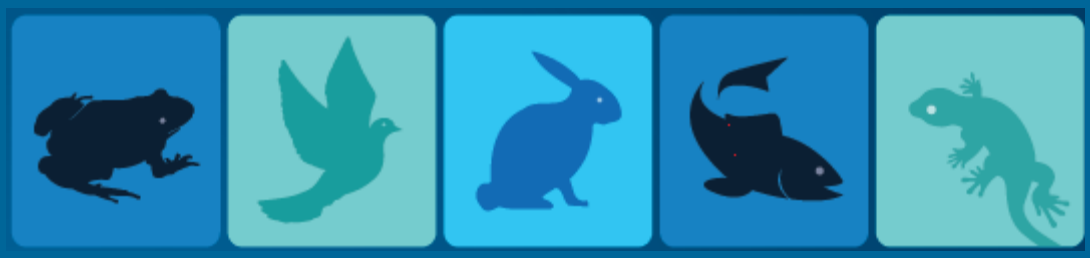
Animal Research Review Panel

Annual Report

2012 - 2013



NSW GOVERNMENT Department of Primary Industries

DISCLAIMERS

The information contained in this publication is based on knowledge and understanding at the time of writing (December 2013). However, because of advances in knowledge, users are reminded of the need to ensure that information upon which they rely is up to date and to check currency of the information with the appropriate officer of the NSW Department of Primary industries or the user's independent adviser.

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NSW GOVERNMENT | Department of Primary Industries

ANIMAL RESEARCH REVIEW PANEL

4 December 2013

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 2012 to 30 June 2013.

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 for the Care and Use of Animals for Scientific Purposes

The Australian Code for the Care and Use of Animals for Scientific Purposes (the Code) 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. The 8th edition of the Code was released in July 2013 with the inclusion of a name change from *the Australian Code of Practice…* to the *Australian Code…*

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, Biosecurity NSW (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 ARRP

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

- the investigation of matters relating to the conduct of animal research and the supply of animals for use in connection with animal research
- the investigation and evaluation of the efficacy of the Code of Practice in regulating the conduct of animal research and the supply of animals for use in connection with animal research
- the investigation of applications and complaints referred to it under the Act
- such other functions as the Minister may from time to time confer or impose on it.

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

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

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

1.3.3 Membership

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

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

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

During the 2012–13 period the membership of the ARRP 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 the Animal Societies' Federation)
- Dr Mike Fleming (nominated by the Minister for the Environment)
- Vacant (nominated by the Minister for Health)
- Professor Anne Keogh AM (nominated by the Animal Societies' Federation)
- Professor Robert Mulley (nominated by the NSW 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 2012–13 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. He is a Senior Team Leader with the Science Division of the Office of Environment and Heritage. Dr Fleming has conducted research in marsupial physiology, wildlife management and biodiversity survey. He has worked extensively in the Northern Territory and New South Wales.

Professor 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. She is Conjoint Professor of Medicine University of NSW, Director of two binational registries, a member of the Advisory Committee on Medical Devices, 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, past president International Society of Heart and Lung Transplantation and past president of the Pulmonary Hypertension Society of Aust and NZ which she formed in 2010. 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'SHANNESSY, BSAgr.
Mr O'Shannessy is the nominee of the RSPCA (NSW). Since completing an Agricultural Science Degree he has been employed as an inspector with the RSPCA NSW and for a period of time was a sales representative for a veterinary pharmaceutical company. He was appointed RSPCA Chief Inspector in May 2005 and was appointed as a member of the ARRP in January 2005.

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 a Professor of Neuroscience and Director of Medical Research at the Australian School of Advanced Medicine, Macquarie University. She has extensive experience in laboratory animal work and her research is in the areas of hypertension and renal disease.

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

The criteria used by the ARRP for assessment of AEC membership were clarified in an ARRP policy document, *Policy 9: Criteria for the Assessment of Animal Ethics Committee Membership* (http://www.animalethics.org.au/policies-and-guidelines/operation). In examining applications from institutions for accreditation as animal research establishments, the membership of AECs are assessed to ensure they are of acceptable composition. The ARRP also assesses, and makes recommendations to the Director-General, on the suitability of all new appointments to AECs. All new AEC appointments must be approved by the Director-General. During audit inspections, the ARRP assesses the operation of the AECs.

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 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 2012–13 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 approximately every 4 years, as well as unannounced visits by inspectors to follow up problems. 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 of Biosecurity NSW 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:

Animal Welfare Unit – Biosecurity NSW
NSW Department of Primary Industries

Locked Bag 5123
PARRAMATTA NSW 2124
Phone: (02) 9842 8090

or at the NSW Department of Primary Industries Head Office:

Animal Welfare Unit - Biosecurity NSW
NSW Department of Primary Industries
161 Kite Street
Locked Bag 21
ORANGE NSW 2800
Phone (02) 6391 3149
Fax (02) 6391 3740
E-mail: animal.welfare@dpi.nsw.gov.au

In the 2012–13 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:

Suzanne Robinson, BRurSc, EMPA, GradCertEmergencyMgt, Senior Manager, 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 ARRP's operational plan for 2012–13. The appendixes to this annual report contain details of many of the operational and strategic functions of the ARRP. These include the dates of, and attendance at, ARRP meetings (Appendixes A and B); dates and attendance of ARRP members at inspections of accredited research establishments and animal supply licence holders (Appendixes C and D); the ARRP Strategic Plan 2011–14 (Appendix E) and Operational Plan for 2012–13 (Appendix F); and ARRP operating expenses (Appendix I).

2.1.1 Strategic Plan 2011–14

During 2011-12 the ARRP revised its 3-year strategic plan. The plan identifies the primary goals of the ARRP and strategies for achieving these goals.

Details of the Plan are given in Appendix E.

2.1.2 Operational Plan for 2012–13

The ARRP Operational Plan for 2012–13, including performance status for each activity, is provided in Appendix F.

2.1.3 Liaison with organisations and individuals

The ARRP 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 2012-13 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.

2.1.4 200th meeting of the ARRP

The 200th meeting of the ARRP was held on 5 December 2012. The occasion was marked by the attendance of the Director-General of NSW Department of Primary Industries, Dr Richard Sheldrake. Dr Sheldrake was familiar with the operations of the ARRP, having held positions in the past as Director of the Animal Welfare Unit and a member of the ARRP.

2.2 Assessment of applications

In 2012–13 there were 142 accredited animal research establishments and 46 holders of animal suppliers' licences.

During 2012–13 the ARRP considered and made recommendations to the Director-General on:

- 10 new applications for accreditation
- 69 renewal applications for accreditation
- 1 new application for an animal suppliers' licence
- 30 renewal applications for animal suppliers' licences.
- 6 extensions to existing accreditations and/or animal suppliers' licences.

2.2.2 Appeal to the Administrative Decisions Tribunal

A research establishment that was approved to house mice applied to extend its Accreditation and Animal Supply Licence to include guinea pigs. The application was refused by the Director-General after consideration of the ARRP's recommendation, on the basis that the establishment did not have satisfactory housing for guinea pigs. The housing was assessed in accordance with the recommendations in the Animal Research Review Panel Guideline 21: Guidelines for the housing of guinea pigs in scientific institutions (http://www.animalethics.org.au/policies-and-guidelines/animal-care). The guinea pigs were to be held in individually ventilated cages with floor area

approximately half that recommended in the guidelines. It was proposed to house the guinea pigs, which are social animals, singly due to the small size of the cages. The reason that satisfactory housing could not be used was space limitations in the Physical Containment Level 3 laboratory to be used by the establishment.

In making the decision to refuse the application it was taken into account that the deviations from the recommendations in the Animal Research Review Panel guinea pig housing guidelines were extreme (approximately half the recommended floor area and housing the guinea pigs in isolation). The only justification for the use of this housing was a lack of space, and this justification was not considered sufficient.

The establishment appealed the Director-General's decision to the Administrative Decisions Tribunal. The appeal involved a three day hearing in May 2013.

The Administrative Decisions Tribunal published its decision, which was to affirm the Director-General's decision to refuse the application for Accreditation and Animal Supply Licence. The decision can be found at: http://www.caselaw.nsw.gov.au/action/PJUDG?jgmtid=167664

2.2.3 LD50 testing

LD50 is a toxicity test used to determine the dose or concentration of a test substance—that is, the lethal dose—that is expected to kill 50% of the animals to which it is administered. For the purposes of the NSW *Animal Research Act, 1985* the definition of LD50 has been broadened. Included are all tests in which a potentially lethal dose of a substance will be administered and is expected to kill a proportion of the individuals in any group of animals to which it is given. In NSW such tests may be undertaken only under the approval of a properly constituted Animal Ethics Committee, with the concurrence of the Minister for Primary Industries. Applications for permission to conduct LD50 tests are evaluated by an ARRP subcommittee. Members of the subcommittee in 2012–13 were Mr Batten and Professor Dart. The subcommittee makes recommendations to the ARRP, which in turn advises the Minister.

In 2012–13 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 ARRP recommended to the Minister that he approve the application on the following conditions:

1) Data is provided in graphical form by 31 January 2014 with figures comparing 2011, 2012 and 2013 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 Virbac Australia Pty Ltd. 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 2014 and April 2015 must be presented by Virbac Australia Pty Ltd to the Animal Welfare Unit by 31 January 2014.

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 2014.

2.3 Assessment of changes to AEC membership

All establishments are required to advise the Animal Welfare Unit of changes to AEC membership. The ARRP 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 the *Australian Code for the Care and Use of Animals for Scientific Purposes* and ARRP Policy 9: *Criteria for Assessment of Animal Ethics Committee Membership (http://www.animalethics.org.au/policies-and-guidelines/operation/criteria-for-assessment)*.

In the 2012–13 year the ARRP assessed and made recommendations to the Director-General on the appointment of 89 members of Animal Ethics Committees.

2.4 Assessment of accreditation and licensing responses

The ARRP 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 2012–13 year the ARRP considered 45 responses from accredited animal research establishments and licensed animal suppliers.

2.5 Subcommittees

The ARRP appoints subcommittees to deal with particular issues. They explore issues in depth and have discussions with relevant members of the scientific and broader communities. Subcommittees provide reports and recommendations to the full ARRP for consideration. Membership of subcommittees is largely drawn from the ARRP. External members of subcommittees are occasionally co-opted on a voluntary basis. Activities of subcommittees in the 2012–13 year included:

- Evaluation of applications for LD50 testing (Professor Dart and Mr Batten)
- Preparation for a 2013 Animal Ethics Seminar (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 2012.

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 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. In the 2012-13 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 and researchers; 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, but has remained short for a number of years.

2.7.2 Seminar for members and executive officers of AECs and animal researchers

In the 2012-13 year, planning was well underway for a seminar for members and executive officers of AECs to be held in October 2013. In previous years the seminars were primarily attended by AEC members and AEC executive officers. It was decided by the ARRP to broaden the 2013 seminar to include animal researchers.

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 ARRP subcommittee working on this project were Professor Dart, Dr Fogarty and Mr Batten. Other members of the ARRP, 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 and the 2013 seminar can be found at the Animal Ethics Infolink website at: http://www.animalethics.org.au/animal-ethics-committees

2.8 Website: Animal Ethics Infolink

Development and maintenance of a website by the ARRP - '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 ARRP 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.animalethics.org.au .

2.9 Site inspections

A list of dates of site inspections undertaken in 2012–13 is provided in Appendix C, and a list of ARRP members attending is given in Appendix D. There were 19 establishments inspected over a period of 25 working days. The length of these inspections ranged from one day to five days.

The ARRP 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 ARRP places a major focus on reviewing the operation of AECs, to ensure that AECs, investigators and institutions understand their responsibilities under the Animal Research Act and the Code. 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 ARRP and Animal Welfare Unit produce policies, guidelines and fact sheets to aid researchers, AECs, research establishments, animal suppliers and members of the broader community to understand and comply with the requirements of the animal research legislation. These documents can be found by following the links from the ARRP's website, Animal Ethics Infolink, www.animalethics.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 ARRP.

When first published, guidelines and policies are sent out to AECs and other groups as appropriate (such as user groups and animal welfare organisations) for comment. The documents are then reviewed in the light of the comments received.

During the 2012-13 year an issue was raised with the ARRP about publication of the results of a study using baboons for shoulder surgery. As the research had occurred 20 years previously, it was decided there was no value in investigating the particular study. However, the ARRP agreed that it raised the broader issue of how AECs make judgements about the value of research, especially for projects with high impacts on the animals involved. It was decided that the development of a guideline document on this issue could be of assistance to AECs. In developing this guideline it was intended that steps would include assessing existing literature and carrying out a survey of AECs for feedback. This project was to be carried out in the 2013 -14 year.

The following policy was undergoing revision during 2012-13:

ARRP Policy 14 Acts of Veterinary Science and the Use of Restricted Drugs

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

A review of the 7th edition of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* was progressed by the NHMRC in the 2012-13 year. The 8th Edition of the Code was published in July 2013 with a name change to the *Australian Code for the Care and Use of Animals for Scientific Purposes.* The revised Code and information on changes between the 7th and 8th editions are available on the NHMRC website at: http://www.nhmrc.gov.au/guidelines/publications/ea28

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 ARRP. 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 ARRP for investigation. The ARRP is bound to investigate formal complaints and to make recommendations to the Director-General for disciplinary action (if it is considered warranted) or dismissal of the complaint. Both the complainant and the individual or institution being investigated have a right of appeal to the Administrative Decisions Tribunal.

The ARRP also has a policy of responding to informal complaints. These may involve varying degrees of investigation, from formal interviews to requests for documents or unannounced visits to animal holding facilities. Complaints may arrive from a variety of sources: the RSPCA may refer matters that fall outside its jurisdiction;

ARRP members may raise matters brought to their attention by members of the community; public concern may be expressed in the media; and complaints may be raised in direct correspondence to the Minister for Primary Industries, the ARRP, or the Animal Welfare Unit.

A summary of the complaints considered in the 2012–13 reporting period is as follows:

Lack of inspections by the Director-General's AEC

A complaint was received from an Accredited Animal Research Establishment utilising the Director-General's AEC that inspections had not been carried out sufficiently frequently by the AEC.

An assessment of the history of the monitoring of the establishment was carried out.

Advice was provided to the establishment that the ARRP and Animal Welfare Unit were aware of the constraints on the Director General's AEC in carrying out inspections of establishments that hold animals, and had therefore implemented a programme of inspections of these facilities. Reports of these inspections were provided to the Director General's AEC. This has meant that inspections of the establishment had been carried out on an approximately four yearly basis, which was in line with the frequency of inspections of other Accredited Animal Research Establishments carried out by the ARRP and the Animal Welfare Unit.

In addition, a condition had been added to the establishment's Accreditation, requiring monthly reporting on research projects to the AEC, to assist the AEC in monitoring the establishment.

It was noted that the Director General's AEC was established, under the Animal Research Act 1985, to provide a service to individuals who were not associated with Accredited Establishments. On a case-by-case basis the AEC also agreed to act as the AEC of small accredited establishments. To date there had been no requirement for any establishment to use the services of the Director-General's AEC. The decision to request the use of this service was at the discretion of the individual/establishment.

AEC approval of invasive and surgical procedures in teaching

A complaint was received that the AEC of an establishment was approving invasive and surgical procedures, including "restricted acts of veterinary science", in teaching.

After consideration of information sought from the establishment, a response was provided that the ARRP agreed in-principle with the mode of operation of approvals by the establishment's AEC, which was in accord with the operation of other AECs, including those approving teaching activities. Advice was also provided that "restricted acts of veterinary science" were not approved to be carried out at the establishment and only occurred at veterinary practices as veterinary treatment for the welfare of the animal.

AEC approval of restricted acts of veterinary science in teaching

A complaint was received that the AEC of an establishment was approving the conduct at its facilities of "restricted acts of veterinary science", such as urinary catheterisation, for teaching.

After investigation, a response was provided that such procedures were not approved by the AEC to be carried out at the establishment. It was also noted that procedures carried out as veterinary treatment for the welfare of the animal were not encompassed by the Animal Research Act 1985.

APPENDIXES

Appendix A: Dates of ARRP meetings 2012–13

Meeting number	Date of meeting
198	18 July 2012
199	26 September 2012
200	5 December 2012
201	20 February 2013
202	1 May 2013

Appendix B: Attendance of members at ARRP meetings 2012–13

	Meeting number				
Member	198	199	200	201	202
Professor Andrew Dart (Chair)	*	A	*	*	*
Dr Regina Fogarty (Deputy Chair)	*	*	A	*	*
Dr Magdoline Awad	*	A	*	*	*
Mr Peter Batten	*	A	*	A	A
Ms Celeste Black	*	A	*	*	*
Dr Mike Fleming	A	*	A	A	*
Prof Anne Keogh	*	*	*	A	*
Professor Robert Mulley	A	*	*	A	A
Mr David O'Shannessy	A	*	*	*	A
Professor Jacqueline Phillips	*	*	*	*	*
Dr Peter Rolfe	*	A	*	A	A

* = Present

A = Absent

Appendix C: Dates of Inspections July 2012 – June 2013

Date
16, 20, 23, 24, 27 July 2012
6 August 2012
2 October 2012
3 October 2012
4 October 2012
10 October 2012
15 November 2012
11 March 2013 (desk top audit)
3 May 2013
15 May 2013
27 May 2013
28 May 2013
29, 30, 31 May 2013
6 June 2013
21, 24, 25, 26, 27 June 2013

Appendix D: Attendance of ARRP members at site inspections 2012–13

Member	Number of days spent on site inspection
Professor Andrew Dart (Chair)	-
Dr Regina Fogarty (Deputy Chair)	1
Dr Magdoline Awad	1
Mr Peter Batten	1
Ms Celeste Black	1
Dr Mike Fleming	1
Professor Anne Keogh AM	4
Professor Robert Mulley	10
Mr David O'Shannessy	-
Professor Jacqueline Phillips	3
Dr Peter Rolfe	-

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

* Numbers on the right refer to items from 2012/2013 Animal Research Review Panel Operational Plan that address the strategies.

Goals and Strategies	
Goal 1: **Effective and efficient implementation of the statutory requirements of the Animal Research Act 1985, the Animal Research Regulation 2010 and the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* .**	
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
Goal 2: **The principles, processes and responsibilities in the *Australian Code of Practice for the Care and***	

Use of Animals for Scientific Purposes **are actively embraced by all involved wherever animals are used.**	
2.1 Promote an understanding of the roles and responsibilities of institutions in supporting the effective operation of their AECs.	2 3 4
2.2 Promote an understanding of the roles and responsibilities of institutions in actively pursing 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
Goal 3: **Researchers and teachers considering using animals are aware of and actively apply the principals set out in the Act, Regulation and the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*.**	
3.1 Promote an understanding of the roles and responsibilities of researchers/teachers through participation in education programmes, to foster an awareness of ethical and scientific issues and the implementation of the 3Rs.	3 4

3.2 Maintain the “Animal Ethics Infolink” website as a resource for AECs, researchers and teachers and members of the community.	3.1
Goal 4: **Methods that complement or replace animal use are used wherever possible.**	
4.1 Encourage AECs critically to assess the adequacy of researchers’/teachers’ attempts to identify alternatives to animal use.	2 3
4.2 Encourage greater awareness of the use of alternatives to animals in research and teaching.	2 3
4.3 Collate and disseminate information on alternatives to animal use.	3.1
4.4 Promote consideration of funding for development and validation of alternatives.	
Goal 5: **Procedures involving animals are regularly reviewed and refined to minimise the number of animals required and to reduce the impact on individual animals.**	
5.1 Encourage a critical review of the design of 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
Goal 6: **When animals are used in research and teaching, their well-being is promoted and there is the anticipation, prompt recognition and alleviation of pain and distress.**	
6.1 Promote the implementation of strategies which will foster the well-being of animals and which will foster the development of appropriate risk management assessments related to pain and distress in animals.	2 3 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
Goal 7: **High standards of housing and routine care are established for animals used in research and teaching.**	
7.1 Evaluate housing and routine care through the ongoing site visit programme.	2
7.2 Develop and disseminate evidence based guidelines for housing and routine care.	4
7.3 Actively participate in the development and review of appropriate national and international standards for housing and routine care.	5.1
Goal 8: **Animals used are supplied in accord with the legislation**	
8.1 Identify areas of non-compliance through scrutiny of records during site visits and investigation of complaints.	1.2 2
8.2 Develop and disseminate appropriate educational material.	3 4
Goal 9: **The community (research, teaching, veterinary, animal welfare and lay) has access to information about animal use for research and teaching in NSW.**	
9.1 Provide information in the annual report on ARRP activities and achievements, areas of concern to the Animal Research Review Panel and statistics on animal use.	1.4 1.5
9.2 Identify options for disseminating information about specific issues of interest and concern both broadly and to specific groups (researchers, teachers, veterinarians, animal welfare, lay).	3 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.	
Goal 10: **The approach to administration of animal research and teaching is harmonised between State and Territory regulatory and funding bodies.**	
10.1 Promote interaction between State and Territory regulatory and funding bodies.	

Appendix F: ARRP Operational Plan July 2012 – June 2013

Activity	Measure of Performance	Time Frame	Status
1. Mandatory			
1.1 Review incoming applications for accreditation and licence	Recommendation to Director-General	3 months (new) 2 months (renewal)	Applications processed and recommendations made to the Director-General
1.2 Investigate formal and informal complaints	Recommendation to Director-General	Interim or final recommendations within 3 months	4 complaints received. 4 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 2011-2012	Report submitted to Minister	December 2012	Report prepared.
1.5 Prepare statistics on animal use for 2011	Statistics collated	December 2012	Statistics collated.
2. Inspections			
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 25
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 2011 AEC annual reports	Assessment carried out	September 2012	2011 reports assessed and feedback provided to estabishments
3. Education			
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 package in light of researcher training material developed.	Content considered	After development of researcher training material.	Await development of researcher training package.
3.4 Plan meeting for members of AECs	Planning finalised	June 2013	Programme

			developed. Meeting to be held 2 October 2013.
4. Policies and guidelines			
4.1 Develop policies/ guidelines where strong need identified (maximum of 2)	Developed as need identified	Ongoing	Identified need to develop guideline to assist AECs in assessing research value / justification.
4.3 Revise current policies and guidelines	Continue programme of revision.	Ongoing	Policy 14 on the use of restricted drugs under revision.
5. Additional			
5.1 Continue liaison with NHMRC	Contact with NHMRC maintained	Ongoing	Invitation to present at Animal Ethics Seminar.

Appendix G: Animal use statistics 2012

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.

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 2012.

Animal species categories used for collection of data

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

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

PURPOSE
1. Stock breeding Breeding protocols to produce new teaching or research stock. Include the animals used to produce progeny and any breeders or progeny culled in the process, NOT the final progeny themselves (as these will be counted under the protocol in which they go on to be used).
2. Stock maintenance Holding protocols for animals maintained for use in other protocols. These animals may be maintained under an ethics authority because they require special management. If they are not held under an authority (e.g. normal stock animals kept mainly for commercial production, but occasionally used in research), then they are counted in the protocol only where they are used for teaching/research. *Examples:* *Fistulated ruminants that are maintained under a holding protocol for use in other short-term feeding trial protocols* *A non-breeding colony of diabetic rats held for research in other protocols*
3. Education Protocols carried out for the achievement of educational objectives. The purpose of the protocol is not to acquire new knowledge but to pass on established knowledge to others. This would include interactive or demonstration classes in methods of animal husbandry, management, examination and treatment. *Examples* *Animals used by veterinary schools to teach examination procedures such as pregnancy diagnosis*
4. Research: human or animal biology Research protocols that aim to increase the basic understanding of the structure, function and behaviour of animals, including humans, and processes involved in physiology, biochemistry and pathology.
5. Research: human or animal health and welfare Research protocols that aim to produce improvements in the health and welfare of animals, including humans.
6. Research: animal management or production Research protocols that aim to produce improvements in domestic or captive animal management or production.
7. Research: environmental study Research protocols that aim to increase the understanding of the animals' environment or its role in it, or aim to manage wild or feral populations. These will include studies to determine population levels and diversity and may involve techniques such as observation, radio-tracking, or capture and release. *Examples* *Pre-logging or pre-development fauna surveys*
8. Production of biological products Using animals to produce products other than e.g. milk, meat, eggs, leather or fur. *Examples* *Use of a sheep flock to donate blood to produce microbiological media* *Production of commercial antiserum* *Production of products, such as hormones or drugs, in milk or eggs from genetically modified animals* *Quality Assurance testing of drugs*
9. Diagnostic procedures Using animals directly as part of a diagnostic process. *Examples* *Inoculation of day-old chicks with Newcastle Disease virus to determine virulence* *Blue-green algae toxicity testing* *Water supply testing using fish*
10. Regulatory product testing Protocols for the testing of products required by regulatory authorities, such as the APVMA. **If the product testing is not a regulatory requirement (e.g. if it is part of a Quality Assurance system only), those animals should be included in the appropriate Purpose category selected from above.** (This would normally be Purpose Category 8 in the case of QA testing.) *Examples* *Pre-registration efficacy or toxicity testing of drugs and vaccines*

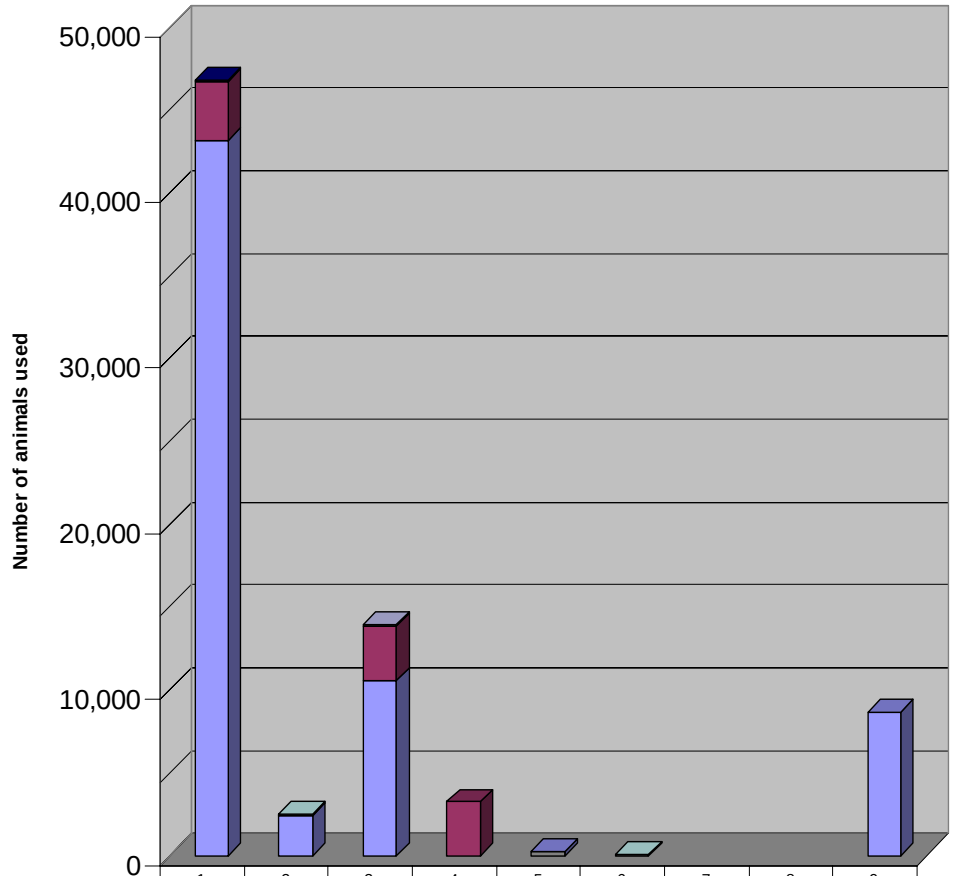
Data collection: procedure categories and guidelines used for classification

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

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

Purpose: Stock Breeding

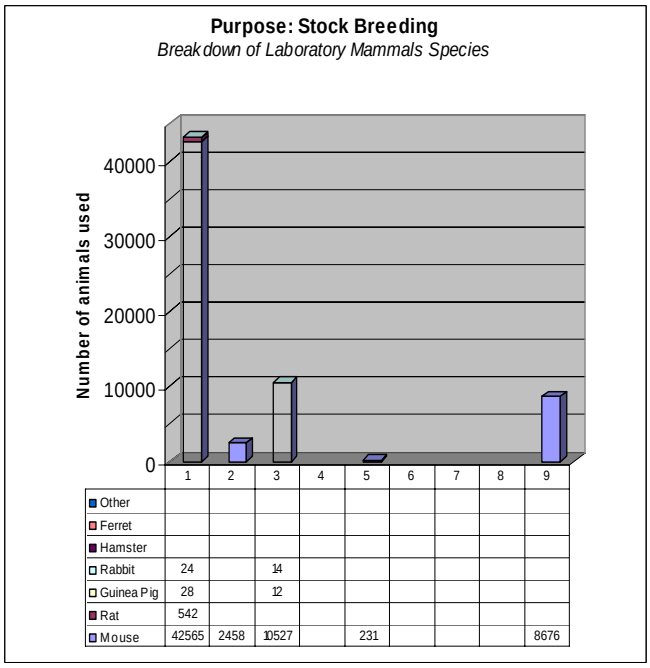
Breeding protocols to produce new teaching or research stock.
Only includes the animals used to produce progeny, NOT the final progeny.

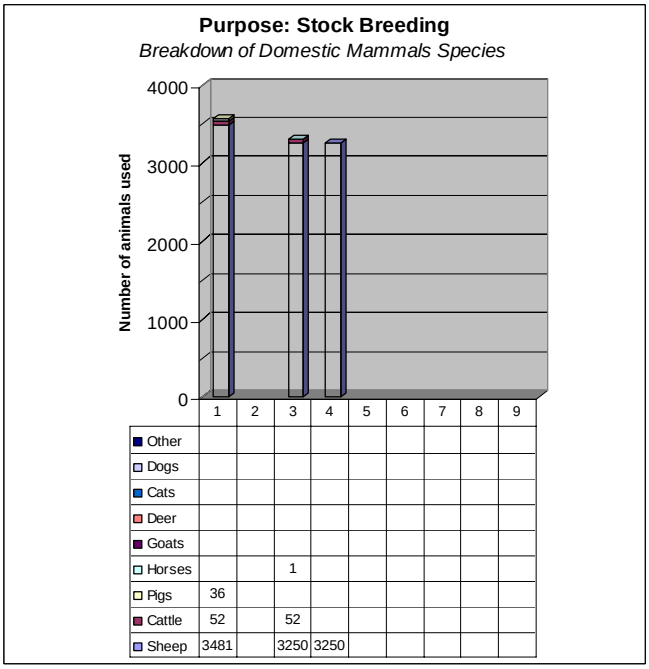


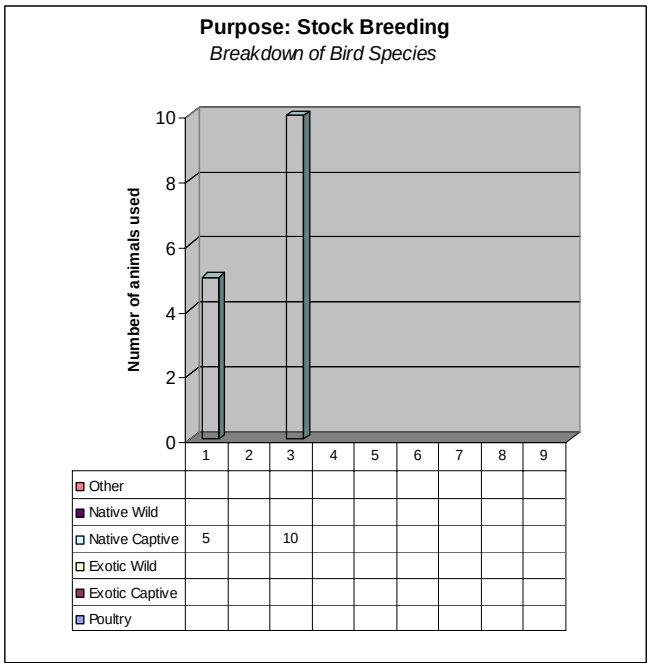
	1	2	3	4	5	6	7	8	9
Exotic Zoo									
Exotic Feral	24								
Nat Mam	66		29						
Primates									
Reptiles			75						
Amphibians			10						
Aquatic		20				50			
Birds	5		10						
Domestic	3569		3303	3250					
Lab Mam	43159	2458	10553		231				8676

Procedure

Refer to following page for a further breakdown of species.

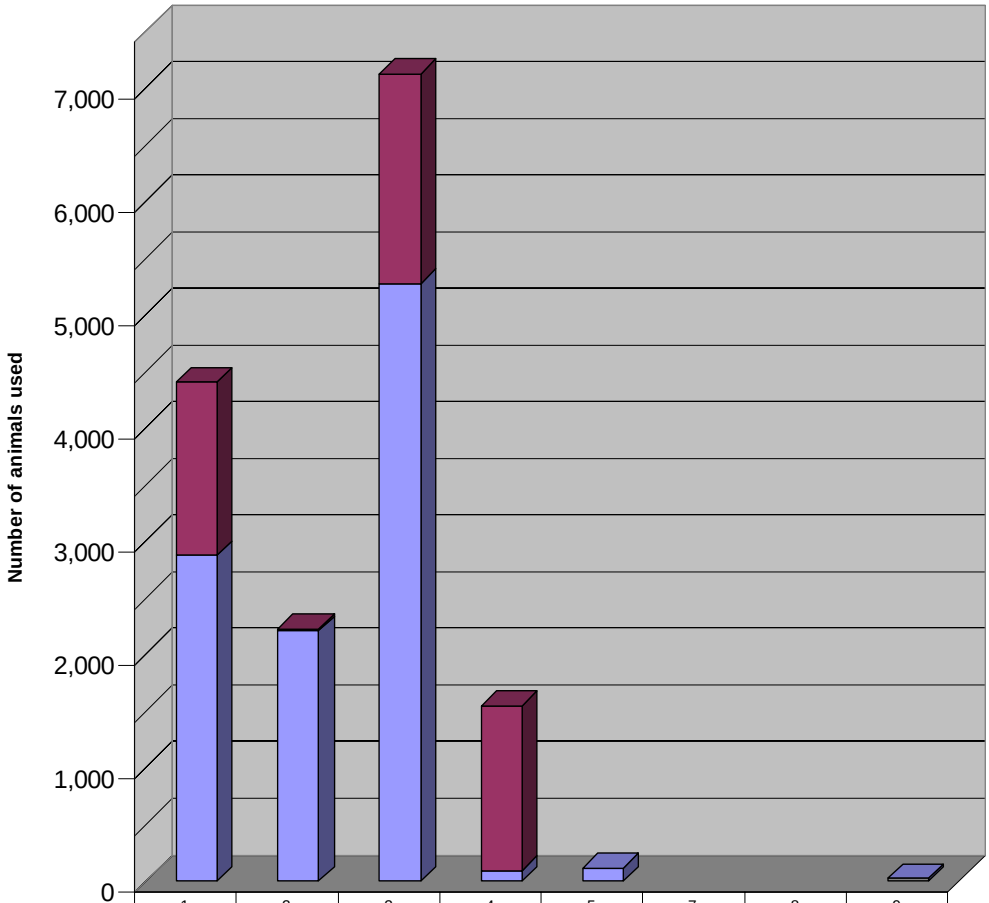

Purpose: Stock Breeding
Breakdown of Laboratory Mammals Species
Number of animals used
40000
30000
20000
10000
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit 24 14
Guinea Pig 28 12
Rat 542
Mouse 42565 2458 10527 231 8676


Purpose: Stock Breeding
Breakdown of Domestic Mammals Species
Number of animals used
4000
3000
2000
1000
0
1 2 3 4 5 6 7 8 9
Other
Dogs
Cats
Deer
Goats
Horses 1
Pigs 36
Cattle 52 52
Sheep 3481 3250 3250


Purpose: Stock Breeding
Breakdown of Bird Species
Number of animals used
10
8
6
4
2
0
1 2 3 4 5 6 7 8 9
Other
Native Wild
Native Captive 5 10
Exotic Wild
Exotic Captive
Poultry

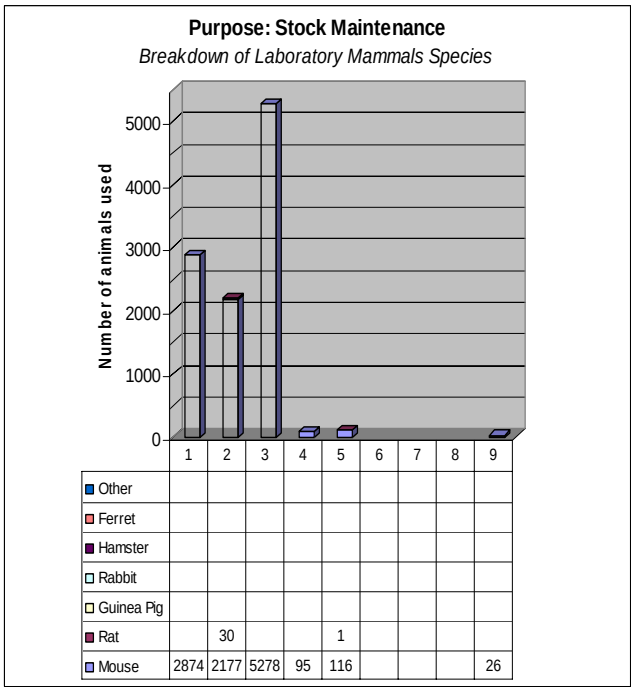
Purpose: Stock Maintenance

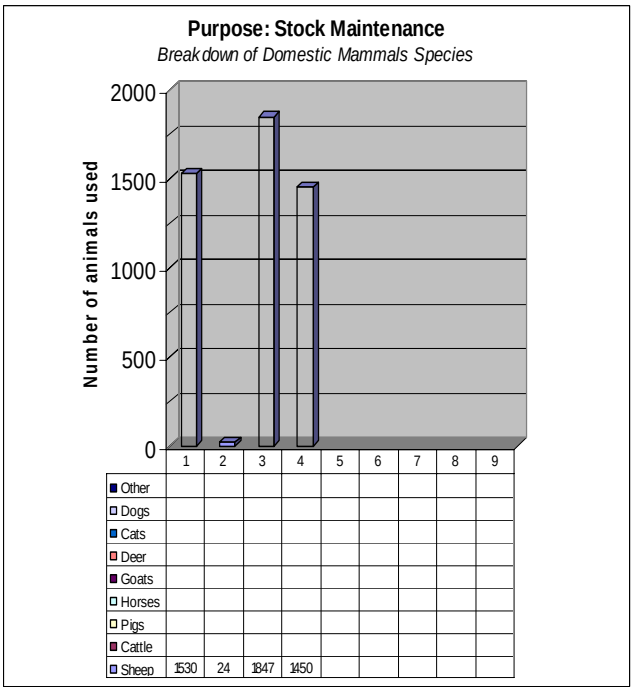
Holding Protocols for animals maintained for use in other protocols .



	1	2	3	4	5	7	8	9
Exotic Zoo								
Exotic Feral								
Nat Mam								
Primates								
Reptiles								
Amphibians								
Aquatic								
Birds								
Domestic	1530	24	1847	1450				
Lab Mam	2874	2207	5278	95	117			26

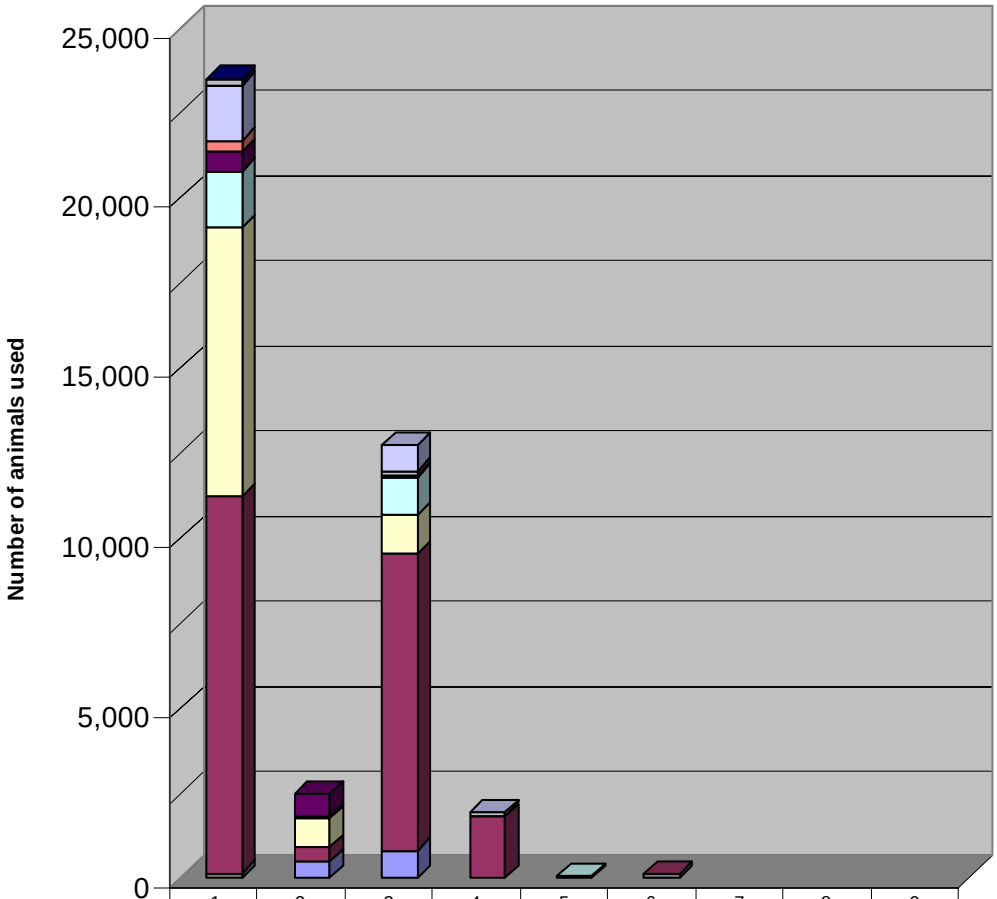
Refer to following page for a further breakdown of species.


Purpose: Stock Maintenance
Breakdown of Laboratory Mammals Species
Number of animals used
5000
4000
3000
2000
1000
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit
Guinea Pig
Rat 30 1
Mouse 2874 2177 5278 95 116 26


Purpose: Stock Maintenance
Breakdown of Domestic Mammals Species
Number of animals used
2000
1500
1000
500
0
1 2 3 4 5 6 7 8 9
Other
Dogs
Cats
Deer
Goats
Horses
Pigs
Cattle
Sheep 1530 24 1847 1450

Purpose: Education

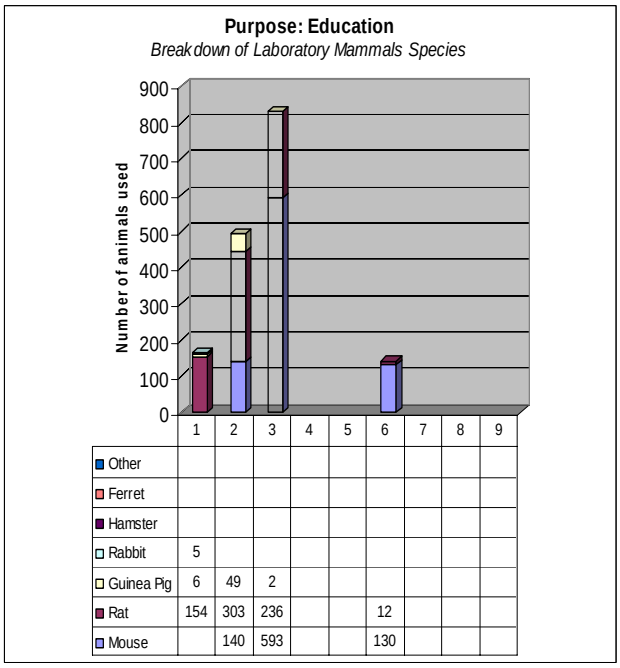
Protocols carried out for the achievement of educational objectives, including interactive or demonstration classes in methods of animal husbandry, management, examination and treatment.

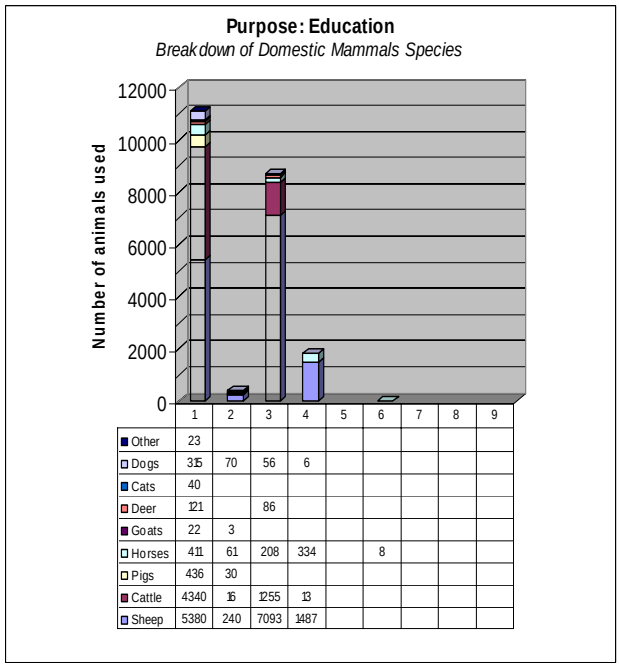


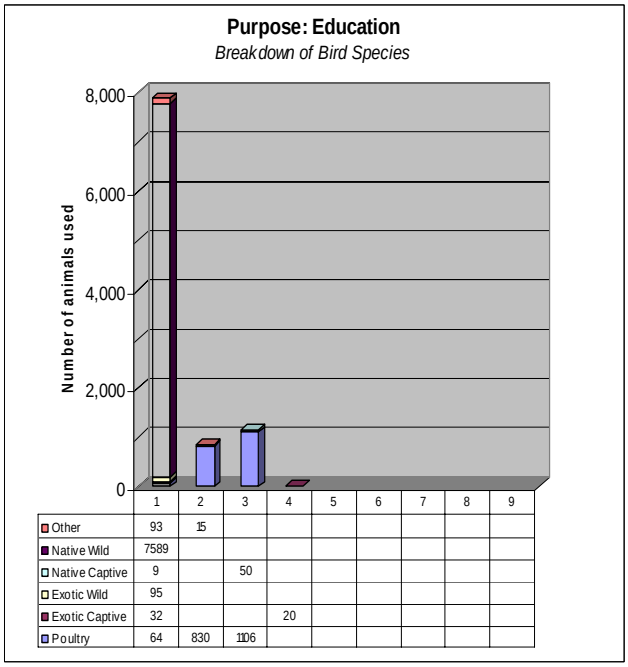
	1	2	3	4	5	6	7	8	9
Exotic Zoo									
Exotic Feral	179								
Nat Mam	1636		744	7					
Primates									
Reptiles	328		119						
Amphibians	581	651	60	6					
Aquatic	1655	84	1124	74	69				
Birds	7,882	845	1156	20					
Domestic	11088	420	8698	1840		8			
Lab Mam	165	492	831			142			

Procedure

Refer to following page for a further breakdown of species.

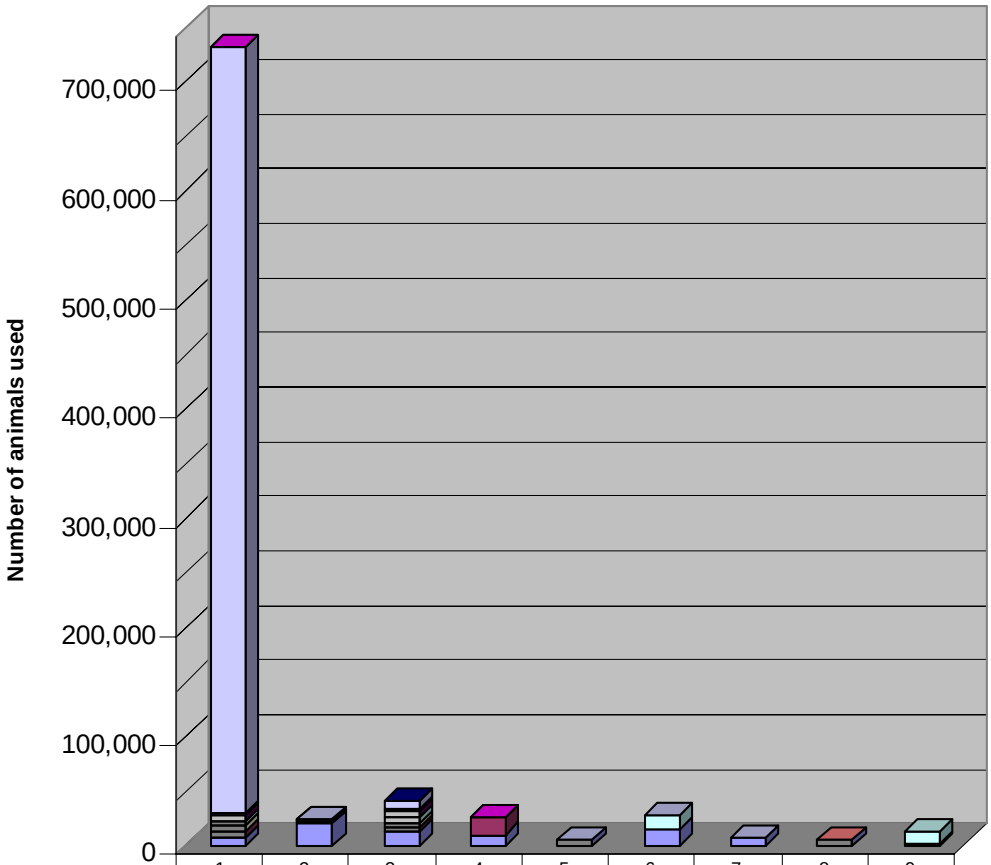

Purpose: Education
Breakdown of Laboratory Mammals Species
Number of animals used
900
800
700
600
500
400
300
200
100
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit 5
Guinea Pig 6 49 2
Rat 154 303 236 12
Mouse 140 593 130


Purpose: Education
Breakdown of Domestic Mammals Species
Number of animals used
12000
10000
8000
6000
4000
2000
0
1 2 3 4 5 6 7 8 9
Other 23
Dogs 315 70 56 6
Cats 40
Deer 121 86
Goats 22 3
Horses 411 61 208 334 8
Pigs 436 30
Cattle 4340 16 1255 13
Sheep 5380 240 7093 1487


Purpose: Education
Breakdown of Bird Species
Number of animals used
8,000
6,000
4,000
2,000
0
1 2 3 4 5 6 7 8 9
Other 93 15
Native Wild 7589
Native Captive 9 50
Exotic Wild 95
Exotic Captive 32 20
Poultry 64 830 1106

Purpose: Research - Human or Animal Biology

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

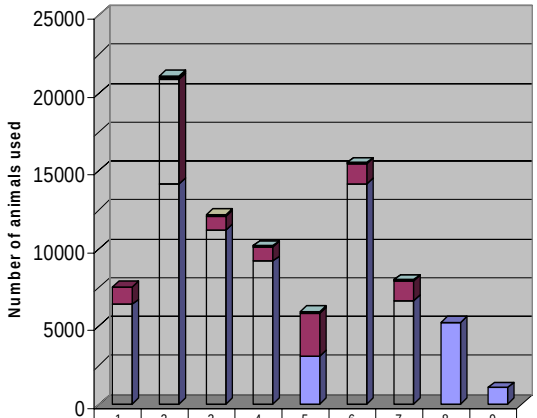


	1	2	3	4	5	6	7	8	9
Exotic Zoo	1			14					
Exotic Feral	84		367						
Nat Mam	701978	68	6218	59	81	20	43		
Primates		8		5	3				
Reptiles	1200	381	2589	54		372		30	
Amphibians	6432	90	4961		43	430			
Aquatic	3302	1623	5681	81		11816			11127
Birds	6011		4958	100		144			
Domestic	5239	123	3944	15272	234				
Lab Mam	7575	21075	12193	10169	5961	15509	8004	5266	1086

Refer to following page for a further breakdown of species.

Purpose: Research - Human or Animal Biology

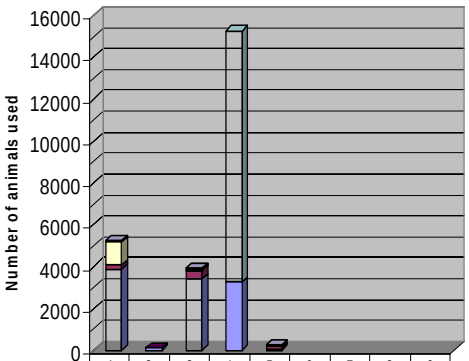
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit		48		59	72	70	21		
Guinea Pig		94	67						
Rat	1161	6723	880	915	2776	1230	1312		
Mouse	6414	14210	11246	9195	3113	14209	6671	5266	1086

Purpose: Research - Human or Animal Biology

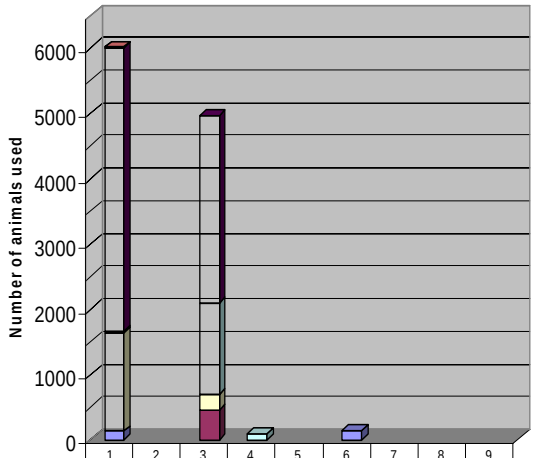
Breakdown of Domestic Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Dogs	52		65		10				
Cats	9								
Deer									
Goats	18	4	18						
Horses			9	12008	18				
Pigs	1100		40	2	27				
Cattle	170		400		103				
Sheep	3890	119	3412	3262	76				

Purpose: Research - Human or Animal Biology

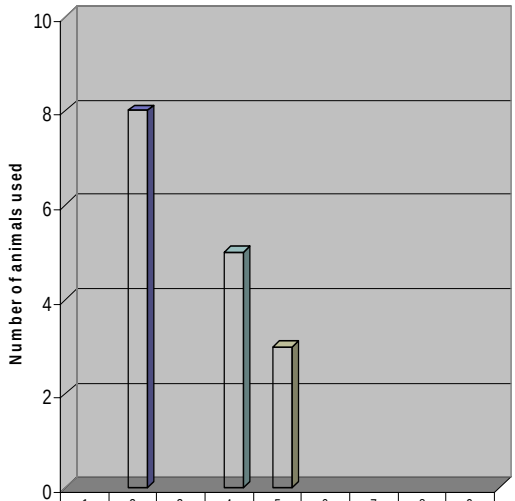
Breakdown of Bird Species



	1	2	3	4	5	6	7	8	9
Other	11								
Native Wild	4342		2862						
Native Captive	24		1398	100					
Exotic Wild	1506		253						
Exotic Captive			445						
Poultry	128					144			

Purpose: Research - Human or Animal Biology

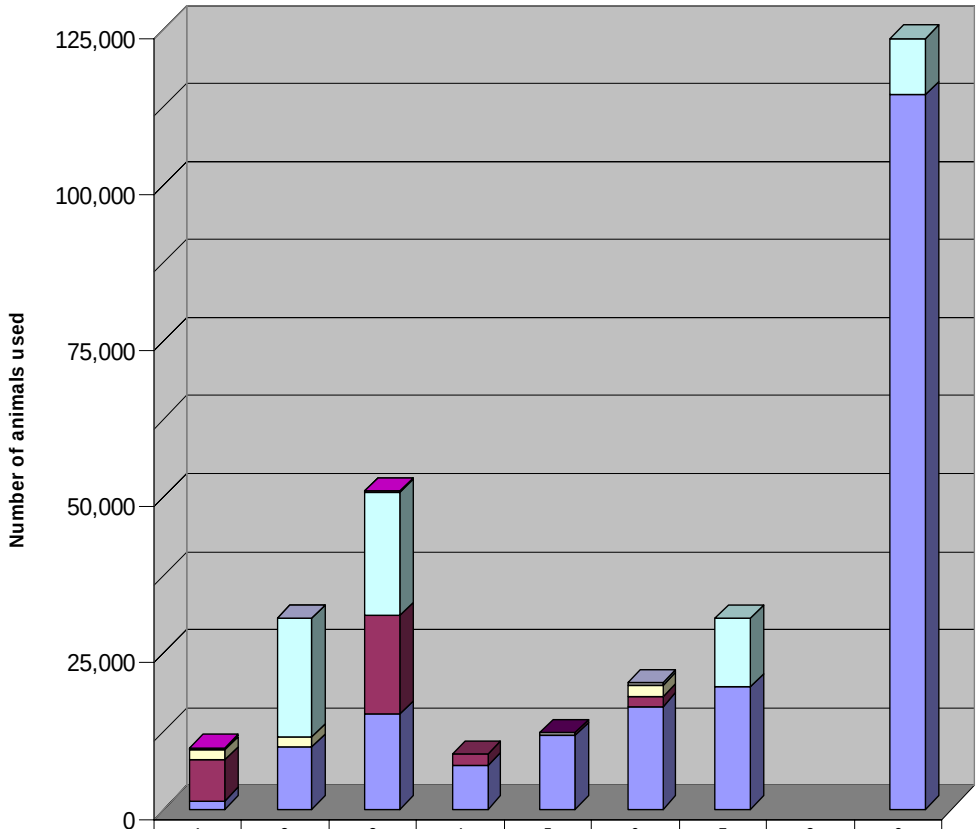
Breakdown of Primate Species



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

Purpose: Research - Human or Animal Health & Welfare

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



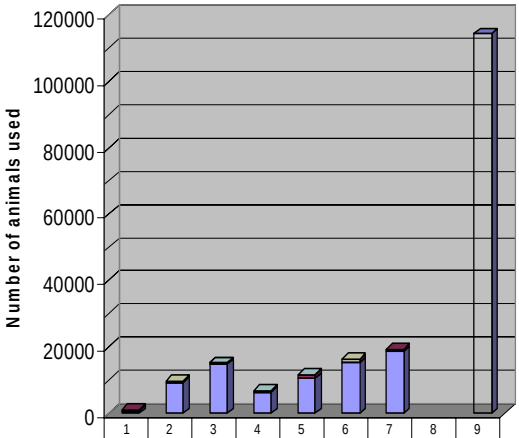
	1	2	3	4	5	6	7	8	9
Exotic Zoo	28		24						
Exotic Feral	183								
Nat Mam	124	2	33			5			
Primates									
Reptiles			41						
Amphibians		16			49				
Aquatic	69	18956	19707			535	11009		9083
Birds	1477	1528	42			1748			
Domestic	6612	41	15718	1689	413	1533	6		
Lab Mam	1336	9963	15292	7054	11745	16472	19509		114333

Procedure

Refer to following page for a further breakdown of species.

Purpose: Research - Human or Animal Health & Welfare

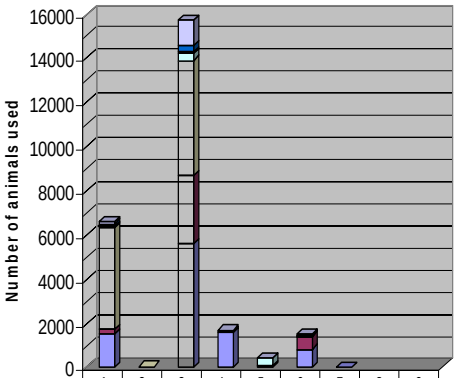
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit			2	3	31				
Guinea Pig		38	189	125		94			
Rat	552	510	312	339	1119	1053	802		
Mouse	784	9415	14789	6587	10595	15325	18707		114333

Purpose: Research - Human or Animal Health & Welfare

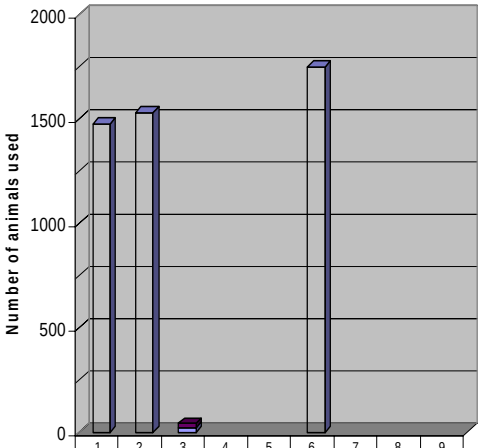
Breakdown of Domestic Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Dogs	123		1179	32	2	90			
Cats	105		264	13					
Deer									
Goats			89						
Horses	42		306	46	350	23			
Pigs	4630	41	5220	8	55	24			
Cattle	210		3079	34		569			
Sheep	1502		5581	1556	6	827	6		

Purpose: Research - Human or Animal Health & Welfare

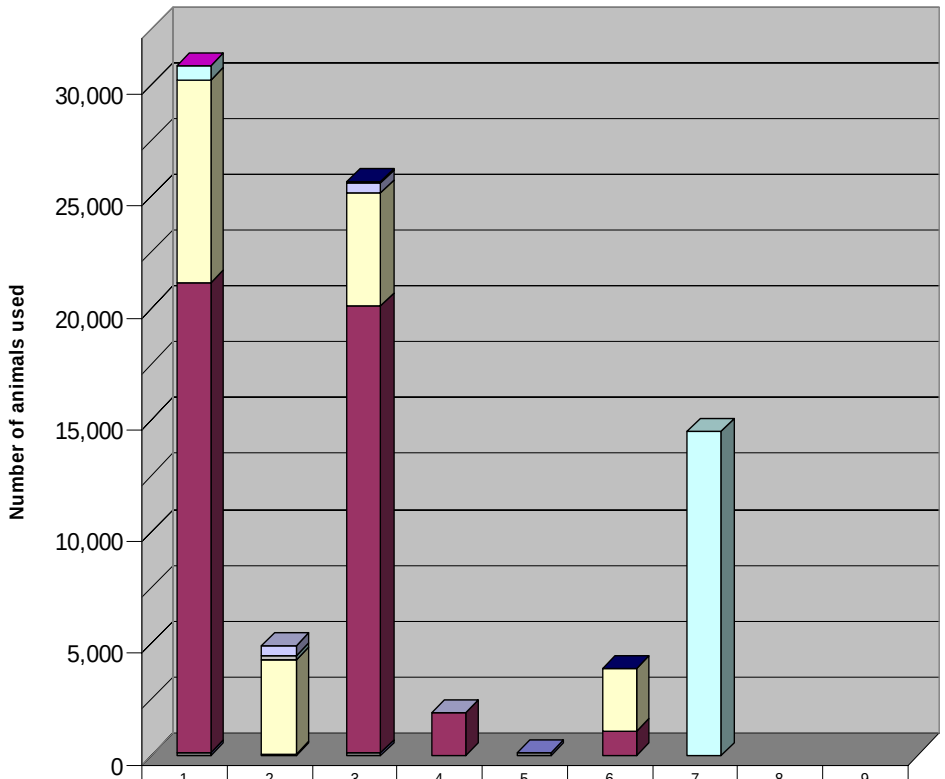
Breakdown of Bird Species



	1	2	3	4	5	6	7	8	9
Other									
Native Wild			18						
Native Captive									
Exotic Wild									
Exotic Captive									
Poultry	1477	1528	24			1748			

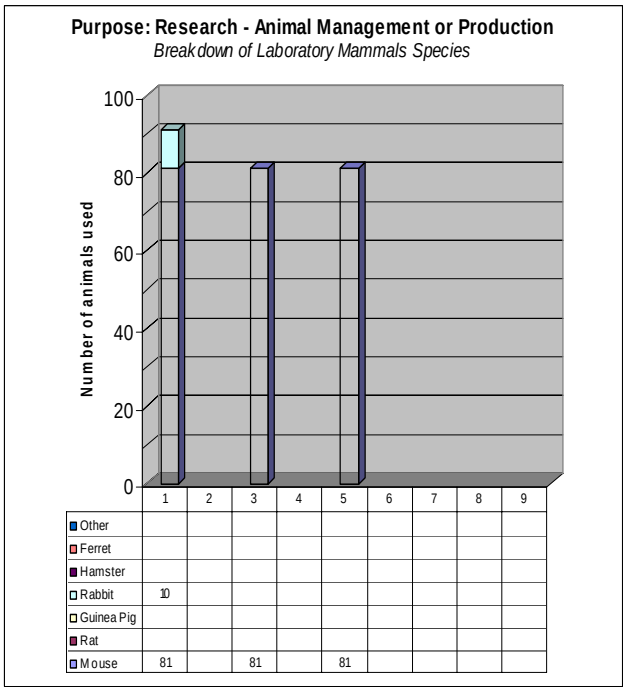
Purpose: Research - Animal Management or Production

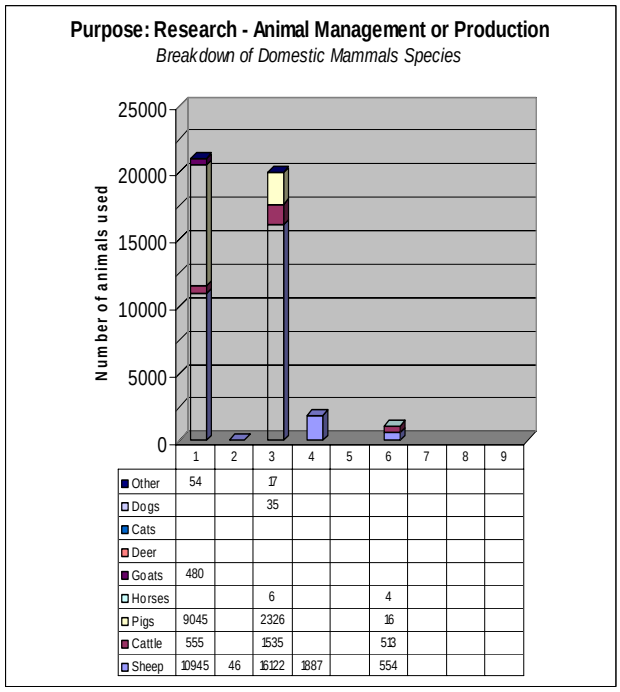
Research protocols which aim to produce improvements in domestic or captive animal management or production .

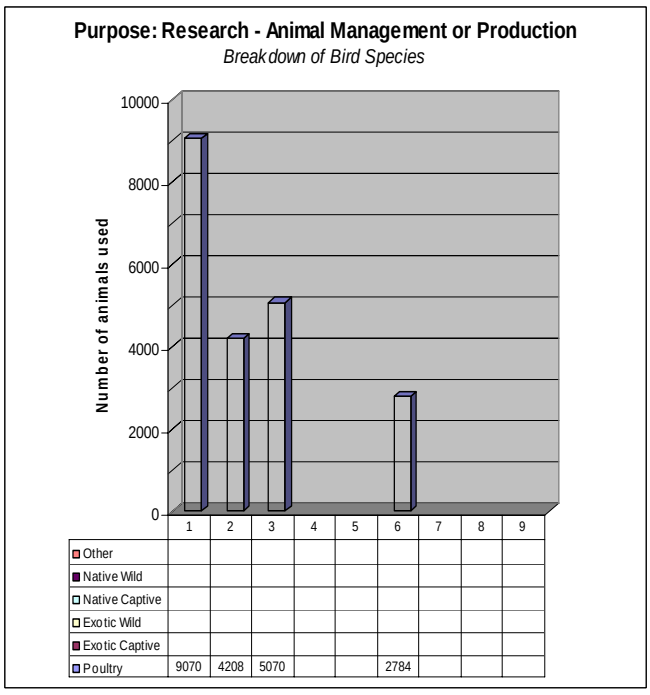


	1	2	3	4	5	6	7	8	9
Exotic Zoo	3								
Exotic Feral			97			15			
Nat Mam		436	402	1					
Primates									
Reptiles									
Amphibians									
Aquatic	620	202		27			14503		
Birds	9070	4208	5070			2784			
Domestic	21079	46	20041	1887		1087			
Lab Mam	91		81		81				

Refer to following page for a further breakdown of species.

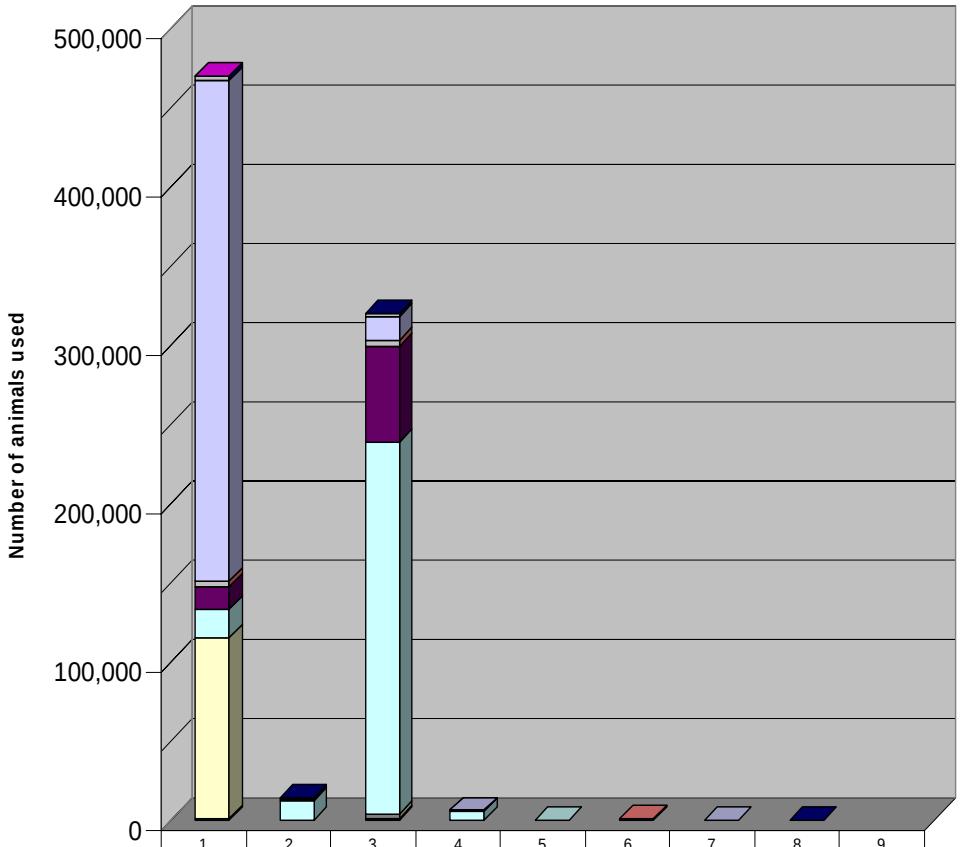

Purpose: Research - Animal Management or Production
Breakdown of Laboratory Mammals Species
Number of animals used
100
80
60
40
20
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit 10
Guinea Pig
Rat
Mouse 81 81 81


Purpose: Research - Animal Management or Production
Breakdown of Domestic Mammals Species
Number of animals used
25000
20000
15000
10000
5000
0
1 2 3 4 5 6 7 8 9
Other 54 17
Dogs 35
Cats
Deer
Goats 480
Horses 6 4
Pigs 9045 2326 16
Cattle 555 1535 513
Sheep 10945 46 16122 1887 554


Purpose: Research - Animal Management or Production
Breakdown of Bird Species
Number of animals used
10000
8000
6000
4000
2000
0
1 2 3 4 5 6 7 8 9
Other
Native Wild
Native Captive
Exotic Wild
Exotic Captive
Poultry 9070 4208 5070 2784

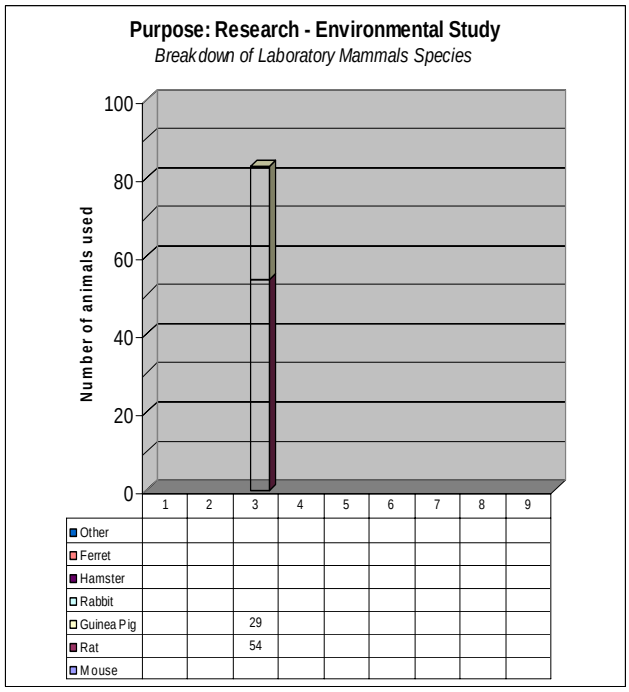
Purpose: Research - Environmental Study

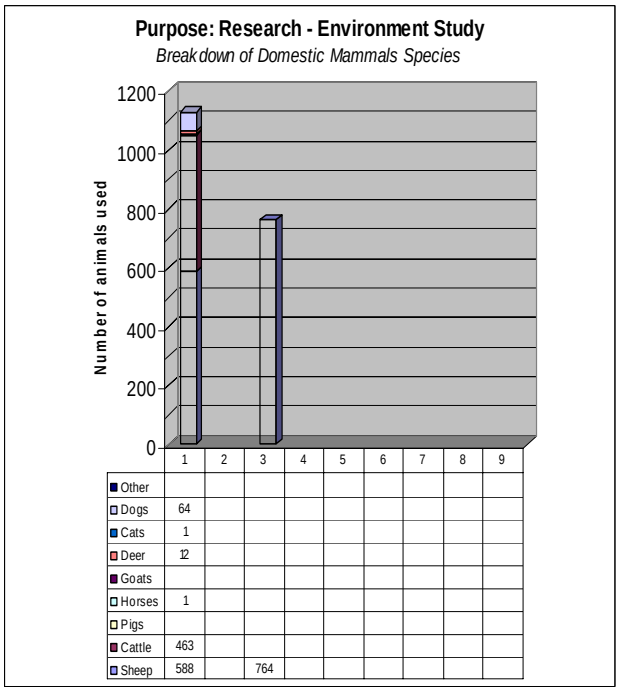
Research protocols which aim to increase the understanding of the animals' environment or its role in it, or that aim to manage wild or feral populations .

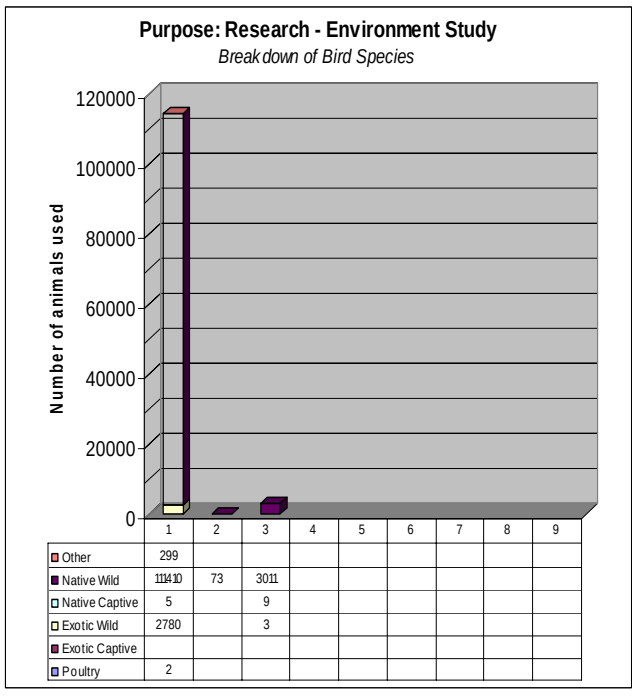


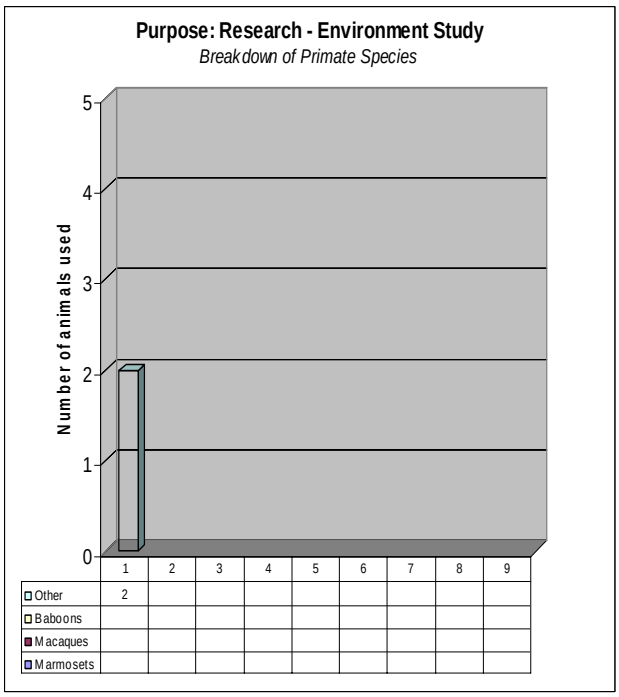
	1	2	3	4	5	6	7	8	9
Exotic Zoo	1								
Exotic Feral	2534	377	2343					110	
Nat Mam	316486	436	14966	702			69		
Primates	2								
Reptiles	3754	25	4034	4		160	64		
Amphibians	13780	373	59935						
Aquatic	17857	12745	235388	5687	483	1036		581	
Birds	114496	73	3023						
Domestic	1129		764						
Lab Mam			83						

Refer to following page for a further breakdown of species.


Purpose: Research - Environmental Study
Breakdown of Laboratory Mammals Species
Number of animals used
100
80
60
40
20
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit
Guinea Pig 29
Rat 54
Mouse

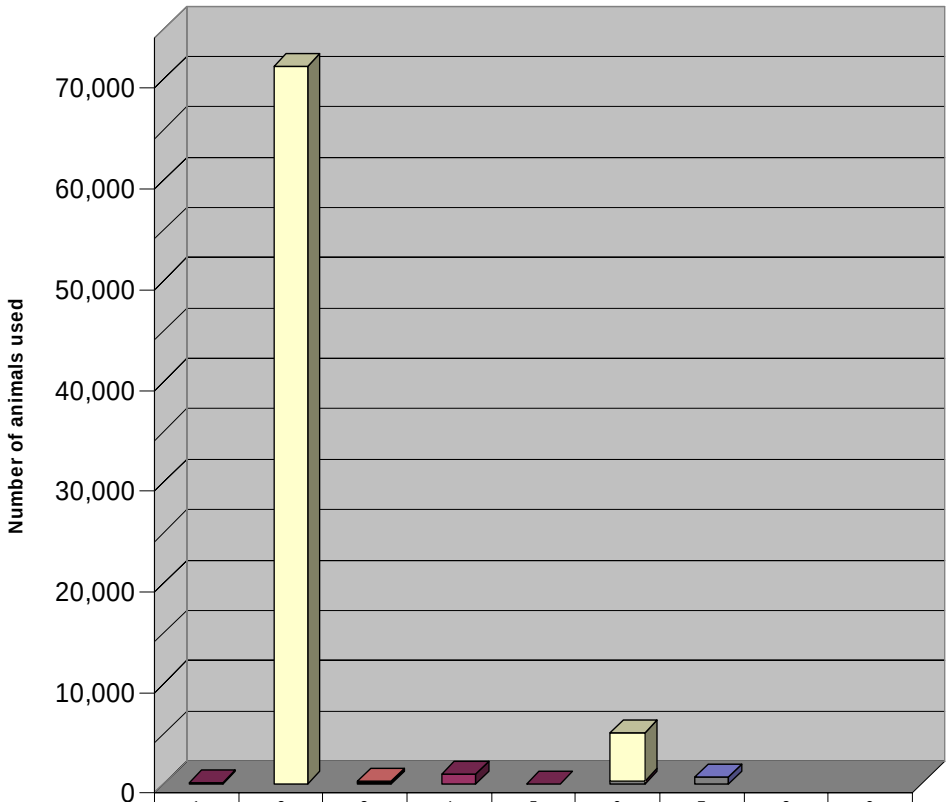

Purpose: Research - Environment Study
Breakdown of Domestic Mammals Species
Number of animals used
1200
1000
800
600
400
200
0
1 2 3 4 5 6 7 8 9
Other
Dogs 64
Cats 1
Deer 12
Goats
Horses 1
Pigs
Cattle 463
Sheep 588 764


Purpose: Research - Environment Study
Breakdown of Bird Species
Number of animals used
120000
100000
80000
60000
40000
20000
0
1 2 3 4 5 6 7 8 9
Other 299
Native Wild 111410 73 3011
Native Captive 5 9
Exotic Wild 2780 3
Exotic Captive
Poultry 2


Purpose: Research - Environment Study
Breakdown of Primate Species
Number of animals used
5
4
3
2
1
0
1 2 3 4 5 6 7 8 9
Other 2
Baboons
Macaques
Marmosets

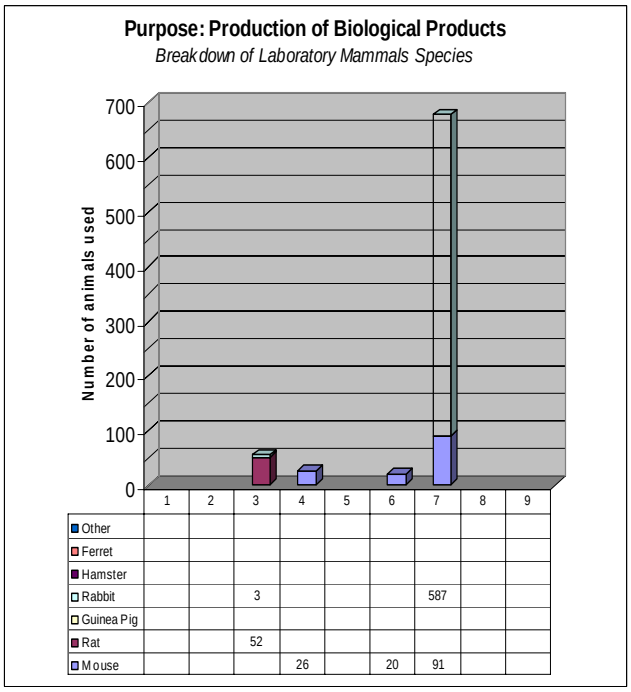
Purpose: Production of Biological Products

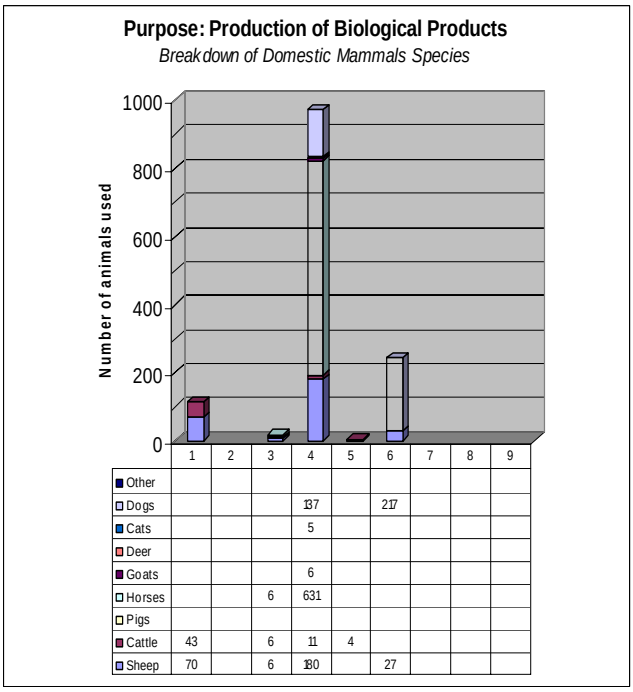
Use of animals to produce products (other than normal milk/meat/egg, etc).

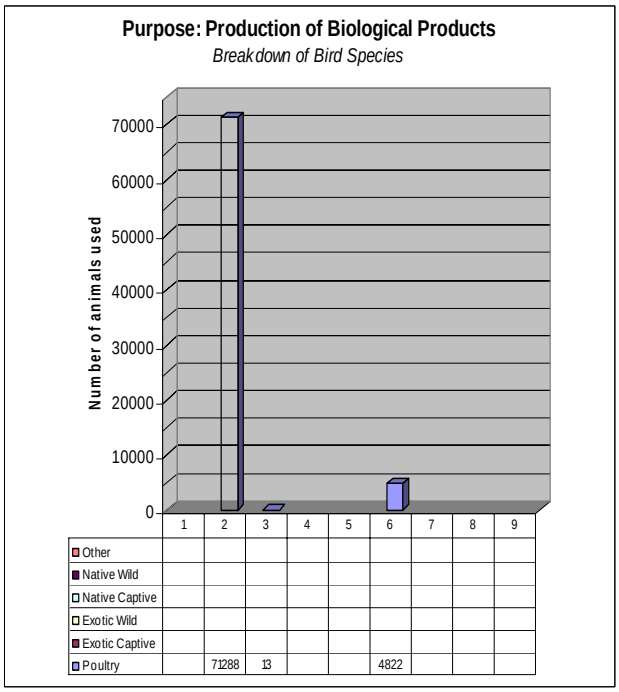


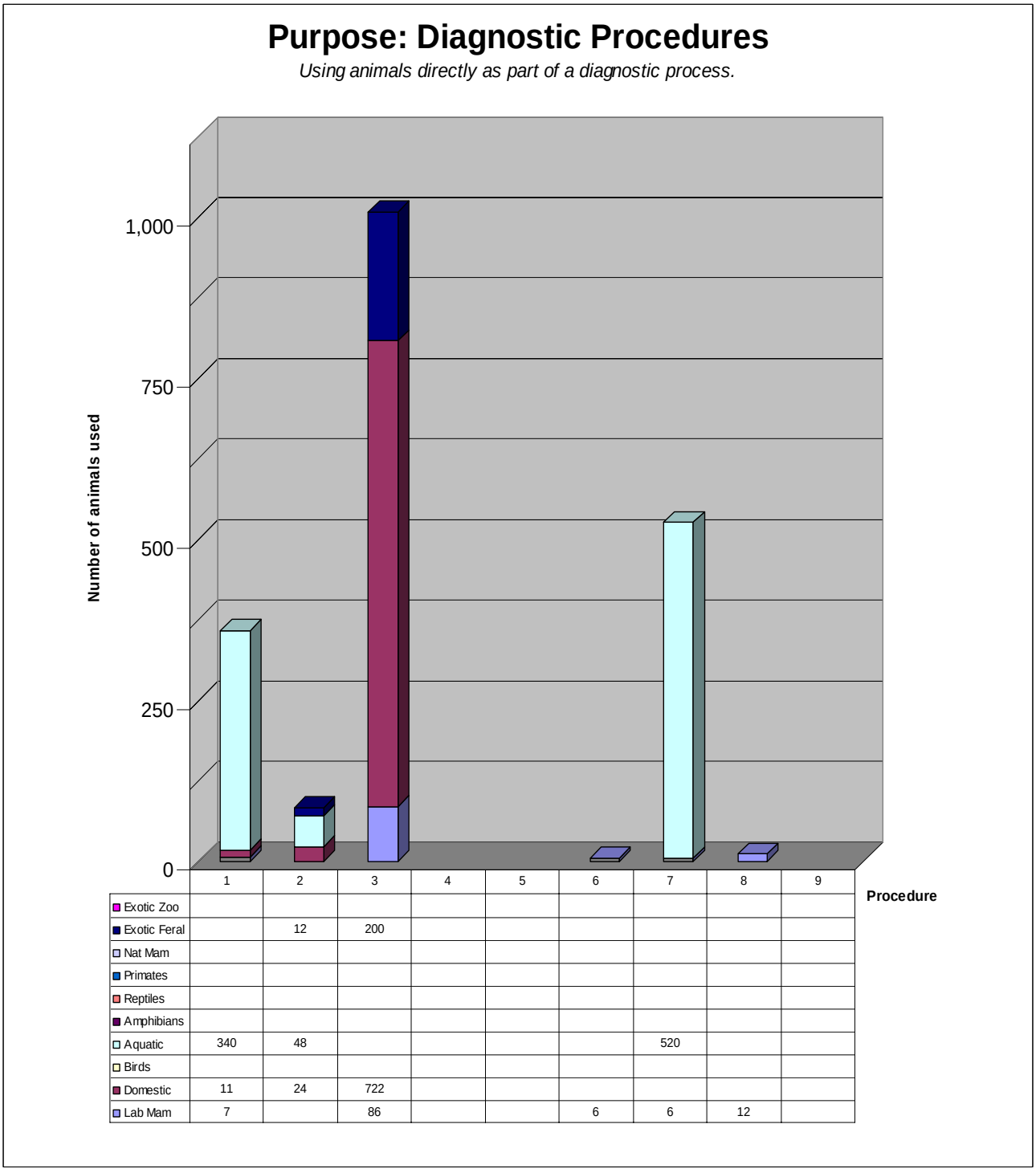
	1	2	3	4	5	6	7	8	9
Exotic Zoo									
Exotic Feral									
Nat Mam									
Primates									
Reptiles			168						
Amphibians									
Aquatic									
Birds		71288	13			4822			
Domestic	113		18	970	4	244			
Lab Mam			55	26		20	678		

Refer to following page for a further breakdown of species.

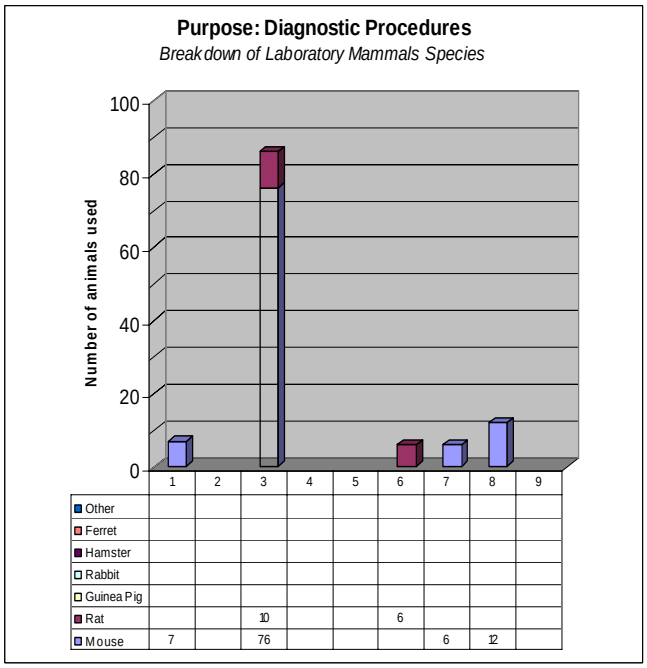

Purpose: Production of Biological Products
Breakdown of Laboratory Mammals Species
Number of animals used
700
600
500
400
300
200
100
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit 3 587
Guinea Pig
Rat 52
Mouse 26 20 91

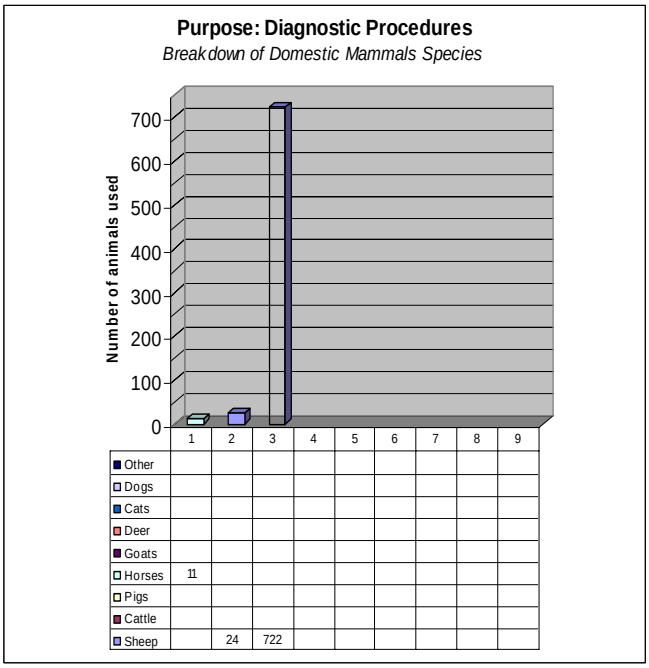

Purpose: Production of Biological Products
Breakdown of Domestic Mammals Species
Number of animals used
1000
800
600
400
200
0
1 2 3 4 5 6 7 8 9
Other
Dogs 137 217
Cats 5
Deer
Goats 6
Horses 6 631
Pigs
Cattle 43 6 11 4
Sheep 70 6 180 27


Purpose: Production of Biological Products
Breakdown of Bird Species
Number of animals used
70000
60000
50000
40000
30000
20000
10000
0
1 2 3 4 5 6 7 8 9
Other
Native Wild
Native Captive
Exotic Wild
Exotic Captive
Poultry 71288 13 4822



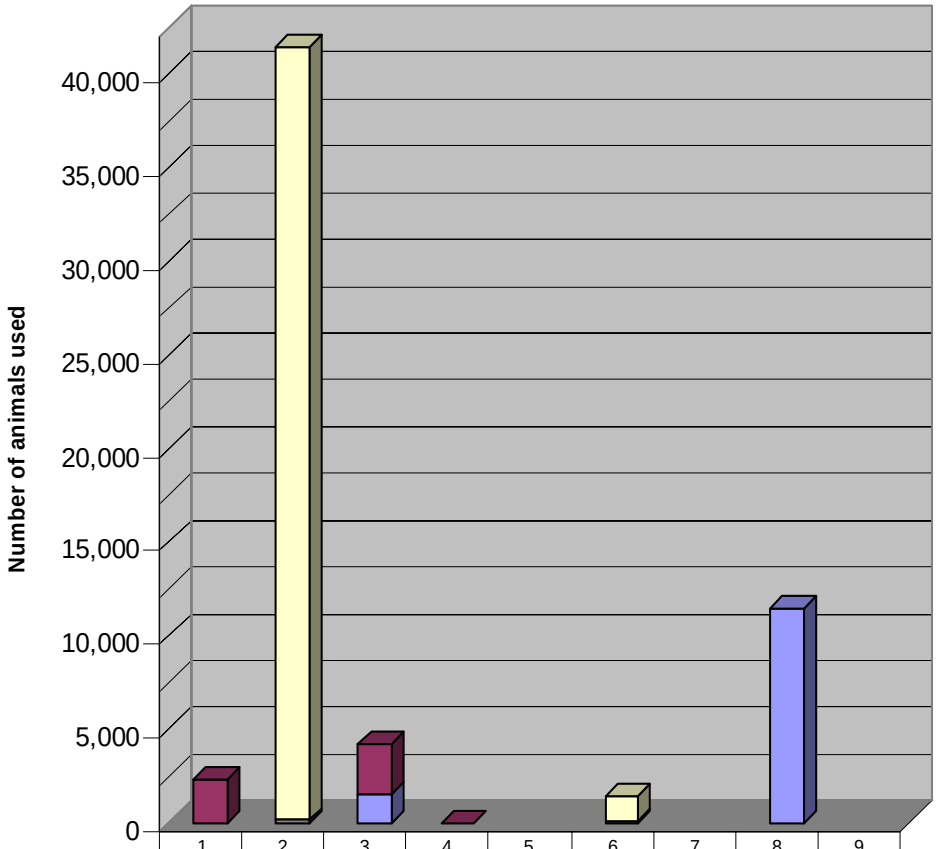
Refer to following page for a further breakdown of species.


Purpose: Diagnostic Procedures
Breakdown of Laboratory Mammals Species
Number of animals used
100
80
60
40
20
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit
Guinea Pig
Rat 10 6
Mouse 7 76 6 12


Purpose: Diagnostic Procedures
Breakdown of Domestic Mammals Species
Number of animals used
700
600
500
400
300
200
100
0
1 2 3 4 5 6 7 8 9
Other
Dogs
Cats
Deer
Goats
Horses 11
Pigs
Cattle
Sheep 24 722

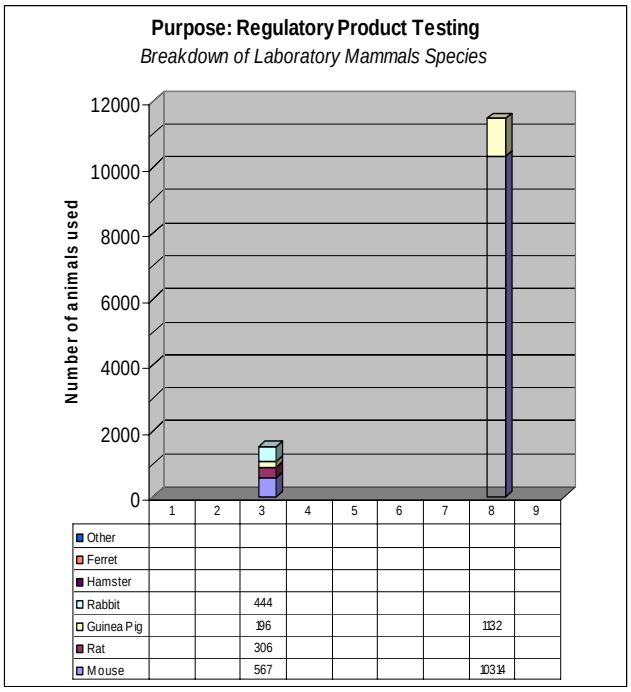
Purpose: Regulatory Product Testing

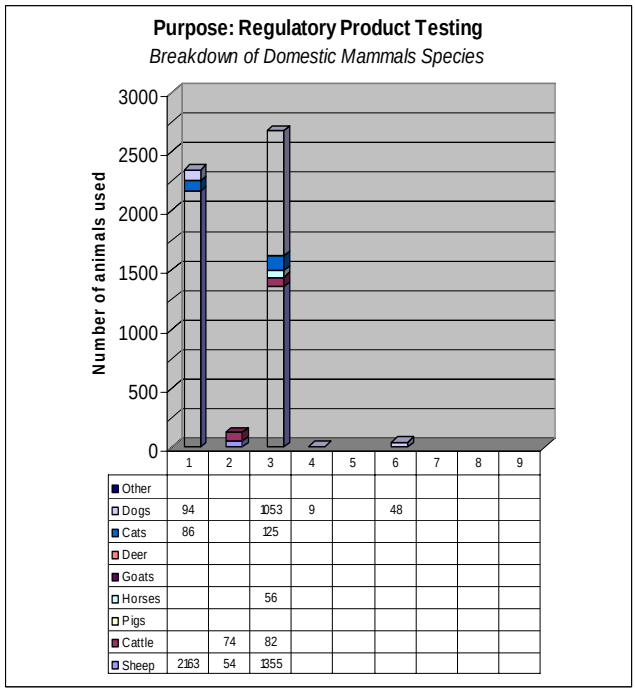
Protocols for the testing of products required by regulatory authorities.

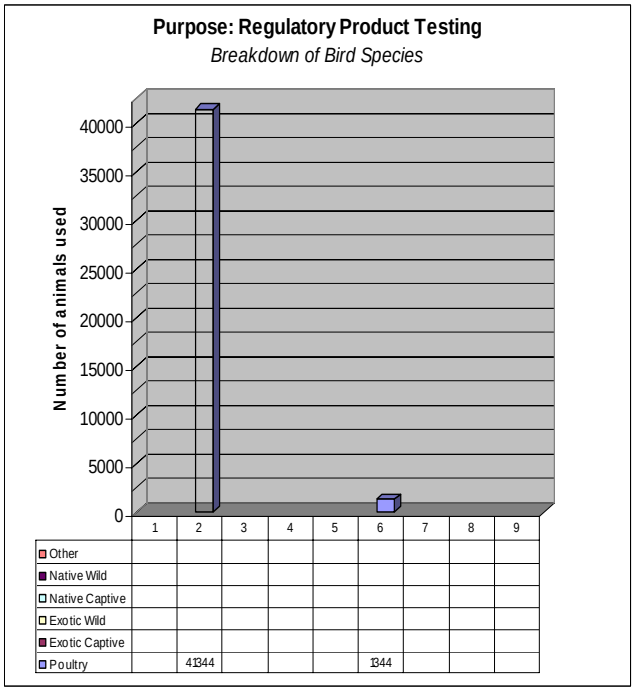


	1	2	3	4	5	6	7	8	9
Exotic Zoo									
Exotic Feral									
Nat Mam									
Primates									
Reptiles									
Amphibians									
Aquatic									
Birds		41344				1344			
Domestic	2343	128	2671	9		48			
Lab Mam			1513					11446	

Refer to following page for a further breakdown of species.


Purpose: Regulatory Product Testing
Breakdown of Laboratory Mammals Species
Number of animals used
12000
10000
8000
6000
4000
2000
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit 444
Guinea Pig 196 1132
Rat 306
Mouse 567 10314


Purpose: Regulatory Product Testing
Breakdown of Domestic Mammals Species
Number of animals used
3000
2500
2000
1500
1000
500
0
1 2 3 4 5 6 7 8 9
Other
Dogs 94 1053 9 48
Cats 86 125
Deer
Goats
Horses 56
Pigs
Cattle 74 82
Sheep 2163 54 1355


Purpose: Regulatory Product Testing
Breakdown of Bird Species
Number of animals used
40000
35000
30000
25000
20000
15000
10000
5000
0
1 2 3 4 5 6 7 8 9
Other
Native Wild
Native Captive
Exotic Wild
Exotic Captive
Poultry 41344 1344

LETHALITY TESTING – 2012

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 2012.

Species	No. used	No. died/ euthanased	Procedure	Justification	Alternatives
Mice	3,748	1,817	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 of further manufacture.	No alternatives available at this time.
Mice	4,778	1,524	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.	The test is based on regulatory guidelines. No alternatives available at this time.
Mice	1,568	799	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	220	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.
Guinea Pigs	1,132	272	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.
Mouse	157	157	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	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	No alternatives exist, which effectively mimic the mucosal and tissue barriers as well as a functioning immune system observed in live mammals.

			knock out strain and the parental wild type strain in an animal model. We subscutaneously infected groups of 10 mice with knock out and wild type strains and monitored mice deaths over a course of 10 days to assess the contribution of the knocked out gene product to the virulence of *S. pyogenes*. At the end of the 10 day experiment, all remaining mice were euthanased. In order to assess the efficacy of novel therapeutic treatments, we infect mice then implement various treatment programs to compare the effectiveness of treatments to protect animals from a virulent bacterial challenge.	(ie mice). Additionally, the development of any new therapeutics for the treatment of bacterial infections must be able to demonstrate efficacy in appropriate animal models of disease.	
Mouse	79	79	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 parental wild type strain in an animal model. We subscutaneously infected groups of 10 mice with knock out and wild type strains and monitored mice deaths over a course of 10 days to assess the contribution of the knocked out gene product to the	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 development of any new therapeutics for the treatment of bacterial infections must be able to demonstrate efficacy in appropriate animal models of disease.	No alternatives exist, which effectively mimic the mucosal and tissue barriers as well as a functioning immune system observed in live mammals.

			virulence of *S. pyogenes*. At the end of the 10 day experiment, all remaining mice were euthanased. In order to assess the efficacy of novel therapeutic treatments, we infect mice then implement various treatment programs to compare the effectiveness of treatments to protect animals from a virulent bacterial challenge.		
Mice	122	122	The mice were infected with the rodent malaria parasite at the dose 1x103 infected red blood cells by intraperitoneal injection. Signs for disease develop between 7 to 10 days post inoculation. Mice which developed signs of severe anaemia (increase breathing) or neurological signs (fitting, coma) or which were unable to right themselves at physical checks three times daily were euthanized by cervical dislocation. Some animals die between checks. Surviving animals are retained for breeding and genotyping.	This project aims to uncover why children in endemic areas die from malaria infection while other survive. Using a murine model of malarial infection, we are aiming to uncover the host genetics contribution to malaria resistance. Four cohorts of mutant mice were used to investigate the role of a red blood cell enzyme or platelets, as these mutant mice have shown a slight increase in resistance to cerebral malaria. There were no survivors.	Unfortunately, there is no other existing model to replace the need to carry out the malaria infections in mice, although our group is utilising cutting-edge sequencing technologies and combining multiple experiments to reduce the number of mice to infect with the malaria parasite.
Mice	20	20	Half of the mice were injected with a novel antimalarial compound (the dose was determined an in vitro malarial culture system) and the other mice with a placebo. The mice were then infected with the rodent malaria parasite Plasmodium chabaudi at the dose 1x103 infected red blood cells by intraperitoneal	Malaria is a devastating disease, killing around 3 million people a year. In the past, we have entertained relative protection through the use of anti-malarial drugs and preventive strategies. However, the parasite causing malaria, *Plasmodium falciparum,* has unfortunately learned resistance to these drugs, rendering them ineffective in protecting us from this killer. This project aims to uncover novel antimalarial compounds to combat this deleterious	Unfortunately, there is no other existing model to replace the need to carry out the malaria infections in mice, although every dug we are testing are investigated first in a *P.falciparum* malaria culture system to only select for an in-vivo testing the compounds that showed efficacy.

			injection. Signs for disease develop between 7 to 10 days post inoculation. Mice which developed signs of severe anaemia (increase breathing) or neurological signs (fitting, coma) or which were unable to right themselves at physical checks three times daily were euthanized by cervical dislocation. Some animals die between checks. No animals survived this test.	disease.	
Mice	5,032	4,927	Approximately 200 ENU affected breeding males produced 5032 weaned progeny. These were infected with the rodent malaria parasite at the dose 1x103 infected red blood cells by intraperitoneal injection. Signs for disease develop between 7 to 10 days post inoculation. Mice which developed signs of severe anaemia (increase breathing) or neurological signs (fitting, coma) or which were unable to right themselves at physical checks three times daily were euthanized by cervical dislocation. Some animals die between checks. 105 Surviving animals are retained for breeding and genotyping.	Malaria is a disease that kills more than 1 million children annually. In endemic areas, some people die from malaria while others survive the infection. Unfortunately, we still know little about the mechanisms underlying the host resistance to malaria infection. In order to better understand this complex phenomenon, we have performed a large-scale ENU (N-Ethyl-N-Nitrosourea) dominant mutagenesis screen for genes that when mutated, render normally susceptible mice resistant to malaria. From this screen we have discovered genes controlling haematological and immunological pathways that are novel determinants in the host response to malaria infection. The major goals of this project are to 1) determine the biological basis of the resistance-causing mutations, and 2) validate the genes as potential antimalarial targets.	Unfortunately, there is no other existing model to replace the need to carry out the malaria infections in mice, although our group is utilising cutting-edge sequencing technologies and combination with other experiments to reduce the number of mice to infect with the malaria parasite.

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 2012 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
The establishment has maintained an ongoing program aimed at rationalising testing which has focussed on eliminating Quality Control testing which is not essential to meet product release requirements. This program covers both lethal and non-lethal testing. In addition, in all cases where clear test outcomes are not obtained upon initial testing, a critical assessment is made to confirm the necessity to perform repeat testing before re-testing occurs. It should however be noted that whilst progress has been made in this regard, there remains a minimum amount of testing necessary to meet regulatory requirements for the assessment of in-process and final product prior to release. Increasing emphasis is being placed by the establishment on the development of in-vitro testing to reduce the use of animals for our vaccine testing. The establishment is relocating a PhD scientist from its head office to run our in-vitro programme and she will start work in January 2013. To support her, the establishment has built a new laboratory and expended considerable capital on equipment. We presented our in-vitro strategy to the APVMA last year and it was met with full support. We believe the planned programme of work will take 5 years. Applications will be made to the APVMA when new assays have been developed and validated. The establishment's in-vitro programme will focus on not just reducing the number of mice that are currently used to titrate rabbit antibody responses but a programme that will target all species. Obviously the role of the APVMA will be crucial in approving in-vitro potency tests hence we will work with them very closely.
We have increased the use of in vitro studies to reduce animal numbers and plan to introduce cell line experiments that may enable further reductions in animal requirements.
We have only proposed *in vivo* studies where we could not find alternatives: we have searched the databases and have been able to refine techniques and reduce animal numbers by replacing some *in vivo* work with *in vitro* assays. Specifically we have developed *in vitro* models for the analyses of T cell proliferation, monitoring the effect of cytokines on the acquisition of effector function in T cells and specific cytokine production in response to antigen.
Replacement strategies included: • The use of in-vitro assays, which enabled the researchers to restrict the use of animals to experiments for which animal use was necessary. This included the use of new cell lines which reportedly reduced the numbers of mice used by approximately 10% • The use of computer based experiments, specifically on the Guinea Pig Ileum. The researchers retained a 50:50 balance between computer based and tissue based experiments. • Abattoir-sourced cow ovaries were obtained on several occasions to test various experimental conditions.
On-going techniques to minimise the impact on animals in teaching include: • Use of cadavers – leg parts of horses sourced from local abattoir for use in shoeing and/or hoof health in equine studies. • Mannequins, audio-visual materials, taxidermed and preserved specimens were used as substitutes for live animals • Ear-tagging of sheep is practiced on cardboard and leather • Injection pads used to practise medication injection for a range of species. • Replicating the taking of blood by catheter using sponges and red cordial

• Faux fur remnants used to practise clipping. Viewing of YouTube clips for demonstration of practices eg clipping.
The establishment implemented the use of a rodent training manikin for handling and procedures of an animal model prior to students working with animals.
The AEC invited Prof of Alternatives to Animal Research Brett Lidbury of Medical Advances Without Animals (MAWA) to speak at their April 2012 meeting. Prof Lidbury spoke about MAWA and options available to replacing animals as research models. At the end of 2012 the AEC began to consider appointing Prof Lidbury to the Committee as a member or as an advisor on alternatives.
A researcher of the molecular parasitology group has been establishing a cell culture system mimicking sheep gut in which the effects of parasite/cell interactions can be studied. This ability to model gut in vitro is replacing animal experimentation, and complements ongoing animal experimentation on parasite resistance.
A comprehensive review of safety data in the public domain and a Category 25 submission to APVMA were conducted. Based on the review, we requested the study design to be non-terminal and only to investigate IV administration as “worst case scenario” and representative of IM administration for systemic toxicity. This was agreed. Therefore, scientific review replaced the need for terminal study design and further groups of dogs for IM administration investigation.
With the increased availability of computer simulations, the university is moving away from the traditional model of having students individually dissect an animal. The current model is for undergraduate students to access a computer/video demonstration, with a hands-on aspect of learning how to correctly handle an animal.
Where living and function tissue is required for physiology/pharmacology courses, animal experimentation is kept to an absolute minimum by complementing experiments with computer simulations. For example, students study propagation on live sciatic nerve effects on muscle and this is complemented with a computer simulation on the ionic events that underlie nerve impulse generation and propagation. Autonomic control now is illustrated by means of a computer simulation which completely replaces studies using freshly isolated guinea pig ileum. The use of live animals is only approved when the experimentation is critical to achieve the learning objectives of the subject by teaching the truly-experimental nature of the discipline, but this work also provides an opportunity for a discussion with students on the ethical considerations of using animals for research.
Cell lines are used for parts of some projects but cannot be used for all studies as they do not always adequately reflect the function of primary cells in tissues.
Artificial rats (e.g Koken rats) may be used by students to practice IV injections into the tail or gavaging. For surgical training, suturing techniques may be practised on non-animal models.(e.g neoprene on cork blocks) before proceeding to culled animals.
Training: Use of electronic aids, inanimate objects, simulation. Computer simulation can be used for training for some procedures e.g. training in aseptic technique.
The use of cell culture experiments where possible to study mechanisms such as astrocytic function in neuronal life and death as an alternative approach to the use of experimental injury in live animals. Thus animals are only used as a source of brain tissue to establish different cultures.
Developing ‘in vitro’ assays to replace ‘in vivo’ testing in animal models. Eg: virus neutralisation assay in mice will be replaced by an ‘in vitro’ laboratory assay for clostridial antigens.
The establishment has been proactively working with regulatory agencies to remove batch release testing required for veterinary vaccines, based on overseas leads.
Use of audio-visual material such as videos, slides, interactive computer programs; Use of abattoir specimens and cadavers; Use of plant tissue as a replacement for animal tissue for certain enzymatic assays; Use of animals killed in road accidents.
Use of computer simulation in teaching subject in place of rats and cats.

Use of road kill in first year practicals Use of fish from fish market in teaching and existing fur pelts for heat transference models.
Where possible. Staff will replace the use of live animals with video or synthetics / cadaver models or by creating computer models.
Reduction
Power analyses are frequently submitted as part of the applications, sometimes at the request of the Animal Ethics Committee, which demonstrate how researchers and teachers calculate the most suitable numbers of animals required to give valid data.
Routine husbandry procedures to be performed on animals coordinated with teaching activities. Sharing of tissue among researchers. Obtaining more data from the use of fewer animals by combining objectives. Close scrutiny of the numbers of animals requested in applications and progress reports to the Committee.
Studies designed to fulfil multiple regulatory requirements to reduce study duplicity for various markets. Biometrician is always involved in the determination of animal numbers required for each study.
In some instances sharing of tissues and samples can increase the sample size in the experiment without increasing animal use. Control groups can be dropped where identical control mice are required for multiple experiments performed concurrently. For example in muscle function studies, animals killed are shared between researchers within the research group and as many as four different experiments can be conducted on muscles from any one animal. The research group always forward plan experimental work to maximise the use of any one animal.
Animal tissues are stained by different methods so that they can be used for separate studies of the central auditory system. Moreover, tissue is collected from the entire brain so that different auditory structures are preserved. This technique reduces the number of animals needed because much data can be gathered from individual animals. The data from these mice will then be used to provide summaries of observations and to enhance future experimental design. The techniques involved in the refinement of our experimental procedures will not only make our experiments more efficient but will contribute to the reduction of animal use for experimentation
The animal numbers used are the minimum required to achieve statistical significance. Furthermore we will collect several tissues from the same animal and try to use them in as many studies as possible. This should help reduce the total number of animals needed for these studies. Additionally every effort has been made to design a study where animals will span several areas of the study (i.e. overlap)
We house mice in groups of 3-5 as far as possible. Cohorts of mice will be used to study in vivo glucose homeostasis prior to tissue collection or islet isolation to study primary islet/beta cell function in vitro: therefore we have refined our studies to use the same mice for both in vivo and in vitro/ex vivo work.
The use of transplant techniques for many of our experiments greatly reduces the number of mice used for studies; transplants are generally more reproducible than transgenics and thus require fewer mice to reach statistically significant findings. Furthermore, breeding of transgenics and knockouts generates large numbers of mice with the incorrect genotype that are simply euthanized; to obtain females carrying 3 trangenes for example, only 6.25% of offspring carry all 3 genes. In comparison, transplantation allows the generation of the exact number and type of transgenic for a given study. Transplantation also only generates a single tumour focus, whereas tumour-susceptible GM mice can often generate multiple tumours, including in critical (and cryptic) organs such as the blood system, lungs and liver, with associated toxicities. 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 number required.
Ex-breeder mice will be used for anatomy studies.
In order to achieve maximal pregnancy rates and so reduce the number of animals used, we will use the Lee-Boot Effect and Whitten Effect. That is, female mice will be housed in groups to synchronise their oestrus cycle (Lee-Boot) and male mouse dirty bedding will be added to their cage prior to mating to ensure oestrus is induced (Whitten). In addition, female mice that do not become pregnant will be re-mated.

Use of the same background strain of all knockout mice in our laboratory means that all knockouts can be compared to the same group of wild type animals. This reduces the number of wild type animals we need to study.
The imaging arm of this study allows us to minimise animal use because each animal is its own control. Cells will be taken from one heart and subjected to two treatment protocols enabling intra-subject comparison, a more powerful statistical test than inter-subject testing.
In the hind limb and wound healing models, each mouse serves as its own control (*e.g.*, sham hind limb, control wound) thereby reducing animal numbers.
Use will be made of “Fishnet”, a virtual atlas of zebrafish development, accessible online, this reduces the need for histology studies of wildtype animals.
We have aimed to reduce the number of mice used by designing experiments that maximises the type of data generated (eg by analysing several parameters simultaneously by two-photon microscopy, micro-CT, histology and serum markers of osteoclastic activity) and the quality of the data (to avoid unnecessary repetition of experiments). We have also reduced mouse numbers used by first optimising our experimental protocols.
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.
In-vitro simulation of the equine metabolism of designer anabolic steroids using horse liver.
One study utilised real-time bioluminescence imaging that allowed the same group of mice to be imaged over time (n = 10 mice) to measure tumour growth inside the body. This removed the need to perform time course experiments requiring large numbers of mice where groups of mice are euthanased at specific time points to obtain an experimental outcome (n = 10 mice x the number of time points).
Through refinement of the experimental protocol, a reduction of the amount of liver tissue required in the experimental protocols has been possible. This has allowed the number of animals used to be reduced by half in recent years. Based on previous refinement of protocols, this allowed the minimal numbers of wild caught fish to be used in experimentation.
Video techniques were utilised to reduce the number of fishes humanely collected, which has allowed the researchers to expand the validity of the study (and include a temporal element) Furthermore, instead of utilising all species proposed, the researchers have been able to refine the project to focus on two of the most common species.
The number of potential animals trapped was reduced by limiting the number of trapping sessions to the smallest number possible.
Due to the fact that the incidence of diabetes in the colony remains consistent, this has allowed researchers to accurately use as low a number as possible to attain significant protection data. Many cell types as possible are harvested from individual mice to ensure multiple experiments are not required to gather immunological data.
Researchers are discussing alternative methods of protein isolation with collaborators such that fewer mice can be used to recover enough protein for global proteomic analysis
An improved statistical modelling design of residue studies resulted in achieving a 50% reduction in animal use for a particular well designed study. This model may be used for future studies.
As a result of discussions and consultation with the AEC regarding the Annual Protocol ‘Use of animals for staff training’ the selection of animals used for staff training takes into account procedures required in other studies, eg blood sampling, fecal sampling, slaughtering, etc. Provision is made, where possible and under supervision, to use selected study animals for training purposes. This has resulted in a reduced number of animals used in this Annual Protocol.
Tissue sharing among researchers.
Transfer of excess rats from one project to another.

Careful selection of the species chosen for study with the aim of reducing variability and reducing animal numbers.
The use of pilot studies which led to the modification of subsequent experiments to maximise the amount of information from the least number of animals.
Different flocks of chickens were observed on Norfolk Island; at least one representative from each major flock was sampled and in most cases several from each flock. As all flocks were well represented, the maximum number of animals, therefore, did not need to be sampled.
Use of chick embryos for preliminary studies allowed the modification of studies to be conducted in hatchlings and a significant reduction in the number of animals used.
Animal tissues that were used for histopathology or gene expression analysis were archived for further analysis and allowed the researchers to reduce the number of experiments.
Animal tissue obtained were analysed by a battery of techniques to obtain the maximum information as possible.
The researchers modified the experimental techniques; therefore, reduced the number of animals required for certain experiments.
Some noted efficient tissue collection and minimisation of errors during the whole experiment resulted in a reduction of animals used.
The use of one control group being used for several simultaneous experiments reduced animal numbers.
A number of researchers reported using statistics to reduce the number of animals for study to the minimum number that would provide scientifically significant results.
Expansion of experimental design allowed for inclusion of multiple hypothesis testing within the same cohort of animals resulting in the use of significantly less animals than the number approved by the ethics committee.
In the initial design of the experiments, care was taken to ensure the minimum number of animals was used in each group to obtain statistically significant results. The use of the opposite leg in the same mouse as a non-treatment control halves the number of mice required for the experiment.
The minimum number of animals to meet APVMA guidelines is always used. A number of GLP and efficacy trials have been shared this year in order to reduce the total number of sheep required. Whenever residue trials are conducted it is our policy to reduce the number of sheep euthanized towards the end of the trial by having results provided by the laboratory in a timely manner so that the trial can be cancelled if the requirements are met before the next group of sheep are euthanised for sampling.
On-going techniques to minimise the impact on animals in teaching include: • Keeping a minimum number of animals on campus required to simulate a mini colony. • Undertaking research activities in association with another organisation, rather than conducting additional activity for the same purpose.
Animal handling training is now conducted using animals already allocated to an experiment. Consequently, the number of animals used for teaching has been significantly reduced from previous years. In 2012, to further reduce the number of animals used fro training, the practice of sourcing animals to use for *Part 2 training – the care and use of laboratory rodents in research and teaching* was discontinued. Animals required for Part 2 training are now solely obtained from using animals allocated to an AEC-approved project. The establishment continues to encourage researchers to harvest and share tissues in instances where animals have been humanely killed. In 2012, the AEC continued to focus its attention on rodent breeding projects and now requires that the number of animals used for experimental purposes presented as a percentage of the total number of animals produced from each breeding colony is presented for the AEC to review at each meeting. This focus on the wastage associated with in-house breeding programs has assisted with significantly reducing the number of animals being used by the establishment.
Approval given (6/11/12) to source male mice required as studs for embryo production from breeding

colony. Males from breeding colony were previously all culled prior to weaning (only females required) and stud males were purchased from ARC. Retired breeders from breeding program culled and used as required for tissues.
• Close scrutiny of the number of animals requested and Biometrician's comments reviewed to ensure numbers are adequate to obtain the desired statistical outcomes, to minimise the number of animals involved in trials and to ensure that trials do not have to be repeated unnecessarily. • Reduction in number of animals used – researchers in a protocol have moved to PCR to reduce the number of animals used. • Re-use of animals – researchers have transferred rabbits in projects to other research institutes for possible future use. • Similar studies have shared the same control animals.
Pilot procedures using reduced animal numbers for new protocols to test their validity. Scavanging systems including storage of excess material and re-using animals where feasible. Through use of analysis of previous studies via literature analysis.
Scientists are encouraged to share experimental animals in different experiments where suitable to reduce animal numbers. An example is using calves from a protocol to obtain data that can be used in a vaccination trial.
The biopsy procedure (insertion of the needle and the withdrawal of a muscle sample) was practiced on a roast (beef rump muscle) purchased from the supermarket prior to Study Day 0. This helped to refine the method used to obtain the muscle samples.
The study design was refined to a dose escalation study because it was non-terminal. This means that each dog received the saline negative control followed by 1X, 3X and 5X proposed dose. Different treatments could be compared within the same dog and repeat dose data was investigated in depth.
This project as a route to registration for will reduce the number of animals that would need to be used to conduct a full set of clinical field and target animal safety studies. This study may reduce the number of dogs required fur future studies if the drug is found to be bioequivalent to Alfaxan®. Pharmacokinetic data can be submitted to regulatory agencies in lieu of field efficacy and safety data if the test and reference times are bioequivalent. Pharmacokinetic data should be obtained from the target species and dogs are an intended target species for this formulation. The number of animals used for each blood collection is the minimum required to validate the analytical testing methods for the analyte of interest. This study may reduce the number of cats required for future studies if the drug is found to be bioequivalent to Alfaxan®. Pharmacokinetic data can be submitted to regulatory agencies in lieu of field efficacy and safety data if the test and reference items are bioequivalent. Pharmacokinetic data should be obtained from the target species and cats are intended target species for this formulation. From an analysis of published literature the number of biopsy collection time points was able to be minimised to five points over a sixty hour period. As this was a pilot study with only two treatment groups this meant the total number of steers needed to assess the study variables was ten (two steers per biopsy time point). The biopsy method used allowed for a non-terminal assessment of the muscle tissue at the site of injection. At the conclusion of the study all animals were able to return to the herd. By agreeing on a non-terminal study with regulators, we can use a dose-escalating study design to investigate safety of buprenorphine thus reducing the number of dogs involved from 32 to 8. Additional data on repeat use will be gained. Six dogs were used in this pilot study; firstly, to determine bioavailability and secondly, to provide pharmacokinetic data. This will help respectively to determine whether further study is warranted; and, if so, to accurately determine the minimum number of dogs required for a pivotal PK study. It is a regulatory requirement to conduct safety studies with 8 animals per group. Had this study been conducted as a terminal study with IV administration only, the total number of animals would have been 4 groups of 8 (32). Because it was agreed that a non-terminal study was sufficient an alternative study design (that is a dose escalation study) could be justified. Only 8 dogs were required and these dogs were treated sequentially starting with saline negative control, followed by 1 X proposed dose, 3 X

proposed dose and finally 5 X proposed dose.
The establishment actively encourages researchers working together to develop projects that can be run in parallel, which uses different tissues of the same animals in order to reduce the overall number of animals. Researchers are also asked to provide power analysis to demonstrate an understanding of how to ensure that the minimal number of animal replicates is used.
Once the brains have been collected they are cut into sections and stored in a cryoprotectant solution so they can be utilised for immunohistochemical experiments. Only if promising data is generated do the researchers proceed to the next experiment.
Conducting a pilot study using different concentrations of compound of interest in order to determine the optimal concentration before increasing the animal numbers in each experimental group. Where there is no information available in the literature regarding response to treatment, statistical analysis is performed following the collection of each data point. Alternating sections of the same brain can be used as a negative control. The use of museum specimens to supplement data on the analysis of gut contents and measurement of internalised reproductive organs (i.e. testis size, number of ovulated eggs). Group sizes are organised to be optimal for insuring full engagement by each student while using as few animals as possible. The number of animals used in teaching exercises is adjusted based on class enrolment sizes. Specimens are shared between students to further minimise numbers used. A bilateral fracture model was chosen to effectively halve the number of animals used when compared with a single fracture model. The bilateral fibula fracture has been performed in several studies on rodents with no adverse effects to health observed (Midura et al., 2005, Chakkalal et al., 2001, Sakai et al., 1999, Dyson and Brookes, 1983.). At the time of all post-mortem procedures a number of tissues and organs were collected for analysis in future studies, thus reducing the need to perform such a large study in the future. In addition, post-mortem analysis also incorporated collection of pup/fetal blood, tissues and organs which will also be analysed as part of a current and future planned study. Using predictive power calculations and taking into consideration a variation between animals and fibre types allowed for the minimum number of animal required to reach statistical significance to be determined. Using the minimum number of trap nights and sites that are necessary to ensure some success in trapping of the species known to occur in the region of interest. Cadavers of small fish are preserved in alcohol so that they are available for future studies. In a study involving studying the effects of temperature on the metabolic scope of freshwater crayfish, researchers used repeated measures analysis to reduce the number of animals used. This involves the researcher determining the standard and maximum metabolic rates of individuals from each species. The same individuals are then tested at each of the different temperatures, hence the need for repeated measures models. Gender may affect both metabolic rate and fighting ability so an equal number of males and females of each species are used. Hence if gender is considered another factor in the experimental design, the replicate level is reduced. Numbers chosen for experiments are based on previous work where the inter-individual variability has already been established. Individuals are used twice. Because they are separate experiments there is no problem with

independence during analysis, and using them repeatedly reduces numbers required.

Using literature and previous experience to determine optimal numbers per experimental group required to reliably detect differences between treatment groups and eliminate biological variance.

Animal numbers required are calculated according to Power analyses that ensure that affects measured will have statistical significance.

The number of animals used is minimised in muscle studies by i) obtaining measurements from many different individual muscle fibres from a given animal, and ii) wherever possible using an experimental design where the various test and matching control conditions are all examined on the same individual muscle fibre, thereby greatly reducing the sample size needed, because it eliminates problems arising from both animal-to-animal and fibre-to-fibre variability.

Wherever possible, applications are required to be endorsed by a Statistician / Biometrician or references provided to appropriate statistical literature.

The number of animals used in teaching exercises is adjusted based on class enrolment sizes. Specimens are shared between students to further minimise numbers used.

Whenever possible animals used are excess stock for culling.

Improvements in neural recording quality and biocompatibility which may emerge from this research may mean that more data could be collected from each animal used - particularly in chronic research - as electrodes could remain viable for longer periods. This would result in fewer animals being required to obtain equivalent data, and so fewer animals being surgically implanted with research devices in future.

For electrophysiological experiments being conducted it is anticipated that by using multichannel experimentation the data collected will fill a large data base which will help reduce animal numbers in the future. Much of this data will form the basis for computer and mathematical models of auditory brain function. Furthermore, we plan on using responses to acoustic stimulation that we have recorded in previous projects as a basis for analysis removing the need for further acoustic trials on more animals.

Using a Latin square type of experimental design in studies of bird diets means each bird can be fed all the diets being tested, thus reducing the need for using a large number of birds.

Using pilot studies to test validity.

Our Biostatistician and advisor, provides invaluable advice regarding issues relating to the minimum numbers of animals required for ensuring that valid statistical data are obtained from animal experimentation.

Approved training protocol endeavours to utilise animals that are no longer required for other protocols to REDUCE the total number of animals used.

Approval was given by the AEC to transfer mice from P263 to P261 to allow the use of animals in more than one protocol and thereby REDUCE the total number of animals used.

Use minimal number of animals required to be statistically appropriate

Study/perform multiple variables/procedures in the same trial to minimise the number of animals used (providing the study is scientifically valid).

Only adopt tests that are required based on previous experience/findings.

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.

For the perch trial, extra hatched chicks that were proposed to be euthanized under another trial were

instead used to evaluate the affect of perches on leg strength..
Continued improvement in statistical analysis for the use of the minimal number of animals.
Where specific lines of mice (genetically modified mice) are bred for research purposes, careful planning by researchers as to the numbers necessary for experimental purposes is required to be undertaken to reduce unnecessary wastage of animals.
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. Training protocol makes use of excess rats and mice that have not been used for experiments and that would otherwise be euthanased to train researchers in various techniques, thus minimising number of animals required in their research applications and providing Certificates of Competency
Investigators are encouraged to share samples obtained in the field with other research organisations to aid in Reduction. The Committee is also keen to reduce the amount of by-catch for experiments involving trapping and the PI has sometimes been asked to consider alternative trapping methods or modifying experiments in order to reduce the amount of by-catch.
Use of sonar detector rather than traps to detect animals Using cell culture to replace animal model Having established that the procedure was not working an in vitro preparation was devised to test the procedure, replacing some animals. High fidelity pressure sensors were used along with high sampling digital to analog converters to ensure that pressure was accurately measured. This accurate measurement reduces the standard deviation in results, and therefore reduces the number of animals required for a sample of statistical import.
The combination of cryopreservation and whole genome sequencing allows us to prioritise the lines based on their potential scientific and therapeutic values and to discontinue ENU strains carrying genes that have been previously described Maintained a small tissue bank for future studies from this tissue left over following analysis. Although only one brain slice with the RVLM region is present in each animal however effective drug concentrations were able to be determined using adjacent brain slices. High fidelity pressure catheters are used (as opposed to fluid filled lines attached to pressure sensors) to ensure accurate measurements and reduce the standard deviation of results and therefore required sample size for the study. Used non-operative controls to reduce the number of animals needed (ie. Different controls weren't needed at different time-points). Each animal underwent a number of behavioural tests, thus reducing the number of animals required. Through rapid analysis of data as it was acquired, it was realised that the full 24 animals were not required and that 10 animals would suffice to provide enough data to satisfy the aims of the pilot study. Brain tissue not relevant to the present study was distributed to other groups for optimization of other protocols involving immunohistochemistry. The majority of rats (98 out of 144) having been used for behavioural experiments were transferred to various teaching protocols. This included for teaching handling, injection and for non-recovery for surgical practice. This provided an invaluable opportunity for refinement of skills by students, but also maximised the scientific benefit afforded by each animal.
Within the Teaching Unit fish are now donated from other aquaculture research projects for use in classroom dissections. Students work in groups with each group member dissecting a very different

species to the others. This allows for experience of a variety of fish species while limiting the numbers used to one per student. For a project it was identified that using a mesh net any larger than 30 meters would risk netting schooling fish such as Sea Mullet and thus be harder to manage bycatch. The Researcher did not persist with the use of the mesh net which resulted in the reduction of the number of non-target fish taken.
Research involving the use of cats and dogs in NSW was undertaken in association with active Veterinary cases and made use of excess from routine samples as far as possible. In this way the use and impact on animals was reduced.
Animals are re-used where possible. In particular 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.
Researchers are encouraged to share tissues wherever possible. This is facilitated by staff. Breeding programs are designed and maintained to produce stock for orders only to reduce numbers and overproduction. Animals used for courses are shared between multiple participants to achieve the best learning outcome whilst reducing overall numbers of animals used.
IVF: instead of breeding extra mice for embryo freezing we are trying to develop techniques and procedures for successful mice rederivation or recover by freezing down 2-cell embryos from culture Use of dead animals for training surgery or other invasive procedures Tissue sharing Archiving by cryopreservation of genetically modified mouse lines no longer required or seldom used Maintaining minimum number of mice breeder pairs to produce experimental stock
The use of a pilot study to determine the correct dosage reduced the number of animals needed in the second part of a study. The establishment of a protocol to share animal tissues with colleagues after an animal was euthanased. Multiple tissue samples were supplied including brains, livers, spleens, hearts, eyes, uterus and lymph nodes. These tissues were harvested post-mortem and stored so they could be made available for use in other research projects. The analysis of data during the collection of tissue allowed tissue collection to cease when a result with statistical significance was reached. This meant that fewer animals were used than anticipated and for which approval was in place. Brain tissue from animals in an Inflammatory Bowel Disease (IBD) model was provided to another group for a study on the association of IBD with depression and anxiety. Improved molecular biology assisted in reducing the number of animals. The use of a design that minimised animal numbers by using the fellow eye as a matched untreated control. This helped add power to the design as inter-ocular differences were less than inter-subject variability. It also enabled a reduction in group sizes to the minimum based on the expected variability and power considerations. It was possible to significantly reduced the number of animals being used by attaining more parameters per mouse thus less mice were used overall.
Provision of animals with unwanted genotype from breeding colonies for training purposes. Communal bio-banking platforms for access to tissue outside of the establishment.
Refinement
Sourcing of external professionals to assist or teach in new or modified techniques Improved peri-and-post operative analgesia to reduce pain from surgery. Compulsory awareness training for use of environmental enrichment.

Additional ultrasound devices were purchased for a wildlife protocol to enable students to use this technology directly to understand the ecology of bats. Similarly the use of 'Songmeters' (waterproof electronic recorders) was trialled for the recording and analysis of amphibians. However, it was recognised that this approach only provided an indirect method of identification and could not replace the need for morphological identification and understanding ecology by looking at structure and function
In 2012, a number of adverse incidents were recorded for the use of funnel traps. Queensland reported the death of two frogs and one skink in two separate incidents to funnel traps. As a result of the number of funnel trapping incidents, the AEC has reviewed the SOPs for funnel trapping and made the following changes: Cumulative weather needs to be considered prior to survey to minimise risk of death. In 2012, a single incident was recorded for an injury to an animal post release. The field rat sustained an injury to its tail after it moved away from the trap site post release. It is believed that this injury occurred when it jumped through the fork of a tree trunk, thereby catching its tail on the way. No attempts were made to recapture the rat for treatment in accordance with the SOPs. As a result of this incident, when reviewing the SOP in 2013, the AEC will add clarification to the release procedure of animals post capture to avoid immediate post release injury.
Addition of meloxicam as analgesic of choice for alleviation of inflammation and pain in musculoskeletal disorders. For subcutaneous injection of bigger volumes of saline into dehydrated mice, injecting and distribution into other skin sites to avoid large bleb formation. When training new staff on surgery, using retention sutures during surgeries for improvement of technique and shorter length of operation. Use of multimodal analgesia for even analgesic dosing eg after abdominal surgery, buprenorphine SC was given followed by carprofen in drinking water. Regular provision of pre-emptive analgesia for mice undergoing embryo transfer and vasectomy. Only use unilateral transfer of embryos so only one skin incision per mouse, and size of incision kept to minimum. If genotyping needs to be performed past weaning age, ear notching is recommended as an alternative to tail biopsies. Minimise bleeding from the ovarian bursa by applying a vasoconstrictor prior to accessing the infundibulum during oviduct transfers. Cross-fostering of genetically modified pups when applicable for increased chances of survival. Use of videos for demonstration of technique prior to performing actual procedures on the animal. More training sessions available on animal handling and restraint. Training of new staff via facility orientation (CHW) continued with only manipulations required by each new research staff member being trained to minimise the impact on the animals being utilised for training.
The establishment has 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.
Sampling from sheep was reduced from 10 times to 3 times to reduce the impact on the sheep.
The increased used in baited camera stations and remote cameras in wildlife and fisheries research. The Committee is yet to receive a report on the success of baited cameras in fisheries research as no

work has been carried out in 2012).

In wildlife studies the Researcher is using infra-red cameras extensively to conduct surveys, replacing the use of cage traps with cameras on the student field survey. They are using cameras to conduct more widespread surveys for long-nosed potoroos.

For several components of the study only the presence of animals within next boxes was recorded with no handling occurring.

Data generated is being added to simulations to minimize the need for sampling in the future. Application of multiple experimental protocols per experiment, recording from multiple sympathetic nerves simultaneously; both approaches increase data yield per experiment.

Saved mRNA and protein extracts from tissue that can be used for future studies

In finch sampling to reduce the need of further animals to be used in other projects, blood and plasma were collected and stored.

Tested the possibility of using hair samples for DNA extraction

Used bloodspot extraction instead of tissue samples as it is less invasive

Distress reduction by manipulation, leaving the animal to rest for 15 min after transportation from the animal house.

Using hair funnels proved a moderately effective means of surveying ground active mammals without the need for live trapping.

Catheter construction has been refined (to minimise fluid collection under the back mount)

Several steps were taken to ensure minimal stress to the birds: (1) individuals of the study species were observed, but never trapped or handled in any way; (2) the distance between the observer and the study species always exceeded 30m; (3) the observer was always quiet and wore dull coloured clothing; (4) birds were only observed one day every two weeks, and no observations were taken during the breeding season; (5) insect collection never occurred in close proximity of the birds

By using plastic *gutterguard* over the pitfall traps we reduced the risk of vertebrate by-catch when surveying bird prey (invertebrates)

Practicing surgical techniques to reduce surgical time

Biopsy sampling methodology has been designed to minimise the impact on the animal (most notably, no animals are captured)

By adopting result-based stopping rules, we reduced the amount of time spent bird watching while maintaining the efficiency of the survey to detect all species present.

We have identified that an air bubble stimulus can be used successfully when conducting learning experiments on benthic sharks. Such a technique has never been documented before. This will save time for future researchers looking to investigate aspects of learning behaviour and so reduce the impacts to other sharks used in such experimental studies.

The AEC usually requires monitoring sheets to be used for laboratory animals with clear intervention parameters and key triggers for intervention.

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.

Improvements to animal housing and management.
Training of researchers.

Use of monitoring checklists to identify, action and report adverse events and the development of an adverse event form. The use of less invasive procedures e.g. sand pads rather than trapping. Use of an Observational Only - Field Research Form (No Trapping, Handling or Spotlighting).
Appropriate training in handling and reduction in the number of blood samples taken on individual animals.
For the probiotics trial, caecal samples were collected during slaughter to avoid euthanasia by cervical dislocation. An extra group of birds was added to include a standard ration with antibiotics for scientific merit.
The research for this Protocol was divided into two stages. An initial pilot study to ensure the research was viable and to REFINE techniques prior to continuing onto the main body of research. The end of year Protocol review reported a successful pilot study and the AEC has approved the second research stage. This pilot study approach has been promoted by the AEC.
Where possible, captured wildlife are returned to their natural environment.
The air-pouch assay has been identified as an effective and less invasive inflammatory model for studying in vivo cell migration in response to proinflammatory factors. It is more favourable to induce a local inflammatory response outside of the body cavity (i.e. in a subcutaneous air-pouch) than a systemic response. The use of the air-pouch protocol would also mean that the investigation of phagocytic cell migration can be achieved by extracting the pouch fluid after treatment. To lessen the impact on the welfare of the animal, each mouse is fed and measured the same time everyday so that they are able to develop a normal routine. Corticosterone is administered through the drinking water. This is the only non-invasive method of delivery, as other studies typically inject this hormone into the body or surgically implant slow hormone releasing pellets, causing undue stress to animals. Studies involving dams and conducted with the pups present in order to avoid undue stress caused by the separation of dams from the pups. Procedures are conducted in the animal's home cage, to avoid the undue stress of excessive transportation. Where animals are singly housed they are provided with enrichment items (cardboard boxes, toilet rolls, etc.) which are alternated weekly. Studies involving domestic pets are performed in the presence of the owners at all times. Only animals that are well trained and socialised and who appear to enjoy being in the presence of humans are chosen. The length of time that the colony is maintained simply for breeding purposes is kept to a minimum. The rats are group housed up until 48 h hours prior to the test day to minimize isolation stress. Habituation to the test apparatus is conducted in low-light conditions, which is believed to be less aversive than high-light conditions. Rats are acclimated to individual housing within the animal house for 1 week with unlimited access to food and water prior to the study commencing to minimize the stress caused by being in a new environment. Before the actual practical exercise starts, students are taught how to handle (catch, hold, tag, weigh) animals properly in order to keep stress levels to a minimum. Students are taught that handling and other forms of interference must be reduced as much as possible and that penalties will apply for students that do not comply. Students are given the instruction to monitor their animals' health and stress, and report any abnormalities to the staff immediately. Students (and staff) receive detailed instructions on the daily maintenance of the animals. Where the animals are to be exposed to a novel item, a habituation period is included in the protocol.

Bird netting is secured and stretched tight over a large frame to great tension in the net that greatly reduces the chance of birds becoming entangled in the net when they perch on it. The net and frame is also anchored to the ground preventing birds from becoming trapped inside the net.

Blood samples taken from dogs are drawn by people experienced in the procedure and Vacutainer systems are used to reduce the time taken to obtain the blood sample. Where possible (if the owner is competent and comfortable), the owner personally restrains their dog for the procedure to reduce stress, otherwise only people suitable animal handling experience are used.

Animals are housed in pairs (minimum) and provided with environmental enrichment.

In line with technique refinement, the stress treatment (corticosterone) will be delivered using slow release implants as opposed to being repeatedly injected into the animals. This delivery technique has been used successfully in birds to elicit experimental changes in blood corticosterone levels while reducing the impact of handling/injecting stress, as the birds only need to be handled once.

The use of microchip scanners and loggers also provides a non-invasive method of monitoring incubation behaviour and nest attendance.

Observing animals using CCTV cameras means animals are not exposed to additional stress as a result of the observers presence.

The use of animals that have been bred in captivity and are therefore already accustomed to handling procedures.

Marking individuals with coloured leg bands to enable identification of individuals without the need for further capture.

In past investigations intraperitoneal injections were used to induce anaesthesia in the animals at the time of surgery. Using gaseous anaesthetic instead minimises stress to the animal by inducing loss of consciousness quickly and easily. In addition, gaseous anaesthetic also allows for a faster recovery post surgery and allows the rat to return to its normal eating, drinking and behavioural habits.

The bone chosen to study bone fractures is the fibula as the animal is put under less stress than if a larger load-bearing limb such as the tibia or femur were fractured.

Elliot traps are opened in the early evening on each of the three trap nights and checked as early as possible the following mornings. These traps are closed after the morning check and left closed throughout the day, to ensure there is no by-catch. SOPs are carefully followed to protect trapped animals. For example, food and bedding is provided in the traps and wrapped in plastic bags to exclude moisture and traps are placed in positions that give them protection from the elements.
Pitfall traps are left open throughout the three days of trapping, but checked in the early morning, and in the early evening. In the event of un-seasonally hot weather they are also checked around midday. Pitfall traps are fitted internally with layers of cardboard and shredded paper to provide cover and shelter for trapped animals.
Animals are released from both types of traps as quickly as possible. Using two supervisors and two groups of students enables animals to be released from the pitfall traps more quickly.

The majority of the captured fish are removed from the Fyke nets within two hours of capture and after removal from the nets are quickly weighed and measured and then released back into the wetland from which they were captured (native species) or euthanased (exotic species). In parallel a small proportion of the larval or juvenile Australian smelt and Carp gudgeons that are captured at three of the sites are euthanased and frozen to be taken to the laboratory for growth analysis using their otoliths. At least two people work together in

the field during the study to ensure rapid removal and processing of captured fish. Furthermore, the number of nets being used does not exceed the number that can be cleared by the field crew.

Historically, poor technology and simplistic approaches to ecophysiology have meant that researchers focused on potentially lethal (e.g. LD50) approaches. Modern respirometry technology and a refinement of scientific thinking has seen ecophysiologists shift their attention to sublethal physiology, or the continuous bioenergetic response of organisms to environmental drivers, rather than to extreme endpoints. Experiments utilise the latest respirometry technology (automated, intermittent-flow respirometry), which ensures animals do not suffer the effects of nitrogenous waste concentration and oxygen depletion during experimentation.
Acclimation times are gradual. That is, animals can, to some degree, adapt to environmental changes if they are subjected to those conditions slowly. Relatively long acclimation times are used for each treatment (maximum rate of change of 2 degrees Celsius every 24 h).
The experimental treatments are within their natural range, that is, the range of temperatures that animals may experience in the wild.
As mentioned above, it is imperative that metabolic rate estimates are obtained from healthy animals only. In our experience, crayfish that are housed individually (so they don't fight) in large, heterogeneous aquaria remain healthiest. Crayfish are housed in large aquaria within the controlled-temperature laboratory, where each aquarium contains environmental enrichment such as gravel for digging in, rocks, and other substrates for cover and climbing (so they remain fit, as they would in the wild).

All electrofishing is performed by trained and qualified operators under the controls set by the Australian Code of Electrofishing Operation and the MDFRC's own operator qualification scheme. This ensures that equipment is operated in a manner that causes no lasting harm to target and non-target fauna. If these codes are not adhered to, hazards may arise.
Captured fish are held in fresh aerated water for the minimum time necessary. Water in the holding buckets is changed every 30 minutes. This ensures that fish are not placed under any undue stress caused by low dissolved oxygen, high temperature or overly polluted by toxic fish waste water.
Fish are processed (identified, length and weight measured) as quickly as possible so that they are out of the water for the minimum time possible. Fish are handled by trained staff members thus reducing processing time. Junior staff are trained by a competent senior staff.

Sampling of fish for population studies are conducted in the spring and autumn seasons in order to reduce any stress on the fish caused by extreme temperatures in summer. Care is taken to minimise the time fish are held before being released. Noxious species are despatched as humanely as possible using an appropriate anaesthetic.
When working with fish, literature and previous experience is used as a reference to guide the number of sites to be sampled, reduce the number of sampling events per year, and to eliminate capture methods which do not provide statistically significant catch data.
Following established parameters for tagging of fish – e.g. only fish longer than 200mm are tagged. This reduces undue stress on smaller fish, while also reducing the number of fish that will be tagged.

Shortening of the experiment period to the minimum time required to obtain significant Results.

Frequently handling animals in advance to condition them to handling procedures.

Employing non-invasive methods of drug delivery such as via the drinking water rather than by surgical implantation of pellets or injection.

When capturing wildlife, animal handling time is reduced to the minimum required and only trained personnel perform handling procedures when required.

The use of suitable and purpose built traps to replace hand capture with nets to reduce capture induced stress.

Administration of a sedative that is appropriate for the species to reduce stress as appropriate.

Daily monitoring by animal care staff in addition to researcher monitoring using a “clinical monitoring sheet”.

Technical procedures such I.P. injections performed only by experienced staff.

Referring to literature to ensure chosen doses of drugs used have been employed in other studies and demonstrated to be well tolerated by animals.

For studies where the impact of hunger on animal behaviour is investigated, experimental time points and locations can be chosen that coincide with natural feeding behaviour rather than capturing, handling, transporting, housing and depriving or restricting food intake of animals.
For example: hunger can be controlled for in Pelicans by simply conducting the same experiments alternately early in the morning and late in the afternoon. The rationale for this is that the pelicans found at boat ramps/fish cleaning stations at the three sites will have little in their stomachs in the morning, whilst later in the afternoon they would have been well fed.

Following Guidelines, such as the NHMRC Guidelines to Promote the Wellbeing of Animals Used for Scientific Purposes, for recommended methods to conduct procedures such as humane euthanasia.

When capturing fish for population studies, they are held in aerated water taken from the catchment site until they have been counted and measured, before being released unharmed at their point of capture. Alternatively, captured fish are held for a limited time and holding buckets are changed regularly to ensure fish are not placed under any undue stress caused by low dissolved oxygen, high temperature or overly polluted (by toxic fish wastes) water.
In studies where fish need to be handled, they are identified, measured and weighed as quickly as possible so that they are out of the water for the minimum time possible. Fish are only handled by trained staff members thus reducing processing time. Junior staff may be trained by competent senior staff only if the senior staff member feels they are ready for it. For those animals to be retained, current best practice and a decision support tool regarding the number of animals to be collected is followed.
When working with fish, literature and previous experience is used as a reference to reduce the sites to be sampled, reduce the number of sampling events per year, and to eliminate capture methods which do not provide statistically significant catch data.

All electrofishing is performed by trained and qualified operators under the controls set by the Australian Code of Electrofishing Operation and the organisations own Operator qualification scheme. This ensures that equipment is operated in a manner that, to the best of our knowledge, causes no lasting harm to target and non-target fauna.

Animals are housed together where possible to reduce stress and are allowed a period of acclimatisation when being transported and/or moved to a new location.

Monitoring of animals using telemetry allows for detailed parameters such as body temperature to be measured without the need for disturbing animals.

Experimental time points are chosen carefully to ensure the impact of disease progression is minimised as much as possible.

Choice of species is considered carefully, for example blood collection procedures might only be performed on pigeons bred in captivity as they are already accustomed to being handled.

Numbers of staff and students permitted in animal holding rooms are limited to minimise

disturbance to animals.

The use of electrophysiological in vitro recording techniques provides a powerful tool to examine activity in neural tissue. These in vitro methods are robust and provide for a much higher yield of results than those derived from in vivo animal model.

Procedures such as neuron distribution mapping are largely performed post mortem, on isolated tissues, but live animals are still needed to provide the brain tissue.

• Increased use of remote controlled infrared digital cameras and acoustic recording devices instead of, or in addition to, trapping to detect species presence or absence.

• Supplementary external expert advice sought from veterinarians.

• Researcher training in microchip insertion.

• Phasing out of toe clipping in small mammals: two researchers commenced studies to compare the efficacy of three different marking methods – nanotransponder microchip tags, toe clipping and ear punching or notching. (Results will be available in 2014.)

• Nanotransponder microchips used to permanently mark pygmy possums instead of ear-tags which can tear from the ear causing injury and failure of animal identification system.

• Approval obtained from NSW Health for staff to use pentobarbitone solution for injection for animal euthanasia in the field where vet services are not available and alternate methods of euthanasia are inappropriate.

Prior to designing this study a review of literature concerning oral moxidectin pharmacokinetics in sheep in the public domain was conducted. This helped to refine the study dosing in order to capture the critical pharmacokinetic parameters. Through the conduct of this study the establishment has gathered information which will help in the refinement of the design of possible future pivotal bioequivalence studies. This study identified the critical time points for blood collection which best describe the rate and extent of drug absorption from the three formulations. In future studies involving these products we will be able to refine the blood collection time points based on the critical time points identified here.

Dogs were kept in their regular housing and their management was as close to that of their daily routine as possible.

Animals were restrained appropriately and bled for plasma harvesting by qualified personnel. The plasma collected during each bleed is stored and utilised in future studies, as blank plasma is required. As such, the number of times an animal is required to be bled is reduced.

Cats were kept in housing to which they were accustomed and aspects of their management were kept as close to that of their daily routine as possible.

A pilot epidural and a pilot biopsy were conducted on two separate animals which were not included in the ten study animals used on Days 1 to 2. The conduct of the pilot epidural and the pilot biopsy allowed for the refinement of procedure techniques prior to the conduct of the actual study. Study personnel were able to become familiar with what was involved with these two procedures. The muscle sample taken from the pilot biopsy animal was prepared and preserved as per the study plan and sent to the designated histopathology laboratory for analysis of the preparation method. From this, it was concluded that the muscle samples we had obtained and our method of preserving them were suitable and conducive to the requirements of the histopathology laboratory.

Prior to the study, and with the review of the use of the drug in published literature, we proposed and agreed to a non-terminal study design with regulators. This study was conducted in order to refine the time points for the pivotal safety study and thus reduce distress of handling of dogs in the pivotal study. The results from the pilot study – particularly cardiorespiratory parameters have demonstrated similar results (eg reduced heart rate but no change in arterial bloods pressure and reduce respiratory rate but sufficient oxygenation) to those in published literature and therefore the non-invasive methods used to measure parameters can be justified.

Dogs were kept in housing and under the husbandry system to which they were accustomed. Dogs were handled sympathetically by experienced and familiar personnel.

Animals were treated in a calm manner. Care was taken when drenching to ensure correct techniques were used. Sheep were monitored closely for the duration of the study (from acclimation to the final faecal collection). The untreated control group was treated with an anthelmintic after the final, post-

treatment faecal samples had been collected. No excessively high FECs were observed in any of the study sheep.

A review of pharmacodynamic and safety data available in the public domain was undertaken and the study was refined such that suitable clinical sign were investigated (variables) in accordance with VICH guidance. In addition, a pilot study was conducted in one dog at 5 X proposed dose to further elucidate the maximum effects, relevant time points and variables that should be investigated in order to design the pivotal study appropriately.

The plasma collected during each bleed was stored and utilised in several studies, thus reducing the number of times an animal is bled.

A full literature review was conducted prior to study development in order to establish the known pharmacodynamics and toxicological effects of buprenorphine in order to measure parameters adequately.

Animals which were used in experiments which require a training component (behavioural tests) have been reused to refine the experiment so less training has to take place. This reduces the time animals spend in the experiment as the training component is not repeated.

In another experiment, experimental procedures could be refined by purchase of new animal handling equipment (bull tilt table) which allows safer handling of animals with less use of anaesthetics, avoidance of using a head bale, and increased safety for operators and animals.

The development of "observational only" for wildlife studies.

Less invasive sampling methods used where possible.

The AEC has guidelines that help replace, refine and reduce the adverse impacts and the numbers of animals used in research overseen by this committee

- Close monitoring of animals and development of monitoring checklists to identify adverse reactions in animals. The AEC will place conditions on projects at the approval stage to ensure that any pain or distress to animals is alleviated quickly in projects where it is impossible to eliminate this completely.
- Use of experienced veterinarians and other staff.
- Restraint time and dose rates kept to a minimum.
- Adoption of less stressful methodologies.
- Suitable housing provided and maintained including controlled environment facility.
- Use of adjuvants known not to produce adverse reactions.
- Procedures used routinely so that animals become accustomed.
- Procedures performed under anaesthesia or sedation when appropriate.
- Close scrutiny of the volume of blood collected.
- Use of the saphenous vein method as the standard technique for blood collection in rodents.
- A number of studies conducted on animals at the owner's property to minimise any possible stress.
- Environment enrichment has been introduced for pigs and rabbits.

Projects with novel animal models, published/established animal models being used for the first time, and/or by a research group without any experience in a model, are required to undertake pilot studies to demonstrate that the animal model functions as expected prior to commencing treatment experiments.

Daily monitoring and twice weekly weighing of animals on modified diets.

Requirement for in vitro toxicity and/or efficacy data prior to giving permission to place biomaterials into animals or administer experimental treatments.

The AEC implemented mandatory training for all animal users. The requirements for training are as follows:

Anyone listed on an approved animal ethics protocol must attend an animal ethics seminar and complete an online test; anyone undertaking the practical aspects of biomedical protocol must undertake the practical training courses provided by the establishment and complete the online theory training and exam; existing experienced staff have the option to complete the online training and exam and then have their existing skills assessed without attending a practical training course.

The AEC continues to require the use of clinical score sheets as a tool to assist in the assessment of an animals' wellbeing and to determine humane endpoints during studies. Principal investigators are required to modify a generic sheet to suit their particular protocol. These sheets are checked during

veterinary rounds, spot inspections by the AEC Executive Officer, animal care staff and the AEC.
The AEC has increased conditions of approval to include the presence of either the Animal Welfare Officer or Animal Facility Manager (a Veterinarian) to oversee high impact or new scientific procedures. The AFM Veterinarian has accompanied researchers in the field to provide training for procedures and oversee animal welfare. In addition, the AEC continues to promote the Code and BAW guidelines on the use of animals for teaching purposes and maintains strong recommendations in regards to research and teaching projects. Researchers are encouraged to deliver treatments to rodents using a technique that involves voluntary consumption of the treatment immersed in a commercially available get, rather through more invasive approaches such as IP injections or removing animals from the cage and individually offering each animal the treatment on food after an overnight fasting. The Animal Welfare Officer continued to revise the stereotaxic surgical procedures and purchased additional equipment to enable aseptic technique to ensure improved standards of care and welfare for the animals. Funds were sourced to allow researchers conducting recovery surgery to attend the Aseptic Surgery Training Course by Box Hill TAFE.
On-going techniques to minimise the impact on animals in teaching include: • Prior to field work activities, students are familiarised with both the animals and the research techniques to be used. This includes visits to zoos, aquaria and museums, demonstrations of the use of equipment and DVDs showing the use of the research methods. Actual field work is kept to a minimum. • For native animals, handling is by the licensed person only, with students observing the techniques. • The number of occasions that an animal is handled is minimised eg lambs are tagged and drenched at the same time to avoid having to re-capture. • Use of a miniature pony to replace foal for handling purposes. • Using treats as a substitute for medication • Students are required to complete animal welfare induction prior to beginning studies • Reduction of lamp size to less intense light; use of red light covers for spotlighting activities Reduction • Timetabling of classes coordinated so that activities are spread over the semester, to avoid over-use of the same animal.
We have purchased a special halter for restraining cattle with minimum stress in order for treatment or blood sampling procedures to occur in a less stressful manner.
Animals will be handled on a weekly basis to reduce stress at the time of performing the procedures. During the procedure animals will be handled as little as possible to reduce any unnecessary stress
All animals are sedated within a short time of arrival at the large animal facility, before induction of general anaesthesia. Anaesthesia in combination with analgesia is maintained for the duration of the study, prior to euthanasia.
The use of the *casper* transparent mutant zebrafish as a background line for the transgenics will reduce the number of adults subjected to ECG and other procedures as they can be “pre-screened” for an arrhythmic phenotype by examination under a microscope.
The training and skill of technicians is important in minimising stress on the animals. All staff working with zebrafish will undergo a training program including the online AALAS Zebrafish husbandry course as well as one-on-one training within the facility to ensure that the animals are managed well.
To reduce pain we have referred to literature for optimal pain control regimens. All animals will be checked twice daily in the first 48 hours or more if any signs of pain are noted. Pain score charts and analgesia charts will be kept for each animal for the 7 days post-transplant. Food and water will be provided at foot level to minimise stretching that can cause abdominal wound pain.
NSAID medication via high energy gel feed will be provided post operatively. This will synergistically enhance the pain reduction effect of the buprenorphine and reduce inflammation after surgery.
We are using a mouse model (A^{vy}) in which the obesity/diabetes phenotype and the epigenotype of the responsible allele are tightly linked to the mouse coat-colour phenotype and thus can be assessed non-invasively, and in which obesity occurs spontaneously and does not require any dietary, pharmacological or genetic manipulation.
In vivo imaging will be used to take serial measurements of pancreatic metastasis/progression/regression. This will enable us to monitor the mice very closely for signs of concealed illness.
Zebrafish embryos and larvae will be manipulated mostly before the free feeding stage, consistent with

the notion of refinement.
Rehoming of retired research horses to suitable new owners.
Spontaneous collection of naturally voided urine from horses for the purpose of drug analyses.
As behaviour was being observed, handling procedures were minimised and selected to reduce stress where possible.
Wild fish were returned to the location where they were caught (tagging).
In order to minimise stress on the dogs, animals were in their own home and treated for fleas using registered products.
In order to minimise the impact on seadragons, the project was mostly observational. In instances where tagging was required, wild seadragons were tagged in their natural habitat.
Methods were employed to reduce the time animals spent in cage traps, handling time, and design of collars was improved to reduce the impact on the wallabies.
Swapping our ethics application forms. This includes a larger section asking each researcher to detail *"Please discuss the ethical issues that the AEC will need to consider when reviewing this proposed experimentation. Your answer should address the 3Rs Replacement, Reduction & Refinement. (See The Code 1.8 - 1.28, 2.2.16 vii, viii, ix). The answer "not applicable" is not acceptable."*
Two studies were performed in 2012 with the aim of refining the allergic dermatitis model (HDM) in dogs. The amount of HDM was significantly reduced resulting in a less severe allergic reaction on the dogs but still achieving an excellent model which is more closely aligned with what occurs in a normal home environment.
Improved peri-and-post operative analgesia to reduce pain from surgery.
Increased awareness and use of environmental enrichment.
A number of researchers reported the use of anaesthesia, analgesia and sedation to reduce pain and distress. These included: • A mild sedation was used, with consent of the owners, to minimise distress to the animals and aid in handling. • The researchers minimised suffering and distress through the use of: (i) anaesthesia, namely isoflurane for most procedures; (ii) clear bottom cages allow minimal handling; • The researchers undertook very strict monitoring of the infected animals after the onset of the syndrome. Euthanasia of the animals once the syndrome had been confirmed i.e. well defined ethical end point. • The researchers used anti-inflammatories and analgesics during the procedures. Constant monitoring of the animals during and after surgery procedures ensured minimal stress to the animals. No animals were in distress after the procedure, until they were terminated.
Modification of housing and facilities and the animal's environment: • The microsurgery laboratory has been extensively upgraded with the latest in microscopy, imaging and instrumentation which means that the animals are provided with the most effective surgery possible with consequent reduction in pain and suffering. • The housing standards; care and procedures, which could cause an actual or potential pain, suffering, distress or lasting harm were always minimized and avoided by all persons involved the study. The animals were actually housed more often in cages of 3 or 4, which gave them more space to move around. Also, manipulation of the mice was kept to the minimum and times of wake/sleep were always respected. • The researchers modified the food by supplying lucerne chaff as a biscuit and included 20% glucose solution during the overnight abstinence of solid food.
Modification of procedures: • Refinement of procedures: well trained and competent researchers, use of small injection volumes and finer gauge needles. • The researchers administered drug doses, which were on the low end of published doses to ensure fish health, and fish did not experience pain or suffering. • Introduced 2-hourly monitoring during the risk period for disease development. Any bird showing clinical signs of coccidiosis was euthanized immediately. This decreased suffering for the control group considerably. • Pain and stress was kept to a minimum by well-established husbandry and experimental techniques.

- Potential stress during capture was minimised by quickly transferring caught lizards into cloth bags and transporting them to the Animal House in a cool esky and an air conditioned car. Lizards were housed for the minimum period of time required and were housed in enclosures that offered them all the necessary components to allow them to thrive. No procedures were performed on the lizards while they were housed and handling each animal was kept to a minimum.
- The researchers submitted two modifications refining the methods to minimize dog frustration and training time, which will in turn minimise the impact on animals used in the project.
- The anatomical studies (which were based on already-dead archival museum specimens) that were included in the overall project had facilitated correct placement of hypodermic needles into the subcaudal venous sinus, which will facilitate future blood sampling in Australian reptiles.
- To reduce the possibility of predators being guided to nests by human presence, the researchers' visits were brief and the direction of approach was varied. To minimise deposition of human scent (on both artificial and natural nests), we wore gloves, and placed equipment on a plastic drop sheet rather than on the soil surface. The researchers sprayed the nest substrate with air freshener as an odour neutraliser to mask the smells of both the turn soil and mucus on the eggs, which may otherwise attract predators.

Appendix I: ARRP expenses

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

Fees and retainers	**4,547.03**
Travel and subsistence	**5,911.93**
Stores (including catering) and printing	**1,181.06**
Freight and postage	**705.25**
TOTAL	**$12,345.27**

Appendix J: ARRP policies and guidelines

(Available from http://www.animalethics.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.animalethics.org.au/reader/animal-care))
   (For establishments housing rabbits)
4. Unless precluded by the requirements of specific projects, chickens should be provided with housing that meets their behavioural needs including straw or other suitable bedding to cover the floors of cages, perches and dust bathing substrate.

(For establishments housing chickens)

5. Dogs should be housed in accordance with ARRP Guideline 14: Guidelines for the Care and Housing of Dogs in Scientific Institutions (http://www.animalethics.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.animalethics.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 ARRP guidelines on wildlife research found at: http://www.animalethics.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.animalethics.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*.