
Breakdown of Domestic Species
Number of animals used
180
160
140
120
100
80
60
40
20
0
1 2 3 4 5 6 7 8 9
Other
Dogs 33 15 175 8 6 18
Cats 8 24

Lethality testing 2006

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 2006.

Species	Number used	Number died/ euthanased	Procedure	Justification	Alternatives
Guinea pig	1830	514	Vaccination followed by challenge with virulent organism	Regulatory testing for vaccines	None available
Mice	4803	2197	Total combining power test – mice challenged with bacterial toxin	Quality assurance testing of in-process vaccine constituents	None available
Mice	10484	4333	Serum neutralisation test – mice challenged with bacterial toxin	Regulatory testing for vaccines	None available
Mice	160	117	Vaccination followed by challenge with virulent organism	Regulatory testing for vaccines	None available
Mice	975	430	L+ test – mice challenged with bacterial toxin	Quality assurance testing of in-process vaccine constituents	None available
Mice	340	128	Bacterial virulence and vaccine efficacy	Vaccine development	None available to mimic tissue barriers and functioning immune system
Zebra finch	23	7	Determination of effects of exposure to pesticide in Australian native birds	No current data exist assessing the toxic effects of pesticide in species that are at high risk of exposure	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	• Wherever possible, alternative methods must be evaluated and, if deemed suitable, adopted to obviate the need for animal participation (e.g. in vitro monoclonal antibody production). • Use of audiovisual material such as videos, slides, interactive computer programs. • Use of plant tissue as a replacement for animal tissue for certain enzymatic assays. • Promotion of the use of artificial serum as a replacement for fetal calf serum in tissue culture.
Reduction in numbers	• Numbers of animals involved were reduced because a new statistical analysis package allowed for better analysis of data. • Several protocols were altered to allow for re-use of animals; e.g. control tumour mice have been used in biodistribution studies. Control mice and rats have also been re-used for training. • It was found possible to spell diabetic rats and re-use them in oral insulin delivery experiments. • Number of animals required for QA testing in vaccine safety tests was queried and requested to be reduced. • Number of birds to be used in a salmonella inhibition trial was reduced. • Documentation for identification of sick birds and reasons for euthanasia was improved. • In vitro tests and appropriate study designs were used to reduce the number of animals used. • Collected tissues were used without the killing of further animals: – use of tissues collected previously and in storage – use of samples collected from abattoir specimens – collection of specimens from animals killed under a different protocol or animals being killed after completion of protocols – use of animals in other protocols, e.g. collection of milk samples from sheep mated for another protocol. • Use of excess commercially produced embryos not suitable for use as donor embryos. • Use of statistical package to help researchers to better design experiments, and provision of a statistician to discuss animal numbers with researchers. • APVMA was approached regarding target animals where a marginal failure rate was evident. There could be a potential saving in the use of animals. • Previously serum was harvested from wild-type and GM mice, but we have established that serum from WT mice is no longer required, so fewer mice than planned are being used. • We have reduced the number of animals used, as we are finding that we don't need to do as many fusions to generate good monoclonal antibodies, while still making good antibodies to more and more targets. • We continue to expand our in vitro studies on the tissues recovered from the mice so that we can obtain the maximum information from the animals we use. • We have shared tissue samples with other scientists, thus reducing the total number of animals used. • Sharing of tissue with other investigators. • Use of in vitro systems before animal studies

Category	Comments
Reduction in numbers	• 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 the number of subsequent experiments on animals. • Use of biometrician's comments before approval by AEC. • Close scrutiny of the number of animals requested. • Number of animals is always determined by statistical analysis or by the minimum number required to satisfy regulatory authority for new drug products. • Continued improvement in statistical analysis for minimal use of animals. • 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; re-use of animals where appropriate after an extended recovery interval; and making surplus tissue available through a tissue availability database and seeking prior agreement from investigators to make the surplus tissue available. The Committee has instigated the consolidation of breeding protocols to ensure that there is no over-breeding; this in turn has reduced the need for culling. • The Animal Ethics Committee continually strives to ensure that investigators fully understand the need to design protocols that will provided maximum beneficial scientific data but at the same time minimize the number of animals required to acquire data. • Use of abattoir specimens and cadavers. • Routine husbandry procedures to be performed on animals in coordination with teaching activities. • Obtaining more data from the use of fewer animals by combining objectives. • Close scrutiny of the numbers of animals requested in applications and progress reports tothe Committee. • Statistical analysis is used to determine animal numbers. • Both eyes of animals are used where possible. • Recycled animals can be used when available, and animals that have completed a study can be recycled to other researchers.
Refinement of techniques	• All staff properly trained in SOPs (standard operating procedures), including ensuring minimum distress in animals. • In wildlife studies: – attention paid to anaesthetic regimes in the field (e.g. portable isoflurane administration) – veterinarian included for anaesthetic administration and any necessary veterinary intersections – edible bait used to provide sustenance for animals after capture – use of radiotelemetry tracking procedures – trapping only when weather conditions are optimal – disposable latex gloves and sterilisation of instruments used to reduce the risk of pathogen transfer between frogs. • The methodology used involved a subcutaneous injection with a small-bore needle and the application of a fleece-retention net. Approximately 28 days after treatment the fleece-retention net is removed. The injection/netting and the wool-harvesting processes are designed to minimise the amount of animal restraint and handling required (approximately 20 to 30 for each operation). This significantly reduced the stress associated with wool removal when compared with the shearing process.

Category	Comments
Refinement of techniques	• Addition of dividers to isolators to prevent birds rushing into corners, thus preventing any injury to a bird in the corner. Introduction of a green light to help calm birds whilst they are being rounded up. • 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. Key to the minimising of distress to animals used is regular review of handling and restraint techniques. • **Step 1.** The Co-chairs of the AEC will review all applications on submission. In projects where experiments or procedures may cause stress or pain to an animal, the Co-chair will consult with Animal House Managers for their recommendations. If required, the Manager will contact and work with the Chief Investigator (CI) of the project to incorporate procedures that will eliminate or reduce (as much as possible) any discomfort to the animal. The CI may then submit a revised application that will proceed to scientific evaluation (Step 2). • **Step 2.** Projects are evaluated by the Category B members and/or the Co-chairs for scientific merit. The results of the evaluation will be presented at the meeting, and this will be followed by an interview/discussion with the CI and/or the supervising investigator for further clarification of specific aspects of the application and the consideration of the appropriate procedure to achieve the 3Rs. • Two projects included techniques to reduce pain and distress. One was a specific project for the training of field technicians in the correct methods of handling birds during extraction from mist nets, as well as in blood sampling and the fitting of radio-tracking devices. The other project used track-recording techniques to estimate the population density of ground-dwelling wildlife species, including feral species, without the requirement to trap animals. • Use of pilot experiments to determine the level of impact and potential toxicity of new products. • Training of animals for sample collection (e.g. training rams to artificial vagina collection to avoid electro-ejaculation). • Continued development of roughage feeding for housed experimental sheep. This has been shown to reduce oral stereotypy: see Vasseur S., Paull D.R., Atkinson S.J., Colditz I.G., Fisher A.D. 2006. Effects of dietary fibre and feeding frequency on wool biting and aggressive behaviours in housed Merino Sheep. *Australian Journal of Experimental Agriculture* 46: 777–782. • Revised anaesthetic and prophylactic antibiotic regiment to ameliorate the occurrence of abscesses as a result of *Pasteurella multocida*. • Revised anaesthetic regime for rodents. • Improved environmental enrichment to provide further stimulation. • Traps are insulated with cotton to provide warmth. Traps are set at dusk and checked at dawn to reduce sun exposure and heat-related illness. Trapping is not conducted when wet weather is forecast. Traps are covered with a plastic cover to protect them from rain. • Lice counting was conducted only when necessary to obtain supporting data for a product registration. • Untreated controls had the potential for fly strike. The study protocol stipulated that animals were checked regularly by the co-operator and any animals with fly strike were treated immediately with an effective registered fly strike product. If more than 15% of the controls were fly struck (indicative of heavy fly pressure) the study would be terminated and all controls would be treated with a fly strike preventive treatment. • Procedures to minimise stress and pain to animals were performed according to NHMRC guidelines.

Category	Comments
Refinement of techniques	• Earlier endpoints of animal xenograft studies have been implemented. • Ongoing mentoring/training of animal handling staff was implemented to ensure their handling techniques remained current. • Additional mouse enrichment is being utilised, i.e. autoclaved cardboard tubing that is replaced at each weekly cage clean. • To prevent death from anaphylactic shock as a consequence of virus injection, an improved regime of pre-injection steroids and antihistamines was used. • We have begun giving saline injections to the animals during the infusion and injection period. This has rehydrated the animals during their treatments. • Nair® is used instead of shaving the mice to remove any remaining hair, as we found that it caused considerably less skin damage and irritation than shaving. • Because of the high doses of irradiation needed to replace the bone marrow in NOD (no-obese diabetic) mice, we have implemented a protocol whereby the irradiation dose is split into two half-doses, with a 2-hour rest in between. This decreases the impact of this level of irradiation on the mice. • We have refined group numbers and monitored blood glucose values in diabetic-prone mice so that the majority of mice can be euthanased before development of overt diabetes. • In order to minimize pain and distress for the animals, postoperative wound management has been altered: wound clips are now used for skin closure rather than sutures as they are less irritating; a topical antibacterial spray is applied (if required) to minimise the risk of infection; and animal housing has been altered to minimise the risk of injury. • We shortened the experimental time point to reduce the chance of lymphomas developing during the experiment. • Development of a biopsy technique in order to avoid euthanasia of animals. • Individual animal identification to ensure animals are used in a minimum amount of trials. • Premedication and use of analgesics in veterinary surgeries. • Use of a frequency of monitoring that ensures fast treatment of animals if required. • The AEC is proactive in ensuring that, unless a very strong case can be made to the contrary, analgesics are used in all animal procedures. • Stalls designed to meet the needs of haltered cattle within the restrictions of the study protocol, including feed bags to enrich the environment. • Lambing times have been rescheduled to avoid the hottest and coldest parts of the year. • Broiler chicken housing designed to provide well in excess of minimum space per bird. • Close monitoring of animals. Use of experienced veterinarians and other staff. • Restraint time kept to a minimum. • Doses rates kept to a minimum. • Adoption of new, less stressful methodologies. Suitable housing provided and maintained. • Controlled environment facility used. • Use of adjuvants known not to produce adverse reactions. • Procedures used routinely so that animals become accustomed. • Procedures performed under anaesthesia when appropriate. • Close scrutiny of the volume of blood collected.

Category	Comments
Refinement of techniques	• Use of the saphenous vein method as the standard technique for blood collection in rodents. • Appropriate training in handling. • Reduction in number of samples taken from individuals. • Relocation of research horses to a farm setting; horses free to roam in a large, well-grassed paddock with other horses. • Spontaneous collection of naturally voided urine in both equines and bovines. • Researchers required to research techniques to ensure that the most current accepted methodology is applied to their research. Guidelines were developed to help prospective researchers in this regard. • Once again the AEC has paid particular attention to anaesthetic and analgesic doses to minimise pain, and a number of modified procedures have been adopted by researchers from the experience of other researchers with these techniques. • We have distributed the publication by DB Morton (1999), *Humane Endpoints in Animal Experimentation for Biomedical Research: Ethical, Legal and Practical Aspects*; it provides researchers and animal house managers with criteria for decision-making in euthanasia of unwell animals. • The investigators must thoroughly evaluate any potential untoward impact of their planned procedures on the nominated animal species and supply appropriate pain control and treatment regimes to reduce such impacts. • Recommended a reduction in the number of pigs housed in pens to be more comparable with other stocking densities. This recommendation was based on information provided by Queensland DPI. • Updated the Committee's guidelines on the use of MS222 in the euthanasia of fish and toads. • Improved peri-and-post operative analgesia to reduce pain from surgery. • Increased awareness and use of environmental enrichment. • Development of Standard Operating Procedures for laboratory animal care. • Yearly training courses for Masters, Honours and PhD students and staff to ensure the correct use of techniques. All Masters, Honours and PhD students are required to be supervised at all times by the Chief Investigator when they are involved with the care of animals. • Pet animals 'on loan' and returned to owners. • Improvements to animal housing and management. • Training of researchers. • Development of a monitoring checklist to identify actions and report adverse events. • Increased awareness and use of environmental enrichment. • All animals are given appropriate general anaesthesia, local anaesthesia, analgesia or sedation for procedures that warrant it. • Animals showing undue distress or pain that cannot be alleviated by treatment and analgesia are euthanased immediately. • Animals are monitored appropriately. • Animals are handled and cared for by experienced handlers and researchers. • Animals are provided with environmental enrichment.

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	$5,094
Travel and subsistence	$6,566
Stores and printing	$10,048
Freight and postage	$2,642
TOTAL	**$24,350**

Appendix J: Abbreviations

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*
ICLAS	International Council for Laboratory Animal Care
NHMRC	National Health and Medical Research Council
NSW DPI	New South Wales Department of Primary Industries
POCTAA	Prevention of Cruelty to Animals Act
RSPCA	Royal Society for the Prevention of Cruelty to Animals
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.dpi.nsw.gov.au/agriculture/livestock/animal-welfare/research-teaching)

- 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 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

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 4.4.19) (See ARRP Guideline 18: *Guidelines for the Housing of Rabbits in Scientific Institutions*, http://www.animalethics.org.au/reader/animal-care.)
   (For establishments housing rabbits)
4. Unless precluded by the requirements of specific projects, chickens should be provided with housing that meets their behavioural needs including straw or other suitable bedding to cover the floors of cages, perches and dust bathing substrate.
   (For establishments housing chickens)
5. 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)
6. 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 which involves animals which have been the subject of genetic modification (involving the introduction of foreign DNA into cells or whole animals) must comply with Clauses 3.3.56 to 3.3.63 of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*.

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