



Animal Research Review Panel

Annual Report

2009 - 2010



DISCLAIMERS

This publication is copyright. Except as permitted under the Copyright Act 1968 (Commonwealth), no part of the publication may be reproduced by any process, electronic or otherwise, without the specific written permission of the copyright owner. Neither may information be stored electronically in any form whatever without such permission.

The information contained in this publication is based on knowledge and understanding at the time of writing (July 2011). 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 the Department of Primary Industries or the user's independent adviser.

The product trade names in this publication are supplied on the understanding that no preference between equivalent products is intended and that the inclusion of a product name does not imply endorsement by the Department of Primary Industries over any equivalent product from another manufacturer.

© Department of Primary Industries
ISSN 0139-9402
Trim: 09/8337
Prepared by Janelle Townsend and Lynette Chave
July 2011



Primary
Industries

ANIMAL RESEARCH REVIEW PANEL

The Hon Katrina Hodgkinson MP
Minister for Primary industries
Minister for Small Business
Level 30 Governor Macquarie Tower
1 Farrer Place
SYDNEY NSW 2000

Dear Ms Hodgkinson

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 2009 to 30 June 2010.

Yours sincerely

Professor Andrew Dart
Chair, Animal Research Review Panel

PART ONE: ORGANISATION.....	5
1.1 The Animal Research Act 1985.....	5
1.2 The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes	5
1.3 The Animal Research Review Panel.....	5
1.4 Animal Ethics Committees	8
1.5 Accreditation and licensing	9
1.6 The Animal Research Act in schools and TAFE	11
1.7 Administration	11
PART 2: REPORT ON WORK AND ACTIVITIES	13
2.1 Administration and planning.....	13
2.2 Assessment of applications	13
2.3 Assessment of changes to AEC membership.....	14
2.4 Assessment of accreditation and licensing responses	14
2.5 Subcommittees	14
2.6 Statistics on animal use.....	15
2.7 Support for Animal Ethics Committees.....	15
2.8 Website: Animal Ethics Infolink	16
2.9 Site inspections.....	16
2.10 Policies, guidelines and fact sheets.....	16
2.11 Review of the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes	17
2.12 Review of the Animal Research Regulation 2005	17
2.13 Initiatives in replacement, reduction and refinement.....	18
2.14 Complaints.....	18
2.15 Attendance at other meetings.....	18
APPENDIXES	20
Appendix A: Dates of ARRP meetings 2009–10	20
Appendix B: Members’ attendances at ARRP meetings 2009–10.....	20
Appendix C: Dates of Inspections July 2009 – June 2010	21
Appendix D: Attendance of ARRP members at site inspections 2009–10.....	21
Appendix E: Animal Research Review Panel Strategic Plan July 2008 – June 2011	22
Appendix F: ARRP Operational Plan July 2009 – June 2010.....	26
Appendix G: Animal use statistics 2009	28
Appendix H: Examples of methods used to implement the ‘3Rs’	53
Appendix I: ARRP expenses.....	59
Appendix J: ARRP policies and guidelines.....	60
Appendix K: Animal Welfare Unit fact sheets	61
Appendix L: Standard conditions for accreditation and animal supply licence.....	61

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 is to protect the welfare of animals used in research and teaching by ensuring that their use is justified, humane and considerate of their needs. The Act incorporates a system of enforced self-regulation, with community participation at the institutional and regulatory levels.

The Act establishes a system of accreditation, licensing and authorisation of organisations and individual researchers. The Act also establishes 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 creates offences for conducting animal research without appropriate authorisation, with substantial custodial and financial penalties.

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 under 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.

1.3 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. Staff of the Animal Welfare Unit (the Department of Primary Industries) provide executive support for the ARRP.

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 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 participating in 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 ARRPP

Section 9 of the Animal Research Act defines the functions of the ARRPP 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 ARRPP, 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 ARRPP under section 9 (d) of the Act since it commenced.

1.3.3 Membership

The ARRPP 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 ARRPP are part-time and are normally appointed for a term of 3 years.

During the 2009–10 period the membership of the ARRPP was:

- Professor Margaret Rose (Chair) (nominated by Vice-Chancellors' Committee)
- Dr Regina Fogarty (Deputy Chair) (nominated by Minister for Primary Industries)
- Ms Stephanie Abbott (nominated by Animal Societies' Federation)
- Dr Magdoline Awad (nominated by RSPCA NSW)
- Mr Peter Batten (nominated by Minister for Education and Training)
- Ms Celeste Black – appointed March 2010 (nominated by Animal Societies' Federation)
- A/Professor Andrew Dart (nominated by Vice-Chancellors' Committee)
- Dr Mike Fleming (nominated by the Minister for the Environment)
- Professor Annemarie Hennessy (nominated by the Minister for Health)
- Dr Nicholas Malikides – retired July 2009 (nominated by Medicines Australia)
- Professor Robert Mulley (nominated by Vice-Chancellors' Committee)
- Mr David O'Shannessy (nominated by RSPCA NSW)
- Dr Peter Rolfe – appointed May 2010 (nominated by Medicines Australia)

Information on members of the Animal Research Review Panel in 2009–10 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 two international journals devoted to the welfare of laboratory animals: *ATLA (Alternatives to 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 Research Governance in South Eastern Sydney and Illawarra Area Health Service, is a conjoint Professor at the University of New South Wales and Honorary Professor with the Centre for Values, Ethics and the Law in Medicine at the University of Sydney and a member of the Working Party on Harmonisation of the International Council for Laboratory animal Science.

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

Dr Regina FOGARTY (Deputy Chair), BVSc, PhD (University of Queensland). Dr Fogarty is the Principal Director, Industry Development Agriculture and Forestry at the 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). Dr Fogarty joined the ARRP in 2003 as the nominee of the then Minister for Agriculture.

Ms Stephanie ABBOTT, BA, LLB (University of Sydney). Ms Abbott joined ARRP in March 2004. She is a nominee of the Animal Societies Federation (NSW). She 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 principal of Kitsune Consulting.

Dr Magdoline AWAD BVSc MACVSc(Animal Welfare) GradCert Mgt(Prof Prac) CMAVA

Dr Awad is a nominee of the RSPCA (NSW). After graduating with a Veterinary Science degree from the University of Sydney, Dr Awad worked in small animal private practice before joining the RSPCA NSW in 1996 as a Veterinarian. She was Deputy Chief Veterinarian from 2004-2008 and currently holds the role of Chief Veterinarian. In 2008 she became a Member of the Animal Welfare Chapter of the Australian College of Veterinary Scientists. She has a particular interest in Shelter Medicine. She was involved in the development of the CAWS Programs (Community Animal Welfare Scheme), Indigenous Dog Health Programs as well as the Pets of Older Persons Program (POOPS) for RSPCA NSW. She became a member of the ARRP in 2008.

Mr Peter BATTEN BSc (Wool and Pastoral Sciences) (UNSW), Dip Ed (Technical) (Sydney CAE)

Mr Peter Batten is Director of the TAFE NSW – Training and Education Support – Industry Skills Unit – Orange and Granville. Peter has 30 years experience in vocational education and training with TAFE NSW including positions dealing with the welfare of animals in teaching including Program Manager Extensive Agriculture, Industry Specialist Livestock Production and Wool and Teacher of Agriculture. Peter joined the ARRP in 2008 as the nominee of the Minister for Education and Training.

Ms Celeste BLACK BA (Harvard), JD (University of Pennsylvania), LLM (Hons) (University of Sydney)

Ms Black joined the ARRP in March 2010 on nomination by the NSW Animal Societies Federation. She is a Senior Lecturer and currently the Associate Dean (Learning and Teaching) at the Faculty of Law, University of Sydney, where she developed and teaches the undergraduate law elective Animal Law. Ms Black is an executive and founding member of the Human Animal Research Network at the University of Sydney.

Professor Andrew DART BVSc PhD Dip ACVS Dip ECVS

Dr Dart is Professor of Equine Veterinary Science and Director of the Research and Clinical Trials Unit of the Faculty of Veterinary Science, the University of Sydney. He has held positions as Director of the Veterinary Teaching Hospital and Deputy Chair and Acting Chair of the Animal Ethics Committee of the University of Sydney. Dr Dart is a Registered Specialist in Equine Surgery and has spent time in private practice and as a Clinical Academic.

Dr Mike FLEMING BSc (Hons) ANU, PhD (Monash)

Dr Fleming is a nominee of the Minister for the Environment and has been with ARRPP since February 2009. Dr Fleming has conducted research in marsupial physiology, wildlife management and biodiversity survey. He has worked extensively in the Northern Territory and New South Wales.

Professor Annemarie HENNESSY

Professor Hennessy joined the ARRPP in 2008. She is the director of the National Baboon Colony and an active medical teacher and researcher. She is a qualified nephrologist and specialises in general medicine, renal medicine and obstetric medicine. She is the Foundation Chair of Medicine at the University of Western Sydney.

Dr Nicholas MALIKIDES BVSc FACVSc PhD DVCS MVCS MPH (University of Sydney)

Dr Malikides joined ARRPP in September 2008 as a nominee of Medicines Australia. He currently is an International Project Leader in Pharmaceutical Development at Novartis Animal Health Switzerland. For 3 years prior to this he was Head of Pre-Clinical Safety and site veterinarian at Novartis Animal Health's R&D centre in NSW and was actively involved in animal welfare issues in these roles. Dr Malikides has been a veterinarian since 1988. He became a Fellow of the Australian College of Veterinary Science (as a specialist in equine medicine) in 2000. In 2003, he completed a PhD in epidemiology and respiratory medicine and subsequently in 2008 completed a Masters of Public Health. He has lectured in epidemiology and evidence based medicine at the University of Sydney's Faculty of Veterinary Science and Medicine and was Lecturer in Equine Clinical Studies at the University of Glasgow. He also has held research, public health and clinical veterinary positions at Sydney University and has spent many years in mixed veterinary practice in Australia and the UK.

Professor Robert MULLEY BA (Macquarie), MScAg (Sydney), PhD (Sydney).

Professor Mulley joined ARRPP in 2008. He is a nominee of the Australian Vice Chancellors' Committee. He is Professor of Animal Science at the University of Western Sydney, and has extensive experience in husbandry and management of farmed livestock, particularly pigs and deer. More recently he has engaged in research on a range of wildlife species.

Mr David O'SHANNESY, 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 ARRPP in January 2005.

Dr Peter ROLFE BVSc, PhD

Dr Rolfe is a nominee of Medicines Australia. He is an employee of Novartis Animal Health.

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 approving and monitoring research within institutions, including inspections of animals and facilities. No animal research may be carried out without AEC approval. AECs 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 *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*, which also provides guidance on how AECs should operate.

Committee membership must include members 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, is not associated with the institution and who has never been involved in the use of animals for research.

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.animaethics.org.au/policies-and-guidelines/operation>). 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 the 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 the Department of Primary Industries for approval. Other conditions may also be stipulated, as relevant to the operation of each institution. (See Appendix L 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 Unit 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 the Department of Primary Industries.

The ARRP may convene an Applications Subcommittee to facilitate the assessment of new applications. The subcommittee is convened on a "needs" basis. Where no need is identified by the Animal Welfare Unit for input by the Applications Subcommittee, recommendations are made by the Unit directly to the ARRP.

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

The criteria against which the ARR 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 is another area of assessment. Details of AEC inspections carried out must be provided. Questions on the source and destination of animals allow the ARR 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 Australian Code of Practice for the Care and Use of Animals for Scientific Purposes 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 2009–10 year is provided in Appendixes C and D. The dates provided represent days on site and do not include preparation and follow-up time, which is often considerable.

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

The examination is carried out by an Animal Welfare Unit Veterinary Inspector and the ARR 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.

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 ARR has considered the report, recommendations may arise to impose additional conditions on the accreditation or licence. 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 ARR report usually contains a number of recommendations—for example, for more effective operation of the AEC, for improvement of the management of research within the institution, or for improvement of the animal facilities. Implementation of recommendations is not mandatory, but the institution is required to advise on how it has responded to the recommendations. If the recommendations have not been implemented, then the reasons for this must be explained.

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

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

The ARRPP aims to carry out full audit visits for all institutions every 3 years, as well as unannounced visits by inspectors to follow up problems. In formulating its 2009–10 operational plan, the ARRPP again recognised that staff availability within the Animal Welfare Unit would mean that reinspections would mostly be conducted on a 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 Unit is a section within the Department of Primary Industries. The functions of the Animal Welfare Unit cover:

- animal research issues under the *Animal Research Act*, including providing executive services to the ARRPP
- general animal care and cruelty issues under the *Prevention of Cruelty to Animals Act*, including the operation of the Animal Welfare Advisory Council under the Minister for Primary Industries
- animal display issues under the *Exhibited Animals Protection Act*, including the operation of the Exhibited Animals Advisory Committee
- Departmental animal welfare activities.

The Animal Welfare Unit can be contacted at:

Animal Welfare Inspectorial Office
Department of Primary Industries
95 Castle Hill Road
WEST PENNANT HILLS NSW 2125
Phone: (02) 9872 0571
Fax: (02) 9871 6938

PO Box 100
BEECROFT NSW 2119

or at the Department of Primary Industries Head Office:

Animal Welfare Unit
Department of Primary Industries
161 Kite Street
Locked Bag 21
ORANGE NSW 2800
Phone (02) 6391 3149
Fax (02) 6391 3570
E-mail: animal.welfare@industry.nsw.gov.au

In the 2009–10 financial year the following staff were assigned, at various times, to provide inspectorial and/or executive support to the ARRPP (amongst their other duties).

Orange:

Ross Burton, BVSc, MVSc, Director, Animal Welfare

Amanda Paul, BVSc, MACVSc (Animal Welfare), Veterinary Officer (part-time)

Grace Cook, Licensing Clerk (part-time)

Frances Kumbley, Branch Support Officer

Tammy Kirby, Licensing Assessment Officer (part-time)

Sydney:

Lynette Chave, BVSc, Leader, Animal Research

Peter Johnson, BVSc, PhD, Veterinary Officer

Janelle Townsend, Branch Support 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 ARRPs operational plan for 2009–10. The appendixes to this annual report contain details of many of the operational and strategic functions of the ARRPs. These include the dates of, and attendance at, ARRPs meetings (Appendixes A and B); dates and attendance of ARRPs members at inspections of accredited research establishments and animal supply licence holders (Appendixes C and D); the ARRPs Strategic Plan 2008–11 (Appendix E) and Operational Plan for 2009–10 (Appendix F); and ARRPs operating expenses (Appendix I).

2.1.1 Strategic Plan 2008–11

During 2008-09 the ARRPs revised its 3-year strategic plan. The plan identifies the primary goals of the ARRPs and strategies for achieving these goals.

Details of the Plan are given in Appendix E.

2.1.2 Operational Plan for 2009–10

The ARRPs Operational Plan for 2009–10, including performance status for each activity, is provided in Appendix F.

2.1.3 Liaison with organisations and individuals

The ARRPs liaises with organisations and individuals to offer advice and to facilitate the implementation of legislative requirements and adherence to replacement, reduction and refinement principles.

For example, Professor Margaret Rose (ARRPs Chair), Dr Regina Fogarty (ARRPs Deputy Chair) and Mr George Davey (Deputy Director-General, Primary Industries) met with representatives of the AEC and management of a major research establishment. The purpose of this visit was to follow up on progress made by the establishment to address significant problems with compliance with the animal research legislation that had been identified at site inspection. Commendation was made on the implementation of measures to address the problems.

2.2 Assessment of applications

In 2009–10 there were 118 accredited animal research establishments and 40 holders of animal suppliers' licences.

During 2009–10 the ARRPs considered and made recommendations to the Director-General on :

- 11 new applications for accreditation
- 53 renewal applications for accreditation
- 2 new applications for animal suppliers' licences
- 33 renewal applications for animal suppliers' licences.

2.2.1 LD50 testing

LD50 is a toxicity test used to determine the dose or concentration of a test substance—that is, the lethal dose—that is expected to kill 50% of the animals to which it is administered. For the purposes of the NSW *Animal Research Act, 1985* the definition of LD50 has been broadened. Included are all tests in which a potentially lethal dose of a substance will be administered and is expected to kill a proportion of the individuals in any group of animals to which it is given. In NSW such tests may be undertaken only under the approval of a properly constituted Animal Ethics Committee, with the concurrence of the Minister for Primary Industries. Applications for permission to conduct LD50 tests are evaluated by an ARRPs subcommittee. Members of the subcommittee in 2009–10 were Mr Batten and Professor Dart. The subcommittee makes recommendations to the ARRPs, which in turn advises the Minister.

In 2009–10 the subcommittee considered one application (6 tests) from an Accredited Animal Research Establishment.

The testing is used in quality control during the manufacturing of vaccines and in the development of new vaccine formulations. The majority of the tests are related to the manufacture of clostridial vaccines, used to protect livestock and companion animals against tetanus, enterotoxaemia, black leg and black disease that are rapidly fatal if contracted by unvaccinated animals. One of the tests is required for quality control of batches of equine salmonella vaccine, used to protect horses against salmonellosis. The ARRPP recommended to the Minister that he approve the application on the following conditions:

- 1) Data is provided in graphical form by 31 January 2011 with figures comparing 2008, 2009 and 2010 calendar years on the following:
 - a) The number of animals used for each quality control test in relation to a relevant measure to be determined by the company. The measure should provide information on the trends in numbers of animals used over time.
 - b) The number of animals used for development and research over time, with an explanation of the purpose eg replacement of a test, refinement of a procedure.
 - c) The total number of animals produced in relation to numbers of animals actually used in tests.
 - d) The number of animals that die in tests and the number euthanased as an early end-point in tests.
- 2) Any application for Ministerial concurrence to conduct LD50 tests between April 2011 and April 2012 must be presented by the company to the Emergencies and Animal Welfare Branch by 31 January 2011.
- 3) The company continues, in consultation with the AEC, 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 existing approved tests or replacing animal tests with alternatives and reports upon these to the Emergencies and Animal Welfare Branch by 31 January 2011.

2.3 Assessment of changes to AEC membership

All establishments are required to advise the Director-General of the Department of Primary Industries of changes to AEC membership. The ARRPP assesses and makes recommendations to the Director-General on the suitability of the qualifications of the new members for the categories of membership to which they are nominated.

The qualifications of AEC members are assessed in accordance with the requirements set out in Clause 2.2.2 of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* and ARRPP Policy 9: *Criteria for Assessment of Animal Ethics Committee Membership*.

In the 2009–10 year the ARRPP assessed and made recommendations to the Director-General on the appointment of 83 members of Animal Ethics Committees.

2.4 Assessment of accreditation and licensing responses

The ARRPP assesses and makes recommendations to the Director-General on responses from accredited animal research establishments and licensed animal suppliers to conditions and recommendations arising from site inspection and / or placed at the time of accreditation and licence application.

In the 2009–10 year the ARRPP made recommendations to the Director-General on 34 responses from accredited animal research establishments and licensed animal suppliers.

2.5 Subcommittees

The ARRPP 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 ARRPP for consideration. Membership of subcommittees is largely drawn from the ARRPP. External members of subcommittees are occasionally co-opted on a voluntary basis. Activities of subcommittees in the 2009–10 year include:

- Evaluation of applications for LD50 testing (Mr Batten and Professor Dart).

- Development of training material for researchers / teachers (Professor Rose, Ms Abbott).
- Preparation for a meeting to be held in April 2011 for members and executive officers of AECs (Ms Abbott, Professor Dart and Dr Fogarty).

2.6 Statistics on animal use

The Animal Research Regulation 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 projects 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 projects in which the animal is used
2. the recording of animals for each year in which they are held in long-term projects
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 2009.

In addition to information on numbers of animals used, information is collected on initiatives in the areas of reduction, replacement and refinement of animal use. A summary of this information is provided in Appendix H.

As an additional means of monitoring accredited animal research establishments, the ARRP recommended that the Annual Reports of AECs be submitted with the submission of annual statistics. The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes requires that each AEC must submit a written report on its activities at least annually to the governing body of the institution for which it acts (Clause 2.2.40). In the 2009-10 year, the ARRP carried out an assessment of these reports, and provided feedback to the AECs and institutions.

2.6.1 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'*. Lethality tests include, but are not limited to, LD50 tests (see item 2.2.1). Figures on lethality testing are included in Appendix G of this report.

2.7 Support for Animal Ethics Committees

The ARRP and the Animal Welfare Unit continue to use various means to support AECs in performing their duties. These means include the conducting of site inspections; the writing of policies, guidelines and fact sheets where a need is identified; the holding of meetings for AEC members; the maintenance of a website dedicated to animal research issues 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.

Examples of these activities in the 2009-10 year are:

- * Provision of comments on a draft document from an AEC dealing with reporting of adverse events.
- * Provision of advice to an AEC requesting guidance on the duration of AEC approvals.
- * The conduct of a workshop examining the training and educational needs of personnel involved in the use of animals for research. Prior to the workshop, a survey had been circulated to AECs seeking feedback on training /educational material currently being offered. There were 37 participants in the workshop representing 23 establishments. A major outcome of the workshop was the establishment of a reference group, the aim of which was to develop training material that would be available on-line and via face-to face presentation.

2.7.1 Register of candidates for AEC membership

Finding interested and suitable members has been a problem experienced by a number of AECs. Categories C (Animal Welfare) and D (Independent) have presented the most difficulty. To help AECs to maintain the required membership, the ARRPP suggested the establishment of a register of AEC members interested in joining other AECs. The Animal Welfare Unit has established a list of names, contact details and the categories that individuals believe they can represent. This list is available to all NSW AECs.

2.7.2 Meeting for members and executive officers of AECs

In March 2010, preparations commenced for a meeting for members and Executive Officers of AECs to be held in April 2011 by the ARRPP in conjunction with the Animal Welfare Unit.

Reports from previous meetings can be found at www.animaethics.org.au.

2.8 Website: Animal Ethics Infolink

Development and maintenance of a website by the ARRPP - 'Animal Ethics Infolink'- is aimed at assisting researchers, teachers and members of Animal Ethics Committees to access information about the operation of the animal research legislation in NSW. In addition to specific information about this legislation, including ARRPP policies and guidelines, this site provides general information about legislation in other states and countries and links to many sites from which useful, general information promoting the humane care and use of animals for scientific purposes can be sourced. The website also gives the general community access to information about animal use for research and teaching in NSW.

The website has been developed and is maintained in conjunction with the Animal Welfare Unit. The Animal Ethics Infolink site is accessible at www.animaethics.org.au.

2.9 Site inspections

A list of site inspections undertaken in 2009–10 is provided in Appendix C, and a list of ARRPP members attending is given in Appendix D. There were 19 inspections conducted over a period of 25 working days. The length of these inspections ranged from one day to four days. The inspections included AECs and the facilities of 24 accredited animal research establishments /licensed animal suppliers.

The ARRPP aims to carry out a routine inspection of each accredited animal research institution approximately every 3 years to maintain personal contact with institutions, AECs and researchers, and to carry out a complete audit of institutional operation under the *Animal Research Act 1985*.

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

2.10 Policies, guidelines and fact sheets

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

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

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

The following guidelines were finalised in 2009-10:

ARRPP Guideline 23: Guidelines for the housing of sheep in scientific institutions

These draft guidelines were amended based on comments received from local and international practitioners and people with expertise in sheep care and management.

The following policy was revised in 2009-10:

ARRP Policy 5: Annual Reporting by Animal Ethics Committees to Accredited Animal Research

In revising this policy, a recommendation was included that, in their annual reports, AECs specifically address the issue of projects approved that have a high negative impact on the welfare of the animals used. The information in the annual report should include measures implemented to reduce the number of high impact projects approved and to reduce the number of animals used in high impact projects.

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

A review of the 7th edition of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* was initiated by the NHMRC. The Animal Research Review Panel provided a submission to the initial targeted request from the NHMRC for comments.

2.12 Review of the Animal Research Regulation 2005

As required by the Subordinate Legislation Act 1989, a review of the Animal Research Regulation 2005 was undertaken in 2010. Under this Act, most regulations are subject to automatic repeal every five years. This process generally involves reviewing the Regulation and determining whether to allow the Regulation to lapse or be remade with or without amendment.

The ARRP endorsed recommended amendments to the Regulation, prior to a revised draft being published for comment. The ARRP also provided a submission to the review.

The changes in the Animal Research Regulation 2010 are summarised as follows:

The changes are summarised as follows:

- An increase in application fees of between 33 and 50 per cent for accreditations as animal research establishments and for animal supply licences. The fees have not been increased since a regulation was introduced in 1990, and do not cover administrative costs to government. The fee increases will go further towards recovering these costs. The increases are considered fair to applicants as there have been no increases in 20 years (Clauses 6 and 13).
- Changing the requirement to report “notifiable details” to the Director-General instead of to the Animal Research Review Panel (Clauses 7 and 14). “Notifiable details” are changes in Directors, changes in Animal Ethics Committee membership and convictions for offences. This will bring the notification of changes into line with the requirement for applications for accreditations and licences to be made to the Director-General.
- Removing the necessity to automatically fill vacant positions on Animal Ethics Committees (Clause 3 of Schedule 2 of the 2005 Regulation). Part 3 Clause 21 prescribes the composition of committee membership, and requires a minimum number of four members. If an establishment appoints committee members additional to the number prescribed, it should not be compelled to refill an additional position.
- Deleting Clause 6 (2) of the 2005 Regulation which prescribes the inclusion of an independent Animal Ethics Committee member, as the clause repeats Section 13 (5) of the Act.
- Removing the requirement for the Director-General to refer decisions on the waiver of fees for animal supply licences for schools to the Minister. This is in keeping with other decision-making powers of the Director-General under the Regulation (Clause 13).
- For members of the Animal Research Review Panel nominated by RSPCA NSW and Animal Societies' Federation (NSW), adding a requirement that their qualifications include involvement in animal welfare (Clause 20).
- Machinery amendments to update the name of the Department and other references, to clarify the meaning of some clauses, and to correct a typographical error.

2.13 Initiatives in replacement, reduction and refinement

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

2.14 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 the Department of Primary Industries, who refers the complaint to the ARR for investigation. The ARR is bound to investigate formal complaints and to make recommendations to the Director-General for disciplinary action (if it is considered warranted) or dismissal of the complaint. Both the complainant and the individual or institution being investigated have a right of appeal. No formal complaints received in the 2009–10 reporting period.

The ARR also has a policy of responding to informal complaints. These may involve varying degrees of investigation, from formal interviews to requests for documents or unannounced visits to animal holding facilities. Complaints may arrive from a variety of sources: the RSPCA may refer matters that fall outside its jurisdiction; ARR members may raise matters brought to their attention by members of the community; public concern may be expressed in the media; and complaints may be raised in direct correspondence to the Minister for Primary Industries, the ARR, or the Animal Welfare Unit. Two informal complaints were received in the 2009–10 reporting period.

A summary of the complaints is as follows:

Informal complaint:

Use of animals for tertiary teaching

An informal complaint was received, alleging that a teaching course at a tertiary institution used animals in the course without offering any alternatives to animal use. Advice was sought from the establishment on the justification for the use of animals and any alternatives offered to students who did not want to use animals. Information was also sought on whether components the teaching explored ethical issues related to animal use.

The information provided confirmed that alternatives to the use of animals were available to students and that components of the course included exploration of ethical issues related to animal use.

The allegations of the complainant were not substantiated.

Informal complaint:

Use of cats in a published study

An informal complaint was received based on a published research paper detailing the use of cats in a study which was approved by an AEC some years earlier. The concerns of the complainant primarily related to whether the use of the animals was humane and whether the research had scientific merit. The complainant had also made representations direct to the research establishment.

Given the historic nature of the complaint and the lack of evidence that the project had not been approved and carried out in accordance with the legislation, an investigation was not undertaken. A response was sent to the complainant outlining the requirements of the animal research legislation.

2.15 Attendance at other meetings

(The costs for attendance at these meetings was not met from ARR expenses).

The Chair of ARR, Professor Margaret Rose, presented the following papers:

1. Challenges to the development and implementation of public policies that seek to achieve animal welfare outcomes. Minding Animals Conference, Newcastle, July 2009.

2. International Perspectives on Animal Welfare: initiatives to harmonise approaches when animals used for scientific purposes, 7th World congress on Alternatives and the Use of Animals in the Life Sciences, Rome, 2009

3. Education and Training in the 3Rs, 7th World congress on Alternatives and the Use of Animals in the Life Sciences, Rome, 2009

4. Advocating the 3Rs through evidence based guidelines that promote the wellbeing of animals used for scientific purposes, FELASA, Helsinki, June 2010

APPENDIXES

Appendix A: Dates of ARRPs meetings 2009–10

Meeting number	Date of meeting
183	22 July 2009
184	23 September 2009
185	9 December 2009
186	24 February 2010
187	12 May 2010

Appendix B: Members' attendances at ARRPs meetings 2009–10

Member	Meeting number				
	183	184	185	186	187
Professor Margaret Rose (Chair)	*	A	*	*	*
Dr Regina Fogarty (Deputy Chair)	*	*	A	*	*
Ms Stephanie Abbott	*	*	*	*	*
Dr Magdoline Awad	A	A	*	*	*
Mr Peter Batten	*	*	*	*	*
Ms Celeste Black	-	-	-	-	*
Professor Andrew Dart	A	*	*	*	*
Dr Mike Fleming	*	*	*	*	A
Professor Annemarie Hennessy	A	A	A	A	*
Dr Nicholas Malikides	*	-	-	-	-
Professor Robert Mulley	*	A	*	A	A
Mr David O'Shannessy	*	*	*	*	A
Dr Peter Rolfe	-	-	-	-	*

* = Present

A = Absent

- = Not applicable

Appendix C: Dates of Inspections July 2009 – June 2010

Date
1/7/09
30/7/09
18/8/09
19-20/08/09
25/8/09
15/9/09
25/9/09
27-30/10/09
20/11/09
2-3/12/09
23/2/10
24/3/10
5/5/10
19/5/10
20/5/10
21/6/10
23-25/6/10
29/6/10

Appendix D: Attendance of ARRП members at site inspections 2009–10

Member	Number of days spent on site inspection
Professor Margaret Rose (Chair)	3
Dr Regina Fogarty (Deputy Chair)	2
Ms Stephanie Abbott	7
Dr Magdoline Awad	-
Mr Peter Batten	1
Ms Celeste Black	1
Professor Andrew Dart	-
Dr Mike Fleming	3
Professor Annemarie Hennessy	-
Dr Nicholas Malikides	-
Professor Robert Mulley	2
Mr David O'Shannessy	2
Dr Peter Rolfe	1

Appendix E: Animal Research Review Panel Strategic Plan July 2008 – June 2011

* Numbers in italics on right refer to items from 2009/2010 operational plan that address the strategies

Goals and Strategies

1. Effective and efficient implementation of the statutory requirements of the Animal Research Act 1985, the Animal Research Regulation 2005 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. | 1.1 |
| 1.2 | Maintain a programme of site visits to effectively monitor compliance with the legislation. | 2 |
| 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. | 2.6 |
| 1.4 | Identify and implement adjuncts to inspections to better ensure compliance with the legislation. | 2.6
3 |
| 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
2 |
| 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. | 3.4
6.1 |
| 1.7 | Prepare an annual report to Parliament on the operations and achievements of the Animal Research Review Panel. | 1.4 |
| 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. | 1.5 |
| 1.9 | Maintain a system for receiving and investigating complaints relating to the requirements of the legislation. | 1.2 |
| 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. | 2 |
| 1.11 | Maintain a system to consider and make recommendations on applications for permission to carry out LD50 tests. | 1.3 |

2. The principles, processes and responsibilities in the Code are actively embraced by all involved wherever animals are used.

- | | | |
|-----|---|----------|
| 2.1 | Promote an understanding of the roles and responsibilities of institutions in supporting the effective operation of their AECs. | 2.6
3 |
|-----|---|----------|

2.2	Promote an understanding of the roles and responsibilities of institutions in actively pursuing programmes for researchers and teachers that underpin their responsibilities under the Code.	3
2.3	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 3
2.4	Promote and foster interaction between AECs and researchers/teachers.	2 3
2.5	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 3 4
2.6	Promote an understanding of the roles and responsibilities of AECs through encouraging participation in AEC training programmes.	2 3 4
2.7	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 3
2.8	Promote discussion and understanding of key technical and ethical issues and foster interaction between AECs by maintaining a programme of meetings of Chairs of AECs and participating in AEC meetings during site inspections.	2 3.2 3.3
2.9	Review the membership and operation of individual AECs to ensure they are operating effectively.	1.1 2
2.10	Develop and promulgate evidence-based guidelines to assist AECs, researchers and teachers to effectively implement the 3Rs.	4
2.11	Promote a critical review of the operation of AECs by the institution with a view to maximising their effectiveness.	2

3. Researchers and teachers considering using animals are aware of and actively apply the principals set out in the Act, Regulation and the *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 participation in education programmes, to foster an awareness of ethical and scientific issues and the implementation of the 3Rs.	3 4
3.2	Maintain the “Animal Ethics Infolink” website as a resource for AECs, researchers and teachers and members of the community.	3.1

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. | 2
3 |
| 4.2 | Encourage greater awareness of the use of alternatives to animals in research and teaching. | 2
3 |
| 4.3 | Collate and disseminate information on alternatives to animal use. | 3.1 |
| 4.4 | Promote consideration of funding for development and validation of alternatives. | |

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. | 2 |
| 5.2 | Ensure close scrutiny by AECs of breeding programmes to minimise overproduction of animals. | 2
3 |
| 5.3 | Ensure close scrutiny by AECs of the competence of researchers to carry out specific procedures | 2
3 |
| 5.4 | Promote the critical evaluation of the monitoring of animals being used in procedures. | 2
3 |
| 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. | 2
3
4.1 |

6. When animals are used in research and teaching, their well-being is promoted and there is the anticipation, prompt recognition and alleviation of pain and distress.

- | | | |
|-----|--|----------|
| 6.1 | Promote the implementation of strategies which will foster the well-being of animals and which will foster the development of appropriate risk management assessments related to pain and distress in animals. | 2
3 |
| 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. | 2
3 |
| 6.3 | Promote awareness by researchers / teachers and animal care staff of signs of well-being, pain and distress in animals. | 2
3 |
| 6.4 | Promote the use of appropriate analgesia and anaesthesia by facilitating access by researchers/teachers to information resources. | 2
3.1 |
| 6.5 | 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. | 2
3 |

- | | | |
|-----|---|---|
| 6.6 | 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. | 2 |
|-----|---|---|

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 programme. | 2 |
| 7.2 | Develop and disseminate evidence based guidelines for housing and routine care. | 4.1 |
| 7.3 | Actively participate in the development and review of appropriate national and international 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. | 1.2
2 |
| 8.2 | Develop and disseminate appropriate educational material. | 3 |

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. | 1.4
1.5 |
| 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). | 3 |
| 9.3 | Review and maintain a web site for the dissemination of information. | 3.1 |
| 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. | 4 |
| 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 and teaching is harmonised between State and Territory regulatory and funding bodies.

- | | | |
|------|--|---|
| 10.1 | Promote interaction between State and Territory regulatory and funding bodies. | 6 |
|------|--|---|

Appendix F: ARRP Operational Plan July 2009 – June 2010

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)	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	1 formal and 1 informal complaint finalised. 2 informal complaints received and finalised.
1.3 Review incoming applications to conduct LD50 tests	Recommendations to Minister	3 months	All applications reviewed and recommendations sent to the Minister.
1.4 Prepare annual report for 2008-2009	Report submitted to Minister	December 2009	Report prepared.
1.5 Prepare statistics on animal use for 2008	Statistics collated	December 2009	Statistics collated.
2. Inspections			
2.1 Conduct site visits of all accredited establishments on a 3 – 4 yearly basis	Number of establishments inspected.	Ongoing	24
	Number of days for inspections		25
	Total number of establishments not inspected within the last 4 years		1
2.2 Inspect new establishments applying for accreditation prior to or within 2 months of accreditation	Number of new establishments inspected	Ongoing	2 (In-State / active/with own AEC)
	Number of new establishments not inspected		0 (In-State / active/with 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 sent	Within 3	Reports sent

reports		months of inspection	
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 ARRPA agenda.
2.6 Consider assessment of AEC annual reports	Assessment carried out	December 2009	2008 reports assessed and feedback provided to establishments.
3. Education			
3.1 Maintain ARRPA website	Site maintained	Ongoing	Website maintained.
3.2 Finalise learning guide to accompany AEC learning package	Guide finalised	June 2010	Await outcome of training material for researchers.
3.3 Facilitate access to education programmes by researchers and teachers	Strategies developed	June 2010	Workshop held, reference group established, reference group meeting held and strategies developed.
4. Policies and guidelines			
4.1 Finalise housing guidelines	Draft of mouse document finalised	March 2010	In progress
	Draft of sheep document finalised	March 2010	Finalised
4.2 Develop policies/ guidelines where strong need identified (maximum of 2)	Developed as need identified	Ongoing	Policy on non-compliance to be developed.
4.3 Revise current policies and guidelines	Policies and guidelines revised	June 2010	Revision in progress
5. Legislation			
5.1 Contribute to Animal Research Regulation review	Input to review provided	June 2010	Input provided.
6. Additional			
6.1 Continue liaison with NHMRC	Meeting held	Ongoing	Comment on NHMRC policies.
6.2 Continue liaison with APVMA via the Animal Welfare Working Group	Contact with APVMA maintained	Ongoing	No action
6.3 Refer items to AAWS Advisory Committee as necessary	Items referred	Ongoing	No items identified.

Appendix G: Animal use statistics 2009

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

The following graphs, one for each **purpose** (see table below) show the numbers of animals used against the category of **procedure** (1–9; see below). The categorisation of procedures aims to give some indication of the 'invasiveness' or 'impact' of the work on the animals involved. **Species** are grouped as indicated below. There were some slight variations from previous years for the grouping of species to fit with the collection of statistics in other States and Territories.

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 thousands of individual animals.

After the graphs, statistics are given on the lethality testing performed in 2009.

Animal species categories used for collection of data

Laboratory mammals	Mice
	Rats
	Guinea Pigs
	Rabbits
	Hamsters
	Ferrets
	Other laboratory mammals (not primates)
Domestic mammals	Sheep
	Cattle
	Pigs
	Horses
	Goats
	Deer
	Cats
	Dogs
	Other domestic mammals
Birds	Poultry
	Exotic Captive
	Exotic Wild
	Native Captive
	Native Wild
	Other birds
Aquatic animals	Fish
	Cephalopods (reporting not mandatory)
	Crustaceans (reporting not mandatory)
Amphibians	Amphibians
Reptiles	Lizards
	Snakes
	Turtles and Tortoises
	Other reptiles

Primates	Marmosets
	Macaques
	Baboons
	Other primates
Native mammals	Macropods
	Possums and gliders
	Native rats and mice
	Dasyurids
	Wombats
	Koalas
	Monotremes
	Bandicoots
	Bats
	Other native mammals
	Seals
	Whales and dolphins
Exotic feral mammals	Camels
	Cats
	Cattle
	Goats
	Hares
	Horses
	Mice
	Pigs
	Rabbits
	Rats
	Dingo/Wild Dogs
	Foxes
	Other exotic feral mammals
Exotic zoo animals	Exotic zoo animals

PURPOSE
<p>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).</p>
<p>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.</p> <p><i>Examples:</i> <i>Fistulated ruminants that are maintained under a holding protocol for use in other short-term feeding trial protocols</i> <i>A non-breeding colony of diabetic rats held for research in other protocols</i></p>
<p>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.</p> <p><i>Examples</i> <i>Animals used by veterinary schools to teach examination procedures such as pregnancy diagnosis</i></p>
<p>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.</p>
<p>5. Research: human or animal health and welfare Research protocols that aim to produce improvements in the health and welfare of animals, including humans.</p>
<p>6. Research: animal management or production Research protocols that aim to produce improvements in domestic or captive animal management or production.</p>
<p>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.</p> <p><i>Examples</i> <i>Pre-logging or pre-development fauna surveys</i></p>
<p>8. Production of biological products Using animals to produce products other than e.g. milk, meat, eggs, leather or fur.</p> <p><i>Examples</i> <i>Use of a sheep flock to donate blood to produce microbiological media</i> <i>Production of commercial antiserum</i> <i>Production of products, such as hormones or drugs, in milk or eggs from genetically modified animals</i> <i>Quality Assurance testing of drugs</i></p>
<p>9. Diagnostic procedures Using animals directly as part of a diagnostic process.</p> <p><i>Examples</i> <i>Inoculation of day-old chicks with Newcastle Disease virus to determine virulence</i> <i>Blue-green algae toxicity testing</i> <i>Water supply testing using fish</i></p>
<p>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.)</p> <p><i>Examples</i> <i>Pre-registration efficacy or toxicity testing of drugs and vaccines</i></p>

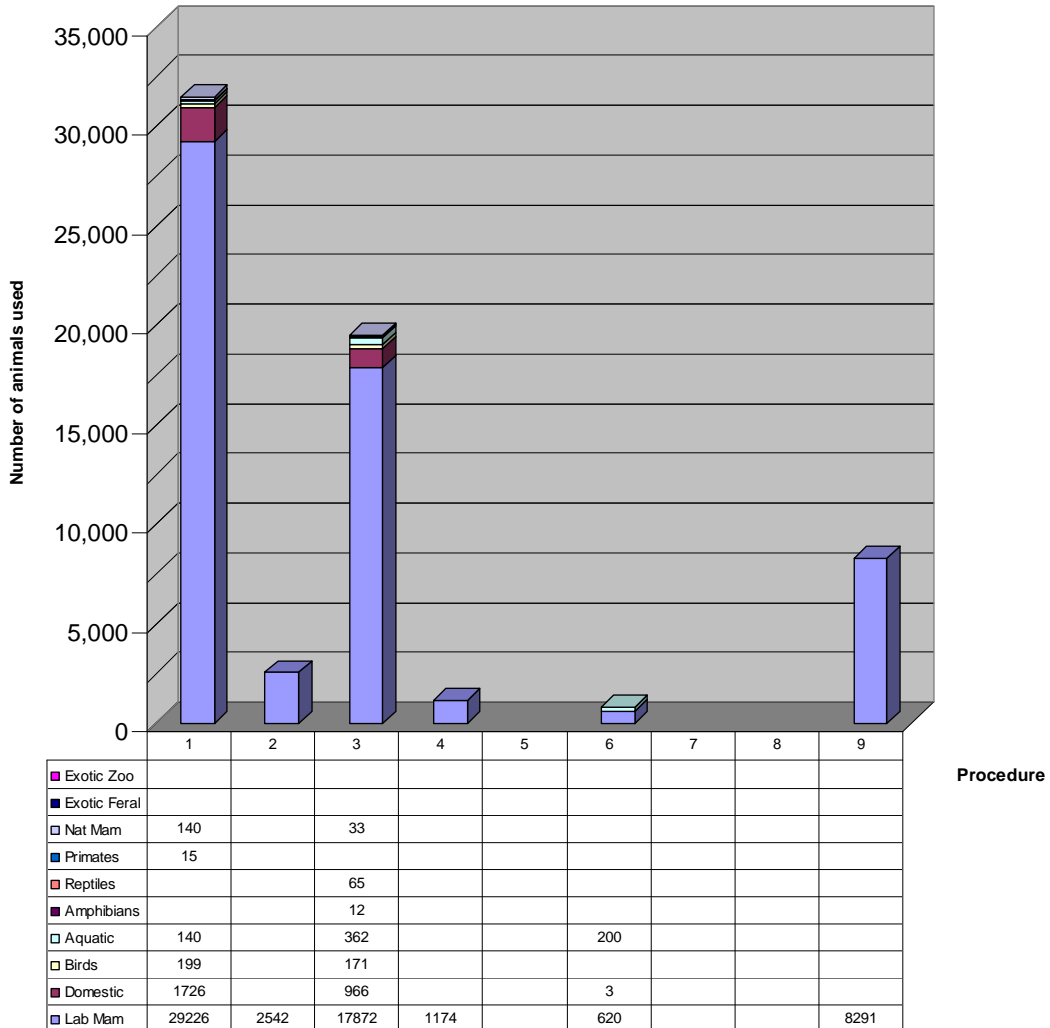
Data collection: procedure categories and guidelines used for classification

1: Observation involving minor interference	6: Minor physiological challenge
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 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.
2: Animal unconscious without recovery	7: Major 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 causes a moderate or large degree of pain/distress that is not quickly or effectively alleviated.
3: Minor conscious intervention	8: Death as an endpoint
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.	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.
4: Minor surgery with recovery	9: Production of genetically modified (GM) animals
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 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.
5: Major surgery with recovery	
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.	

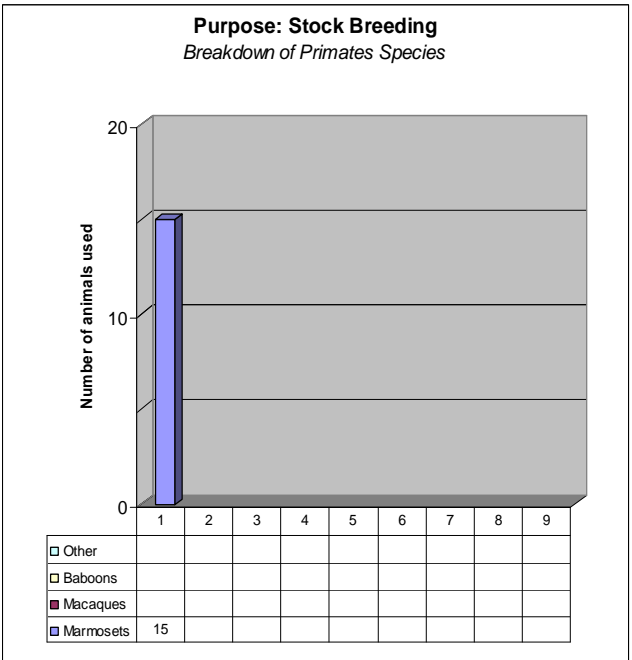
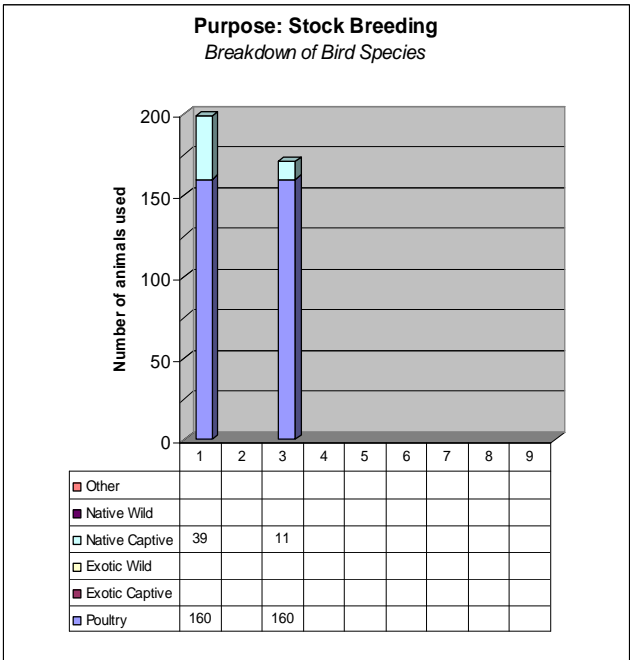
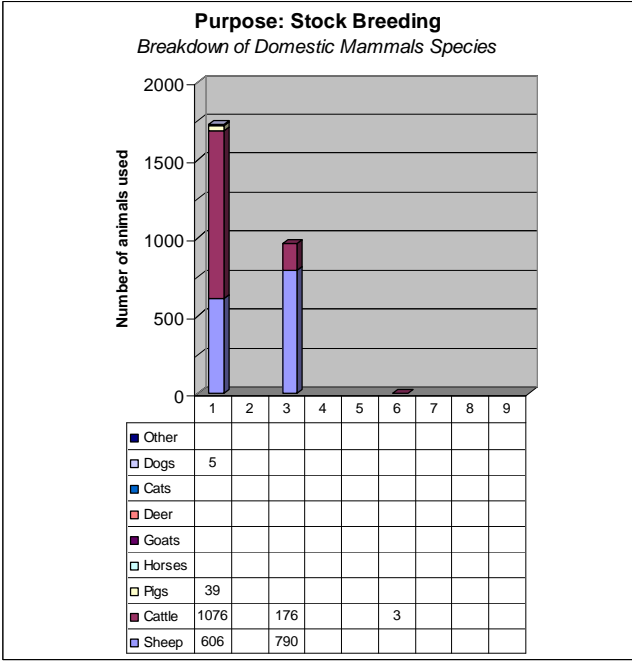
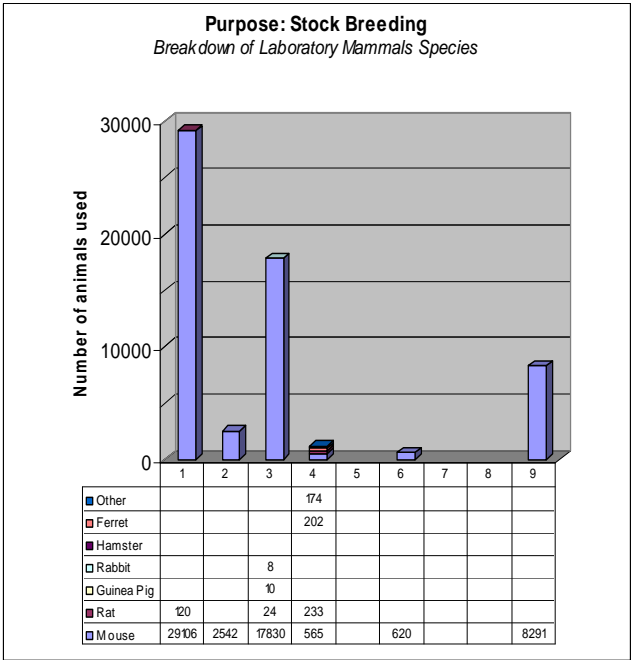
The following graphs (one for each purpose) show the numbers of animals used against the category of procedure (Categories 1 to 9).

Purpose: Stock Breeding

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

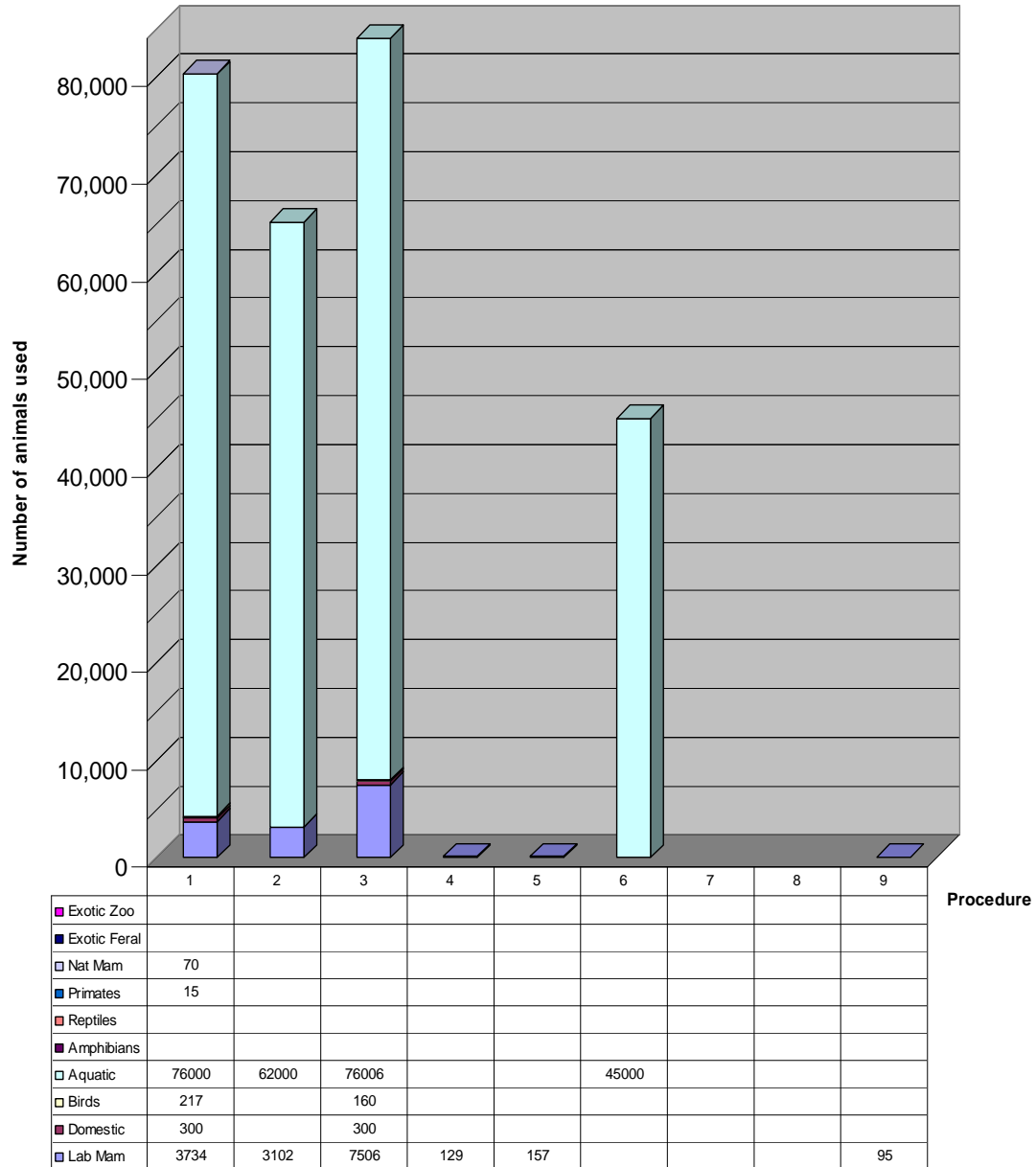


Refer to following page for a further breakdown of species.

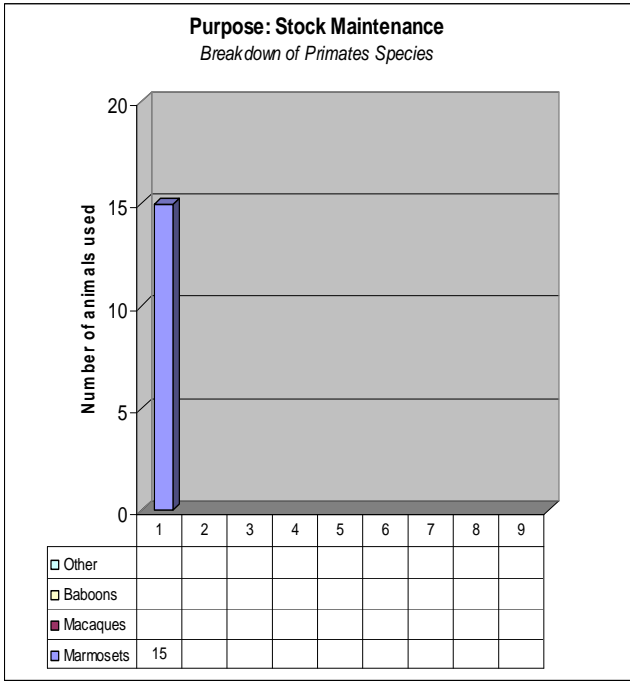
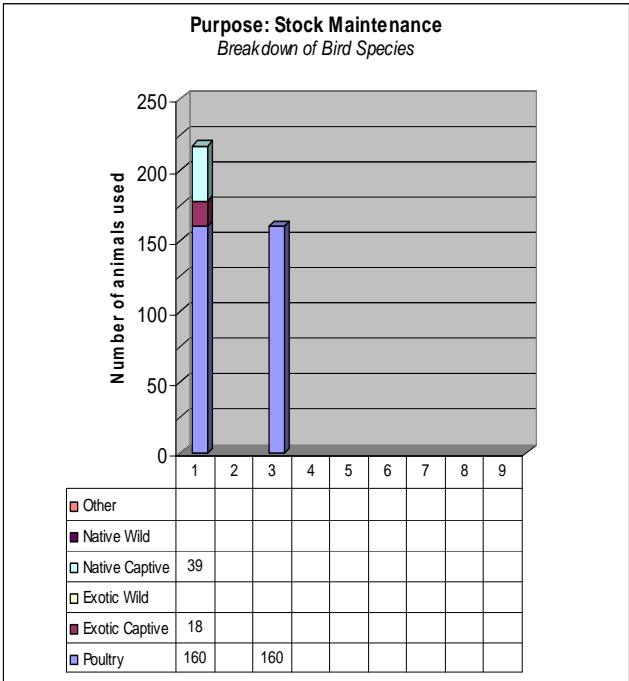
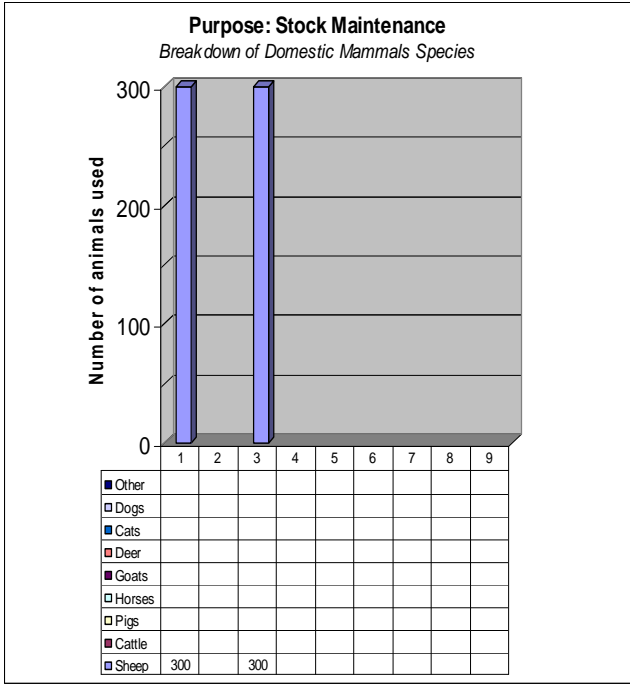
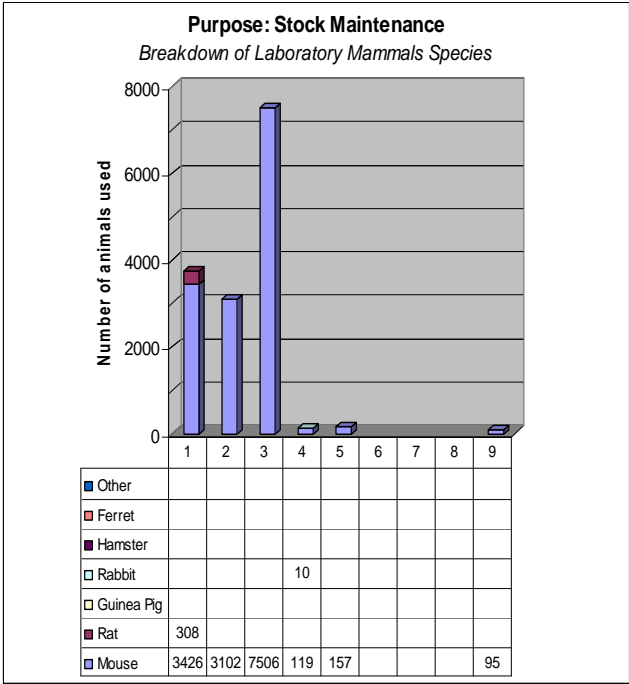


Purpose: Stock Maintenance

Holding Protocols for animals maintained for use in other protocols.

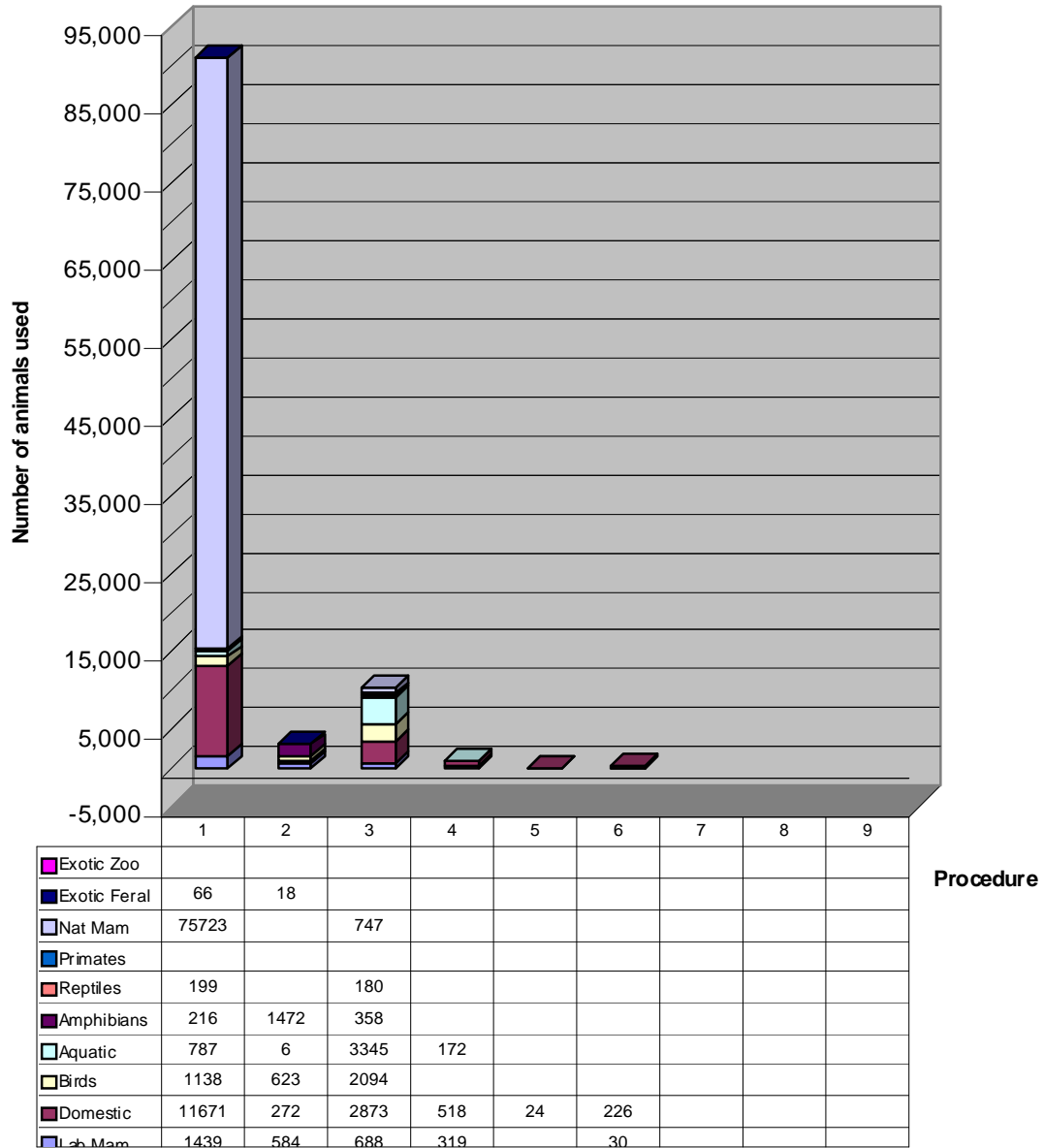


Refer to following page for a further breakdown of species.



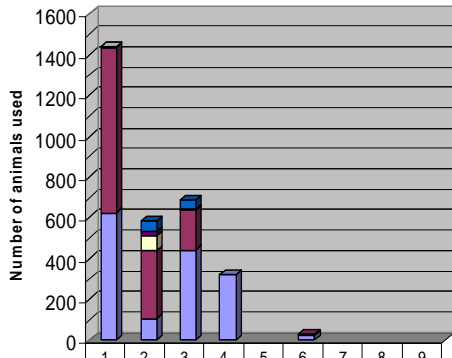
Purpose: Education

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



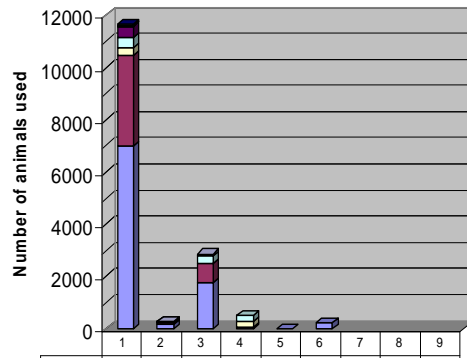
Refer to following page for a further breakdown of species.

Purpose: Education
Breakdown of Laboratory Mammals Species



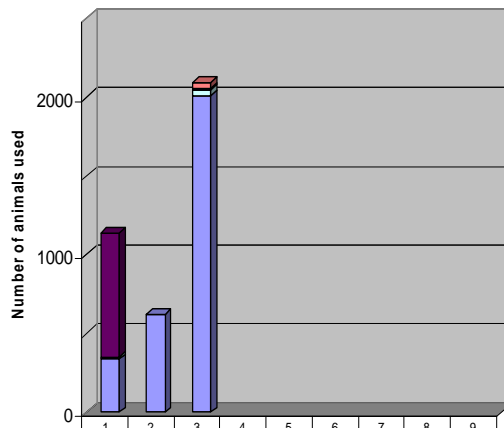
Other		48	48						
Ferret									
Hamster		24							
Rabbit	4								
Guinea Pig		73	4						
Rat	810	333	194		6				
Mouse	625	106	442	319					

Purpose: Education
Breakdown of Domestic Mammals Species



Other	14								
Dogs	74	9	72						
Cats	9								
Deer									
Goats	417	4							
Horses	433	1	288	226					
Pigs	241	21	240						
Cattle	3502	51	734						
Sheep	6981	186	1779	52	24	226			

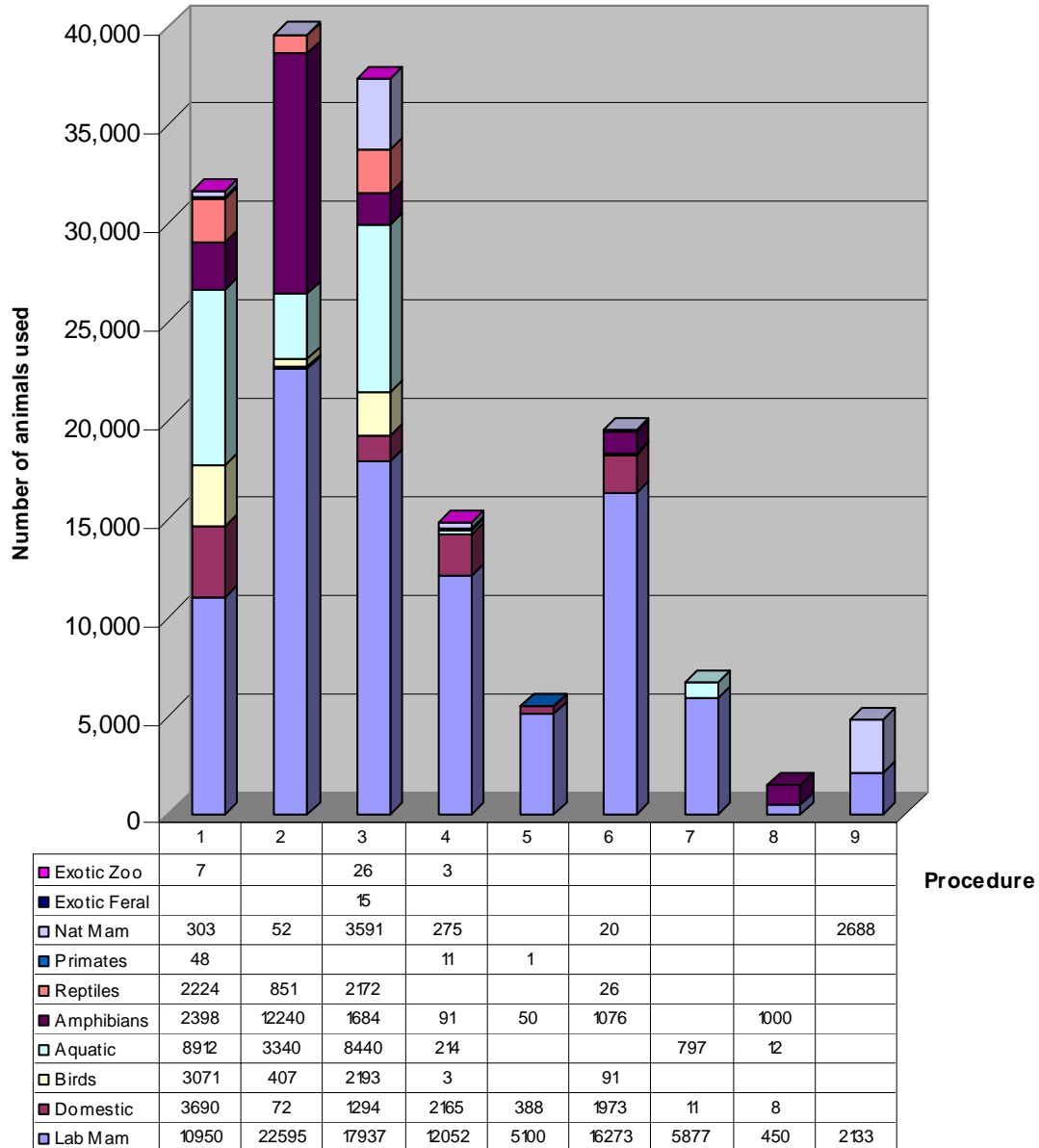
Purpose: Education
Breakdown of Bird Species



Other			40						
Native Wild	787		5						
Native Captive	15		40						
Exotic Wild									
Exotic Captive	1								
Poultry	335	623	2009						

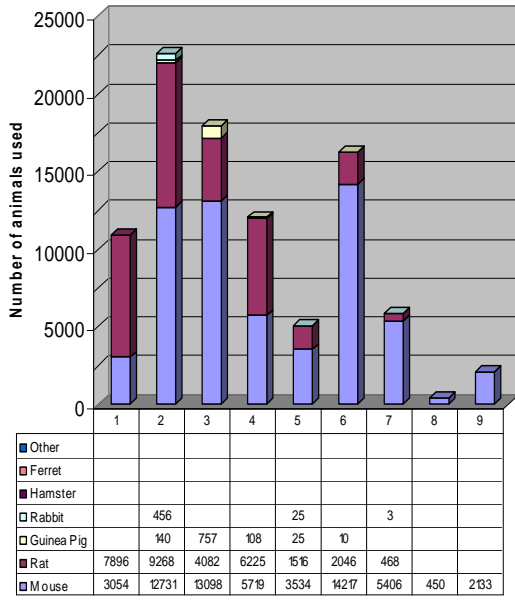
Purpose: Research - Human or Animal Biology

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

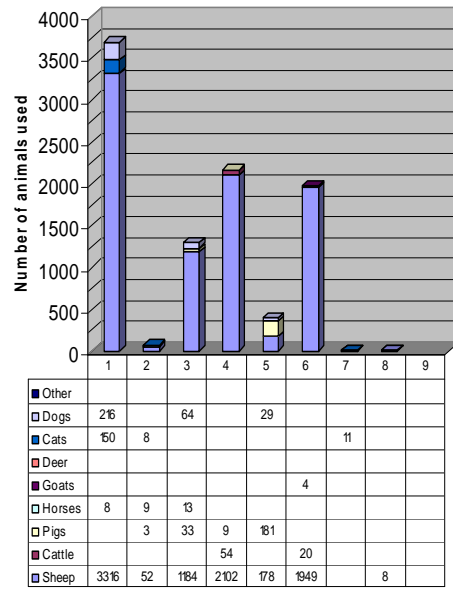


Refer to following page for a further breakdown of species.

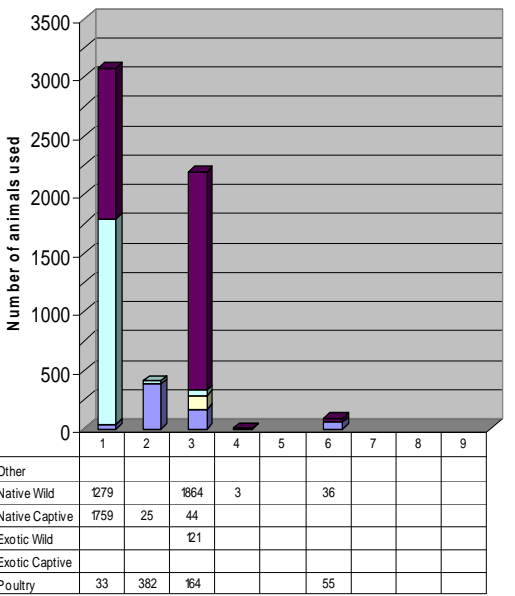
Purpose: Research - Human or Animal Biology
Breakdown of Laboratory Mammals Species



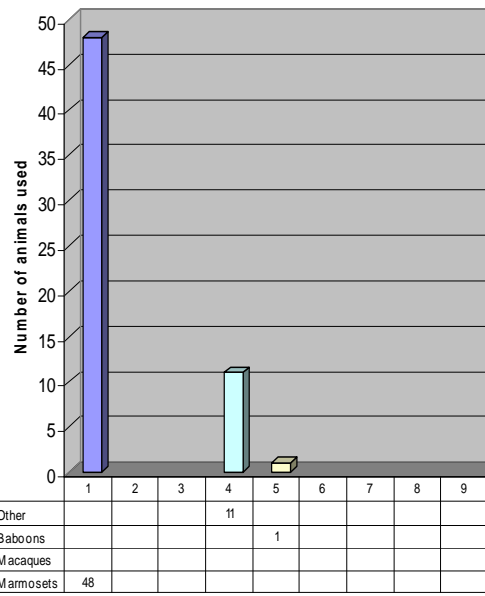
Purpose: Research - Human or Animal Biology
Breakdown of Domestic Mammals Species



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

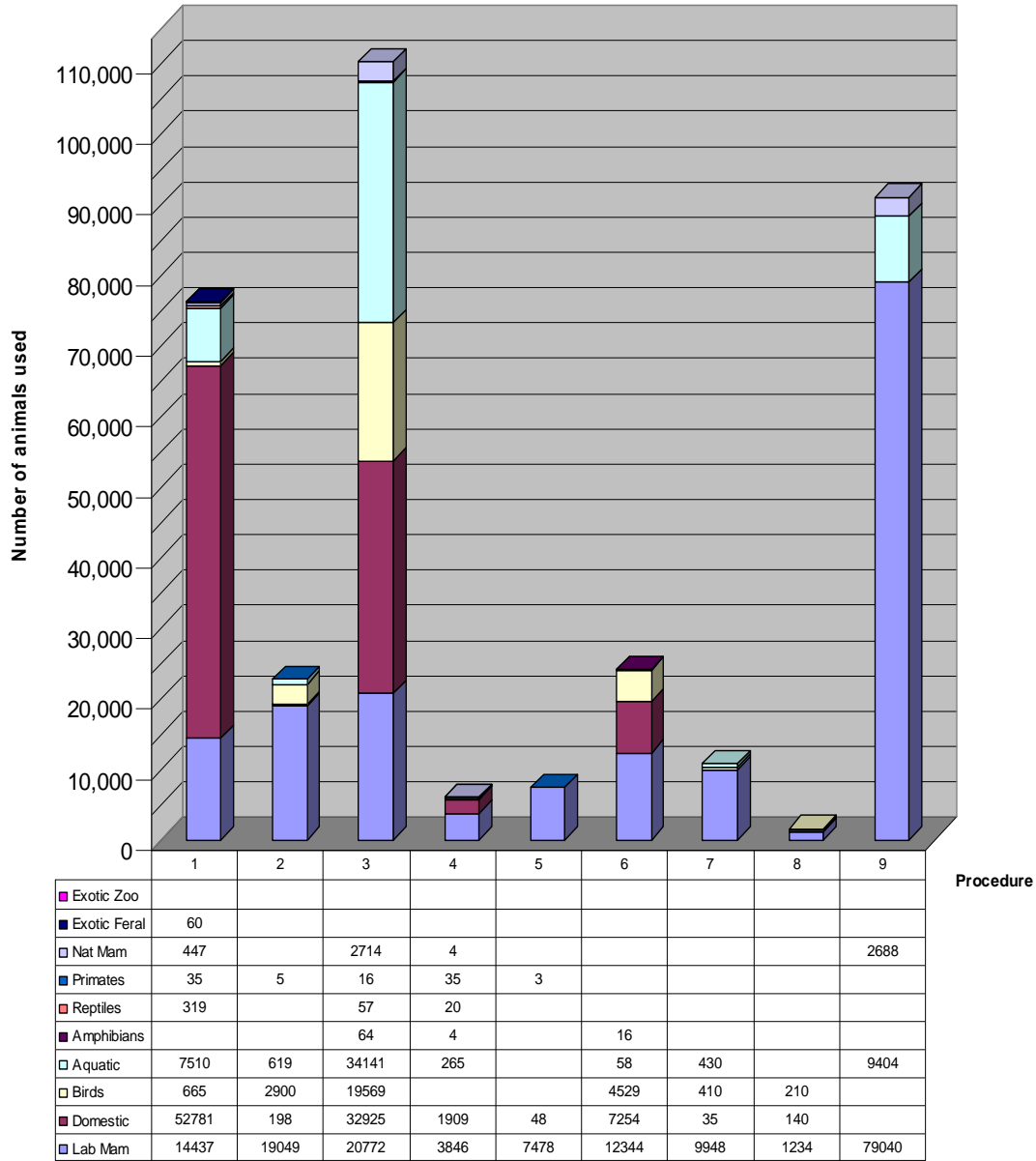


Purpose: Research - Human or Animal Biology
Breakdown of Primate Species



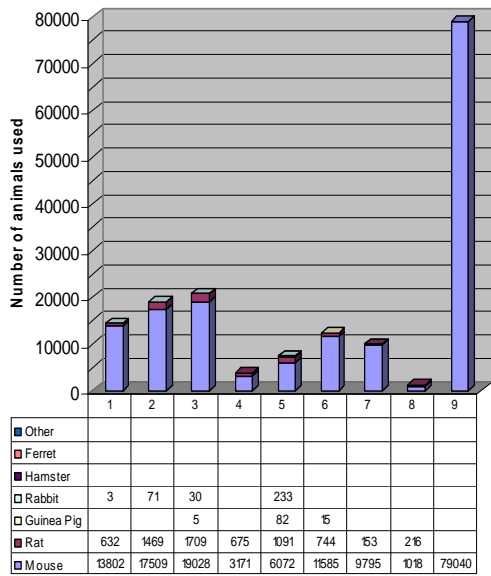
Purpose: Research - Human or Animal Health & Welfare

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

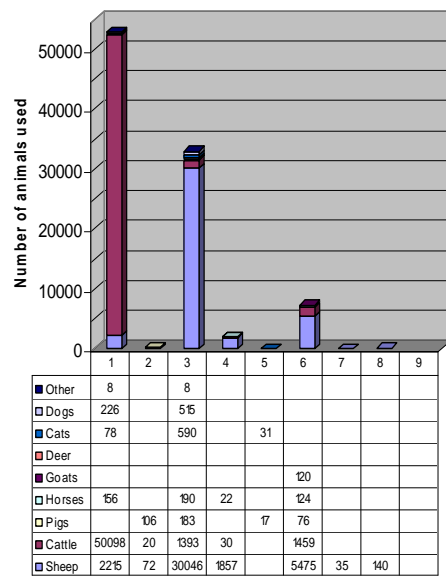


Refer to following page for a further breakdown of species.

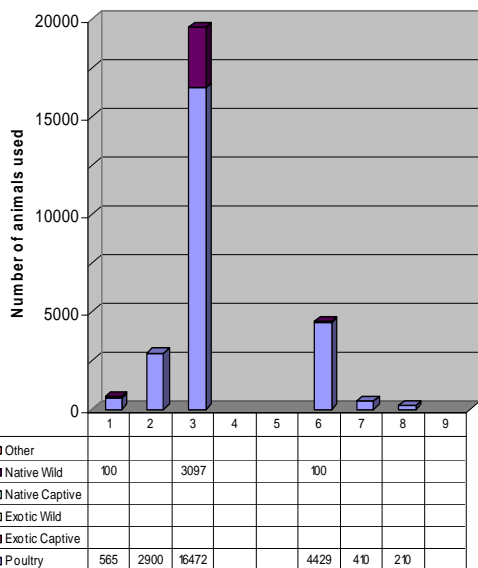
Purpose: Research - Human or Animal Health & Welfare
Breakdown of Laboratory Mammals Species



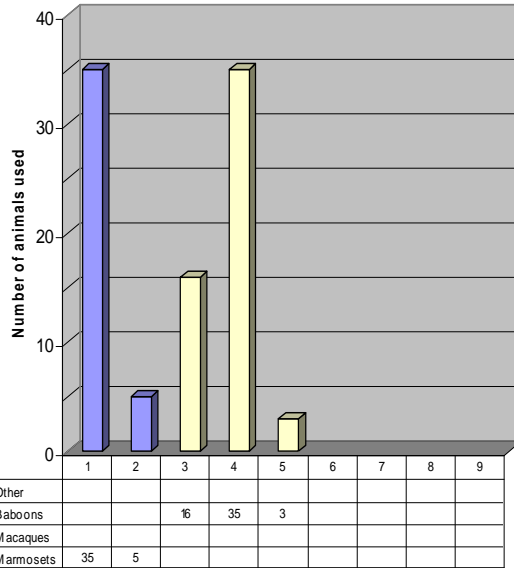
Purpose: Research - Human or Animal Health & Welfare
Breakdown of Domestic Mammals Species



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

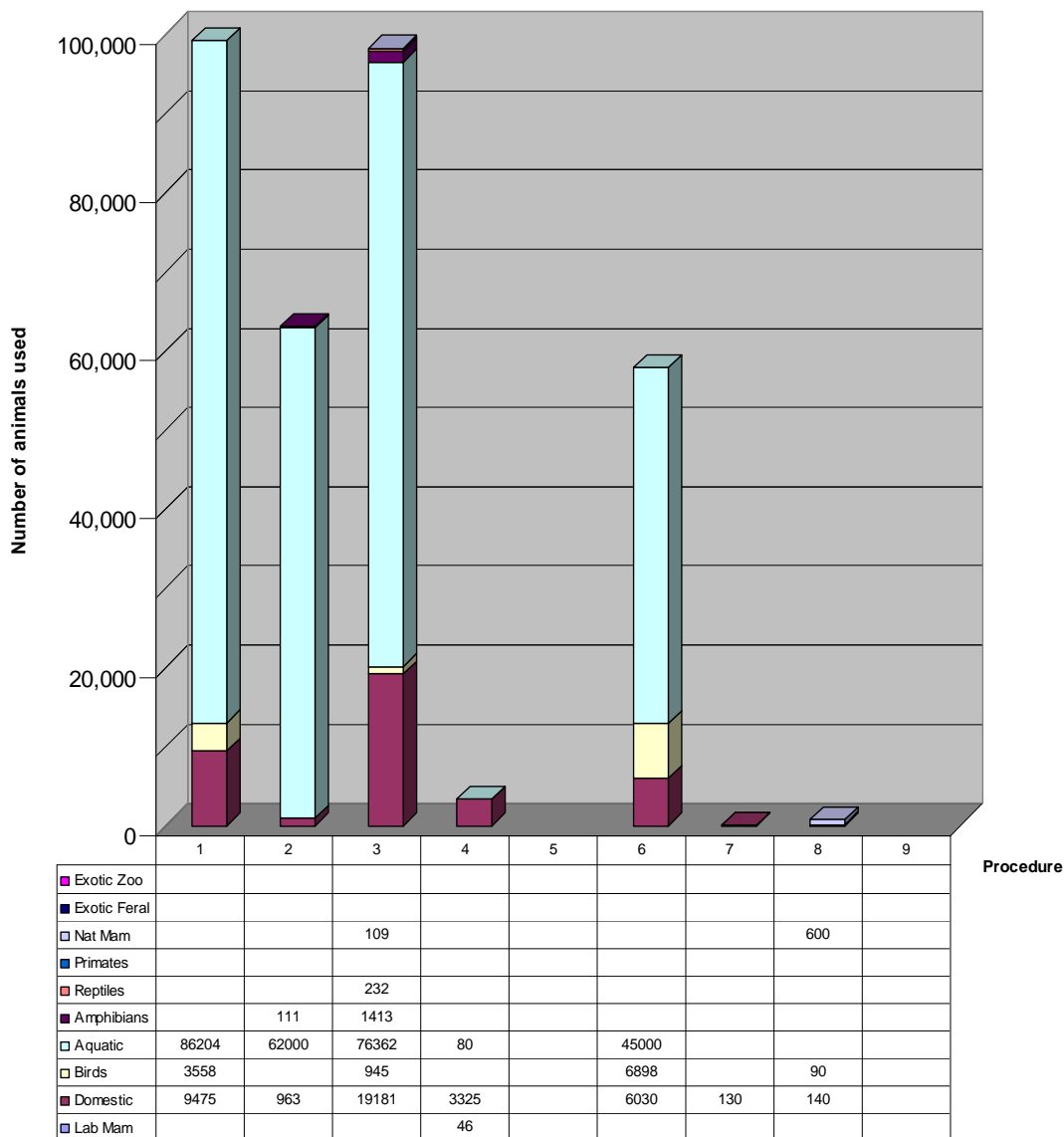


Purpose: Research - Human or Animal Health & Welfare
Breakdown of Primate Species



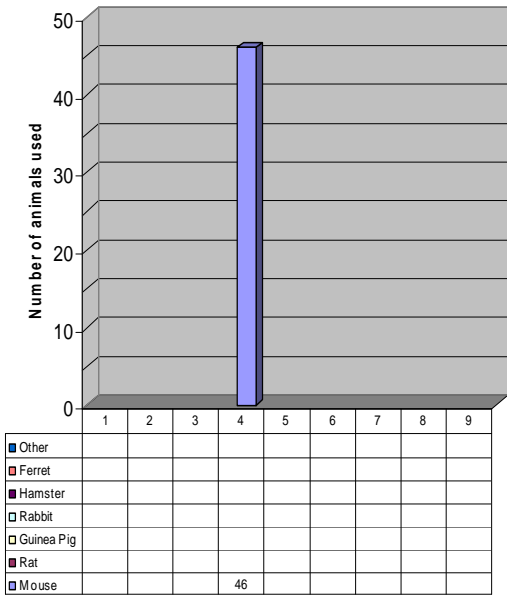
Purpose: Research - Animal Management or Production

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

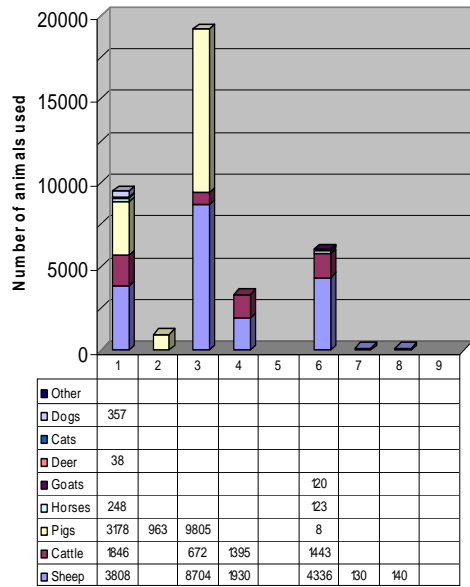


Refer to following page for a further breakdown of species.

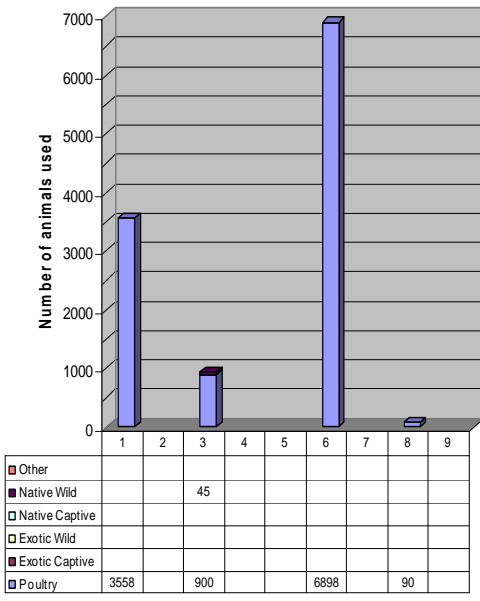
Purpose: Research - Animal Management or Production
Breakdown of Laboratory Mammals Species



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

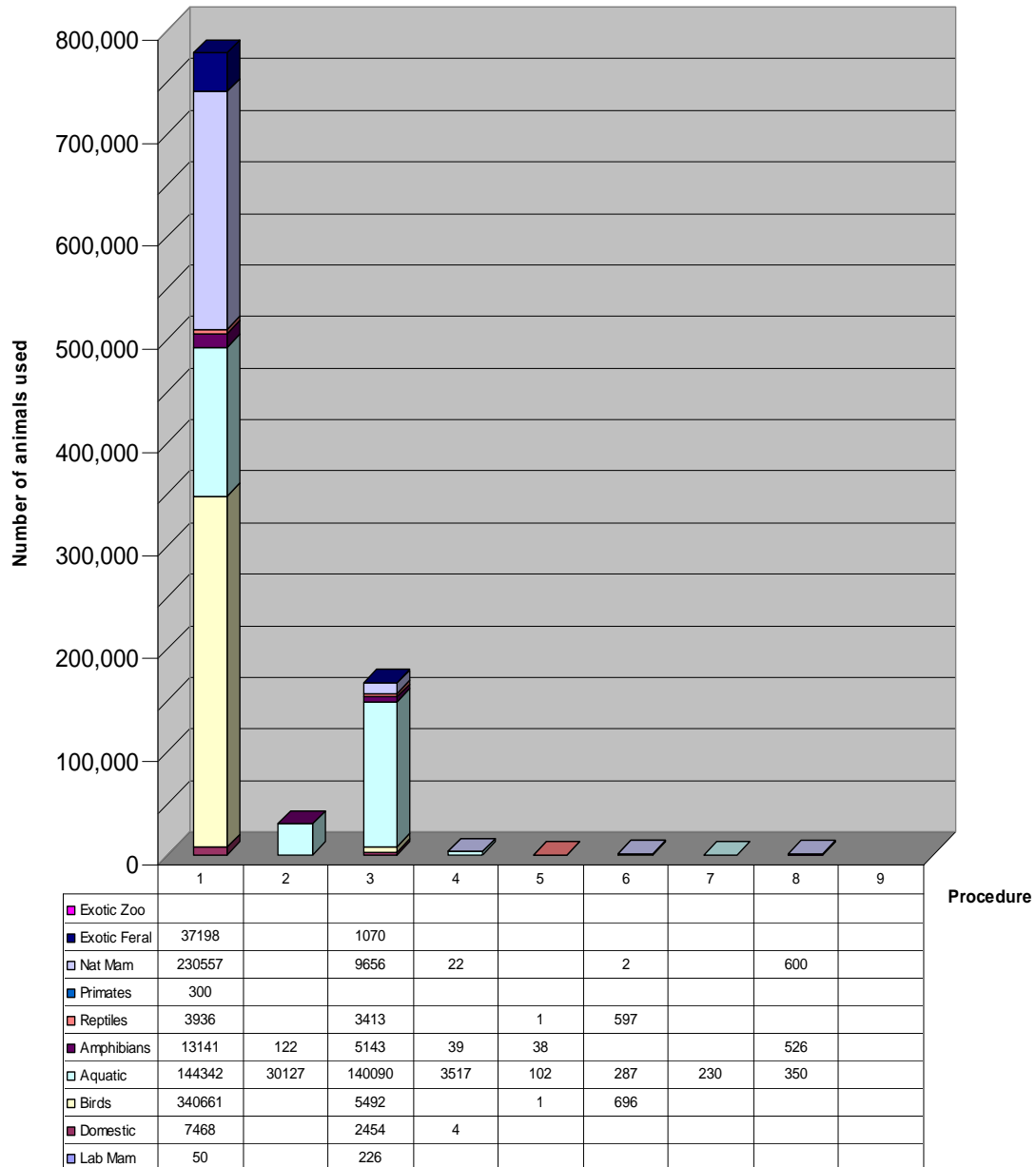


Purpose: Research - Animal Management or Production
Breakdown of Bird Species



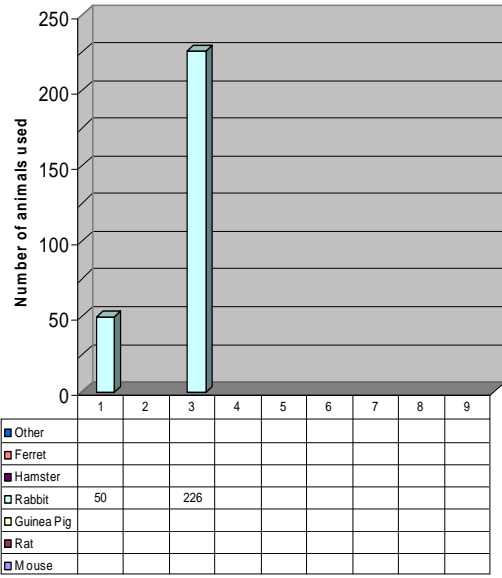
Purpose: Research - Environmental Study

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 .

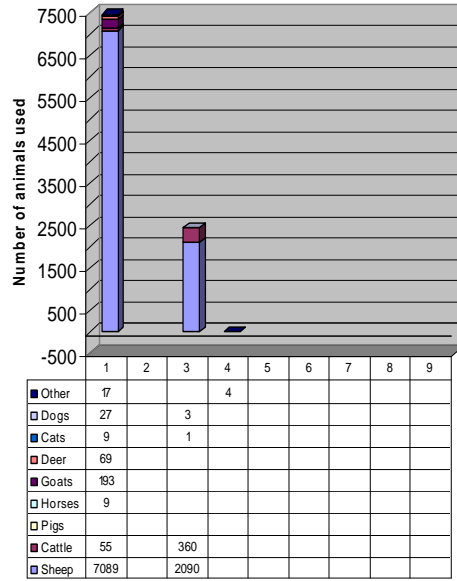


Refer to following page for a further breakdown of species.

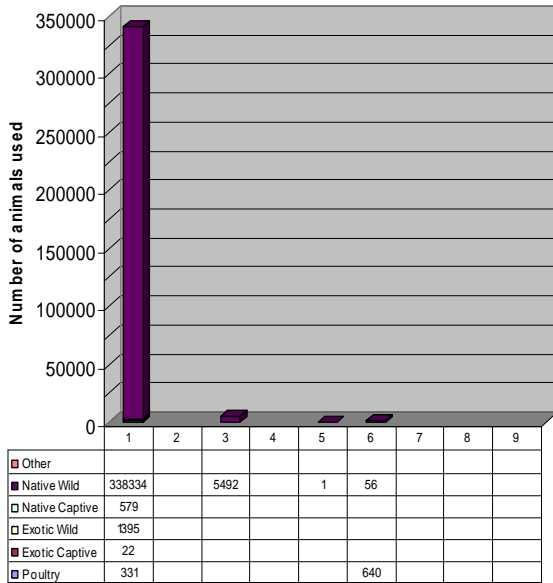
Purpose: Research - Environmental Study
Breakdown of Laboratory Mammals Species



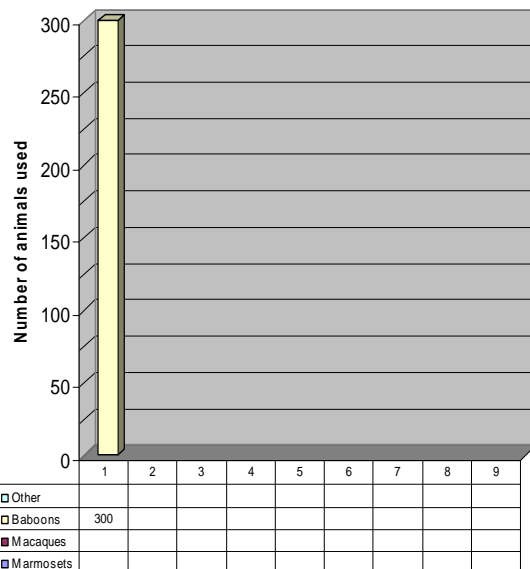
Purpose: Research - Environment Study
Breakdown of Domestic Mammals Species



Purpose: Research - Environment Study
Breakdown of Bird Species

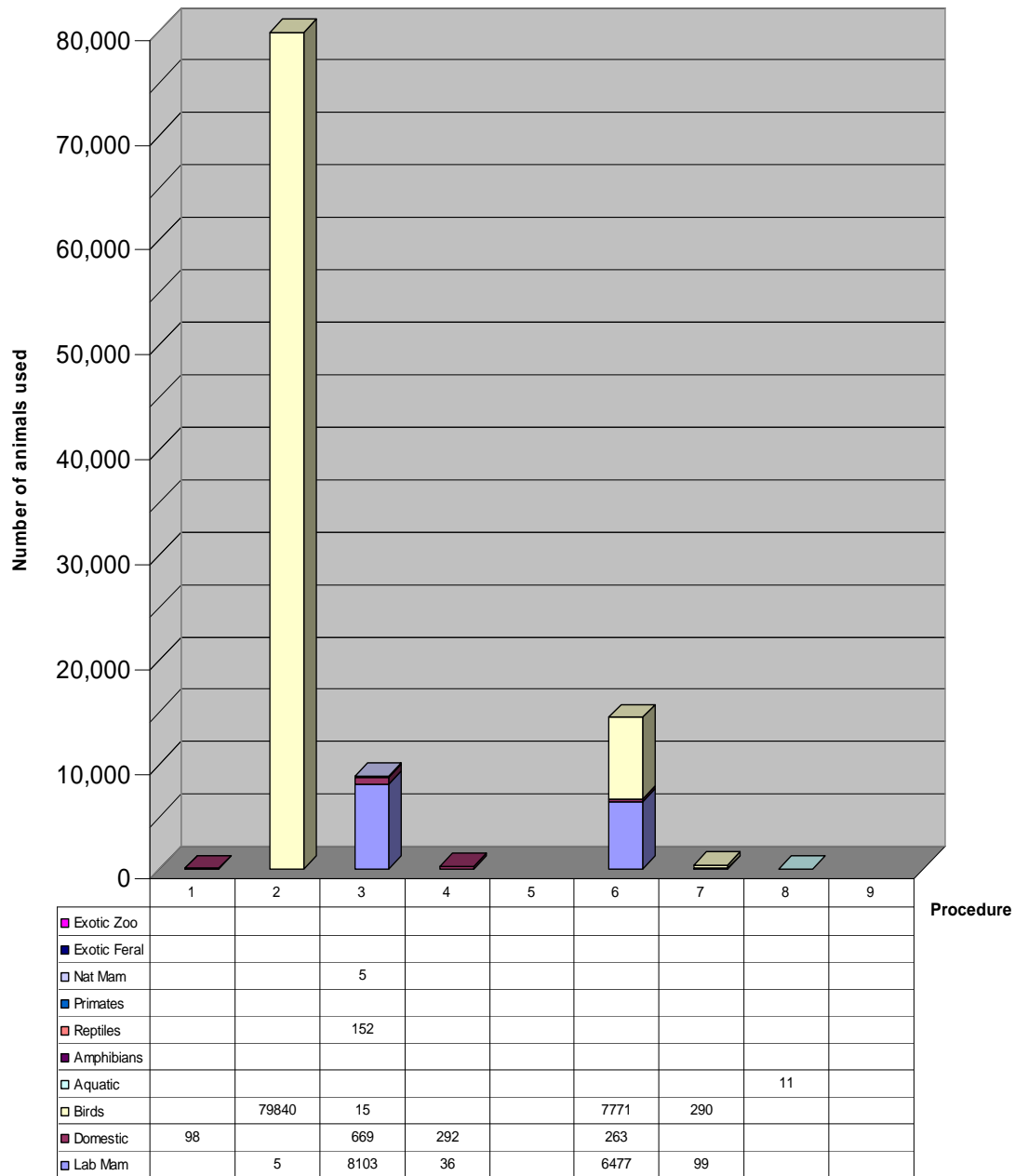


Purpose: Research - Environment Study
Breakdown of Primate Species



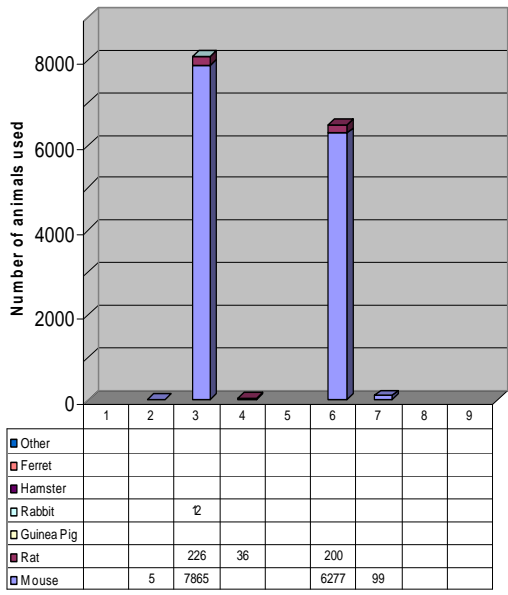
Purpose: Production of Biological Products

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

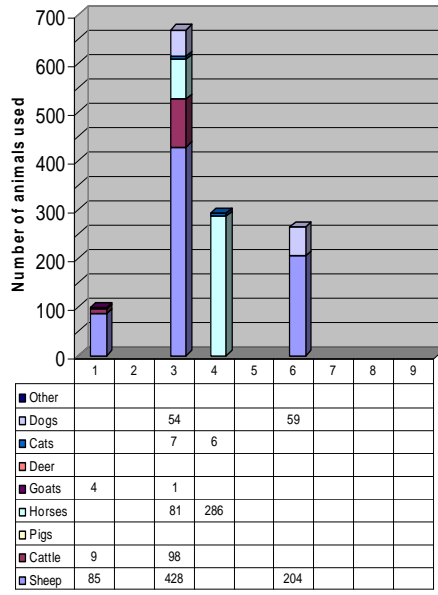


Refer to following page for a further breakdown of species.

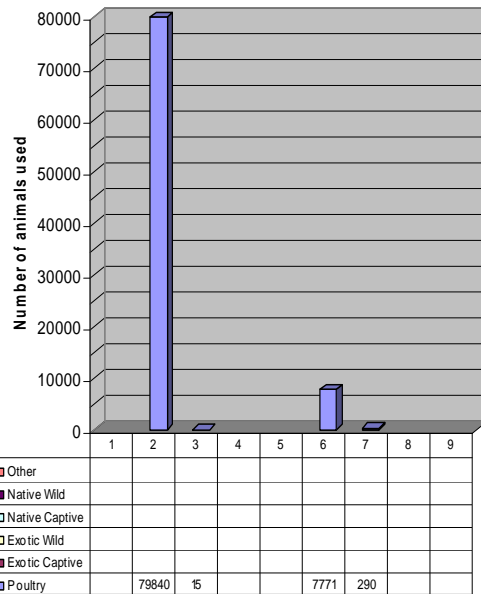
Purpose: Production of Biological Products
Breakdown of Laboratory Mammals Species



Purpose: Production of Biological Products
Breakdown of Domestic Mammals Species

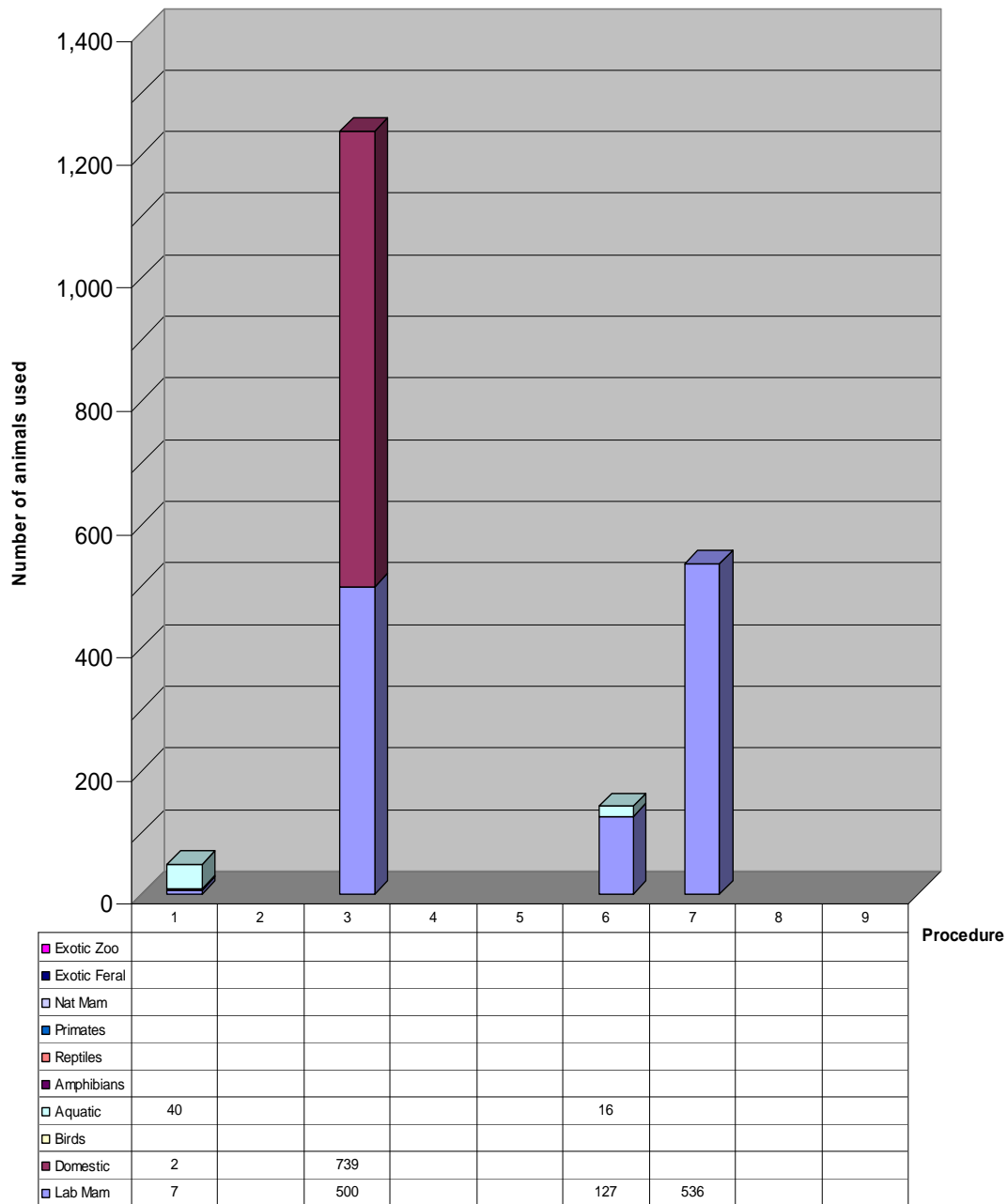


Purpose: Production of Biological Products
Breakdown of Bird Species



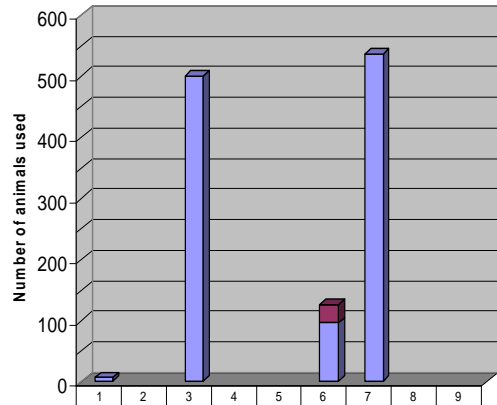
Purpose: Diagnostic Procedures

Using animals directly as part of a diagnostic process.



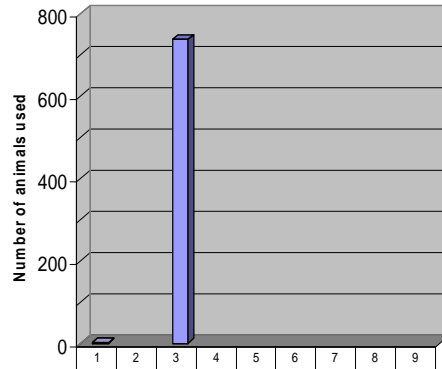
Refer to following page for a further breakdown of species.

Purpose: Diagnostic Procedures
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit									
Guinea Pig									
Rat						31			
Mouse	7		500			96	536		

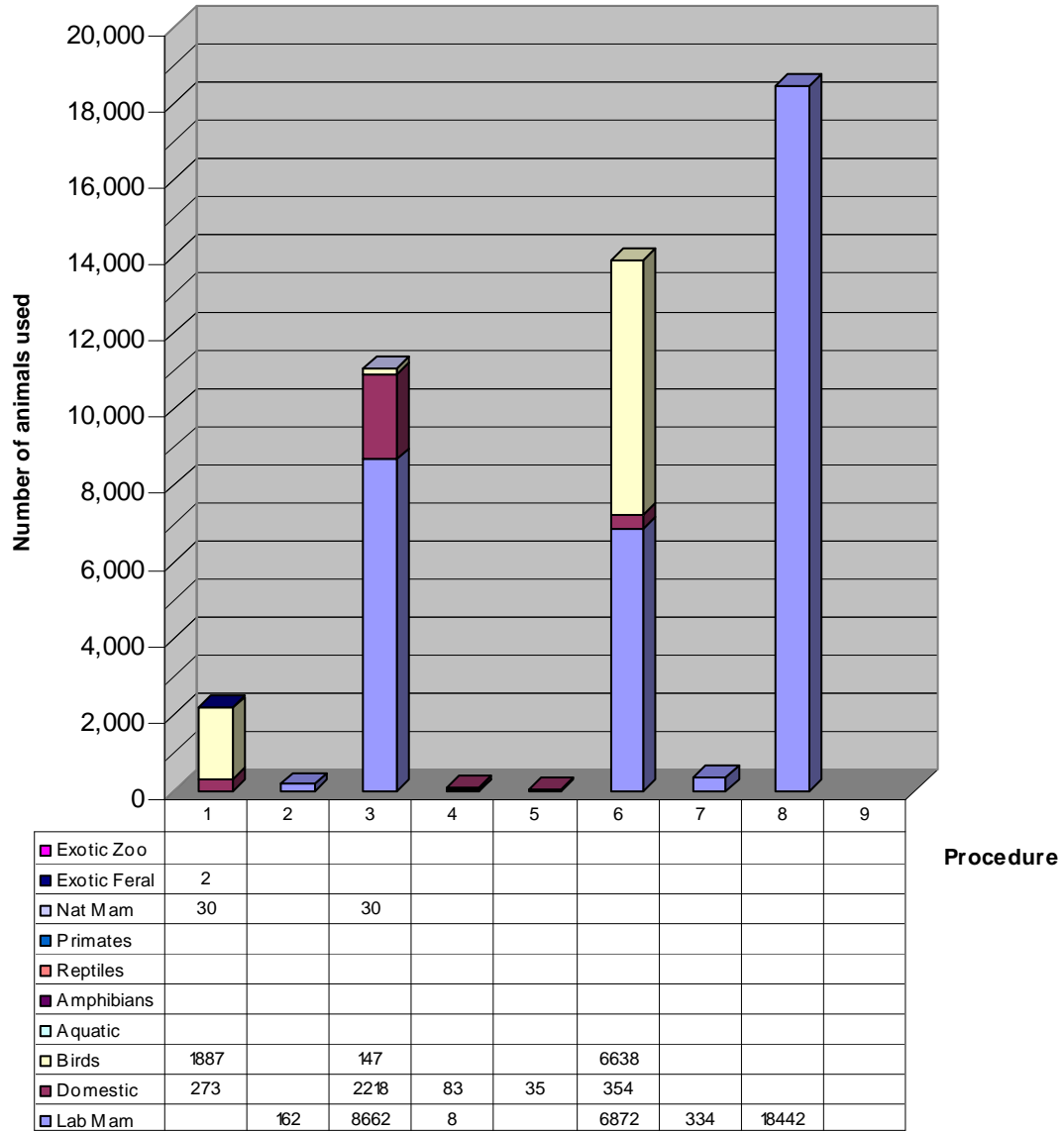
Purpose: Diagnostic Procedures
Breakdown of Domestic Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Dogs	2								
Cats									
Deer									
Goats									
Horses									
Pigs									
Cattle									
Sheep			739						

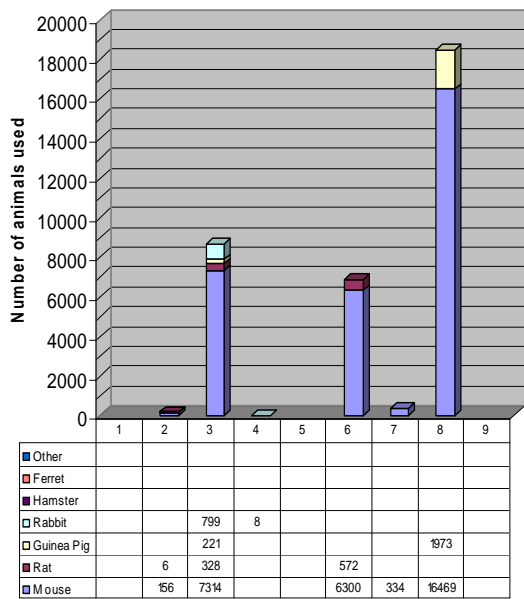
Purpose: Regulatory Product Testing

Protocols for the testing of products required by regulatory authorities.

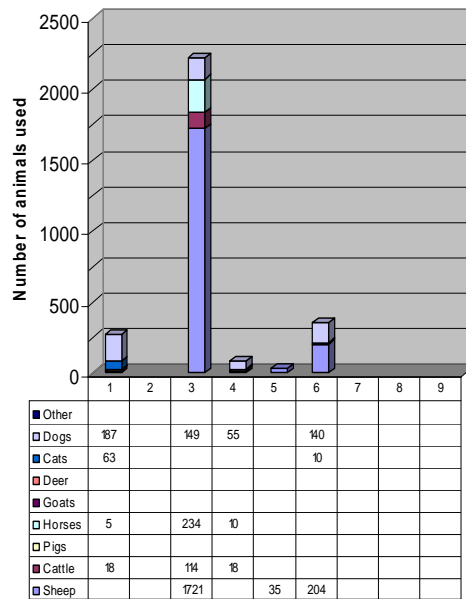


Refer to following page for a further breakdown of species.

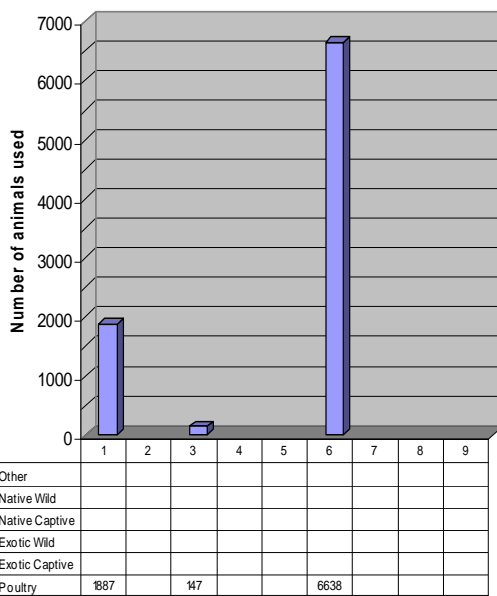
Purpose: Regulatory Product Testing
Breakdown of Laboratory Mammals Species



Purpose: Regulatory Product Testing
Breakdown of Domestic Mammals Species



Purpose: Regulatory Product Testing
Breakdown of Bird Species



LETHALITY TESTING – 2009

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'. Lethality tests include, but are not limited to, LD50 tests.

The following are the figures reported on animal use for lethality testing in 2009.

Species	No. used	No. died/ euthanased	Procedure	Justification	Alternatives
Mice	7187	2396	Serum neutralisation test in mice: susceptible animals are challenged with test toxin/antibody dilutions to determine antibody titre.	Regulatory testing required to demonstrate efficacy (potency) of vaccines prior to release. Testing of stability batches and new product formulations.	This test is based upon regulatory guidelines. No alternatives available at this time.
Mice	4210	2072	L+ titration in mice. Susceptible animals are challenged with test toxin in order to determine potency of antigen preparation.	In-process testing of production and development antigen growths to allow stop/go decision during manufacturing process.	No alternatives available at this time.
Mice	120	60	Challenge of vaccinated mice with target organisms to demonstrate efficacy of vaccine.	Regulatory testing required to demonstrate efficacy (potency) of vaccines prior to release.	No alternatives available at this time.
Guinea Pigs	1973	533	Vaccinated animals are challenged with test organism in order to demonstrate protection and hence vaccine efficacy.	Regulatory testing required to demonstrate efficacy (potency) of vaccines prior to release. Assessment of in-process or development material to determine suitability for further manufacture.	This test is based on regulatory guidelines. No alternatives available at this time.
Mice	4952	2707	Total Combining Power test in mice: susceptible animals are challenged with test antigen/toxin/antibody dilutions to determine potency of antigen preparations.	In-process testing of vaccine constituents to allow evaluation of suitability for further manufacture.	No alternatives available at this time.
Northern Trout Gudgeon	5	5	Exposure to dry cane toad skin	Assessing the toxicity of dead cane toads	No further lethality tests needed to assess toxicity of dead cane toads.
Chelosania brunnea (Chameleon dragon)	1	0	Ingestion of cane toads	Assess toxicity of cane toads	Trial for each species terminated once response to toxicity determined.
Tiliqua multifasciata (Centralian blue-tongue)	2	0	Ingestion of cane toads	Assess toxicity of cane toads	Trial for each species terminated once response to toxicity determined.
Varanus	1	0	Ingestion of cane	Assess toxicity of cane	Trial for each species

glauerti (Kimberley rock monitor)			toads	toads	terminated once response to toxicity determined.
Varanus scalaris (Spotted tree monitor)	2	0	Ingestion of cane toads	Assess toxicity of cane toads	Trial for each species terminated once response to toxicity determined.
Varanus storri (Storr's goanna)	2	0	Ingestion of cane toads	Assess toxicity of cane toads	Trial for each species terminated once response to toxicity determined.
Boiga irregularis (Brown tree snake)	1	0	Ingestion of cane toads	Assess toxicity of cane toads	Trial for each species terminated once response to toxicity determined.
Demansia olivacea (Olive whip snake)	1	0	Ingestion of cane toads	Assess toxicity of cane toads	Trial for each species terminated once response to toxicity determined.
Dendrelaphis punctulata (Green tree snake)	1	0	Ingestion of cane toads	Assess toxicity of cane toads	Trial for each species terminated once response to toxicity determined.
Antaresia childreni (childrens python)	1	0	Ingestion of cane toads	Assess toxicity of cane toads	Trial for each species terminated once response to toxicity determined.
Pseudonaja nuchalis (Western brown snake)	1	0	Ingestion of cane toads	Assess toxicity of cane toads	Trial for each species terminated once response to toxicity determined.
Suta ordensis (Curl snake)	1	0	Ingestion of cane toads	Assess toxicity of cane toads	Trial for each species terminated once response to toxicity determined.
Pseudechis australis (king brown snake)	2	2	Ingestion of cane toads	Assess toxicity of cane toads	Trial for each species terminated once response to toxicity determined.
Acanthophis praelongus (death adder)	1	1	Ingestion of cane toads	Assess toxicity of cane toads	Trial for each species terminated once response to toxicity determined.
Planigale maculate (Common planigale)	1		Ingestion of cane toads	Assess toxicity of cane toads	Trial for each species terminated once response to toxicity determined.
Bufo marinus (Cane toad)	536	97	Offered as prey	Assess toxicity of cane toads	Trial for each species terminated once response to toxicity determined.
Mice	243	243	In order to assess the contribution of specific virulence determinants to disease causation via "knock out" the virulence gene under study, and then compare the virulence of the	The contribution of specific virulence determinants to the pathogenesis of microbial pathogen can only be assessed in a live animal model of virulence. As mucosal and tissue barriers as well as a functioning immune system are required, these studies can	No alternatives exist, which effectively mimic the mucosal and tissue barriers as well as a functioning immune system observed in live mammals.

			knock out strain and the parental wild type strain when infected with <i>S.pyogenes</i> .	only be conducted in live mammals (ie mice).	
--	--	--	---	--	--

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 for the 2009 reporting year. 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).

Replacement
Devices purchased for use in surgical training for vascular anastomosis – alternative to using rats.
Cane toads no longer used for undergraduate anatomy lessons.
Observational studies using Siamese fighting fish no longer included in undergraduate psychology teaching.
Due to the regulations on monoclonal antibody production and the necessity for researchers to investigate alternative methods to ascities model using in vitro techniques such as bioreactors, wave bags etc we have seen a large reduction in the number of animals for these purposes.
Use of videos, DVDs and CD ROMs to replace or supplement the use of animals in teaching protocols, where necessary.
Researchers establishing correlation between in vitro and in vivo effects, for future use of the techniques with human cells lines rather than with animals.
A program of experimental assessment of cell mediated immune response through the use of an invitro gamma interferon assay to assess the immune response of sheep to <i>Corynebacteria pseudotuberculosis</i> (CLA) was implemented in 2009. Currently there exists no alternative to target animals challenge work to assess CLA vaccine efficacy, so the development of an in vitro test (which will need to be evaluated alongside challenge in a future study) could result in the replacement of target animal challenge with a laboratory based assay.
We have moved away from animals (sheep) for investigating potential interactions between two drugs and are now using a range of in vitro models for progressing this work.
The use of computer simulation in a teaching subject in place of cane toads.
More <i>Coxiella</i> sp and <i>Rickettsia</i> sp isolation and culture work is being done in tissue culture (in vitro) using VERO and DH82 cells and less by SCID mouse inoculation.
Use of plant tissue as a replacement for animal tissue for certain enzymatic assays.
Reduction
The establishment has maintained an ongoing program aimed at rationalising testing which has focussed on eliminating Quality Control testing which is not essential to meet product release requirements. This program covers both lethal and non-lethal testing. In addition, in all cases where clear test outcomes are not obtained upon initial testing, a critical assessment is made to confirm the necessity to perform repeat testing before re-testing occurs. It should however be noted that whilst progress has been made in this regard, there remains a minimum amount of testing necessary to meet regulatory requirements for the assessment of in-process and final product prior to release.
The number of animals used at each Study site was the minimal number of animals required to comply with the APVMA ectoparasiticides Guideline 21: Blowfly Specific (Flystrike Preventatives and Treatments) Efficacy Submissions
A pilot study was conducted, therefore reducing the number of animals required to gain enough information to

determine if the company's formulation was similar enough to pioneer to bring it to full development.
A pilot study was conducted, therefore reducing the number of dogs required to gain evidence of similar plasma profiles of the product in dogs.
Although a larger, higher powered study would have been preferred, a Latin Square trial design in 5 dogs supplied useful, initial data regarding the safety and efficacy of the Test Items.
A study was designed as a pilot study to reduce the number of animals required to obtain enough data to help determine which product will be carried forward to a pivotal, GLP, tissue residue study.
The protocol was written in a manner that ensured once a range of preconceived events were captured for a given protocol, the protocol was not repeated. This effectively reduced the total number of animals used from a possible 27 to a total of 13.
Continued improvement in statistical analysis for minimal use of animals.
Commenced investigation regarding ways to reuse rats at end of nonrecovery experiments and prior to euthanasia – ongoing in 2010.
Euthanased rats from approved protocols used for undergraduate anatomy lessons instead of purchasing euthanased mice from outside supplier.
Suitable rats (eg that have not had drugs or surgical interventions) rehomed for use as breeding and education animals for training animal science students.
A surgical teaching protocol was amended to use all available rat strains so that animals that could not be rehomed could be utilised at end of other protocols.
New and improved technology has been developed during the year to improve the efficiency of stored serum processing to hopefully reduce the numbers of animals used in the production process.
Close scrutiny of the number of animals requested and Biometrician's comments reviewed to ensure numbers are adequate to obtain the desired statistical outcomes, to minimise the number of animals involved in trials and to ensure that trials do not have to be repeated unnecessarily.
Similar studies have shared the same control animals.
Numbers have been substantially reduced as pilot data showed statistically significant results were obtainable with smaller numbers.
The number of animals has been reduced by dividing tissue from sacrificed animals between multiple analytical experiments.
Where possible we have been sharing experimental animals for organ collection with other researchers in the group.
During this project we were able to reduce the number of animals per group from 10 to 8, and sometimes less, as we accumulated consistent data for treatments.
The efficiency of MEF cell isolation and culture procedures have been optimised to minimise the number of embryos required for these studies.
Experiments have been refined such that the number of donor cells (and therefore donor animals) can be reduced.
We are generating immortalised cell lines from our GM animals for use in signalling studies. This will ultimately reduce animal usage.
We have limited our signalling studies to the gender exhibiting the most marked metabolic phenotype, which effectively halves potential animal usage.
Multiple tissues are collected from all experimental animals and stored to prevent the possibility of extra animals being required to study different tissues.
The use of the microsyringer to induce lung fibrosis should create a more reproducible model, hence reducing the number of animals necessary to reach significance in case of different outcomes.
Where possible pilot studies were performed. These indicated that the full study would not be worthwhile, or to modify the study to a smaller cross-sectional analysis, resulting in less mice being used.

<p>This protocol was conducted at a cattery facility that uses the same cats for other studies eg palatability tests, at the conclusion of this study the cats will be available for further use. A statistical power calculation was used to determine the minimum number of cats to provide a statistically valid result.</p>
<p>This study was conducted on commercial pasture beef properties. Protocol design included a statistical power calculation that dictated the minimum number of animals to ensure statistical validity of the data.</p>
<p>Encourage and facilitate tissue sharing from healthy culls for relevant projects.</p>
<p>Excess/unused animals re-allocated to other active projects if possible.</p>
<p>Pilot procedures using reduced animal numbers for new protocols to test their validity.</p>
<p>Through use and analysis of previous studies via literature analysis.</p>
<p>The committee has focused strongly on experimental plans throughout the reporting period and has required researchers to supply statistical evidence to determine animal numbers that are involved in experiments. This has led to both refinement of experiments and a reduction in numbers used. In addition many projects are now being developed in a staged process, whereby at the completion of a stage the results are presented to the AEC prior to the commencement of the next stage. This prevents projects from moving forward unnecessarily.</p>
<p>Tissue sharing is encouraged and promoted in all new applications. The establishment has a number of research groups where the tissues obtained from a single animal are used by multiple researchers to reduce to overall number of animals used . The promotion and membership of the Ethitex Database The use of tissues such as abattoir obtained tissues is supported.</p>
<p>Researchers with projects with low impact studies, such as observational studies, are encouraged to use these animals in more than one low impact study instead of euthanasia thus leading to reduction of animals.</p>
<p>When animals are used as a source of tissues for subsequent in vitro studies, blood and tissues that were not immediately needed were routinely collected and stored for possible future use.</p>
<p>Continuous telemetric recording of heart rate and arterial pressure increases power of statistical analysis; therefore, a fairly small sample size is required to observe a significant difference.</p>
<p>Where the safety profile (with respect to local vaccine site reactivity) of discovery phase vaccines is a potential unknown, in collaboration with our biometrician, we have elected to reduce group numbers by around 30%. Once local site reaction safety is established, the power can then be increased to evaluate product efficacy. By separating the studies to address safety and efficacy we will minimise the use of animals while still maintaining scientific rigour in the assessment of new vaccines. This is useful methodology where local vaccine site reaction safety is potentially more of a concern than efficacy with these early stage formulations.</p>
<p>Increased level of quality in clinical studies (eg GCP) means less studies need to be repeated, and therefore less animals used.</p>
<p>6 Shared Tissue Notifications were received ie notices of sharing tissue from deceased rats and mice with other researchers eg blood, skin, brains, lenses, livers and hearts.</p>
<p>Transfer unused animals between protocols instead of ordering additional animals.</p>
<p>Many animals euthanized after reaching a pre-determined study end point have had tissues taken for histological studies different to the primary study in which the animal was used.</p>
<p>Cadavers are kept frozen/formalin preserved for 1-2months following euthanasia for the opportunity to use the tissue for histological studies.</p>
<p>Routine husbandry procedures to be performed on animals coordinated with teaching activities.</p>
<p>Every effort is made to use the minimum number of animals per group in studies and if possible using one common control group for 2 similar studies.</p>
<p>Animals within designated projects can be used for a non-invasive procedure (tear collection) for a PhD student. Therefore eliminating the use of separate animals for this study.</p>
<p>Ethitex website (animal sharing) is utilised.</p>
<p>The Committee has established a Biological Non-Human Tissue Database through which researchers are</p>

able to share excess tissue, thus replacing the use of live animals with the use of stored tissue.
Approval of new techniques for embryo freezing rather than continuous breeding to maintain lines.
Consolidating breeding protocols to ensure no over-breeding which in turn reduces the need for culling.
Refinement
New wafers that have been designed in a way that reduced adverse impacts on animals (namely reptiles).
A red filter has also been applied to spotlights to reduce the impact of bright lights on nocturnal fauna.
All staff were trained in animal husbandry and had prior experience in sheep husbandry practices before the commencement of the Study. All facilities used during the Study were designed for sheep and allowed them to flow freely through the yards.
Trained Study personnel were used to perform all animal duties for the duration of the study. Handling facilities were designed to allow for the unobstructed flow of cattle from pen to pen, therefore reducing stress of movement and stress of human handling/prodding during the study. The yards were also designed to reduce stress during handling by allowing the animals to see, hear and smell the other animals enrolled in the Study.
All personnel involved in the study had extensive animal handling experience. Injection sites were clipped of hair and aseptically prepared before administration of each formulation. This allowed for convenient monitoring of the injection site.
All owners of dogs were trained in offering the tablets to the dogs by the Investigator. A positive outcome of this study will be that an S4 drug is freely accepted by the majority of dogs rather than the traditional method of 'pilling' which causes anxiety to both dog and owner.
It was determined that the original scoring system did not provide enough information for each dog during anaesthesia, therefore, a visual analogue scoring system (VASS) was developed and used in conjunction with the original scoring system.
Appropriate training in handling and reduction in the number of blood samples taken on individuals.
Refined tracking device technology employed on elephant seals in the Antarctic and Subantarctic.
Approval of Standard Operating Procedures for analgesia and anaesthesia in recovery surgery for rodents.
Evaporator cooling pads installed to lower summer temperatures.
Accommodation of research horses in a large paddock on a professional horse spelling/pretraining farm.
Rehoming of a retired research horse to suitable new owners and location.
Spontaneous collection of naturally voided urine for the purpose of drug analyses.
In November 2009, the Committee published the 3 rd edition of the Guide to Acceptable Procedures and Practices for Aquaculture and Fisheries Research. This is a web-based document available at: http://www.dpi.nsw.gov.au/fisheries/aquaculture/publications/general/a-guide-to-acceptable-procedures-and-practices-for-aquaculture-and-fisheries-research
Close monitoring of animals and development of monitoring checklists to identify adverse reactions in animals. The AEC will place conditions on projects at the approval stage to ensure that any pain or distress to animals is alleviated quickly in projects where it is impossible to eliminate this completely.
Use of experienced veterinarians and other staff.
Restraint time and dose rates kept to a minimum.
Use of adjuvants known not to produce adverse reactions.
Procedures used routinely so that animals become accustomed.
Close scrutiny of the volume of blood collected.
Use of the saphenous vein method as the standard technique for blood collection in rodents.
A number of studies conducted on animals at the owner's property to minimise any possible stress.
Environment enrichment has been introduced for pigs and rabbits.

We reduced the dose of insulin used in the insulin tolerance tests to minimise hypoglycaemia.
After analysing our data, we found that there are no mice that end up with reasonable transplant outcomes that do not have improved glucose values in the 7-14 day post-transplant window. Therefore, we now sacrifice mice that show no improvement earlier, sparing them a longer period of frank diabetes.
We introduced experiments that focused on early time-points in the disease process. And as such, the animals were often culled for analysis before they reached peak disease score. When earlier time-points were analysed, smaller group numbers could be used due to less variability.
We performed preliminary tests on mice to determine the optimum irradiation dose necessary in order to perform bone marrow transplantation with minimal impact on mice: we found that splitting the irradiation dose into two half dose, two hours apart, is less toxic to the mice, while still producing the same outcome.
We have refined the irradiation procedure so that we give a split dose of 2 x 400rad, instead of one dose of 900rad. The split dose has a lower detrimental impact on the animals.
Mammary surgical procedure has been improved, utilising smaller incisions resulting in faster recovery.
We refined our research procedures to reduce the amount of trauma during surgery by reducing the size of the incision, perfecting the anaesthetic dose and by reducing the total time of surgery.
We have optimised the endpoints of our experiments so that the mice are culled at a point when only a subset of mice have developed early tumours in the colon, and before they get sick due to metastasis.
A very experienced Investigator and technical assistance ensured flea infestation and counting had minimal impact on cats during procedures
The AEC may request pilot studies as an opportunity to refine the experimental strategy and experimental procedures for new projects that involve either invasive techniques or the development of new techniques.
The AEC request Chief Investigators to provide appropriate training and supervision until researchers are proficient in all animal related tasks for the project(s). For modifications or new applications that involve technically demanding animal procedures that are not within the expertise of the group, the AEC will request training of the research personnel by animal users that are experienced in the technique. The AEC may also request that researchers provide evidence of competency to the Animal Facility Manager and/or the consulting veterinarian before the researchers are approved to conduct the specific animal experiments independently.
Required improved housing and husbandry of pigs.
The development of “observational only” for wildlife studies. Less invasive sampling methods used where possible.
The implementation of a Pilot Study allowed the research group to develop an experimental design with reduced time and less impact on the animals for the second phase of the experiment.
The Farm Management Team has developed a Livestock Management model which tracks animals through research experiments and back to resource flocks to ensure that individual animals are not subjected to repeated experimentation.
The stress of trapping will be minimised by the provision of bedding material, adequate food and weather-proofing over the trap. Animals will be released within 2 hours of sunrise. Traps will not be left open during the day particularly in summer months. Trapping will not be carried out during inclement weather. All animals are released on the morning of capture and at the location where they are caught. Animals with pouch young will be immediately released without further handling to minimise the chances of any young becoming detached. Trapping is avoided where possible during known period where pouch young would be small. Where necessary small mammals will be handled with bare hands to eliminate the risk of a compression injury to the animal. Most often the small mammals are placed in a cloth bag for identification. Larger mammals such as possums or bandicoots are not handled. Animals being transported will be for identification purposes only and will not be held any longer than 1 working week. The method of transportation will be in either a breathable Hessian style bag or plastic enclosure that has breathing holes and a warm material base. While in transport animals will be located in a shady site within the vehicle. If being held whilst other traps are being checked the animal will be stored outside the vehicle in a shady location to prevent overheating. Animals are kept warm in the style of bags

chosen.
Equipment was modified to flush off the system to prevent Hydrogen sulphide poisoning in the future from organic material build up as well as grading fish according to size to prevent "harassment" from other larger fish and placing nets over tanks to prevent fish suicides.
Where systemic disease was identified in homozygous animals after 3 months of age, the animals were bred as heterozygous crosses and homozygous progeny were culled by 6 weeks of age.
Use of in vitro buccal adhesive tests to generate an optimal product for in vivo trials.
Use of diazepam to reduce distress due to handling (wallabies).
Use of tadpoles in experiments involving studies of external factors on infection with chytrid. Because this infection does not cause disease in tadpoles, infection levels could be monitored with minimal impact on well-being. Post-metamorphic animals were used only after the results were confirmed with tadpoles.
Stricter requirements for ensuring adequate nutritional status and animal health status (eg parasite control) in livestock species. This improves animal well being, as well as reducing the morbidity/mortality rate in clinical studies.
Handling, administration of anaesthetics and bleeding procedure are only conducted by accredited animal services technicians to minimise adverse incidents or discomfort to the animals.
Wildlife Study – Veterinarian included for anaesthetic administration and any necessary veterinary interventions.
Wildlife Study – Edible bait to provide sustenance for animals after capture.
Wildlife Study – Trapping only when weather conditions are optimal.
To reduce the risk of pathogen transfer between frogs: the use of disposable latex gloves and sterilisation of instruments.
Use of remote underwater video instead of trapping and releasing fish as a less intrusive research method.
Animal health monitoring sheets have been revised in 2009 to improve the detection of any adverse impacts on the animals.
Encouraged and approved the use of remote cameras in place of trapping for survey of small and medium sized mammals.
It is a prerequisite for all applicants to address the 3Rs and to discuss the answers with the AEC at a meeting. This resulted in the identification of a number of procedures that were improved to address the processes of replacement, reduction and refinement. Experimenters were provided with information material about the 3 Rs throughout the year, and the University personnel attended conferences and workshops on these topics.
A rigorous handling and training procedure was put in place for a recent study involving horses, which not only trained personnel but also the horses. This resulted in minimal restraint (halter only) for the horses during the procedures required for the study.
Rodents were re-homed rather than euthanased whenever possible.
Wildlife: <ul style="list-style-type: none"> * Greater use of photographs and hair samples for identification purposes * Closure of Elliott traps during the day and reopening late afternoon * Processing of capture animals as much as possible on site * Ensuring all personnel are trained in wildlife care/rescue procedures
A pilot study was carried out using tracking tunnels to determine the presence of small native mammals and the value of a full capture-mark-release study in the area.
The use of passive infra-red sensors to detect wildlife movement.

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	\$9,075
Travel and subsistence	\$7,164
Stores and printing	\$2,078
Freight and postage	\$794
TOTAL	\$19,111

Appendix J: ARRP policies and guidelines

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

Policies

2. Payment of External Members of Animal Ethics Committees (revised 15/5/2009)
3. Procedures Prohibited under the NSW Prevention of Cruelty to Animals Act (revised 24/4/2009)
4. Non-Research Animals at Accredited Animal Research Establishments (revised 4/8/2010)
5. Annual Reporting by Animal Ethics Committees to Accredited Animal Research Establishments (revised 17/2/2010)
- 5a. Institutional Support for Animal Ethics Committees
6. Differentiation Between Acts of Animal Research and Acts of Veterinary Treatment
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

Guidelines

1. Opportunistic Research on Free-Living Wildlife
2. Captive Wildlife
3. Individuals and Institutions Engaged in Collaborative Research
4. Use of Animals in Post-graduate Surgical Training
5. Collection of Voucher Specimens
6. Use of Pitfall Traps
7. The Use of Feral Animals in Research
8. Teaching Artificial Insemination and Pregnancy Testing in Cattle
9. Radio Tracking in Wildlife Research
10. 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
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
22. Draft Guidelines for the Housing of Mice in Scientific Institutions
23. Guidelines for the Housing of Sheep in Scientific Institutions

Appendix K: Animal Welfare Unit 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 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

Appendix L: Standard conditions for accreditation and animal supply licence

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 the 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 only be housed in cages 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.animaethics.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. Dogs should be housed in accordance with ARRP Guideline 14: Guidelines for the Care and Housing of Dogs in Scientific Institutions (<http://www.animaethics.org.au/policies-and-guidelines/animal-care>).
(For establishments housing dogs)

6. Unless otherwise approved by the Animal Ethics Committee, animals should be housed in accordance with the ARRPP guidelines on animal housing for specific species found at: <http://www.animaethics.org.au/policies-and-guidelines/animal-care>.
7. Unless otherwise approved by the Animal Ethics Committee, wildlife studies should be carried out in accordance with the ARRPP guidelines on wildlife research found at: <http://www.animaethics.org.au/policies-and-guidelines/wildlife-research>.
8. Animals (other than exempt animals) may only be obtained from a licensed animal supplier (see <http://www.animaethics.org.au/policies-and-guidelines/animal-supply>).
9. 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)
10. A response to conditions {xx} of the inspection report of {date} must be provided to the Director-General of the Department of Primary Industries by {date—within 3 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*.

