



**Animal Research Review Panel**

**Annual Report**

**2011 - 2012**



**Department of  
Primary Industries**

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Prepared by Janelle Townsend and Lynette Chave



## Department of Primary Industries

### ANIMAL RESEARCH REVIEW PANEL

5 December 2012

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 2011 to 30 June 2012.

Yours sincerely

**Professor Andrew Dart**  
Chair, Animal Research Review Panel

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## **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 Reference Group, under the auspices of the National Health and Medical Research Council (NHMRC). The Code Reference group includes representatives from NHMRC, the Commonwealth Scientific and Industrial Research Organisation, the Australian Research Council, Universities Australia, the state government ministries with responsibility for animal welfare, commonwealth government departments for the sectors of environment, education and primary industries, 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 NSW 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: 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. The current 3 year term expires on 30 September 2013.

During the 2011–12 period the membership of the ARRPP was:

- A/Professor Andrew Dart (Chair) (nominated by the NSW Vice-Chancellors' Committee)
- Dr Regina Fogarty (Deputy Chair) (nominated by the Minister for Primary Industries)
- Dr Magdoline Awad (nominated by RSPCA NSW)
- Mr Peter Batten (nominated by the Minister for Education and Training)
- Ms Celeste Black (nominated by Animal Societies' Federation)
- Dr Mike Fleming (nominated by the Minister for the Environment)
- Dr Craig Godfrey (nominated by the Minister for Health). Resigned August 2011.
- Professor Anne Keogh AM (nominated by Animal Societies' Federation). Appointed October 2011.
- Professor Robert Mulley (nominated by Vice-Chancellors' Committee)
- Mr David O'Shannessy (nominated by RSPCA NSW)
- Professor Jacqueline Phillips (nominated by the NSW Vice-Chancellors' Committee)
- Dr Peter Rolfe (nominated by Medicines Australia)

Information on members of the Animal Research Review Panel in 2011–12 is as follows:

**Professor Andrew DART(Chair) 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. Professor Dart was appointed as Chair of the ARRP in December 2010.

**Dr Regina FOGARTY (Deputy Chair), BVSc, PhD (University of Queensland).** Dr Fogarty is the Director of the Office of Agricultural Sustainability and Food Security, a policy group within 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.

**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 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.

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

Dr Fleming is a nominee of the Minister for the Environment and has been with ARRP 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.

**Dr Craig Godfrey BVSc**

Dr Godfrey was the NSW Minister for Health nominee and was appointed as a member of ARRP in 2010. He held the position of Director of Animal Care for the Western Sydney Local Health Network and the Executive Officer of this establishment's AEC. He has conducted research in paediatric orthopaedic surgery at the Children's Hospital at Westmead and has worked in animal welfare, medical research and pharmaceuticals in both Australia and Canada.

**Professor Anne Keogh AM MBBS (hons), MD, FRACP, FCSANZ, FPVRI**

Professor Anne Keogh is a nominee of the NSW Animal Societies Federation. She is the Senior Heart Transplant Cardiologist St Vincent's Hospital Sydney, head of Human Clinical research in heart failure and pulmonary hypertension, current president of the Pulmonary Hypertension Society of Aust and NZ which she formed in 2010. She is Conjoint Professor of Medicine Uni NSW, past president International Society of Heart and Lung Transplantation and sits on multiple Global and National Scientific Advisory Boards. She has been Trustee of Medical Advances without Animals from 2006, and has worked with a broad range of Australian and International animal welfare groups for 20 years, Australia Day Ambassador for 7 years. She was awarded the Order of Australia (AM) in June 2012 for services to transplantation, heart failure and animal welfare.

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

Professor Mulley joined ARRP in 2008. He is a nominee of the NSW 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 ARRP in January 2005.

**Professor Jacqueline Phillips. BVSc Hons (Uni of Syd), PhD (ANU)**

Professor Phillips is a nominee of the NSW Vice-Chancellors' Committee and was appointed to the ARRP in 2010. Professor Phillips is a registered veterinarian who has worked in small animal and mixed practice. She has served on Animal Ethics Committees as a Category A member at the Australian National University (ACT) and Murdoch University (WA). She is currently Director of Medical Research at the Australian School of Advanced Medicine, Macquarie University. She has extensive experience in laboratory animal research and her field of research expertise is cardiovascular neuroscience.

**Dr Peter ROLFE BVSc, PhD**

Dr Rolfe is a nominee of Medicines Australia. He is an employee of Novartis Animal Health, a registered veterinary surgeon and has had a career in research and research management and in various public and private sector roles. He currently manages research programs for the research and development of innovative pharmaceuticals for use in farm and companion animals.

## 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 Trade & Investment, 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 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.

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 ARRP. These include applications from individuals or organisations about which the ARRP has particular concerns, or situations where the application is sufficiently different from the norm to raise policy implications.

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

Monitoring of animal care and use by the AEC is another area of assessment. Details of AEC inspections carried out must be provided. Questions on the source and destination of animals allow the ARRP to double-check compliance with the Act’s provisions relating to animal supply.

### 1.5.2 Conduct of site inspections

Following the evaluation of written applications, the second phase of the process of assessing establishments is the site inspection. The aim of site inspections is to determine whether institutions and individuals are complying with the legislation. The *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 2011–12 year is provided in Appendixes C and D. The dates provided represent days on site and do not include preparation and follow-up time, which is often considerable.

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

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

On the day(s) of the inspection the inspection team initially looks at the animals and the facilities and talks with researchers. This examination includes assessing a broad range of items such as the physical condition of animals, animal care and management, and records related to the animals held. After examining animals and facilities, the inspection team sits in on a scheduled meeting of the AEC, which allows it to view the operation of the AEC and the interaction of its members. At the end of the meeting, time is taken to discuss with the AEC issues arising from the inspection and to solicit feedback from AEC members. Additional important considerations are how the committee liaises with researchers and whether it has developed its own policies or guidelines for procedures of particular concern, such as blood collection techniques, methodology for monoclonal antibody production, and standards for wildlife transportation and the recognition and relief of pain.

A meeting is usually held with the head of the institution at the beginning or end of the inspection. Any serious concerns are immediately referred to the institution at the appropriate level.

As soon as possible after the inspection, a detailed report is prepared. The report covers an evaluation of the AEC and an assessment of the animals' wellbeing, housing and holding, and their care and monitoring. Once the ARRP has considered the report, recommendations may arise 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 ARRP report usually contains a number of recommendations—for example, for more effective operation of the AEC, for improvement of the management of research within the institution, or for improvement of the animal facilities. Implementation of recommendations is not mandatory, but the institution is required to advise on how it has responded to the recommendations. If the recommendations have not been implemented, then the reasons for this must be explained.

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

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

The ARRP aims to carry out full audit visits for all institutions every 3 years, as well as unannounced visits by inspectors to follow up problems. In formulating its 2011–12 operational plan, the ARRP 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 NSW 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 ARRP

- 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:

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or at the NSW Department of Primary Industries Head Office:

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 Phone (02) 6391 3149  
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 E-mail: [animal.welfare@industry.nsw.gov.au](mailto:animal.welfare@industry.nsw.gov.au)

In the 2011–12 financial year the following staff were assigned, at various times, to provide inspectorial and/or executive support to the ARRP (amongst their other duties).

**Orange:**

Ross Burton, BVSc, MVSc, Director, Animal Welfare (Long service leave February 2012)  
 Suzanne Robinson, BRurSc, EMPA, GradCertEmergencyMgt, Acting 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 2011–12. 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 2011–14 (Appendix E) and Operational Plan for 2011–12 (Appendix F); and ARRPs operating expenses (Appendix I).

#### **2.1.1 Strategic Plan 2011–14**

During 2011-12 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 2011–12**

The ARRPs Operational Plan for 2011–12, 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.

During the 2011-12 year the main method of liaison was via discussions during, and feedback after, site inspections. Additionally recommendations were made in the process of assessing Accreditation and Licence applications.

### **2.2 Assessment of applications**

In 2011–12 there were 130 accredited animal research establishments and 44 holders of animal suppliers' licences.

During 2011–12 the ARRPs considered and made recommendations to the Director-General on:

- 15 new applications for accreditation
- 23 renewal applications for accreditation
- 2 new applications for animal suppliers' licences
- 3 renewal applications for animal suppliers' licences.
- 2 extensions to existing accreditations and/or 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 2011–12 were Mr Batten and Professor Dart. The subcommittee makes recommendations to the ARRPs, which in turn advises the Minister.

In 2011–12 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 2013 with figures comparing 2010, 2011 and 2012 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 2013 and April 2014 must be presented by the company to the Animal Welfare Unit by 31 January 2013.
- 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 Animal Welfare Unit by 31 January 2013.

### **2.3 Assessment of changes to AEC membership**

All establishments are required to advise the Animal Welfare Unit 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* (<http://www.animalethics.org.au/policies-and-guidelines/operation/criteria-for-assessment>).

In the 2011–12 year the ARRPP assessed and made recommendations to the Director-General on the appointment of 80 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 2011–12 year the ARRPP considered 39 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 2011–12 year included:

- Evaluation of applications for LD50 testing (Professor Dart and Mr Batten)
- Preparation for a 2013 seminar for AEC members and Executive Officers (Professor Dart, Dr Fogarty and Mr Batten).

## **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 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 2011.

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 2011-12 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 seminars for AEC members; the maintenance of a website dedicated to animal research issues (Animal Ethics Infolink) 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.

### **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 ARRP 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 Seminar for members and executive officers of AECs**

In the 2011-12 year, planning was undertaken for a seminar for members and executive officers of AECs to be held in October 2013.

In an effort to ensure that the programme for the meeting will meet the needs of AECs, comment was sought from all NSW AECs on topics they wished to discuss and the format for conducting the meeting. Valuable feedback was provided and has been used, in conjunction with comments gathered from evaluation forms completed at previous meetings, to structure a programme accordingly. The members of the ARRPP subcommittee working on this project were Professor Dart, Dr Fogarty and Mr Batten. Other members of the ARRPP, including Professor Keogh AM and Professor Phillips have assisted with ideas for the programme and contacting potential presenters.

The Australian Catholic University has again generously offered to host the meeting at its MacKillop Campus.

Information on previous seminars can be found at the Animal Ethics Infolink website at:  
<http://www.animaethics.org.au/animal-ethics-committees>

## **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 information promoting the humane care and use of animals for scientific purposes can be sourced. The website also gives the broader 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](http://www.animaethics.org.au).

## **2.9 Site inspections**

A list of dates of site inspections undertaken in 2011–12 is provided in Appendix C, and a list of ARRPP members attending is given in Appendix D. There were 19 establishments inspected over a period of 27 working days. The length of these inspections ranged from one day to nine days.

The ARRPP aims to carry out a routine inspection of each accredited animal research establishment approximately every 4 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](http://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.

ARRPP Guideline 22: Guidelines for the housing of mice in scientific institutions ([http://www.animaethics.org.au/\\_data/assets/pdf\\_file/0004/249898/Guideline-22-mouse-housing.pdf](http://www.animaethics.org.au/_data/assets/pdf_file/0004/249898/Guideline-22-mouse-housing.pdf)) was finalized and published in April 2012 based on comments received on the draft version of the document. The comments received, which were detailed and included those from internationally recognized experts in mouse behaviour and care, were valuable in producing the finalized version.

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

A review of the 7<sup>th</sup> edition of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* was progressed by the NHMRC in the 2011-12 year. The Animal Research Review Panel made a submission to the review.

## **2.12 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.

## **2.13 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, 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. One formal complaint was considered in the 2011–12 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. Three informal complaints were considered in the 2011–12 reporting period.

A summary of the complaints is as follows:

### **Animals at a teaching establishment**

Two complaints related to the care of animals and whether teaching procedures using animals were appropriate. Some of the matters related to inadequate animal care were substantiated. The establishment had undertaken disciplinary action for the teachers involved, and instituted mechanisms to prevent a recurrence.

### **Level of care provided to animals**

A complaint was received about the level of care provided to animals at a research establishment. Investigations, including an examination of records and a site inspection did not substantiate the complaint.

### **Welfare of cattle held in pens**

The substance of the complaint was that cattle, in a research trial assessing worm treatments, were in poor condition and distressed. Prompt inspection by the Animal Ethics Committee that had approved the project showed that the animals were in satisfactory condition and were behaving normally. The trial was being run in accordance with the protocol approved by the Animal Ethics Committee.



## APPENDIXES

### Appendix A: Dates of ARRP meetings 2011–12

Meeting number	Date of meeting
193	20 July 2011
194	28 September 2011
195	7 December 2011
196	22 February 2012
197	2 May 2012

### Appendix B: Attendance of members at ARRP meetings 2011–12

Member	Meeting number				
	193	194	195	196	197
Professor Andrew Dart (Chair)	*	*	*	*	*
Dr Regina Fogarty (Deputy Chair)	*	*	*	*	*
Dr Magdoline Awad	A	*	*	*	*
Mr Peter Batten	*	*	*	*	A
Ms Celeste Black	*	*	*	*	*
Dr Mike Fleming	*	*	*	*	*
Dr Craig Godfrey	*	–	–	–	–
Prof Anne Keogh	–	–	*	A	*
Professor Robert Mulley	*	*	*	*	A
Mr David O'Shannessy	*	*	*	*	*
Professor Jacqueline Phillips	A	*	A	*	*
Dr Peter Rolfe	A	A	*	A	A

\* = Present

A = Absent

– = Not applicable

**Appendix C: Dates of Inspections July 2011 – June 2012**

Date
13-14/07/11
29/09/11
28/10/11
18/11/11
22/11/11
23/11/11
30/11/11
29/11/11, 01/12/11
8/12/11
14/03/12
23/03/12, 27/03/12, 10/04/12
20/03/12
26/03/12, 14-18/05/12, 22-24/05/12
26/05/12
13/06/12

**Appendix D: Attendance of ARRPs members at site inspections 2011–12**

Member	Number of days spent on site inspection
Professor Andrew Dart (Chair)	1
Dr Regina Fogarty (Deputy Chair)	3
Dr Magdoline Awad	3
Mr Peter Batten	2
Ms Celeste Black	2
Dr Mike Fleming	3
Dr Craig Godfrey	2
Professor Anne Keogh AM	2
Professor Robert Mulley	1
Mr David O'Shannessy	3
Professor Jacqueline Phillips	2
Dr Peter Rolfe	1

## Appendix E: Animal Research Review Panel Strategic Plan July 2011 – June 2014

\* Numbers on the right refer to items from 2011/2012 Animal Research Review Panel Operational Plan that address the strategies.

Goals and Strategies	
<b>Goal 1:</b>	
<b>Effective and efficient implementation of the statutory requirements of the Animal Research Act 1985, the Animal Research Regulation 2010 and the <i>Australian Code of Practice for the Care and Use of Animals for Scientific Purposes</i> .</b>	
1.1 Maintain a system to accredit and licence 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 documentation of these methods on a regular basis to help ensure high standards of efficiency, effectiveness and consistency.	2.5
1.4 Identify and implement adjuncts to inspections to better ensure compliance with the legislation.	2.5 3
1.5 Monitor compliance with the Act, Regulation and Code of Practice 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 of Practice to ensure that it is effective in regulating the conduct of animal research and teaching and the supply of animals for research and teaching.	5.1
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 3
1.11 Maintain a system to consider and make recommendations on applications for permission to carry out LD50 tests.	1.3
<b>Goal 2:</b>	
<b>The principles, processes and responsibilities in the <i>Australian Code of Practice for the Care and</i></b>	

<b>Use of Animals for Scientific Purposes are actively embraced by all involved wherever animals are used.</b>	
2.1 Promote an understanding of the roles and responsibilities of institutions in supporting the effective operation of their AECs.	2 3 4
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 of Practice.	2 3 4
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 of Practice 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 of Practice 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 members and Executive Officers of AECs and participating in AEC meetings during site inspections.	2 3.4
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 4
<b>Goal 3:</b> <b>Researchers and teachers considering using animals are aware of and actively apply the principals set out in the Act, Regulation and the <i>Australian Code of Practice for the Care and Use of Animals for Scientific Purposes</i>.</b>	
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
<b>Goal 4:</b>	
<b>Methods that complement or replace animal use are used wherever possible.</b>	
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.	
<b>Goal 5:</b>	
<b>Procedures involving animals are regularly reviewed and refined to minimise the number of animals required and to reduce the impact on individual animals.</b>	
5.1 Encourage a critical review of the design of projects before applications are submitted to AECs.	2 3 4
5.2 Ensure close scrutiny by AECs of breeding programmes to minimise overproduction of animals.	2 3 4
5.3 Ensure close scrutiny by AECs of the competence of researchers to carry out specific procedures.	2 3 4
5.4 Promote the critical evaluation of the monitoring of animals being used in procedures.	2 3 4
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
<b>Goal 6:</b>	
<b>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.</b>	
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 4

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 4
6.3 Promote awareness by researchers / teachers and animal care staff of signs of well-being, pain and distress in animals.	2 3 4
6.4 Promote the use of appropriate analgesia and anaesthesia by facilitating access by researchers/teachers to information resources.	2 3 4
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 4
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
<b>Goal 7:</b>	
<b>High standards of housing and routine care are established for animals used in research and teaching.</b>	
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
7.3 Actively participate in the development and review of appropriate national and international standards for housing and routine care.	5.1
<b>Goal 8:</b>	
<b>Animals used are supplied in accord with the legislation</b>	
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 4
<b>Goal 9:</b>	
<b>The community (research, teaching, veterinary, animal welfare and lay) has access to information about animal use for research and teaching in NSW.</b>	
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 4

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.	3 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.	
<b>Goal 10:</b> <b>The approach to administration of animal research and teaching is harmonised between State and Territory regulatory and funding bodies.</b>	
10.1 Promote interaction between State and Territory regulatory and funding bodies.	

**Appendix F: ARRP Operational Plan July 2011 – June 2012**

Activity	Measure of Performance	Time Frame	Status
<b>1. Mandatory</b>			
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	4 informal and one formal complaints received.  3 informal and 1 formal complaints 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 2010-2011	Report submitted to Minister	December 2011	Report prepared.
1.5 Prepare statistics on animal use for 2010	Statistics collated	December 2011	Statistics collated.
<b>2. Inspections</b>			
2.1 Conduct site visits of accredited animal research establishments on a 3 – 4 yearly basis (for those establishments in-State, active and with own AEC)	Number of establishments inspected  Number of days for inspections	Ongoing	19  27
2.2 Inspect new establishments applying for accreditation prior to or within 2 months of accreditation (for those establishments in-State, active and with own AEC)	Number of new establishments inspected	Ongoing	N/A
2.3 Review and send inspection reports	Reports sent	Within 3 months of inspection	Reports sent
2.4 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 “Site Inspection / Accreditation Responses” section of ARRP agendas.
2.5 Assessment of 2010 AEC annual reports	Assessment carried out	December 2011	2010 reports assessed and feedback provided to establishments.
<b>3. Education</b>			
3.1 Maintain ARRP website	Site maintained	Ongoing	Website maintained.
3.2 Develop training material for researchers/teachers via reference group	Reference group meetings held		On hold pending outcome of Code of Practice Review
3.3 Consider content of AEC learning	Content considered	After development	Await development



package in light of researcher training material developed.		of researcher training material.	of researcher training package.
3.4 Plan meeting for members of AECs	Planning initiated	December 2011	Planning initiated.
<b>4. Policies and guidelines</b>			
4.1 Develop policies/ guidelines where strong need identified (maximum of 2 )	Developed as need identified	Ongoing	None identified.
4.3 Revise current policies and guidelines	Continue programme of revision.	Ongoing	1 revised (draft mouse housing guideline).
<b>5. Additional</b>			
5.1 Continue liaison with NHMRC	Contact with NHMRC maintained	Ongoing	Comment on Code of Practice revision.  Invitation to present at AEC members seminar.
5.2 Prepare 3 year strategic plan for 2011 - 2014	Plan prepared	September 2011	Plan prepared.

## Appendix G: Animal use statistics 2011

**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 2011.

### Animal species categories used for collection of data

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

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

<b>PURPOSE</b>
<p><b>1. Stock breeding</b> 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><b>2. Stock maintenance</b> 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. <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><b>3. Education</b> 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. <i>Examples</i> <i>Animals used by veterinary schools to teach examination procedures such as pregnancy diagnosis</i></p>
<p><b>4. Research: human or animal biology</b> 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><b>5. Research: human or animal health and welfare</b> Research protocols that aim to produce improvements in the health and welfare of animals, including humans.</p>
<p><b>6. Research: animal management or production</b> Research protocols that aim to produce improvements in domestic or captive animal management or production.</p>
<p><b>7. Research: environmental study</b> 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. <i>Examples</i> <i>Pre-logging or pre-development fauna surveys</i></p>
<p><b>8. Production of biological products</b> Using animals to produce products other than e.g. milk, meat, eggs, leather or fur. <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><b>9. Diagnostic procedures</b> Using animals directly as part of a diagnostic process. <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><b>10. Regulatory product testing</b> Protocols for the testing of products required by regulatory authorities, such as the APVMA. <b>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.</b> (This would normally be Purpose Category 8 in the case of QA testing.) <i>Examples</i> <i>Pre-registration efficacy or toxicity testing of drugs and vaccines</i></p>

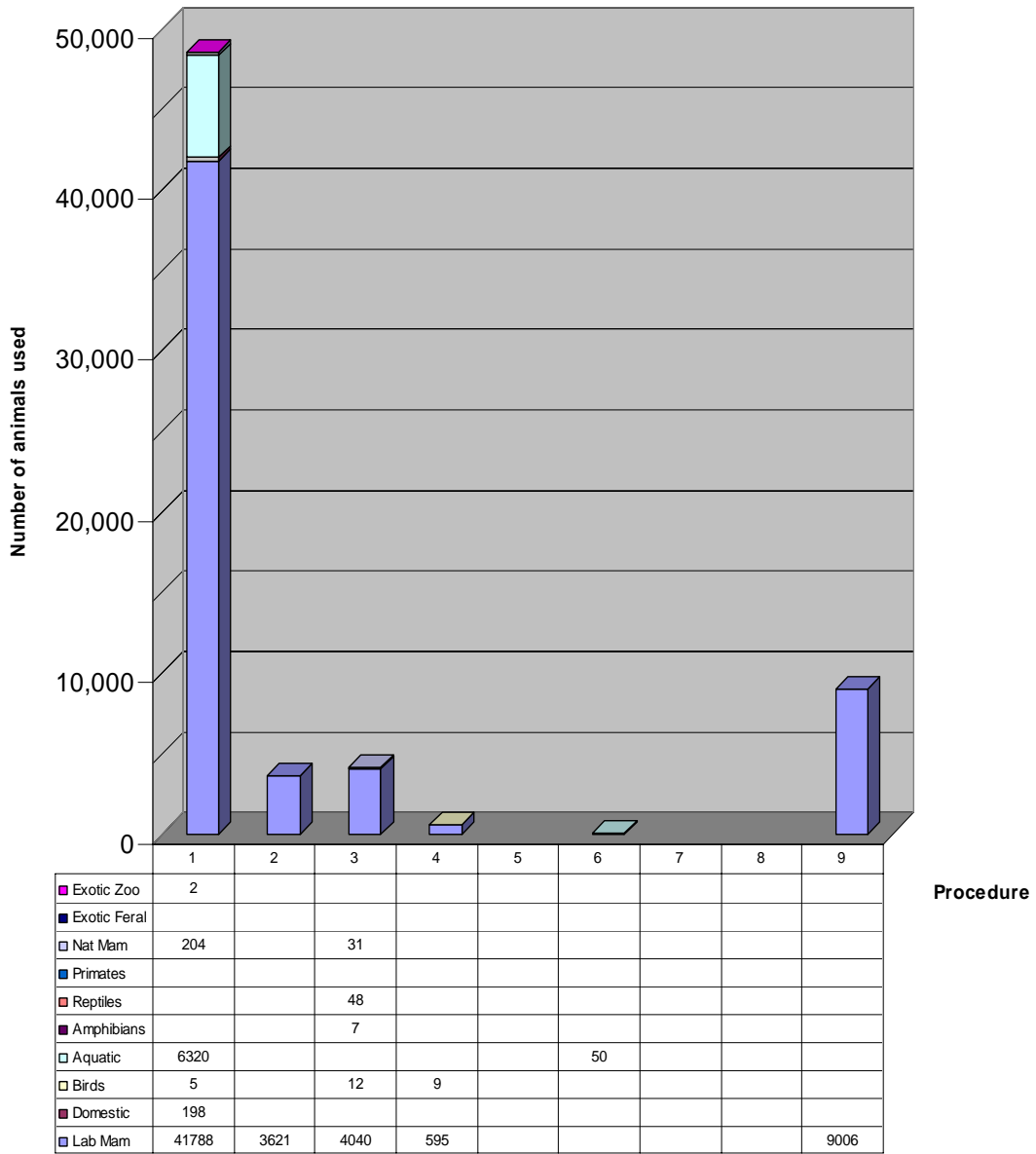
**Data collection: procedure categories and guidelines used for classification**

<b>1: Observation involving minor interference</b>	<b>6: Minor physiological challenge</b>
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.
<b>2: Animal unconscious without recovery</b>	<b>7: Major physiological challenge</b>
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.
<b>3: Minor conscious intervention</b>	<b>8: Death as an endpoint</b>
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.
<b>4: Minor surgery with recovery</b>	<b>9: Production of genetically modified (GM) animals</b>
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 <b>all</b> animals used in GM production, other than the final progeny, which are used in a different category of procedure.
<b>5: Major surgery with recovery</b>	
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).***

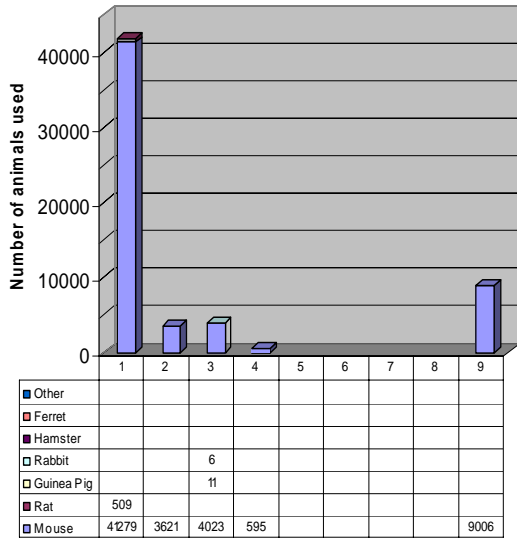
## Purpose: Stock Breeding

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

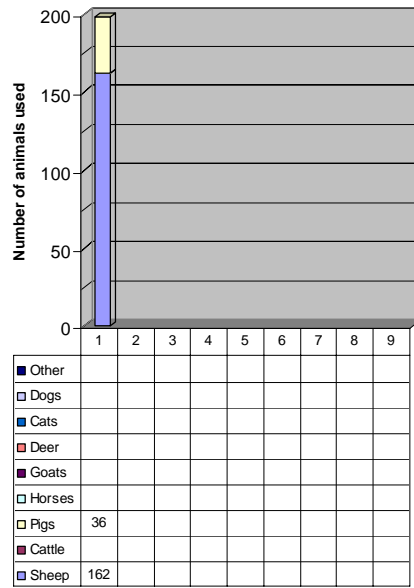


*Refer to following page for a further breakdown of species.*

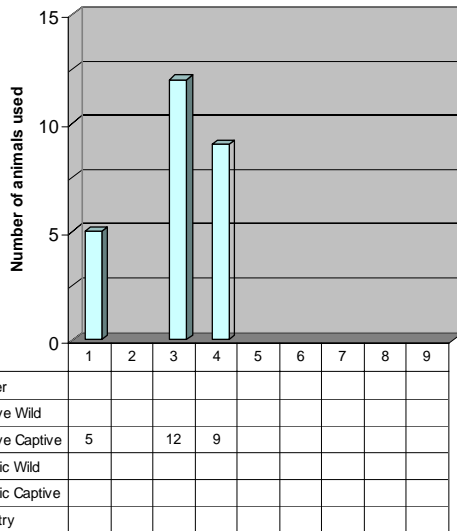
**Purpose: Stock Breeding**  
Breakdown of Laboratory Mammals Species



**Purpose: Stock Breeding**  
Breakdown of Domestic Mammals Species

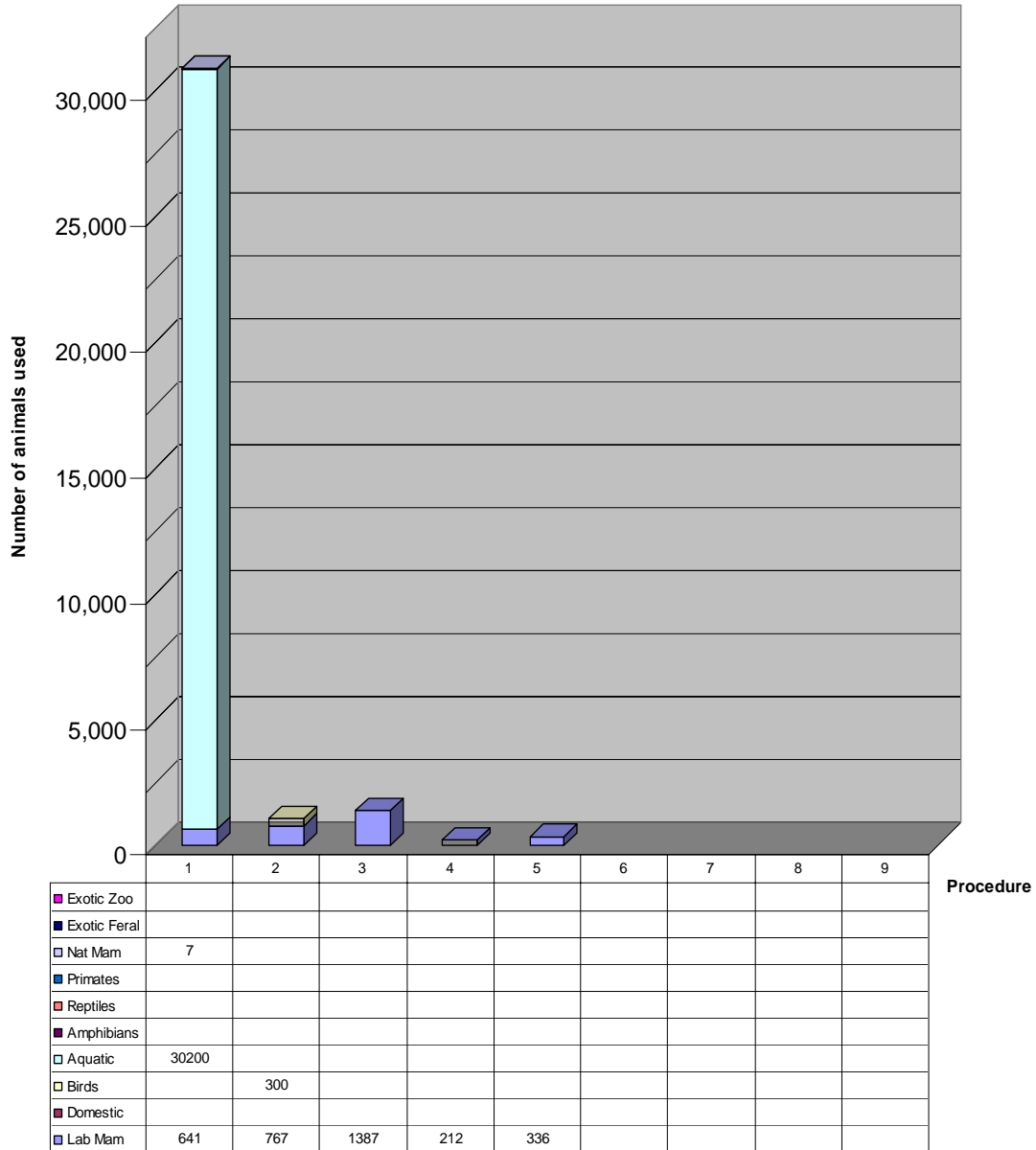


**Purpose: Stock Breeding**  
Breakdown of Bird Species



## Purpose: Stock Maintenance

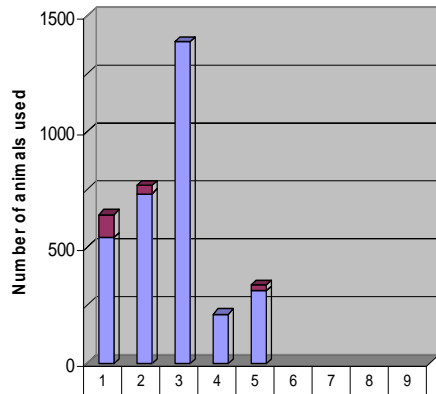
*Holding Protocols for animals maintained for use in other protocols .*



*Refer to following page for a further breakdown of species.*

**Purpose: Stock Maintenance**

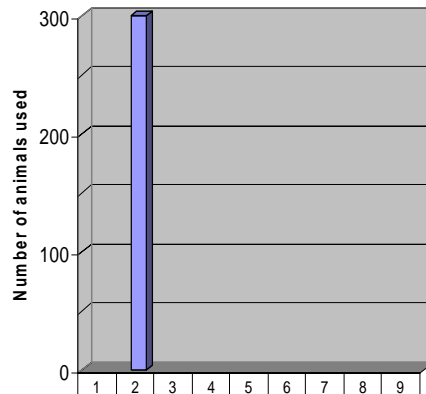
*Breakdown of Laboratory Mammals Species*



Other									
Ferret									
Hamster									
Rabbit									
Guinea Pig									
Rat	100	36			23				
Mouse	541	731	1387	212	313				

**Purpose: Stock Maintenance**

*Breakdown of Bird Species*

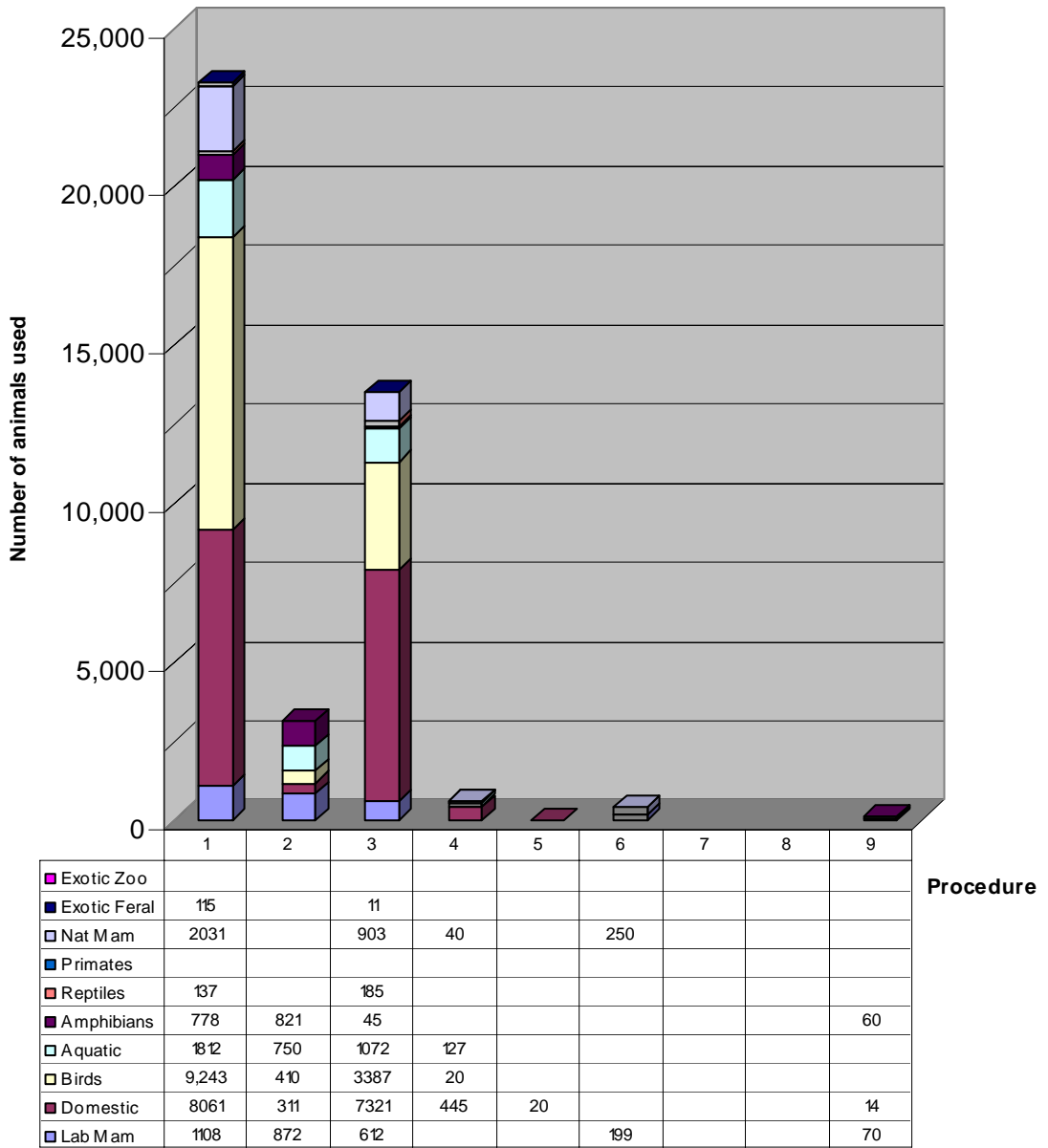


Other									
Native Wild									
Native Captive									
Exotic Wild									
Exotic Captive									
Poultry		300							

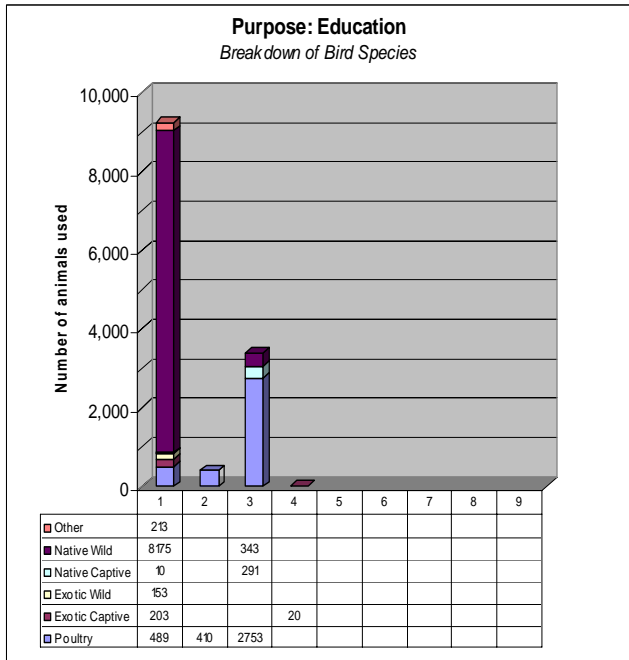
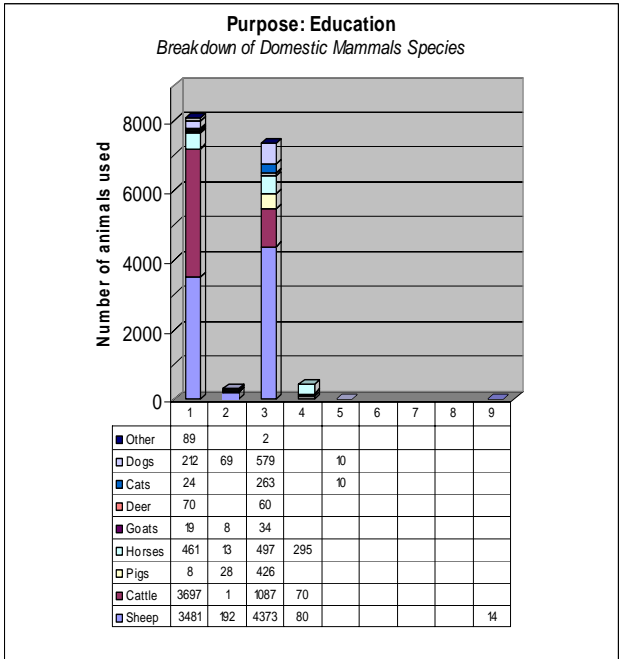
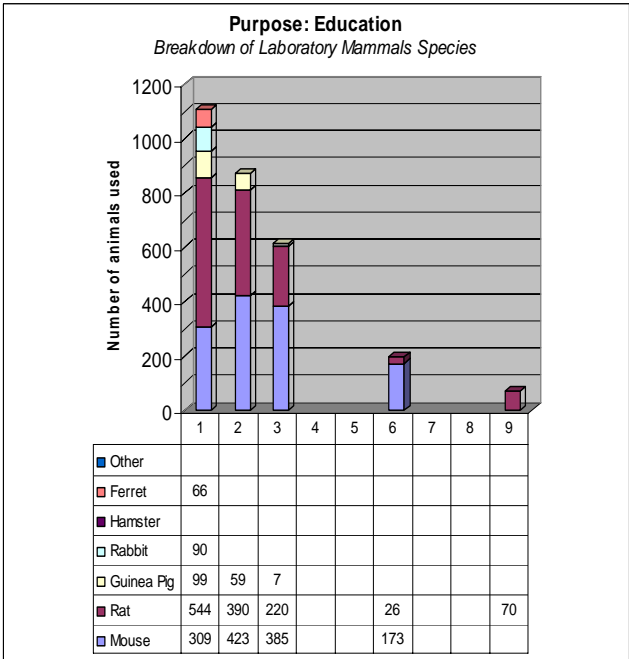


## Purpose: Education

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

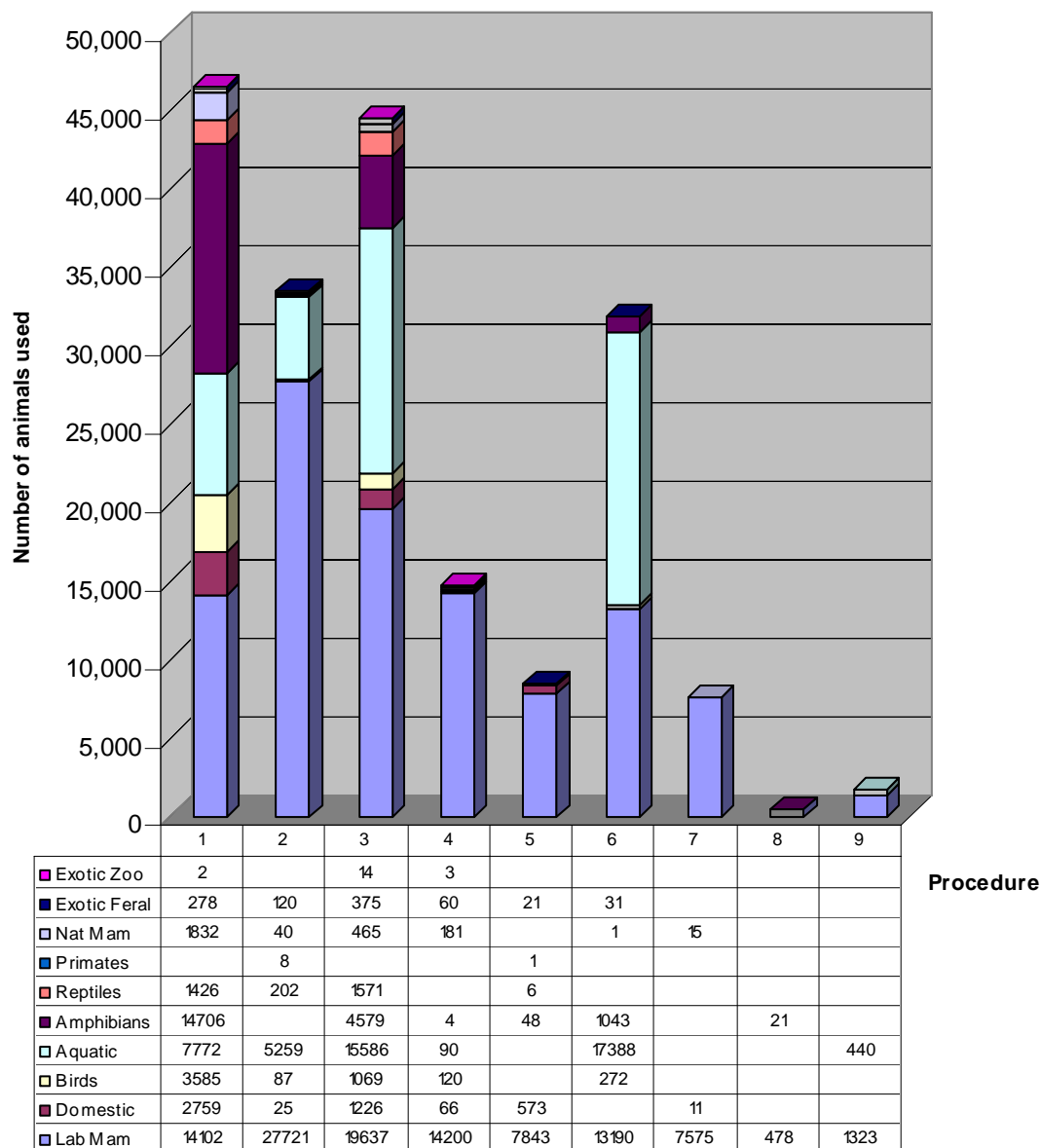


Refer to following page for a further breakdown of species.



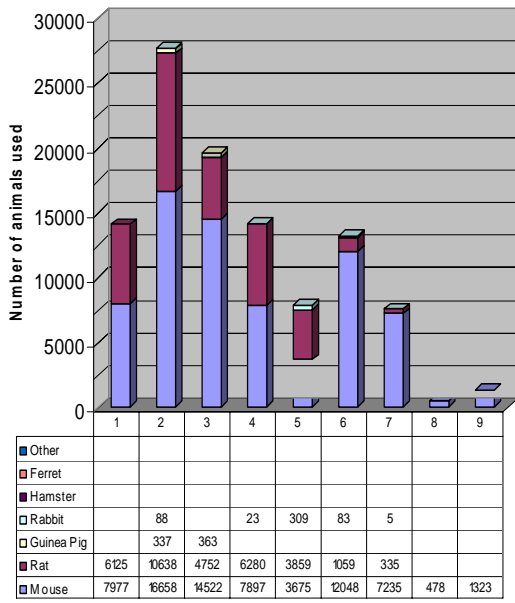
## Purpose: Research - Human or Animal Biology

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.

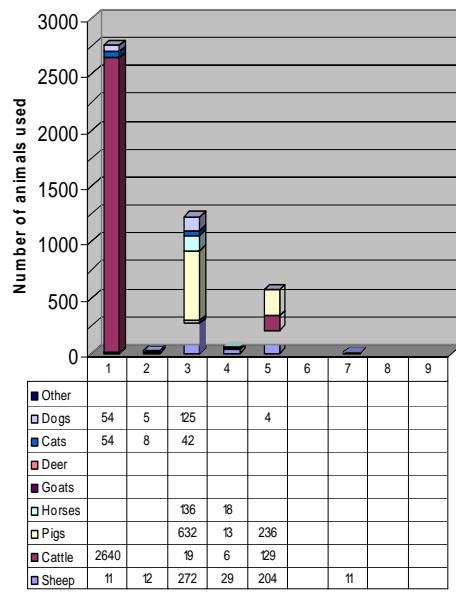


Refer to following page for a further breakdown of species.

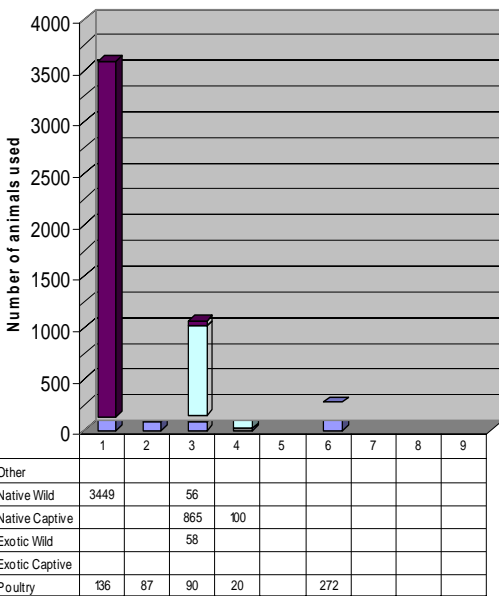
**Purpose: Research - Human or Animal Biology**  
Breakdown of Laboratory Mammals Species



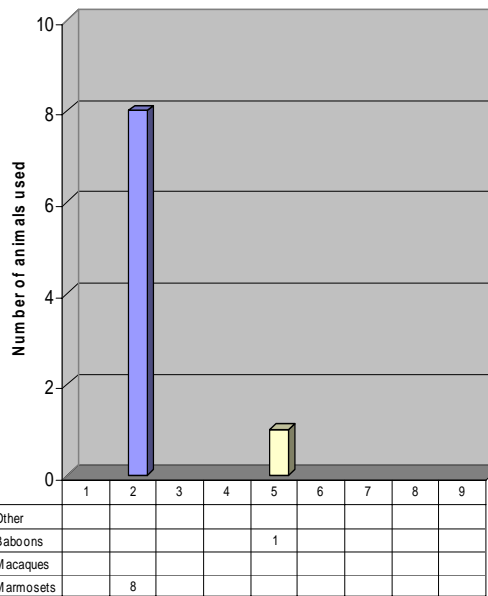
**Purpose: Research - Human or Animal Biology**  
Breakdown of Domestic Mammals Species



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

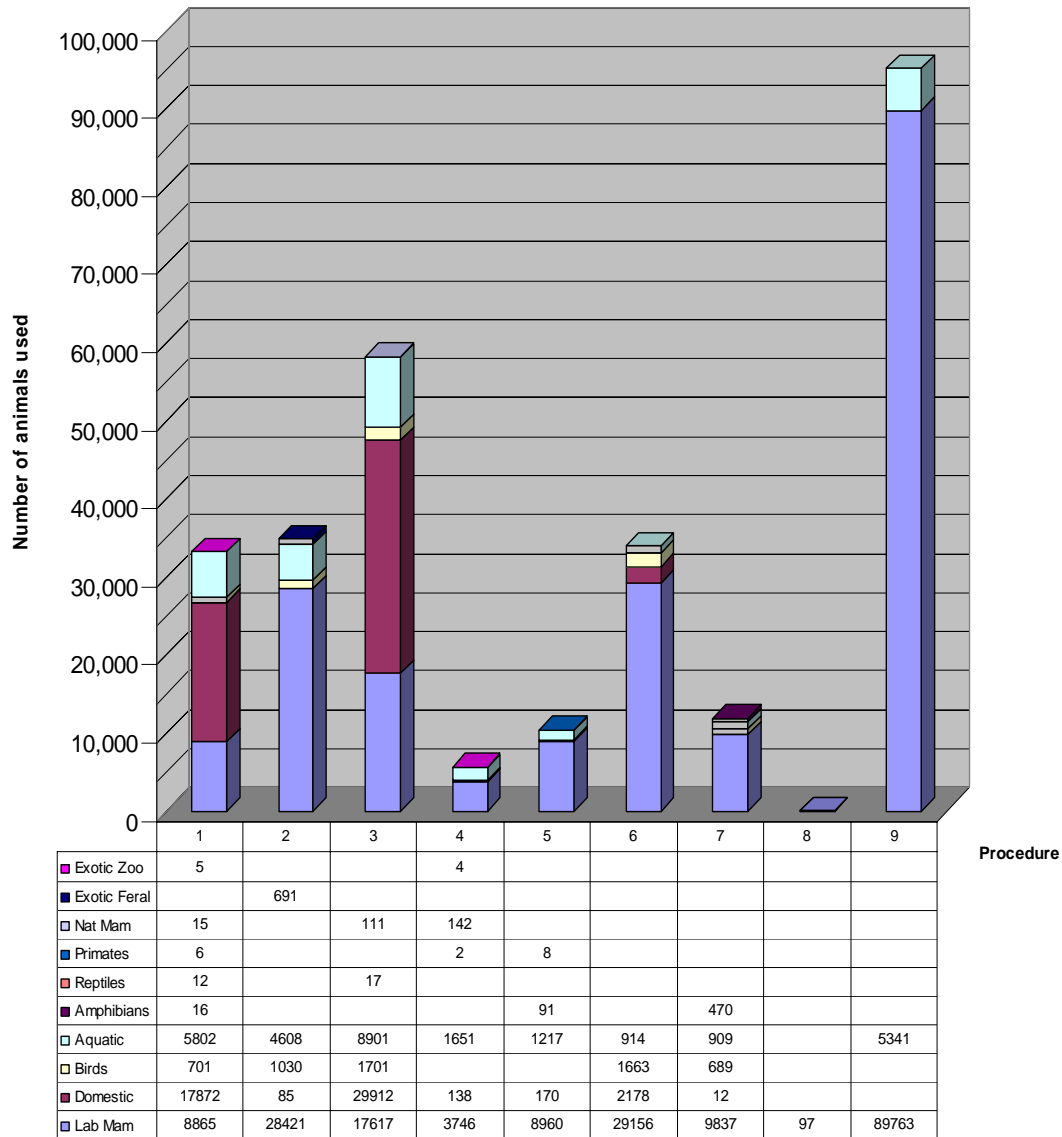


**Purpose: Research - Human or Animal Biology**  
Breakdown of Primate Species



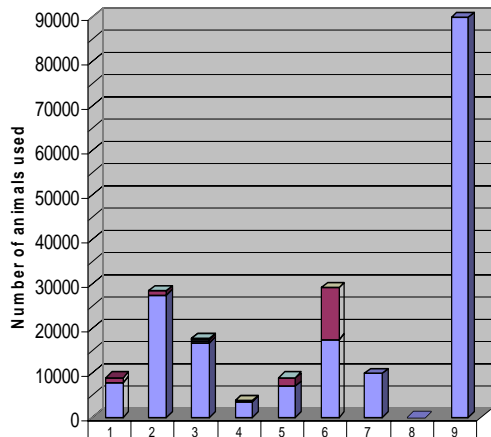
## Purpose: Research - Human or Animal Health & Welfare

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



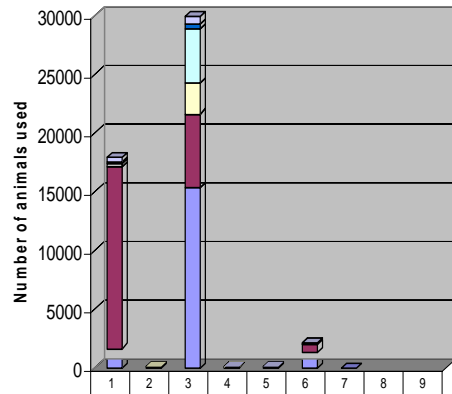
*Refer to following page for a further breakdown of species.*

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



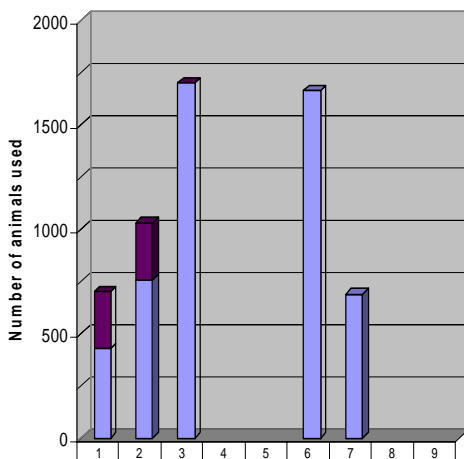
Species	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit		2	8		61				
Guinea Pig		73	33	157	73	28			
Rat	1056	879	858	63	1862	1589			
Mouse	7809	27467	16718	3526	6964	17539	9837	97	89763

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



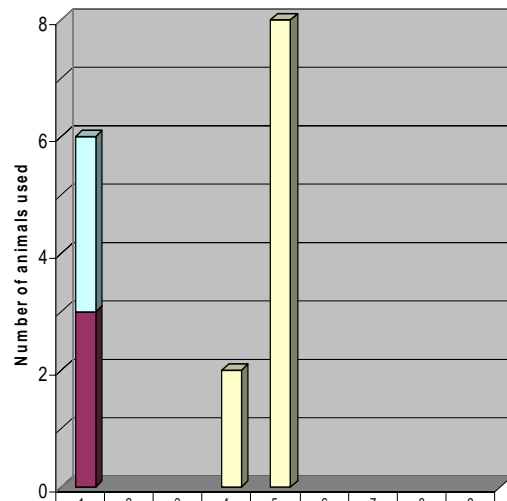
Species	1	2	3	4	5	6	7	8	9
Other									
Dogs	386		697	20	71	90			
Cats	8		406						
Deer									
Goats			56			8			
Horses	151		4524	10	58	47			
Pigs	200	34	2632	51	36	4			
Cattle	15436		6266	10		713			
Sheep	1691	51	15331	47	5	1316	12		

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



Species	1	2	3	4	5	6	7	8	9
Other									
Native Wild	271	271	1						
Native Captive									
Exotic Wild									
Exotic Captive									
Poultry	430	759	1700			1663	689		

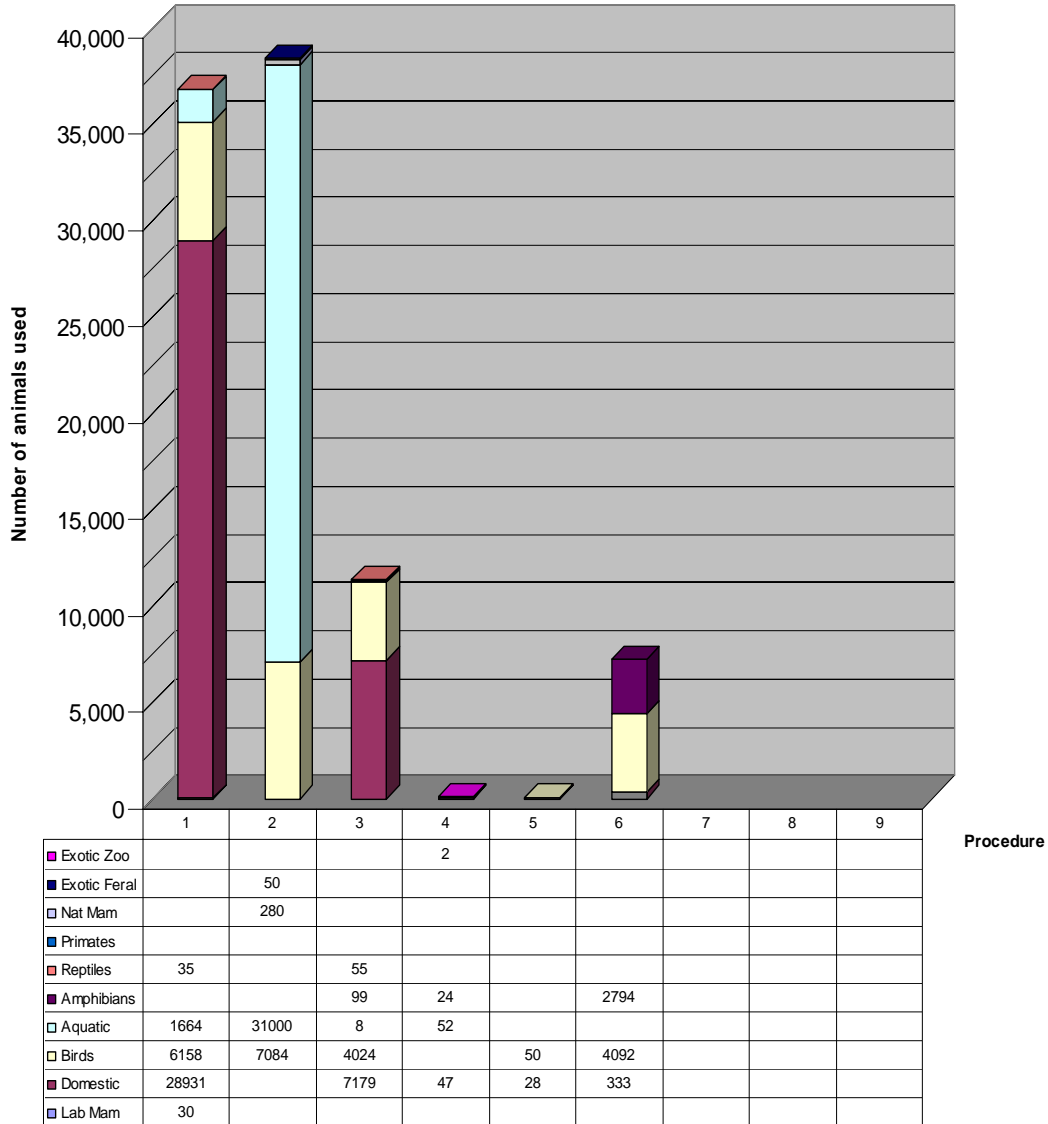
**Purpose: Research - Human or Animal Health & Welfare**  
*Breakdown of Primate Species*



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

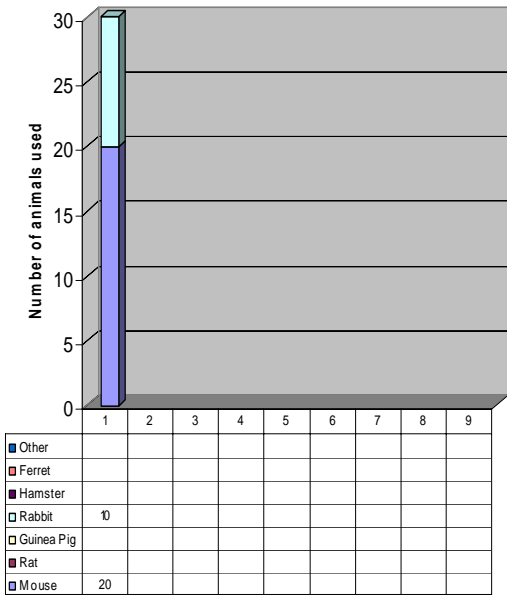
## Purpose: Research - Animal Management or Production

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

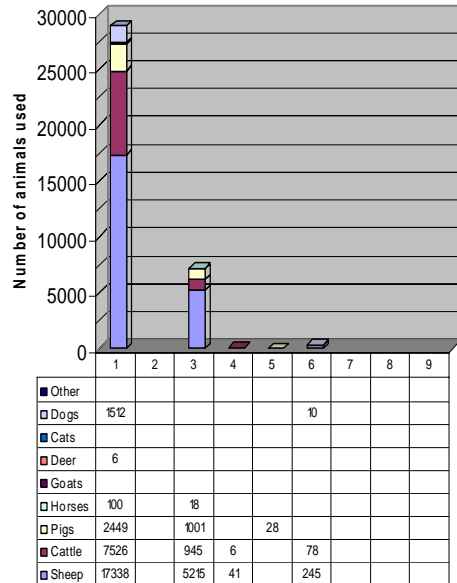


*Refer to following page for a further breakdown of species.*

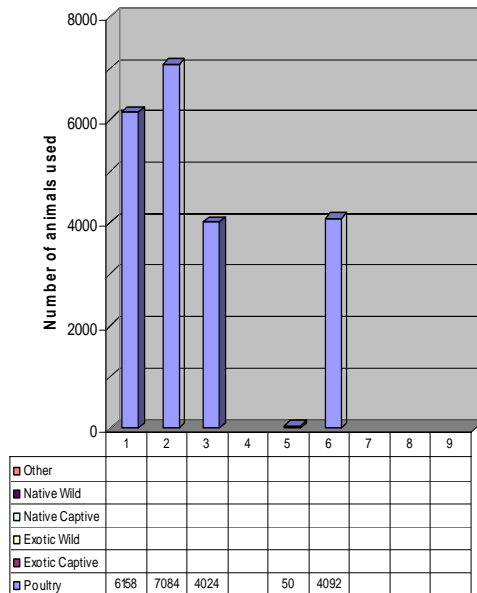
**Purpose: Research - Animal Management or Production**  
*Breakdown of Laboratory Mammals Species*



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



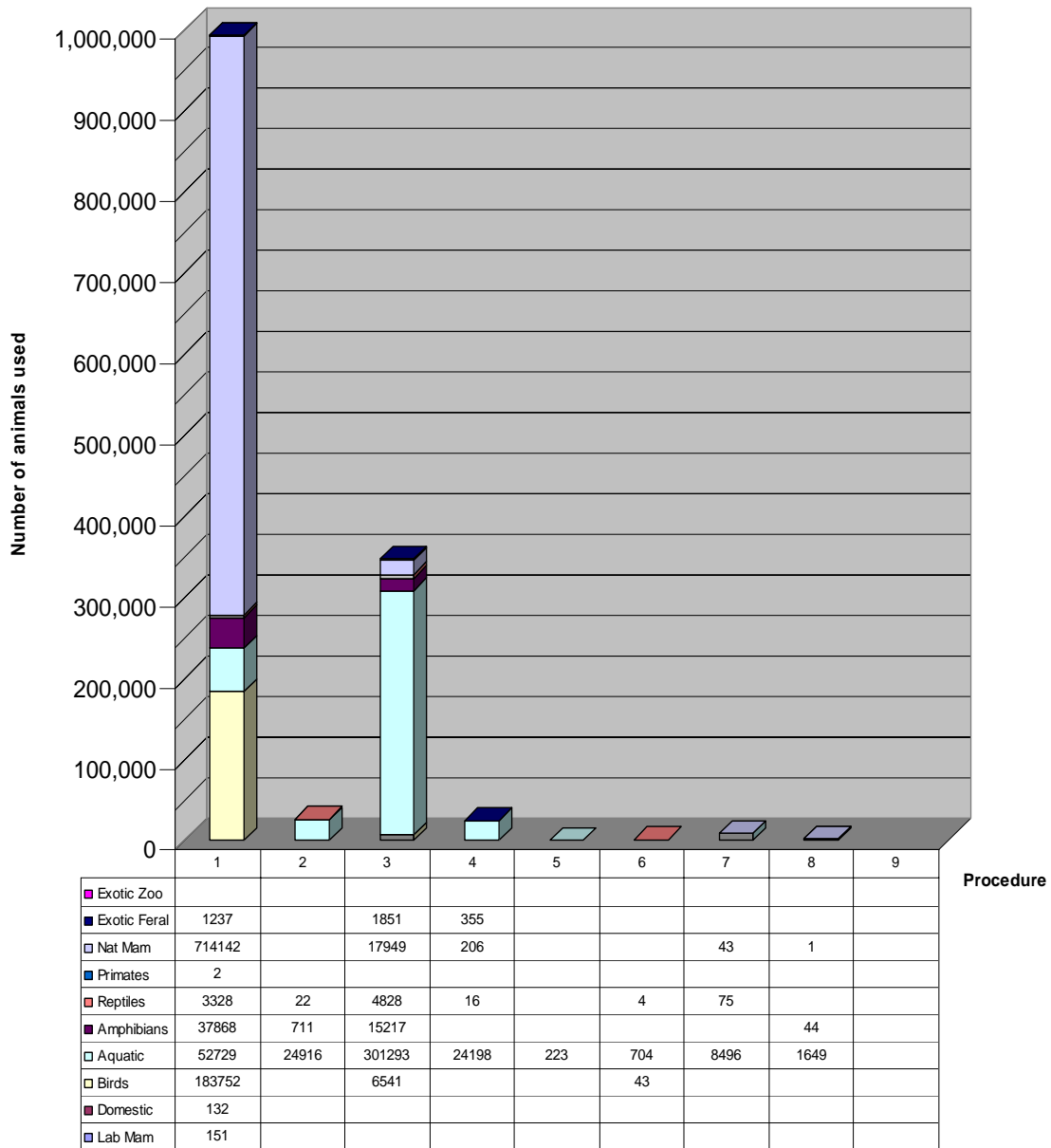
**Purpose: Research - Animal Management or Production**  
*Breakdown of Bird Species*





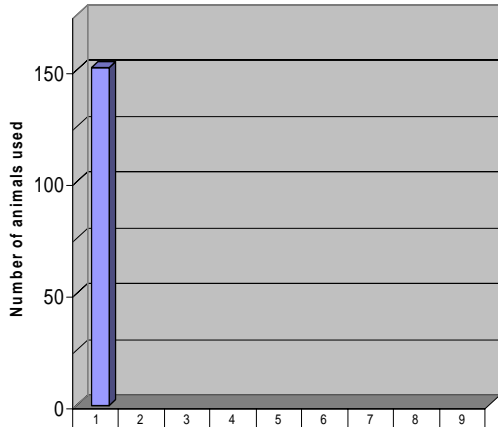
## Purpose: Research - Environmental Study

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.



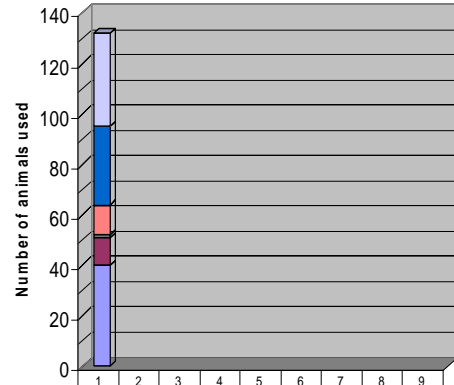
Refer to following page for a further breakdown of species.

**Purpose: Research - Environmental Study**  
*Breakdown of Laboratory Mammals Species*



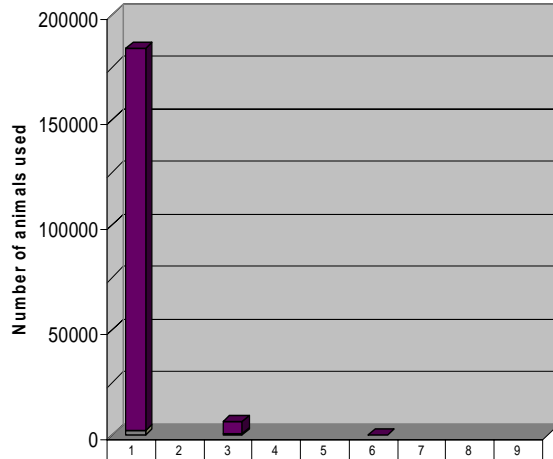
Other									
Ferret									
Hamster									
Rabbit									
Guinea Pig									
Rat									
Mouse	151								

**Purpose: Research - Environment Study**  
*Breakdown of Domestic Mammals Species*



Other									
Dogs	37								
Cats	31								
Deer	12								
Goats									
Horses	1								
Pigs									
Cattle	11								
Sheep	40								

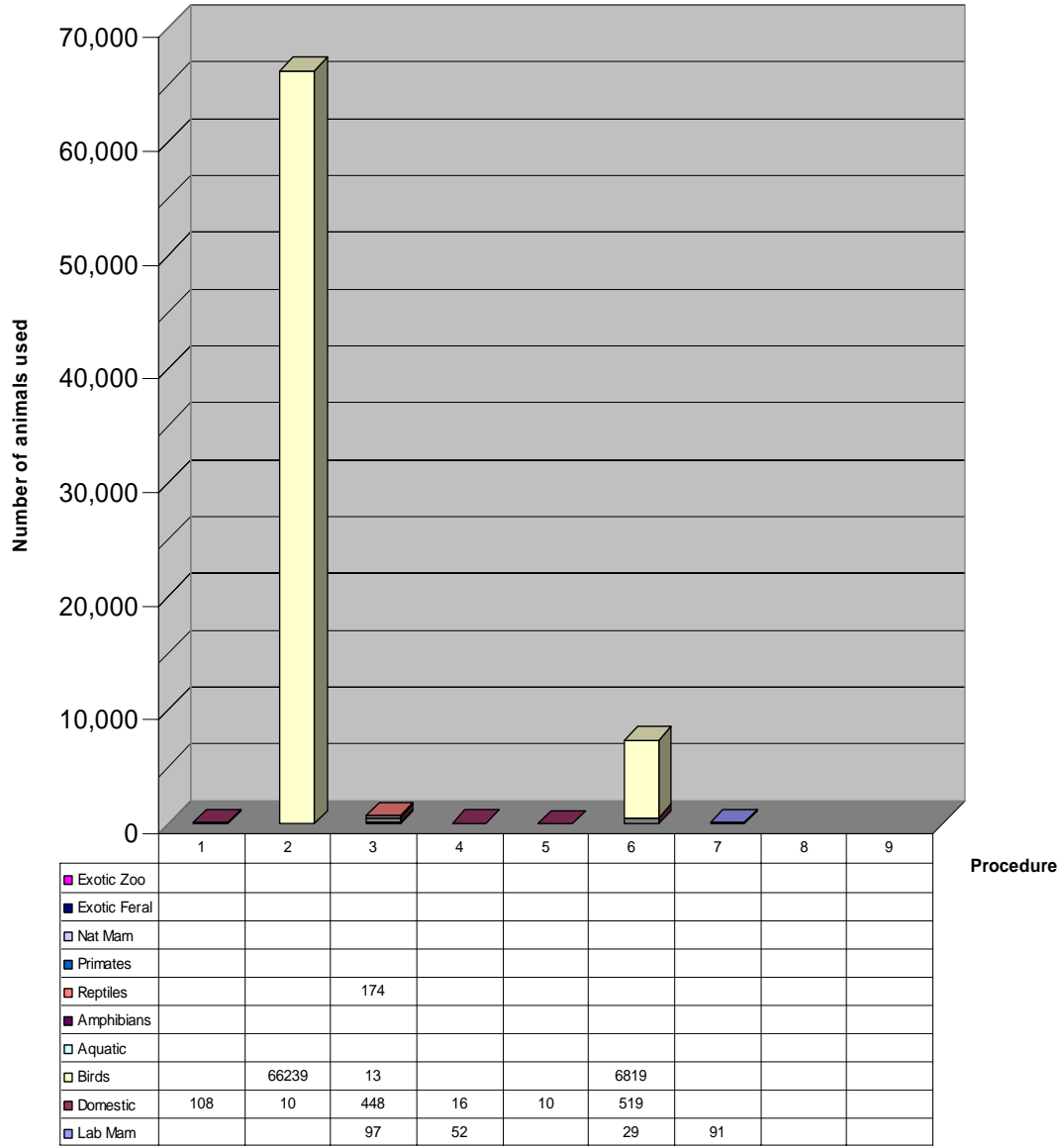
**Purpose: Research - Environment Study**  
*Breakdown of Bird Species*



Other									
Native Wild	18401		5650			43			
Native Captive	413		884						
Exotic Wild	1938		3						
Exotic Captive			4						
Poultry									

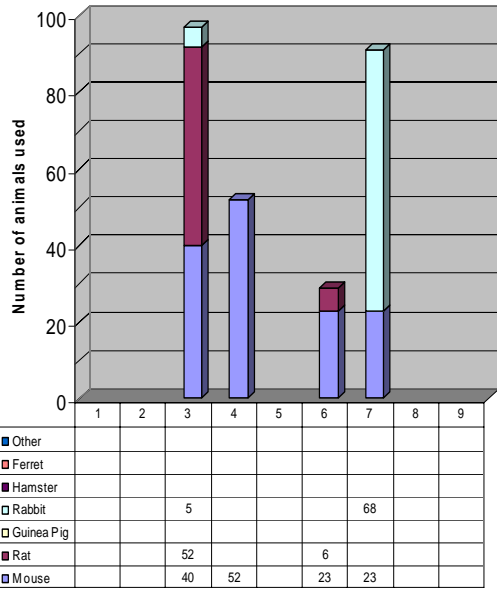
## Purpose: Production of Biological Products

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

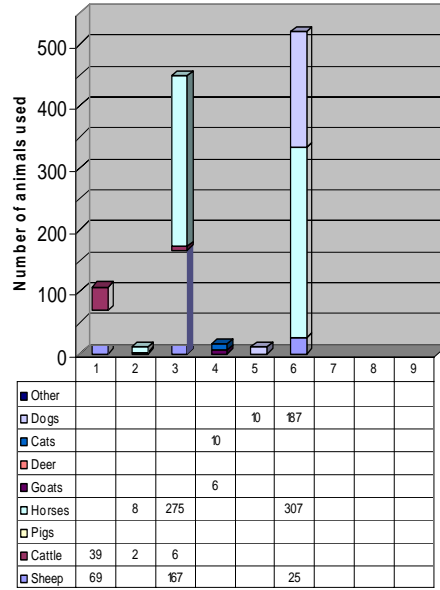


Refer to following page for a further breakdown of species.

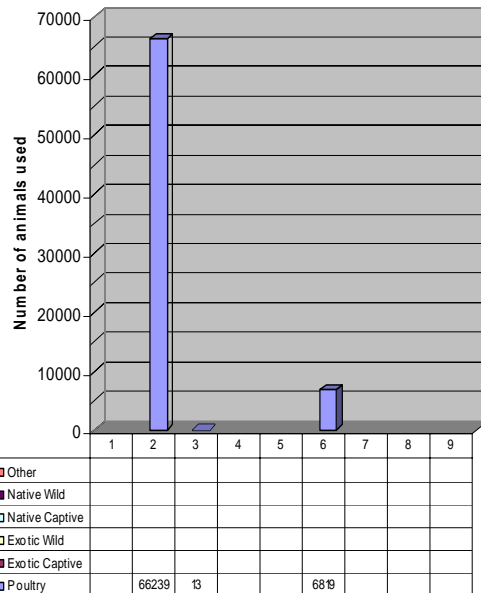
**Purpose: Production of Biological Products**  
*Breakdown of Laboratory Mammals Species*



**Purpose: Production of Biological Products**  
*Breakdown of Domestic Mammals Species*

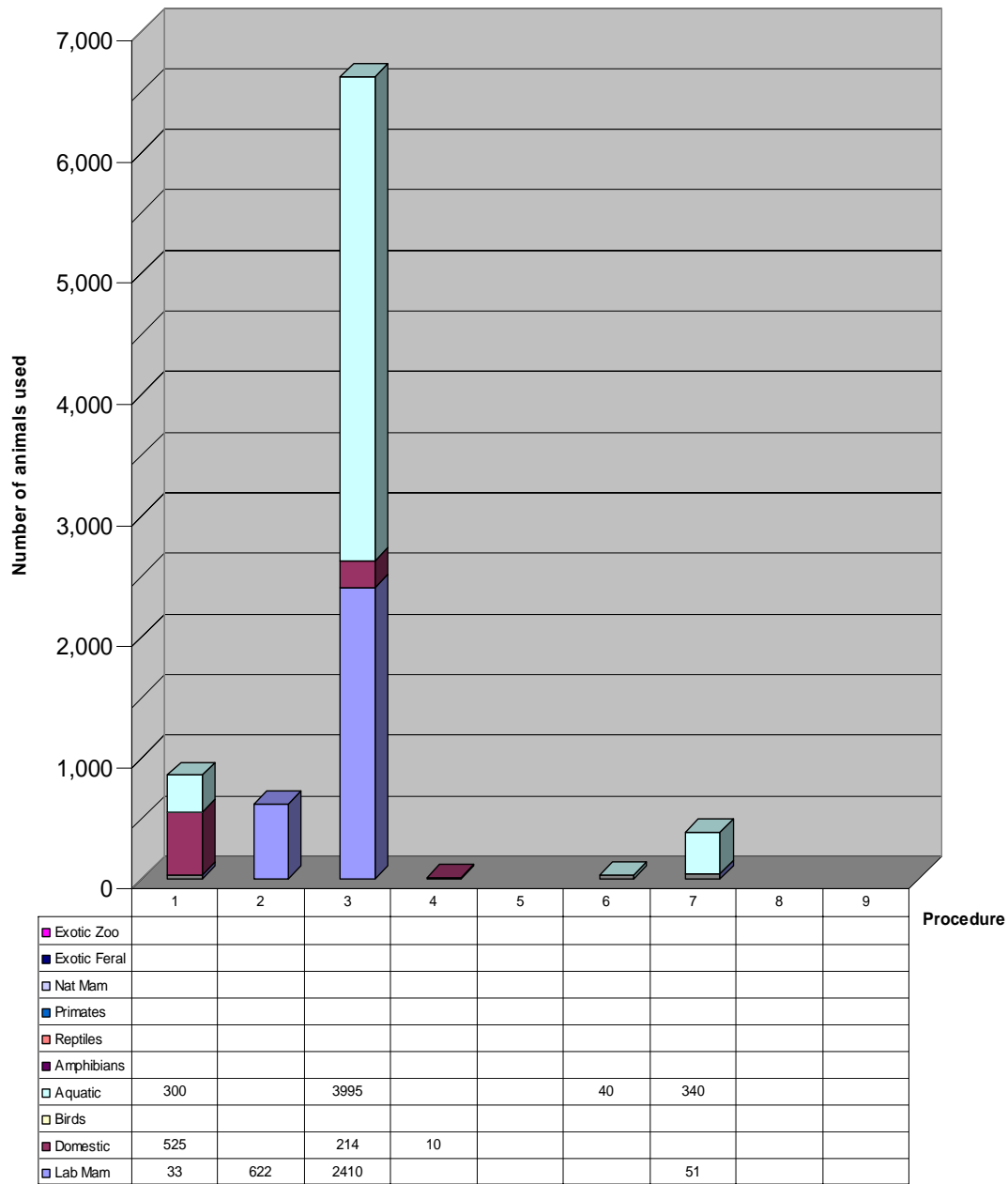


**Purpose: Production of Biological Products**  
*Breakdown of Bird Species*



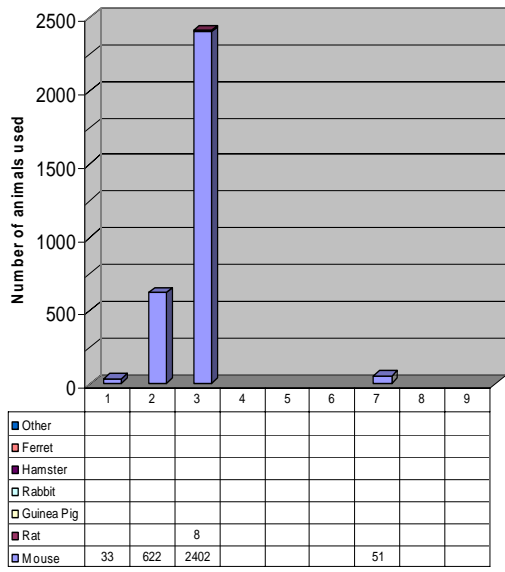
## Purpose: Diagnostic Procedures

Using animals directly as part of a diagnostic process.

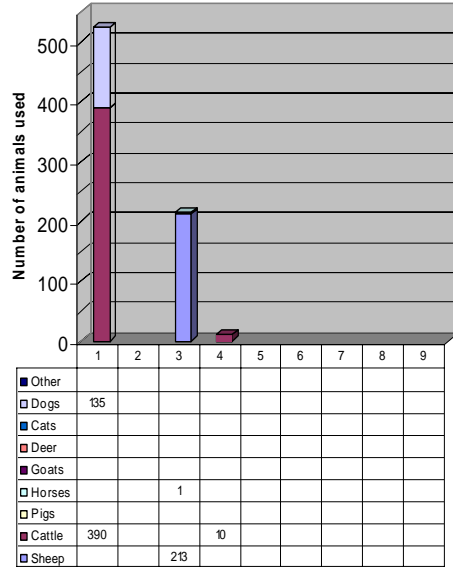


Refer to following page for a further breakdown of species.

**Purpose: Diagnostic Procedures**  
*Breakdown of Laboratory Mammals Species*

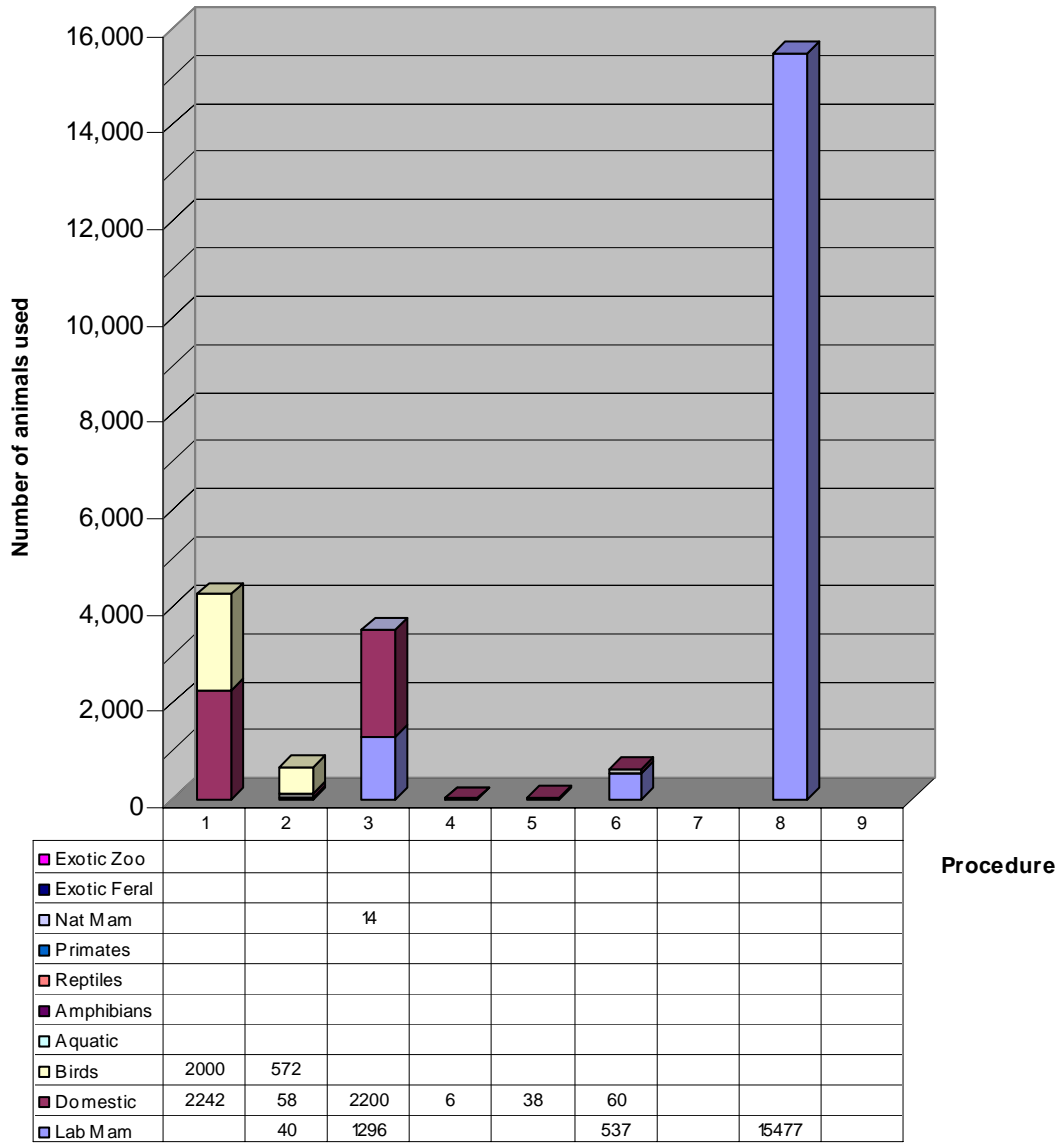


**Purpose: Diagnostic Procedures**  
*Breakdown of Domestic Mammals Species*



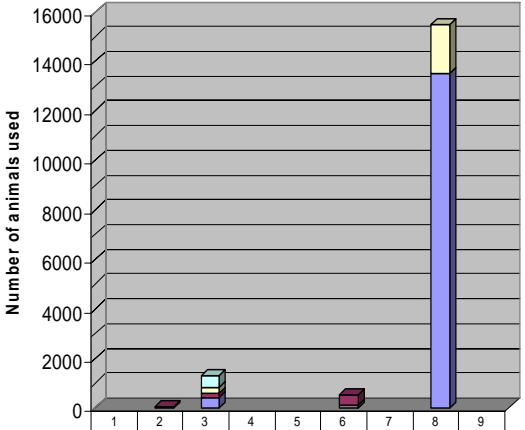
## Purpose: Regulatory Product Testing

Protocols for the testing of products required by regulatory authorities.



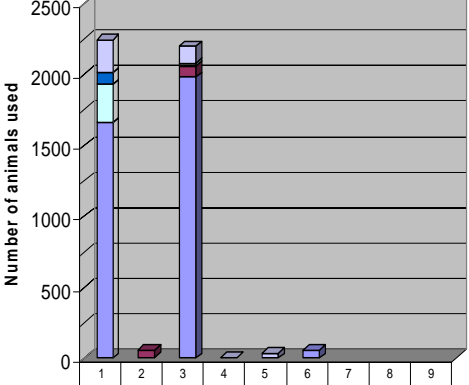
Refer to following page for a further breakdown of species.

**Purpose: Regulatory Product Testing**  
*Breakdown of Laboratory Mammals Species*



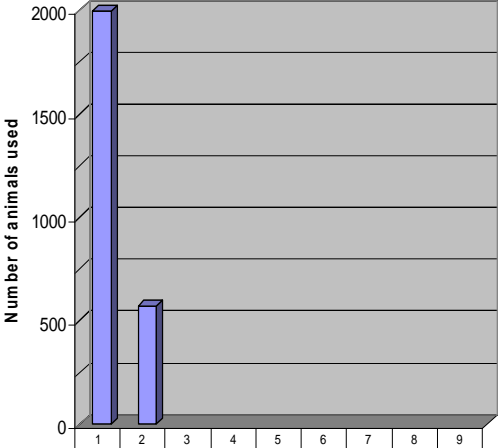
Species	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit			475						
Guinea Pig			230					1978	
Rat		40	205			418			
Mouse			386			119		13499	

**Purpose: Regulatory Product Testing**  
*Breakdown of Domestic Mammals Species*



Species	1	2	3	4	5	6	7	8	9
Other									
Dogs	229		123						
Cats	86			6	38				
Deer									
Goats									
Horses	269		21						
Pigs									
Cattle		49	74						
Sheep	1658	9	1982						60

**Purpose: Regulatory Product Testing**  
*Breakdown of Bird Species*



Species	1	2	3	4	5	6	7	8	9
Other									
Native Wild									
Native Captive									
Exotic Wild									
Exotic Captive									
Poultry	2000	572							



## LETHALITY TESTING – 2011

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 2011.

Species	No. used	No. died/ euthanased	Procedure	Justification	Alternatives
Guinea Pigs	1,978	580	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 upon regulatory guidelines. No alternatives available at this time.
Mice	2,320	772	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	5,820	2,353	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	5,119	2,555	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.
Mice	200	100	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.
Mice	222	222	In order to assess the contribution of specific virulence determinants to disease causation, it is a standard microbial procedure to "knock out" the virulence gene under study, and then compare the virulence of the knock out strain and	The contribution of specific virulence determinants to the pathogenesis of microbial pathogens and the efficacy of therapeutic treatments 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 only be conducted in live mammals (ie mice). Additionally, the	No alternatives exist, which effectively mimic the mucosal and tissue barriers as well as a functioning immune system observed in live mammals.

			the parental wild type strain in an animal model.	development of any new therapeutics for the treatment of bacterial infections must be able to demonstrate efficacy in appropriate animal models of disease	
Fish (Eel tailed catfish, murray cod, golden perch, silver perch)	850	850	48 hour exposure to low dissolved oxygen.	<p>There is a lack of information regarding the influence of hypoxia (low dissolved oxygen) and associated blackwater events on freshwater organisms. In particular there is very little information concerning the lethal and sub-lethal dissolved oxygen requirements for juvenile fishes and invertebrates. Most research focused on hypoxic events in freshwater ecosystems is centred around catastrophic mortality of adult fish (ie fish kills) while the impacts on earlier life history stages and taxonomic groups remains largely unstudied. High mortality rates in early life history stages may significantly influence recruitment to adult populations and subsequent community ecosystem structure.</p> <p>This project aims to determine lethal (LC50) and sub-lethal dissolved oxygen concentrations and behavioural avoidance responses of four species of fish and two species of crustaceans. Survival rates and behavioural avoidance responses will be compared across species/taxonomic groups and between laboratory-created hypoxic blackwater and hypoxic freshwater. It is anticipated that these results may provide a starting point to guide hypoxia thresholds for riverine bioto and water management practices.</p>	Unfortunately, to obtain the data essential to guide improved water management practices, no alternatives or modification could be developed to obtain accurate information. However, LC50 was determined through this project. Consequently, no further experimentation involving lethality testing will be conducted during the course of this project.

## 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 2011 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
Use of computer simulation in teaching subject in place of rats and cats.
Use of cadavers – leg parts of horses were sourced from local abattoir for use in shoeing and/or hoof health in equine studies.
Use of road kill in first year practicals.
Mannequins, audio-visual materials, taxidermed and preserved specimens were used as substitutes for live animals where trainees were inexperienced and the learning outcomes able to be met by substitute means.
Ear-tagging of sheep was practised on cardboard and leather.
Injection pads were used to practise medication injection for a range of species.
The establishment has recently purchased a rodent training manikin to allow handling and procedures of an animals model prior to students working with animals.
<i>In vitro</i> cattle models were used to rank formulations based on the ability to facilitate drug passage across skin, thus reducing the number of formulations taken to the <i>in vivo</i> level of testing.
Devices used , including the BEAT machine, for surgical training for vascular anastomosis as an alternative to using rats.
Utilising and chemical broth to simulate the brain environment to characterise some fundamental electrochemical properties of equipment without using animals.
Surgical techniques were practiced on animals that were euthanased for another reason.
A literature review was performed instead of using animals.
The use of videos to demonstrate some aspects of fish management are used to replace the use of fish where possible.
An artificial feeding system for mosquitoes has been successfully developed which means rats do not have to be used.
Developed ELISA in place of virus neutralisation test in mice.
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. Work is currently being undertaken to remove the target safety test for animal species. An application is to be made early 2012 to the APVMA. 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. It should be noted that LD50 numbers have been reduced this year.
As with previous years, the AEC engaging a Bio-Statistician has paid significant dividends. Over this period our initial Bio-Statistician was replaced by a colleague who has had extensive experience in both animal experimentation statistical treatment as well as having worked on a Human Ethics Committee. Both of these Committee members have worked directly with PIs and have designed efficient and effective protocol applications that reflect minimal use of animals while maintaining

meaningful statistical numbers.
Continued improvement in statistical analysis for the use of the minimal number of animals.
We obtain animal eyes from labs when they are euthanasing animals. The use of these eyes means we do not need live animals for that project.
The practice of sharing tissue from deceased rats and mice with other researchers eg blood, skin, brains, lenses, livers and hearts. Transfer of unused animals between protocols instead of ordering additional animals.
Many new studies undergo a pilot study to optimise animal numbers – often statistically significant results can be obtained with smaller numbers of animals.
Close scrutiny of the number of animals requested and Biometrician's comments reviewed to ensure numbers are adequate to obtain the desired statistical outcomes.
Reduction in number of animals used – researchers in a protocol have moved to PCR to reduce the number of animals used.
Similar studies have shared the same control animals.
Tissue sharing is encouraged by the AEC. A Tissue Sharing Application to identify the possibility of sharing tissues is used by investigators. Animal care staff, or other investigators, can then source required tissues. In addition, multiple tissues are collected from all experimental animals and stored to prevent the possibility of extra animals being required to study different tissues.
Two techniques we have now developed and incorporated into our studies have the impact of reducing the numbers of animals used. These techniques are the injection of trypan blue into donor transplant females and our cell transplant experiments with retroviral gene expression. The injection of trypan blue allows the visualisation of the epithelium in the live mammary gland so that we can guarantee that epithelium has been transplanted into the host animal and thus avoid the waste of experimental animals.  Secondly our mammary primary cell transplants with retroviral transgene expression allows us to investigate the effect of gene over-expression in the mammary gland without the generation of transgenic mice.  Finally the use of mammary transplantation to produce many test glands from a single donor animal avoids producing a large breeding colony. This technique is particularly useful for rare genotypes and greatly reduced animal usage in these cases.
Depending on the tumour implantation rate from the pilot study, the number of mice used in the subsequent experiments may be reduced. We also aim to collect and store as many relevant tissues (e.g tumour, liver) and biofluids (eg. plasma, urine) for analyses. For example, urine samples can be used for pilot metabolic analysis of potential urinary metabolite biomarkers.
The use of a xenogen in vivo imaging system allows data from multiple time points to be obtained from a single mouse thus reducing the numbers required.
Serial transplantation of bone marrow reduces the number of donor mice needed.
Data from previous studies were used to reduce the number of animals.
Tissue sharing among researchers.
Transfer of excess rats from one project to another.
The number of animals used for teaching has been significantly reduced from previous years. Where possible, animal handling training is now conducted using experimental animals.
The establishment discontinued breeding rodent lines that are readily available from commercial suppliers. This has significantly reduced the number of animals bred and culled for the supply of research.
The establishment continues to encourage researchers to harvest and share tissues in instances where animals have been humanely killed.
The Committee continues to maintain a Biological Non-Human Tissue Database through which researchers are able to share excess tissue, thus replacing the use of live animals with the use of stored tissue. In addition, to make these tissues more widely available, the Committee has joined the Ethitex tissue sharing database which facilitates tissue sharing throughout Australia.

<p>The Committee has minimised animal usage by the following techniques:</p> <p>careful scrutiny of the numbers of animals requested to ensure that sufficient numbers are used to provide a statistically valid result, thus preventing the need for repeat experiments and use of additional animals, approval of new techniques for embryo freezing rather than continuous breeding to maintain lines, re-use of animals, where appropriate, after extended recovery interval and making surplus tissue available through a Biological Non-Human Tissue Database and seeking prior agreement from investigators to make surplus tissue available, consolidating breeding protocols to ensure no over-breeding which in turn reduces the need for culling.</p>
<p>By comparing data from this study with data from other studies the duration of the study and the number of blood collections taken was able to be reduced.</p>
<p>Pharmacokinetic data from this study was compared with data obtained in a previous study in order to reduce the number of animals required in this study.</p>
<p>Only adopt tests that are required based on previous experience/findings. For example, a protocol was changed based on a finding from the phase 2 study that there is some level of protection against <i>Salmonella</i> challenge if blood samples are analysed for specific antibody. Therefore, the proposal was modified to only include blood tests rather than challenge the birds with <i>S. Typhimurium</i> and culture caeca for analysis (reducing number of birds from 150 to 90).</p>
<p>In field trials, only use farms that have a history of the presence of the target organism, so as to reduce the number of animals used.</p>
<p>Research involving the use of cats and dogs in NSW was undertaken in association with active Veterinary cases and utilised excess from routine samples as far as possible. In this way reducing both use and impacts on animals.</p>
<p>Sharing tissues to allow use in dataset of another or a future protocol.</p>
<p>Utilising videotapes of predators for presentation in behavioural labs (with birds and fish).</p>
<p>Performing preliminary work on vascular ultrasound, utilising endothelial cultures, to reduce the overall number of animals required.</p>
<p>Keeping the number of animals in surveys to the minimum required for statistical analysis (in dolphin surveys).</p>
<p>Use of strong biological effects (for example the extremely different red and black morphs of Gouldian Finches) allowed a smaller sample size than if using a model system with more subtle levels of variation.</p>
<p>Sharing of brain and spinal column tissue from experimental and control mice with other research groups.</p>
<p>As the female murine reproductive tract was divided into two uterine horns/oviducts/ovaries, tissues for two different analyses were collected from the same mouse. This method of sample collection allowed the number of animals required for each procedure to be halved.</p>
<p>Experiments designed to enable maximum use of tissues obtained from animals euthanased at the appropriate ages. For example, tissue from one side of the brain (or other structures) was used for molecular analyses (which needed specific tissue processing requirements) and then the other side could be used for other assays, such as protein work etc. Most tissue is collected for archiving at – 80°C. For example, while the main focus was on the nervous system, heart, lung, kidneys, liver, spleen, skeletal muscle, and bone were collected from euthanased animals. This tissue was then available for future use by research groups that have ethical approval.</p>
<p>Experiments planned in such a way that a minimum number of animals were required to obtain meaningful data which included the use of two cohorts of animals in a study to test all of the hypotheses. This was possible through the use of state-of-the-art technology to achieve multiple measures on one sample and a design that enabled multiple parameters to be assessed in one animal.</p>
<p>A reduction in the numbers of animals with unwanted genotypes in one tier of the breeding schedule by using homozygous breeders.</p>
<p>Identified microRNA were investigated stringently. Wherever possible multiple samples were taken from the same mouse to limit the total number required. Only microRNA that had promising results in preliminary experiments were further investigated, limiting the number of animals required.</p>
<p>Combining trials to have 1 group of birds as a single control group instead of 2 separate trials and 2 control group of birds.</p>

Use of surplus SPF males from supply company saving the use of 10-20,000 chicks.
Breeding programs are designed and maintained to produce stock for orders only to reduce numbers and overproduction.
Genetically modified animals are bred as the desired genotype as far as possible to reduce numbers.
Refinement of “adoptive T cell transfer” techniques so that fewer T cells are required, and thus fewer donor mice needed.
<i>In vitro</i> cell culture studies were performed prior to <i>in vivo</i> animal studies. As a result of this, fewer animals were used than originally planned, as agents that proved ineffective in cell culture experiments did not progress to the animal model stages.
Excess animals that were not of the desired genotype that were destined to be culled were used by other researchers to establish various methods and techniques.
Utilisation of computer modelling has reduced the number of animals required in alcohol behavioural studies. In other research groups, computer simulations have allowed the prediction of retinal ganglion cells responses in various experimental paradigms. This has contributed to the reduction in the number of animal experiments to confirm their behaviour in response to light stimulation as well as in other experimental conditions such as adaption and contrast adaption.
Student practical classes are designed with one cane toad between two students to allow twice the information and experience to be gained per toad.
Actively promoting the Ethitex website for all research projects involving terminal studies.
Establishing the first ever annual establishment award for the reduction or replacement of animals in research.
Improved experimental design and statistical analysis for animal research projects – improved data collection and ensuring appropriate number of animals used as experimental and control; using historical controls when possible (or experimental animal as the control) so less animals are used.
Data and resource sharing – archiving of genetically modified mice thru cryopreservation; cryopreservation also facilitates transfer of frozen mouse sperm and embryos to other facilities or collaborators; less breeding for seldom-used strains; animal tissue sharing between research groups whenever possible.
Researchers reminded on a monthly basis to utilize their mice for experiments instead of stock animals getting culled due to old age.
Breeding minimum numbers of GM animals per strain as required including regular review of in-house breeding of inbred and outbred mouse strains as per demand.
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. Cadavers are kept frozen/formalin preserved for 1-2 months following euthanasia for the opportunity to re-use the animals for histological studies.
In vitro culturing with naive serum of sheep is now not required therefore the numbers of animals required as blood donors has been reduced.
Pooling samples to reduce animal numbers, as always use statistical power to determine animal numbers and study outcome.
For potency testing, not to use negative controls, design studies to obtain more information to avoid separate / multiple studies.
Obtaining more data from the use of fewer animals by combining objectives.
DNA amplification by polymerase chain reaction (PCR) to detect microbial presence and quantification now being used in experiments whose microbial viability is irrelevant. This has reduced mice usage.
<b>Refinement</b>
In 2011, a number of adverse incidents were recorded for the use of funnel traps. As a result of the number of incidents the AEC has reviewed the SOPs for funnel trapping and made the following changes: <ul style="list-style-type: none"> <li>• Under extreme temperatures, traps are either closed during the day or re-checked in the afternoon. If this cannot occur due to logistical reasons, additional measures must be implemented to reduce the risk of heat stress on fauna species. Additional measures will include the use of at least two saturated sponges and abundant shelter (leaf litter/bark)</li> </ul>

<ul style="list-style-type: none"> <li>• within the trap, the placement of traps in shady areas, and checking traps within 3 hours of sunrise.</li> <li>• Reference to traps being checked only once has been removed from the methods.</li> </ul> <p>In addition, an audit will be undertaken on funnel trapping in 2012 to assess the change in procedure.</p>
<p>In 2011, a single incident was recorded for fish mortality during seine netting. Low oxygen level in the water was the likely result of mortality. As a result of this incident, the AEC has reviewed the SOPs for seine netting in extreme conditions (high temperatures) and made the following changes:</p> <ul style="list-style-type: none"> <li>- Trapping should not be undertaken above 30 degrees C water temperature.</li> <li>- Where possible, density of fish to be checked with a hand net prior to seine netting.</li> <li>- Where possible, seine netting should occur in deep areas and shady conditions.</li> </ul>
<p>The use of less invasive procedures e.g. sand pads rather than trapping.</p>
<p>Use of an Observational Only - Field Research Form (No Trapping, Handling or Spotlighting).</p>
<p>Fistulated cattle used for the "Rumen Sensor Project" and for use in the "Feed Efficiency Project". The animals being fistulated have previously been used in an experiment which did not impact on them in a significant way. If fistulated animals would not be available, the rumen sensors could only be retrieved after euthanasia of the animals. Having readily available fistulated steers enables repeated retrieval of the rumen sensors with little impact on the animals.</p>
<p>Skin samples were taken from skin removed during the surgical fistulation process for a different project. The use of skin that had to be removed anyway reduces the need to sample other animals.</p>
<p>Reducing stress by acclimatization of animals upon arrival or prior to use in behavioural experiments.</p>
<p>The installation of livestock water troughs in the new outdoor dog runs. The troughs are big enough for the dogs to jump into and provide both enrichment and a means of cooling down in hot weather.</p>
<p>Providing a small amount of straw given daily to pigs to play with and chew, the straw appears to occupy the pigs for a significant amount of time. The pigs are provided with dust-free wood shavings as bedding but the straw is further enrichment.</p>
<p>The installation of a new cooling system in one of the livestock facilities is providing cooler conditions for livestock during the hotter months.</p>
<p>One-on-one training of researchers for particular techniques eg suturing, tail vein injections, bleeding, proper handling and restraint.</p>
<p>Ensuring that researchers and animal technicians performing abdominal surgeries make the smallest incision possible to access particular organs and tissues thus making healing faster, eg during hepatic or bile duct or uterine procedures.</p>
<p>The researcher's protocol has become more efficient, reducing the number of animals necessary for each experiment.</p>
<p>The testing of human regulatory DNA requires whole animal assays. Zebrafish is currently the simplest animal in which this can be undertaken, and is done without killing adult females to obtain embryos (as done in the mouse). Zebrafish females can lay eggs every week, which are used for experiments, and the adult fish are solely necessary to generate embryos and can be reused for this purpose.</p>
<p>Incorporation of infra-red and remote cameras in observational studies has eliminated the need to trap animals.</p>
<p>Faecal samples were collected from freshly deposited faecal pats, avoiding the need to restrain cattle.</p>
<p>For any experiments that may induce pain in animals, the incorporation of analgesic is mandated in line with the principle of refinement. The AEC acknowledges that some drugs take a period of time before it takes effect, and thus requests the researchers administer the drug intra-operatively, as opposed to post-operatively.</p>
<p>Pre- and post-surgical procedures were refined, in order to improve animal welfare with regard to the aspiration of food or secretions during anaesthesia.</p>
<p>Horses destined for the sale-yards are re-used for multiple experiments where possible. This is advantageous for both the welfare of the animals as they are habituated to the researchers, and also benefits the researchers as the horses do not have to be re-trained.</p>
<p>Regarding Animal Research Authority which related to the Wildlife Conservation Teaching unit, cage traps were completely replaced with automated cameras on survey transects, so that no trapping of medium-sized mammals occurred. It demonstrates the 3 Rs to students (by advising of what we did previously) and introduces them to a new survey technique. Furthermore, the Researcher was able to obtain more information on Potoroos and other medium-sized mammal than when we have used cage</p>

traps. The same researcher has also used these motion-activated cameras to detect use of glider poles and ropes connecting between poles in a project. The researcher feels the camera technique is working really well and detecting frequent use of the poles and ropes.
We have upgraded a number of our facilities (e.g. sheep yards and holding pens) to help reduce the level of stress imposed on the animals when we need to handle them.
The use of cameras in preference to traditional trapping methods minimised the need for animal handling.
The amendment of a protocol to increase the speed and accuracy of measurements and therefore reduce animal handling time.
When considering new applications the AEC is always looking for ways of reducing adverse impacts on the animals involved. This includes the use of monitoring sheets for laboratory animals with clear intervention parameters and key triggers for intervention. A number of researchers have been asked to provide this information prior to their experiments being approved. The Committee is also keen to reduce the amount of “by-catch” (non target species) for experiments involving humane trapping. Principal Investigators have been asked to consider alternative techniques or modifying experiments in order to avoid by-catch.
At the Annual training program for investigators explanation of the importance of the 3 Rs was emphasised when planning work whether for teaching or research. This resulted in the identification of a number of refined procedures. Examples include a switch from using intraperitoneal injections of ketamine/xylazine to induce anaesthesia to the use of isoflurane gas and a significant investment to purchase two racks of standard metabolic caging systems.
Outdoor housing in large, well-equipped aviaries for finches and bantams.
Film recording of microsurgery for later reflection and an opportunity for improvement by the surgeon.
Utilising local anaesthetic in addition to general anaesthetic in surgical wounds.
Adoption of Standard Operating Procedures for analgesia and anaesthesia in recovery surgery for rodents.
Increasing use of targeted remote infra-red cameras to replace/supplement trapping for wildlife surveys and monitoring. Limited use of hair-tubes for small mammals which may otherwise result in by-catch of small reptiles. Strategic trapping methods to minimise risk of trap losses. Modifications made to collars used for attaching telemetry devices to flying-fox. Utilisation of advanced technology which reduces size and weight of tracking devices.
Training was provided to study personnel on the correct handling of dogs for jugular vein blood sampling. Blood samples were only taken by veterinarians or study personnel previously trained in this procedure. Dogs in this study were not placed on a table for bleeding, as this made them very uncomfortable. Rather, they were handled on the floor where they were more at ease.
This study was conducted in surroundings familiar to the dogs, which were able to undertake normal activities with only minimal interference.
All staff were trained in animal husbandry and had prior experience in cattle husbandry practices before the commencement of the study. All facilities used during the study were designed for cattle.
The plasma collected during each bleed was stored and utilised in several studies, thus reducing the number of times an animal is bled.
Trained study personnel were used to perform all animal handling in these studies, including an external expert being on hand during the study. The test formulation was administered by a veterinarian and the owner of the dogs was present to ensure the dogs remained calm throughout the study period. Several dogs were administered IV fluids during the anaesthetic period to compensate for fluid loss during this time.
The Committee encourages researchers to undertake a pilot study if the impact of the proposed study interventions on animal health and well-being is unknown.  We have distributed the publication by DB Morton (1999) “Humane endpoints in animal experimentation for biomedical research: ethical, legal and practical aspects” which provides criteria for decision-making in euthanasia of unwell animals, to researchers and animal house managers.



<p>The establishment continued to use Thermal Threshold Technology to assess pain in animals. This is a non invasive technique using technology developed in the UK and replaces other technology such as hot plates and carrageenan injections.</p>
<p>The Animal Welfare Officer revised surgical procedures and purchased additional equipment to enable aseptic technique to ensure improved standards of care and welfare for the animals. Additional building modifications for a dedicated aseptic surgery room are also proposed.</p>
<p>Improved peri-and-post operative analgesia to reduce pain from surgery.</p>
<p>Accommodation of research horses in a large paddock on a professional horse spelling/pre-training farm. Rehoming of retired research horses to suitable new owners. Spontaneous collection of naturally voided urine for the purpose of drug analyses.</p>
<p>New and improved technology has continued to be developed during the year, in an attempt to improve the efficiency of stored serum processing to hopefully reduce the numbers of animals used in the production process.</p>
<p>Cats, rabbits and guinea pigs are group housed in pens/rooms ie not caged.</p>
<p>Use of remote underwater video instead of trapping and releasing fish as a less intrusive research method. Use of pilot studies to refine techniques before large numbers of animals are used.</p>
<p>Specific and individual surgical training in anaesthesia and surgical techniques is provided to inexperienced investigators, or when attempting new procedures. Perfecting anaesthetic doses and decreasing the amount of trauma during surgery results in a reduction in total surgery time and a better outcome for the animal. All surgical cases receive analgesia, as often as is required. Animals recover from anaesthesia on a heat mat and are monitored throughout.</p>
<p>As well as a general health checklist, all projects identify specific endpoints for their particular procedures. Refining these endpoints reduces the impact of a procedure and improves animal welfare.</p>
<p>Mice are lethally irradiated for subsequent reconstitution in many studies involving immunology and inflammation. The use of a split total dose of irradiation, given with a 4-hour break between doses, has resulted in much better survival rates and study outcomes.</p>
<p>This protocol has been modified to eliminate a second adjuvant vaccination</p>
<p>Finalisation of the trial of Suprelorin as a contraceptive in mice and its inclusion as the main method of producing companion females.</p>
<p>While recovering from surgery, rats will be patted 3-5 minutes each day to minimise any stress due to individual housing.</p>
<p>We have chosen ovarian cancer cell lines that do not metastasize and therefore do not make the mice extremely sick. We have optimised the endpoints of these experiments so that the mice are euthanized before the tumours have grown to be larger than 10% of their body mass.</p>
<p>To prevent pup rejection by the mother, the stress experienced by the dam is kept to a minimum and the time the pups are removed from the nest is limited. The pups are only returned to the nest after being rewarmed. If the smell of the pups is altered by ethanol or iodine, the same substance is applied to all pups in the litter and gently rubbed with some tissue from the nest. The dam was preconditioned to frequent handling and novel odours.”</p>
<p>Researchers are encouraged whenever possible to minimise and restrict the volume of drugs/fluids given through intraperitoneal injection (IP) to 1% of body weight. For larger IP volumes, the dose is split into 2 smaller doses and administered 30min apart.</p>
<p>Use of adjuvants known not to produce adverse reactions.</p>
<p>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.</p>
<p>In 2011 Professional development programs were created and delivered, emphasising the need for alternative practices. On-line induction/refresher for teachers; face-to-face workshop for managers; AARP training day for AEC members; DPI Wildlife techniques for teachers.</p>
<p>Prior to field work activities, students were familiarised with both the animals and the handling techniques to be used. This included visits to zoos, aquaria and museums to become familiar with the animals, demonstrations of the use of equipment and DVDs showing the use of the research methods. Actual field work was kept to a minimum.</p>

Shearing of rams – stress on rams during shearing was minimised by using sedation.

For native animals, handling is by the licensed person only, with students observing the techniques.

#### Appendix I: ARRП expenses

**Note:** The following figures do not include the time and costs incurred by individual ARRП 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 ARRП business) is not included in the figures.

Fees and retainers	4,421.13
Travel and subsistence	1,298.73
Stores (including catering) and printing	1,625.61
Freight and postage	472.40
<b>TOTAL</b>	<b>\$7,817.87</b>

## **Appendix J: ARRPP 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. Guidelines for the Housing of Mice in Scientific Institutions (April 2012)
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 Animal Welfare Unit of the NSW Department of Primary Industries within 30 days of membership changes. The revised composition of the AEC must meet the approval of the Director-General.
3. Rabbits should be housed in groups in pens. Rabbits may 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 ARRP 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 ARRPs 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 Animal Welfare Unit of the NSW 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*.

