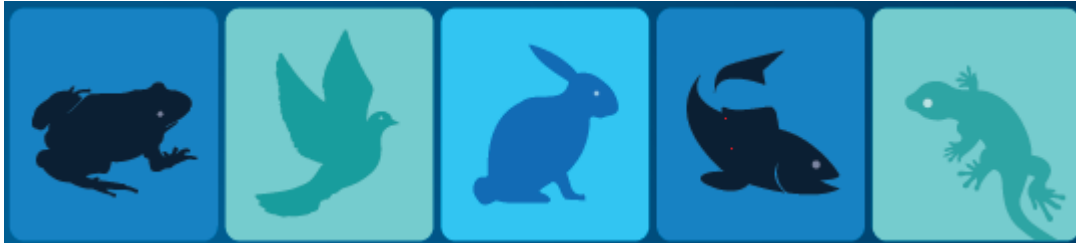




Department of  
Primary Industries

# Animal Research Review Panel

## Annual Report 2015 -16



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Animal Research Review Panel Annual Report 2015-16

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**More information**

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Animal Welfare Unit

[www.animaethics.org.au](http://www.animaethics.org.au)

[www.dpi.nsw.gov.au](http://www.dpi.nsw.gov.au)

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Disclaimer: The information contained in this publication is based on knowledge and understanding at the time of writing (March 2017). However, because of advances in knowledge, users are reminded of the need to ensure that information upon which they rely is up to date and to check currency of the information with the appropriate officer of the Department of Primary Industries or the user's independent adviser.



## Department of Primary Industries

### ANIMAL RESEARCH REVIEW PANEL

1 December 2016

The Hon Niall Blair MLC  
Minister for Primary Industries  
Minister for Lands and Water  
52 Martin Place  
SYDNEY NSW 2000

Dear Mr Blair

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 2015 to 30 June 2016.

Yours sincerely

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

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## 1. Framework under the Animal Research Act 1985

### 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 document and is included under the Animal Research Regulation 2010. The Code is reviewed regularly by the Code Reference Group, under the auspices of the National Health and Medical Research Council (NHMRC). The Code Reference group includes representatives from NHMRC, the Commonwealth Scientific and Industrial Research Organisation, the Australian Research Council, Universities Australia, the state government ministries with responsibility for animal welfare, commonwealth government departments for the sectors of environment, education and primary industries, the RSPCA and Animals Australia.

### 1.3 The Animal Research Review Panel

The Animal Research Review Panel has responsibility for overseeing the effectiveness and efficiency of the animal research legislation, investigating complaints, and evaluating compliance of individuals and establishments with the legislation.

The constitution, membership and mode of operation of the Panel are set out in the *Animal Research Act 1985*. The Panel has twelve members with equal representation from industry, government and animal welfare groups. This provides for a range of expertise in regulating the conduct of animal research in New South Wales.

Apart from developing overall policy on animal research issues, the Panel is closely involved in the administration of the legislation. This is achieved through evaluating applications for accreditation and licences of research establishments, conducting site visits to assess compliance, and investigating complaints. The Panel also has a role in considering amendments to the Animal Research Regulation. NSW Department of Primary Industries animal welfare officers provide executive support for the Panel.

#### 1.3.1 Mission statement

- To protect and enhance the welfare of animals used in scientific research, testing and teaching in New South Wales.
- To promote an understanding within the New South Wales community of the ethical and technical issues involved in the use of animals for scientific purposes.

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The strength of the Panel 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 Animal Research Review Panel

Section 9 of the Animal Research Act defines the functions of the Panel 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 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 Panel 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: 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 Panel are part-time and are normally appointed for a term of 3 years.

During the 2015–16 period the membership of the Panel 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; resigned December 2014)

Dr Magdoline Awad (nominated by RSPCA NSW)

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Dr Mike Fleming (nominated by the Minister for the Environment)  
Professor Annemarie Hennessy (nominated by the Minister for Health)  
Ms Emma Hurst (nominated by the Animal Societies' Federation)  
Professor Anne Keogh AM (nominated by the Animal Societies' Federation)  
Mr John Mills (nominated by the Minister for Education and Training; appointed 30 July 2015)  
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 2015–16 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 was 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.

**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 Annemarie HENNESSY BMdSu, PhD**

Professor Hennessy was previously a member the ARRP from 2008 to 2010. She was re-appointed in January 2014. She is the director of the National Baboon Colony and an active medical teacher and researcher. She is a qualified nephrologist and specialises in general



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medicine, renal medicine and obstetric medicine. She is the Dean, School of Medicine, at the University of Western Sydney.

**Ms Emma Hurst BA(Psy), PGDip(Psy), M(HealthPsy) .**

Ms Hurst is a registered psychologist who has worked in the areas of adolescent mental health, aged care, child therapy, addictions, and health promotion research. Ms Hurst has worked in a range of settings such as mental health services, universities, and specialist early intervention services. She is particularly interested in the promotion of animal advocacy and runs a research animal rehoming service. Ms Hurst was appointed to the Panel in 2014 as a nominee of the Animal Societies Federation.

**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 at St Vincent's Hospital Sydney, Head of Human Clinical Research in heart failure and pulmonary hypertension, and Joint Head Clinical Research at the Victor Chang Cardiac Research Institute. She is Conjoint Professor of Medicine University of NSW, Director of two binational registries, 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.

**Mr John Mills, BSAgr(Syd), Grad Dip Ed, Cert IV Training & Assessment**

Mr Mills is the nominee of the Minister for Education and Training. He is the Manager Industry Liaison – Agrifood for TAFE NSW with responsibility for providing support for the delivery of training using animals throughout TAFE NSW. He is a member of the TAFE NSW Animal Ethics Committee and has extensive experience in commercial beef cattle and merino sheep production along with 20 years' experience delivering Vocational Education and Training in the agriculture sector. He became a member of the Panel in 2015.

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

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

**Mr David O'SHANNESY, BSAgr.**

Mr O'Shannessy is the nominee of the RSPCA (NSW). Since completing an Agricultural Science degree he has been employed as an inspector with 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 in the Faculty of Medicine and Health Science, Macquarie University. Her research is in the areas of hypertension and renal disease.

**Dr Peter ROLFE BVSc, PhD (Syd)**

Dr Rolfe is a nominee of Medicines Australia. He is an employee of Elanco 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 global programs for the

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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 establishments, 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 establishment, 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 Panel for assessment of AEC membership are documented in a Panel policy document, *Policy 9: Criteria for the Assessment of Animal Ethics Committee Membership* (<http://www.animaethics.org.au/policies-and-guidelines/operation>). In examining applications from establishments for accreditation as animal research establishments, the membership of AECs are assessed to ensure they are of acceptable composition. The Panel also assesses, and makes recommendations to the Secretary, on the suitability of all new appointments to AECs. All new AEC appointments must be approved by the Secretary. During site inspections, the Panel 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 Panel for consideration. The Panel 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.

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

- 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 Panel are referred to the delegate of the Secretary of the Department of Industry, 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 a condition that any site inspection is satisfactory and to a condition requiring the reporting of changes in AEC membership to the Secretary for approval. Other conditions may also be stipulated, as relevant to the operation of each establishment. (See Appendix K 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 Department of Primary Industries Animal Welfare officers, according to criteria developed by the Panel. Arising from these assessments, recommendations on the applications are made to the Panel. The Panel considers the recommendations and then makes recommendations on the applications to the Secretary.

The Panel 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 Department for input by the Applications Subcommittee, recommendations are made by the Department directly to the Panel.

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

The criteria against which the Panel 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 Panel 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 establishments 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 establishments 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 animals held.

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 2015–16 year is provided in Appendices C and D. The dates

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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 establishment 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 a Department Animal Welfare Veterinary Inspector and the Panel 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 and animal care staff. 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 establishment at the beginning or end of the inspection. Any serious concerns are immediately referred to the establishment 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 Panel 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 Panel 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 establishment, 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 Panel 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 Panel also conducts revisits to establishments (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 Panel aims to carry out full audit visits for all establishments 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

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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 NSW**

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**

Administration is by NSW Department of Primary Industries Animal Welfare, the functions of which include:

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

DPI Animal Welfare can be contacted at:

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

## **2. Report on work and activities**

### **2.1 Administration and planning**

Administrative functions have varied from activities such as assessments of Accreditation and Licensing, to formulating the Panel's operational plan for 2015–16. The appendices to this annual report contain details of many of the operational and strategic functions of the Panel. These include the dates of, and attendance at, Panel meetings (Appendixes A and B); dates and attendance of Panel members at inspections (Appendixes C and D); the Animal Research Review Panel Strategic Plan 2014–17 (Appendix E) and Operational Plan for 2015–16 (Appendix F); and Panel operating expenses (Appendix I).

#### **2.1.1 Strategic plan 2014 – 17**

The Panel's 3-year strategic plan for 2014-17 identifies the primary goals of the Panel and strategies for achieving these goals and is provided in Appendix E.

#### **2.1.2 Operational plan for 2015-16**

The Panel Operational Plan for 2015–16, including performance status for each activity, is provided in Appendix F.



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### 2.1.3 Liaison with organisations and individuals

The Panel 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 2015-16 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.

There was ongoing communication with an Accredited Establishment following the investigation of a complaint, to enable the assessment of the effectiveness of measures put in place to deal with the issues identified.

## 2.2 Assessment of applications

In 2015–16 there were 144 Accredited Animal Research Establishments and 42 holders of Animal Supply Licences. During 2015–16 the Panel considered and made recommendations to the Secretary on:

- 9 new applications for Accreditation
- 60 renewal applications for Accreditation
- 2 new applications for Animal Supply Licences
- 30 renewal applications for Animal Supply Licences.
- 1 extension to existing Accreditation and/or Animal Supply Licence.

### 2.2.1 LD50 testing

LD50 is a toxicity test used to determine the dose or concentration of a test substance—that is, the lethal dose—that is expected to kill 50% of the animals to which it is administered. For the purposes of the *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 a Panel subcommittee. Members of the subcommittee in 2015–16 were Professor Dart and Dr Fleming. The subcommittee makes recommendations to the ARRP, which in turn advises the Minister.

In 2015–16 the subcommittee considered one application (five 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 Panel recommended the Minister approve the application on the following conditions:

- 1) Data is provided in graphical form by 31 January 2017 with figures comparing 2014, 2015 and 2016 calendar years on the following:
  - a) The number of animals used for each quality control test in relation to a relevant measure to be determined by the establishment. The measure should provide information on the trends in numbers of animals used over time.

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- b) The number of animals used for development and research over time, with an explanation of the purpose – for example 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 2017 and April 2018 must be presented by the establishment to the Animal Welfare Unit by 31 January 2017.
  - 3) The establishment 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 2017.

### 2.3 Assessment of changes to AEC membership

All establishments are required to advise the Department of changes to AEC membership. The Panel assesses and makes recommendations to the Secretary 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 Panel Policy 9: *Criteria for Assessment of Animal Ethics Committee Membership* (<http://www.animaethics.org.au/policies-and-guidelines/operation/criteria-for-assessment> ).

In the 2015–16 year the Panel assessed and made recommendations to the Secretary on the appointment of 106 members of Animal Ethics Committees.

### 2.4 Assessment of Accreditation and Licence responses

The Panel assesses and makes recommendations to the Secretary 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 2015–16 year the Panel considered 17 responses from Accredited Animal Research Establishments and Licensed Animal Suppliers.

### 2.5 Subcommittees

The Panel 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 Panel for consideration. Activities of subcommittees in the 2014–15 year included:

- Evaluation of applications for LD50 testing (Professor Dart and Dr Fleming)
- Preparation for the 2015 Animal Ethics Seminar (Dr Fogarty sub-committee Chair, Professor Dart, Professor Keogh, Ms Hurst and Professor Hennessy)
- Rehoming animals (Ms Hurst sub-committee Chair, Dr Fogarty and Dr Awad).

### 2.6 Statistics on animal use

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The Animal Research Regulation 2010 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 the recording of:

- an animal in all projects in which the animal is used.
- animals for each year in which they are held in long-term projects.
- 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 used on a national basis. Figures are collected on a calendar year rather than by financial year.

Appendix G of this report summarises animal usage in 2015.

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 annual reports of AECs are required to 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 2015-16 year, the Panel 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 Panel. 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 Panel and the Department 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 Panel 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 find potential members, the Department maintains 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 Animal Ethics Seminar

An Animal Ethics Seminar was held in September 2015. The seminar was for members of Animal Ethics Committees and people involved in the care and use of animals for research and teaching. In an effort to ensure that the programme for the seminar would meet the needs of



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AECs, comment was sought from all NSW AECs on topics they wished to discuss and the format for conducting the seminar. Valuable feedback was provided and used, in conjunction with comments gathered from evaluation forms completed at previous seminars, to structure the programme. The members of the Panel subcommittee on this project were Dr Fogarty, Professor Dart, Professor Keogh, Ms Hurst and Professor Hennessy. Other members of the Panel assisted with ideas for the programme and contacting potential presenters.

The quality of the programme and the presenters attracted 160 participants. The presentations were varied, engaging and informative. Topics ranged from anaesthesia and analgesia in rabbits, rodents and fish; the basics of assessing research design (in language accessible to non-statisticians); and roles and challenges faced by animal care staff.

The inclusion of a segment of “interpretive dance” in the final presentation guaranteed the attention of the audience (this involved the demonstration of how to “talk” to laboratory rabbits with hand signals, and the benefits to the animals of this form of communication).

As for previous seminars, the North Sydney venue was provided free of charge by the Australian Catholic University. The lecture theatre had been extensively renovated and provided an elegant and comfortable setting that facilitated both the delivery of presentations and interaction with audience members.

The feedback on the seminar was almost universally positive, with many attendees wanting it to be an annual rather than biennial event. It was pleasing that the considerable amount of background organisation culminated in such a successful day.

Information on previous seminars and the 2015 seminar can be found at the Animal Ethics Infolink website at: <http://www.animaethics.org.au/animal-ethics-committees> .

## **2.8 Website: Animal Ethics Infolink**

Development and maintenance of a website by the Panel and Department - ‘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 Panel 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 Animal Ethics Infolink site is accessible at [www.animaethics.org.au](http://www.animaethics.org.au) .

## **2.9 Site inspections**

A list of dates of site inspections undertaken in 2015–16 is provided in Appendix C, and a list of Panel members attending is given in Appendix D. There were 15 establishments inspected over 20 working days. The length of these inspections ranged from one day to six days.

The Panel aims to carry out a routine inspection of each Accredited Animal Research Establishment approximately every 4 years to maintain personal contact with establishments, AECs and researchers, and to carry out a complete audit of establishment operation under the *Animal Research Act 1985*.

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

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## 2.10 Policies and guidelines

The Panel and Department produce policies and guidelines 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 Panel's website, [Animal Ethics Infolink](#) (see Appendix J for a list of guidelines and policies).

New policies and guidelines are produced to fill needs identified by the Panel.

## 2.11 Initiatives in replacement, reduction and refinement

Information collected from the 'Annual Return on Animal Use' submitted by each research establishment 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 Panel. A list of some of the initiatives can be found in Appendix H.

## 2.12 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 Secretary, who refers the complaint to the Panel for investigation. The Panel is bound to investigate formal complaints and to make recommendations to the Secretary for disciplinary action (if it is considered warranted) or dismissal of the complaint. Both the complainant and the individual or establishment being investigated have a right of appeal to the NSW Civil and Administrative Tribunal (NCAT).

The Panel 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; Panel 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 Panel, or the Department.

In the 2015–16 reporting period 2 complaints were received, investigated and finalised. There was also ongoing follow up on measures implemented for two complaints received in the previous reporting year.

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## APPENDICES

### Appendix A: Dates of Animal Research Review Panel meetings 2015–16

Meeting number	Date of meeting
213	16 July 2015
214	24 September 2015
215	3 December 2015
216	3 March 2016
217	5 May 2016

### Appendix B: Attendance of members at Panel meetings 2015–16

Member	Meeting number				
	213	214	215	216	217
Professor Andrew Dart (Chair)	*	*	*	*	*
Dr Regina Fogarty (Deputy Chair)	*	*	N/A	N/A	N/A
Dr Magdoline Awad	A	*	*	*	*
Dr Mike Fleming	*	A	A	*	*
Professor Annemarie Hennessy	A	A	A	*	*
Ms Emma Hurst	*	*	A	*	*
Prof Anne Keogh	A	A	*	A	*
Mr John Mills	N/A	*	*	*	*
Professor Robert Mulley	*	*	*	*	*
Mr David O'Shannessy	A	*	*	*	*
Professor Jacqueline Phillips	A	A	*	A	*
Dr Peter Rolfe	*	A	*	A	*

\* = Present

A = Absent

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## Appendix C: Dates of Inspections July 2015 – June 2016

Dates
19/8/15
13/11/15
9/2/16
11/2/15
7/3/16
23/3/16
1/4/16
12/4/16
17/5/16
20/4/16
26/4/16
11/5/16
4/6/16
31/5/16
8/6/16
14/6/16
16/6/16
21/6/16
23/6/16
21/6/16

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#### Appendix D: Attendance of Panel members at site inspections 2015–16

Member	Days
Professor Andrew Dart (Chair)	-
Dr Regina Fogarty (Deputy Chair)	-
Dr Magdoline Awad	-
Dr Mike Fleming	2
Professor Annemarie Hennessy	-
Ms Emma Hurst	2
Professor Anne Keogh AM	-
Mr John Mills	2
Professor Robert Mulley	1
Mr David O'Shannessy	2
Professor Jacqueline Phillips	2
Dr Peter Rolfe	-

## Appendix E: Animal Research Review Panel Strategic Plan July 2014 – June 2017

\* Numbers on the right refer to items from 2015/2016 Animal Research Review Panel Operational Plan that address the strategies.

Goals and Strategies	
<b>Goal 1:</b> <b>Effective and efficient implementation of the statutory requirements of the Animal Research Act 1985, the Animal Research Regulation 2010 and the <i>Australian Code for the Care and Use of Animals for Scientific Purposes</i>.</b>	
1.1 Maintain a system to accredit and licence all establishments and individuals in NSW conducting research and teaching using animals.	1.1
1.2 Maintain a programme of site visits to effectively monitor compliance with the legislation.	2
1.3 Review the methods of conducting site visits and documentation of these methods on a regular basis to help ensure high standards of efficiency, effectiveness and consistency.	
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 with respect to the conduct of animal research and teaching and the supply of animals for research and teaching.	1 2
1.6 Active participation in national reviews of the Code to ensure that it is effective in regulating the conduct of animal research and teaching and the supply of animals for research and teaching.	
1.7 Prepare an annual report to Parliament on the operations and achievements of the Animal Research Review Panel.	1.4
1.8 Maintain and review the system for collection and analysis of statistics on animal use for research and teaching, to ensure that it provides useful information which accurately reflects the use of animals, without imposing an undue administrative burden on institutions or Government.	1.5
1.9 Maintain a system for receiving and investigating complaints relating to the requirements of the legislation.	1.2
1.10 Provide opportunities to the research, teaching, veterinary, animal welfare and lay communities to provide feedback on the activities of the Animal Research Review Panel and respond appropriately.	2 3
1.11 Maintain a system to consider and make recommendations on applications for permission to carry out LD50 tests.	1.3
<b>Goal 2:</b> <b>The principles, processes and responsibilities in the <i>Australian Code for the Care and Use of Animals for Scientific Purposes</i> are actively embraced by all involved wherever animals are used.</b>	
2.1 Promote an understanding of the roles and responsibilities of institutions in supporting the effective operation of their AECs.	2 3 4
2.2 Promote an understanding of the roles and responsibilities of institutions in actively pursuing programmes for researchers and teachers that underpin their responsibilities under the Code.	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 through visits and all communications from the Animal Research Review Panel to institutions, AECs, researchers/teachers and animal care staff.	2 3 4
2.6 Promote an understanding of the roles and responsibilities of AECs through encouraging participation in AEC training programmes.	2 3 4
2.7 By identifying problems and suggesting remedies, provide assistance to institutions, AECs and researchers/teachers to ensure that the principles, processes and responsibilities in the Code are actively embraced.	2 3
2.8 Promote discussion and understanding of key technical and ethical issues and foster interaction between AECs by maintaining a programme of meetings of members and Executive Officers of AECs and participating in AEC meetings during site inspections.	2 3.2
2.9 Review the membership and operation of individual AECs to ensure they are operating effectively.	1.1 2
2.10 Develop and promulgate evidence-based guidelines to assist AECs, researchers and teachers to effectively implement the 3Rs.	4
2.11 Promote a critical review of the operation of AECs by the institution with a view to maximising their effectiveness.	2 4
<b>Goal 3: Researchers and teachers considering using animals are aware of and actively apply the principals set out in the Act, Regulation and the <i>Australian Code for the Care and Use of Animals for Scientific Purposes</i>.</b>	
3.1 Promote an understanding of the roles and responsibilities of researchers/teachers through participation in education programmes, to foster an awareness of ethical and scientific issues and the implementation of the 3Rs.	3 4
3.2 Maintain the "Animal Ethics Infolink" website as a resource for AECs, researchers and teachers and members of the community.	3.1
<b>Goal 4: Methods that complement or replace animal use are used wherever possible.</b>	
4.1 Encourage AECs critically to assess the adequacy of researchers'/teachers' attempts to identify alternatives to animal use.	2 3
4.2 Encourage greater awareness of the use of alternatives to animals in research and teaching.	2 3
4.3 Collate and disseminate information on alternatives to animal use.	3
4.4 Promote consideration of funding for development and validation of alternatives.	
<b>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.</b>	
5.1 Encourage a critical review of the design of projects before applications are submitted to AECs.	2 3 4
5.2 Ensure close scrutiny by AECs of breeding programmes to minimise overproduction	2

of animals.	3 4
5.3 Ensure close scrutiny by AECs of the competence of researchers to carry out specific procedures.	2 3 4
5.4 Promote the critical evaluation of the monitoring of animals being used in procedures.	2 3 4
5.5 Promote the critical evaluation by AECs and researchers of the impact of the type of housing / holding on experimental animals and awareness of its implications for experimental results.	2 3 4
<b>Goal 6: When animals are used in research and teaching, their well-being is promoted and there is the anticipation, prompt recognition and alleviation of pain and distress.</b>	
6.1 Promote the implementation of strategies which will foster the well-being of animals and which will foster the development of appropriate risk management assessments related to pain and distress in animals.	2 3 4
6.2 Ensure that AECs and researchers/teachers focus on the possible impact of procedures at the planning stage and implement appropriate strategies for monitoring and alleviation.	2 3 4
6.3 Promote awareness by researchers / teachers and animal care staff of signs of well-being, pain and distress in animals.	2 3 4
6.4 Promote the use of appropriate analgesia and anaesthesia by facilitating access by researchers/teachers to information resources.	2 3 4
6.5 Promote awareness of the effects of handling and other interactions with humans on levels of pain and distress and the use of strategies to minimise adverse impacts.	2 3 4
6.6 Monitor and identify deficiencies in anticipation, recognition and relief of pain and distress during site visits and ensure deficiencies are rectified, including by provision of pre-operative analgesia where appropriate.	2
<b>Goal 7: High standards of housing and routine care are established for animals used in research and teaching.</b>	
7.1 Evaluate housing and routine care through the ongoing site visit programme.	2
7.2 Develop and disseminate evidence based guidelines for housing and routine care.	4
7.3 Actively participate in the development and review of appropriate national and international standards for housing and routine care.	5.1
<b>Goal 8: Animals used are supplied in accord with the legislation</b>	
8.1 Identify areas of non-compliance through scrutiny of records during site visits and investigation of complaints.	1.2 2
8.2 Develop and disseminate appropriate educational material.	3 4
<b>Goal 9: The community (research, teaching, veterinary, animal welfare and lay) has access to information about animal use for research and teaching in NSW.</b>	
9.1 Provide information in the annual report on ARRP activities and achievements, areas of concern to the Animal Research Review Panel and statistics on animal use.	1.4 1.5
9.2 Identify options for disseminating information about specific issues of interest and	3



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concern both broadly and to specific groups (researchers, teachers, veterinarians, animal welfare, lay).	4
9.3 Review and maintain a web site for the dissemination of information.	3.1
9.4 Provide opportunities for and encourage the community (researchers, teachers, veterinarians, animal welfare, lay) to have an input into legislative review, development of standards for housing and care and policy development.	3 4
9.5 Ensure that information about animal use provided by the Animal Research Review Panel is in lay terms where appropriate.	
9.6 Encourage institutions to provide information about their animal use direct to the general community.	
<b>Goal 10: The approach to administration of animal research and teaching is harmonised between State and Territory regulatory and funding bodies.</b>	
10.1 Promote interaction between State and Territory regulatory and funding bodies.	

## Appendix F: Animal Research Review Panel Operational Plan July 2015 – June 2016

Activity	Measure of Performance	Time Frame	Status
<b>1. Mandatory</b>			
1.1 Review incoming applications for accreditation and licence	Recommendation to the Secretary	3 months (new) 2 months (renewal)	Applications reviewed.
1.2 Investigate formal and informal complaints	Recommendation to the Secretary	Interim or final recommendations within 3 months	Complaints investigated and recommendations made.
1.3 Review incoming applications to conduct LD50 tests	Recommendations to the Minister	3 months	Applications reviewed and recommendations to Minister.
1.4 Prepare annual report for 2014-2015	Report submitted to the Minister	December 2015	Report submitted December 2015.
1.5 Prepare statistics on animal use for 2014	Statistics collated	December 2015	Statistics collated and included in 2014-2015 annual report.
<b>2. Inspections / Monitoring</b>			
2.1 Conduct site visits of accredited animal research establishments on a 4 yearly basis (for those establishments in-State, active and with own AEC)	Number of establishments inspected	Ongoing	15
	Number of days for inspections		20
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	0
2.3 Review and send inspection reports	Reports sent	Within 3 months of inspection	15 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 ARRPP agendas.
2.5 Assessment of 2014 AEC annual reports	Assessment carried out	October 2015	2014 reports assessed and feedback provided to establishments.
2.6 Assess qualifications of new AEC members	Recommendation to the Secretary	Ongoing	Qualifications assessed and recommendations made to Secretary.
<b>3. Education</b>			
3.1 Maintain ARRPP website	Site maintained	Ongoing	Some website pages maintained. Revisions required.
3.2 Hold 2015 Animal Ethics Seminar	Planning implemented	September 2015	Successful seminar held.
3.3 Commence planning 2017 Animal Ethics seminar	Planning commenced	March 2016	Not commenced.
<b>4. Policies and guidelines</b>			
4.1 Develop policies/ guidelines where strong need identified (maximum of 2 )	Developed as need identified.		G24: High impact projects published.
4.3 Revise current policies and guidelines	Continue programme of revision.	Ongoing	0 revised
<b>5. Additional</b>			
5.1 Input into proposed Regulation	Input provided.	Timeframe	Consultation

amendment.		dependent on development and release of consultation document.	document not released.
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## Appendix G: Animal use statistics 2015

**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 2015.

### Animal species categories used for collection of data

<b>Laboratory mammals</b>	Mice	<b>Primates</b>	Marmosets
	Rats		Macaques
	Guinea Pigs		Baboons
	Rabbits		Other primates
	Hamsters	<b>Native mammals</b>	Macropods
	Ferrets		Possums and gliders
	Other laboratory mammals (not primates)		Native rats and mice
<b>Domestic mammals</b>	Sheep		Dasyurids
	Cattle		Wombats
	Pigs		Koalas
	Horses		Monotremes
	Goats		Bandicoots
	Deer		Bats
	Cats		Other native mammals
	Dogs		Seals
	Other domestic mammals		Whales and dolphins
<b>Birds</b>	Poultry	<b>Exotic feral mammals</b>	Camels
	Exotic Captive		Cats
	Exotic Wild		Cattle
	Native Captive		Goats
	Native Wild		Hares
	Other birds		Horses
<b>Aquatic animals</b>	Fish		Mice
	Cephalopods (reporting not mandatory)		Pigs
	Crustaceans (reporting not mandatory)		Rabbits
<b>Amphibians</b>	Amphibians		Rats
<b>Reptiles</b>	Lizards		Dingo/Wild Dogs

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	Snakes
	Turtles and Tortoises
	Other reptiles

	Foxes
	Other exotic feral mammals
<b>Exotic zoo animals</b>	Exotic zoo animals

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

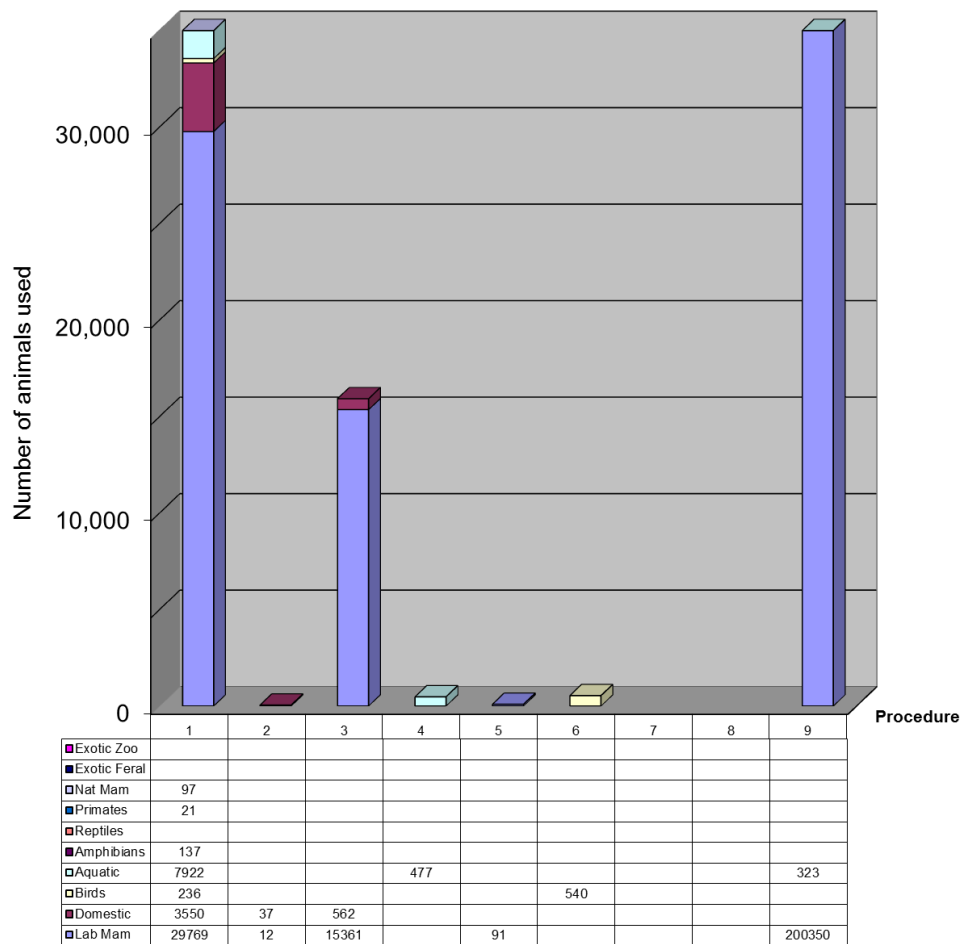
## Data collection: procedure categories and guidelines used for classification

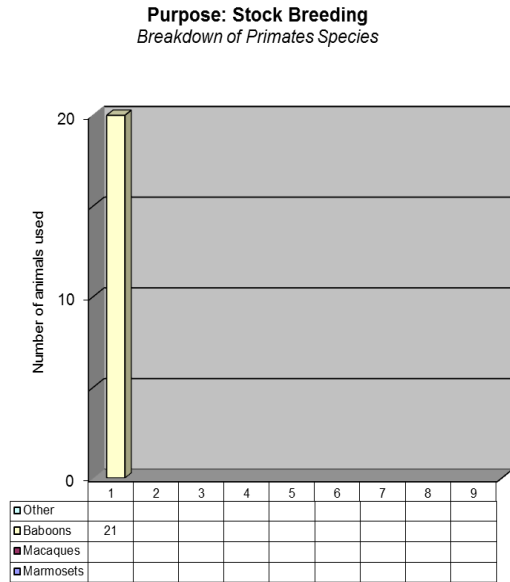
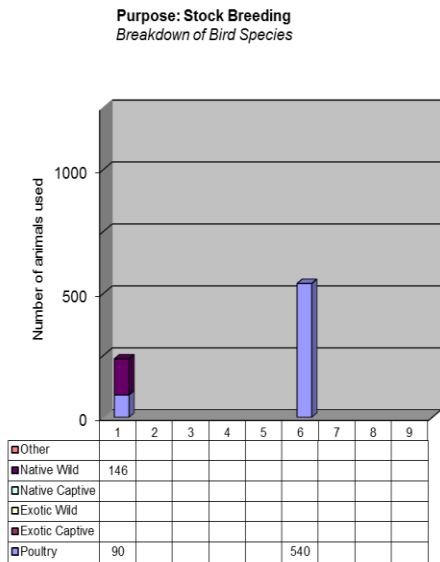
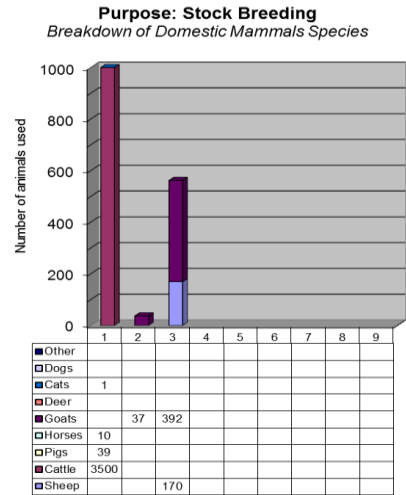
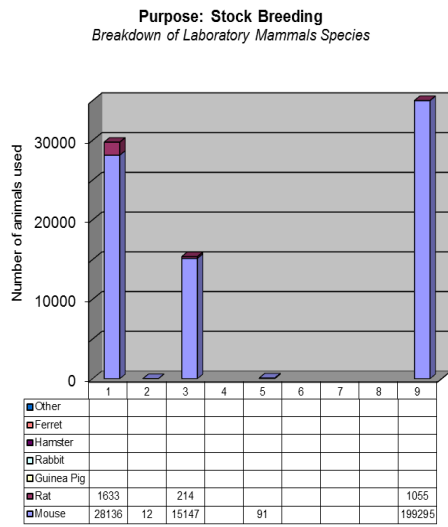
<b>1: Observation involving minor interference</b>	<b>6: Minor physiological challenge</b>
Animals are not interacted with, or, where there is interaction, it would not be expected to compromise the animal's welfare any more than normal handling, feeding, etc. There is no pain or suffering involved.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

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

## Purpose: Stock Breeding

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

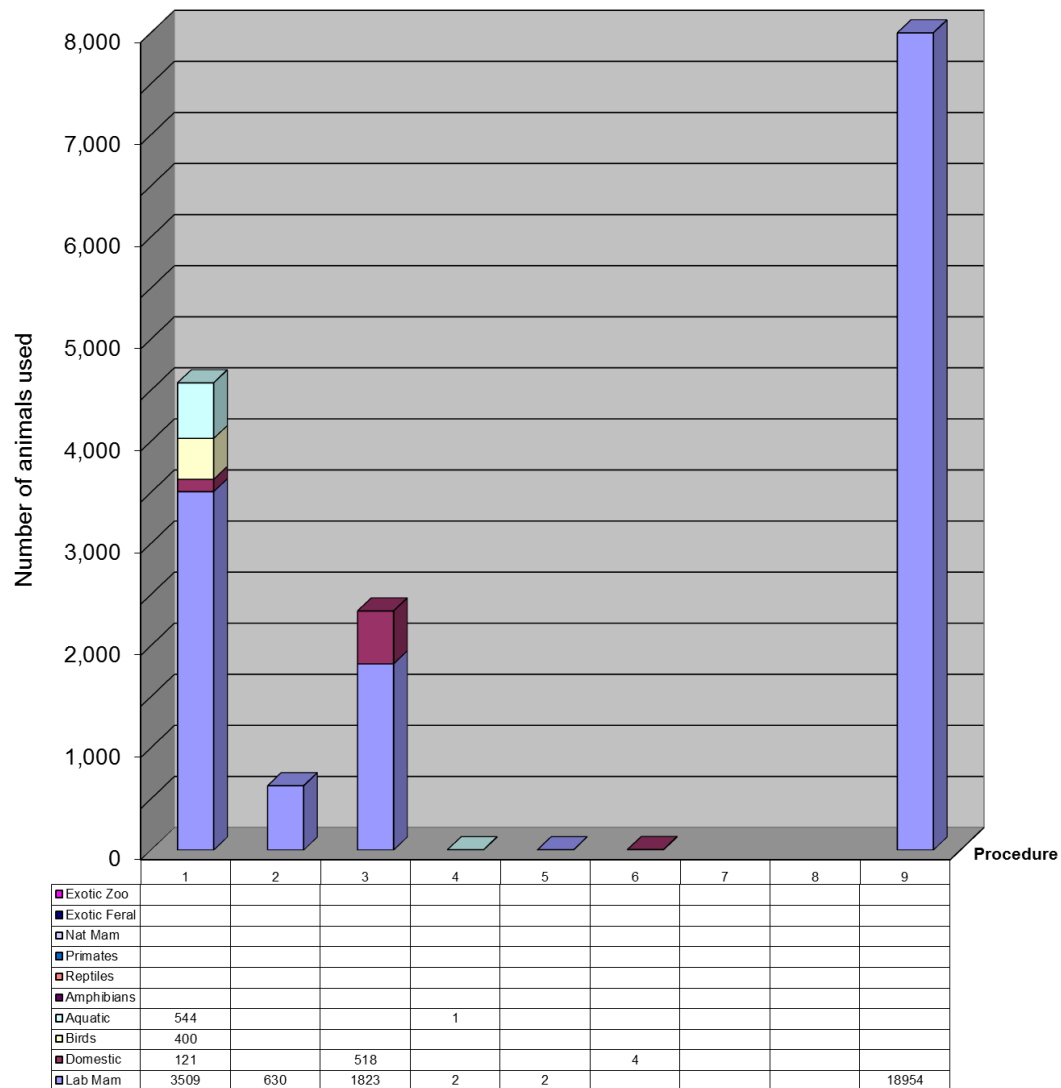


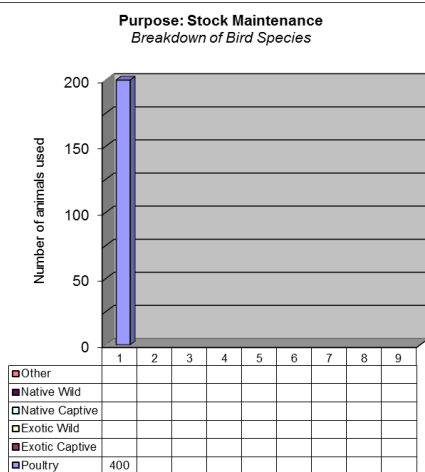
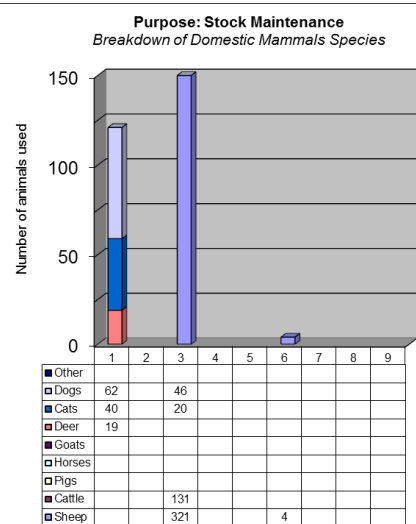
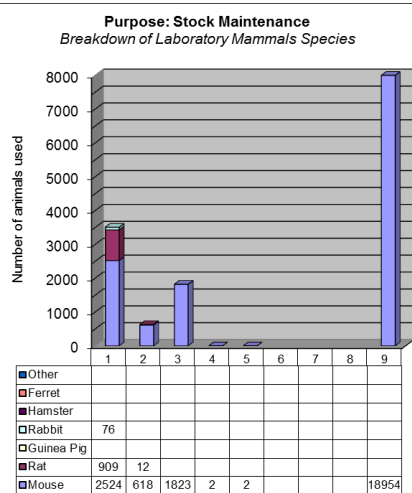




## Purpose: Stock Maintenance

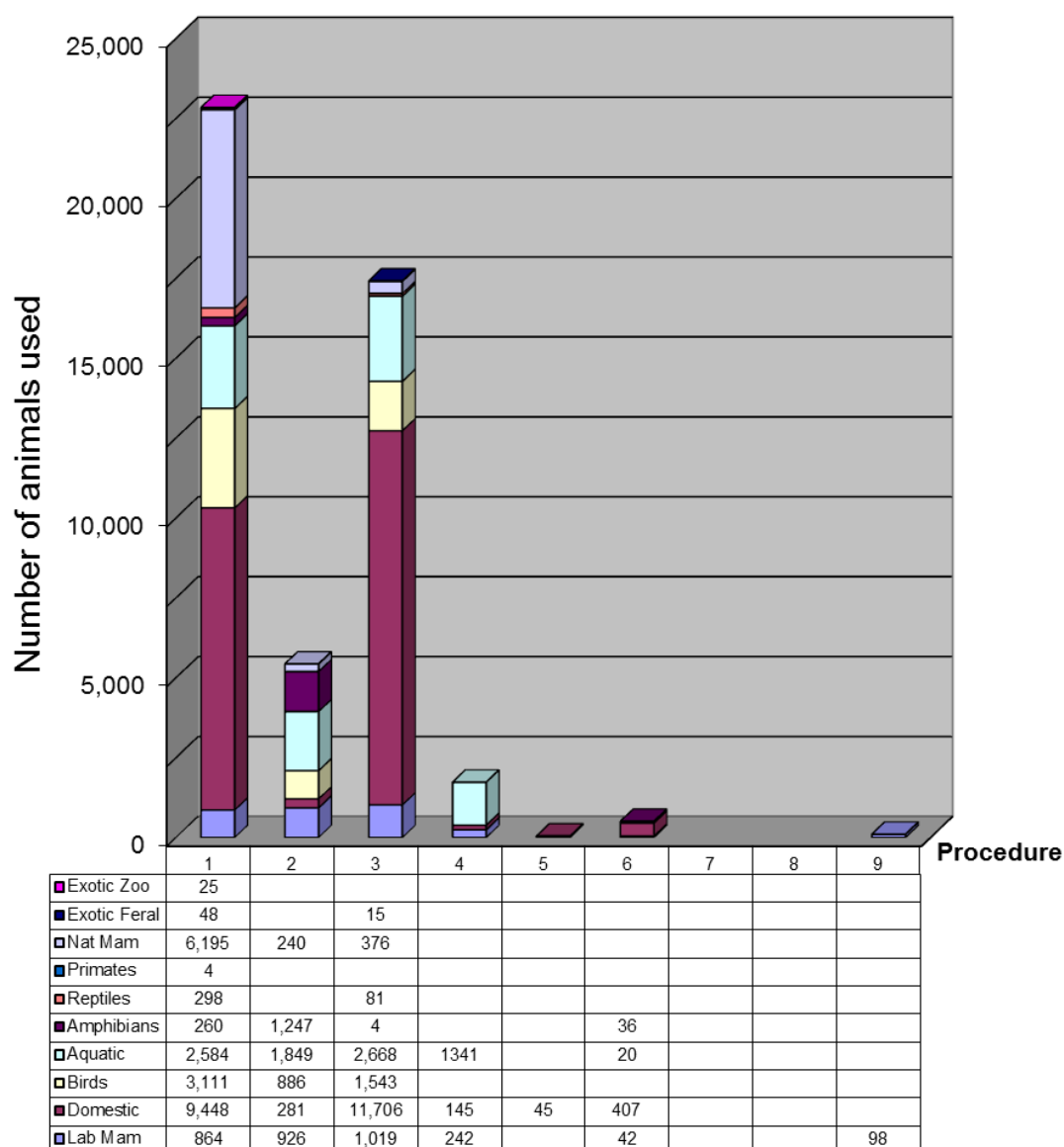
*Holding Protocols for animals maintained for use in other protocols.*



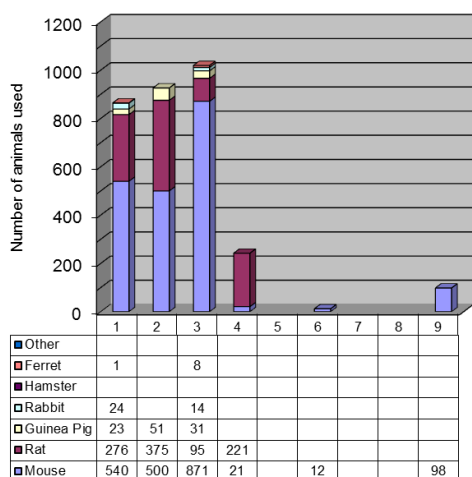


## Purpose: Education

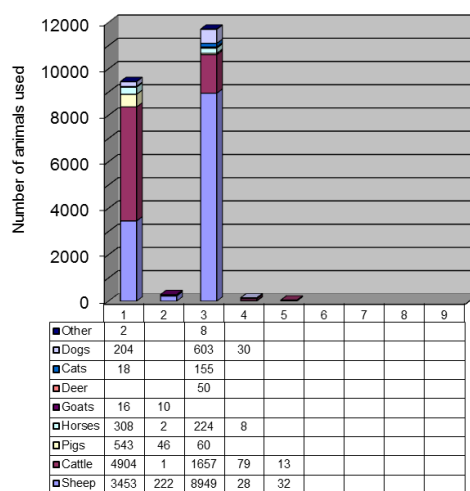
Protocols carried out for the achievement of educational objectives, including interactive or demonstration classes in methods of animal husbandry, management, examination and treatment.



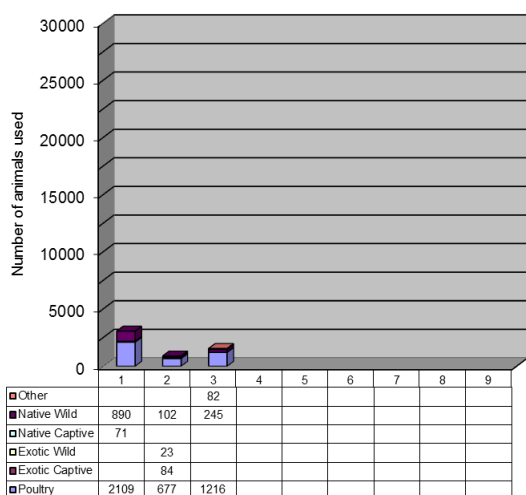
**Purpose: Education**  
Breakdown of Laboratory Mammals Species



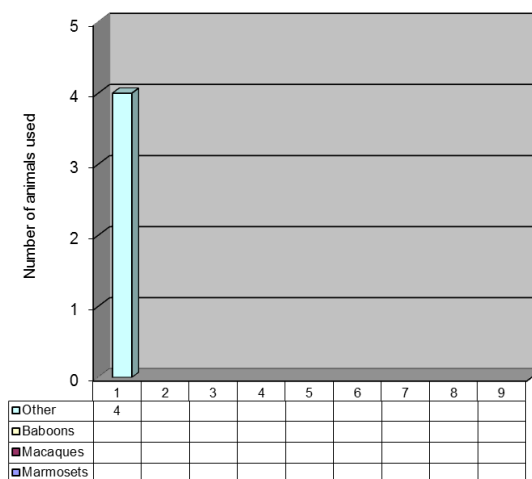
**Purpose: Education**  
Breakdown of Domestic Mammals Species



**Purpose: Education**  
Breakdown of Bird Species

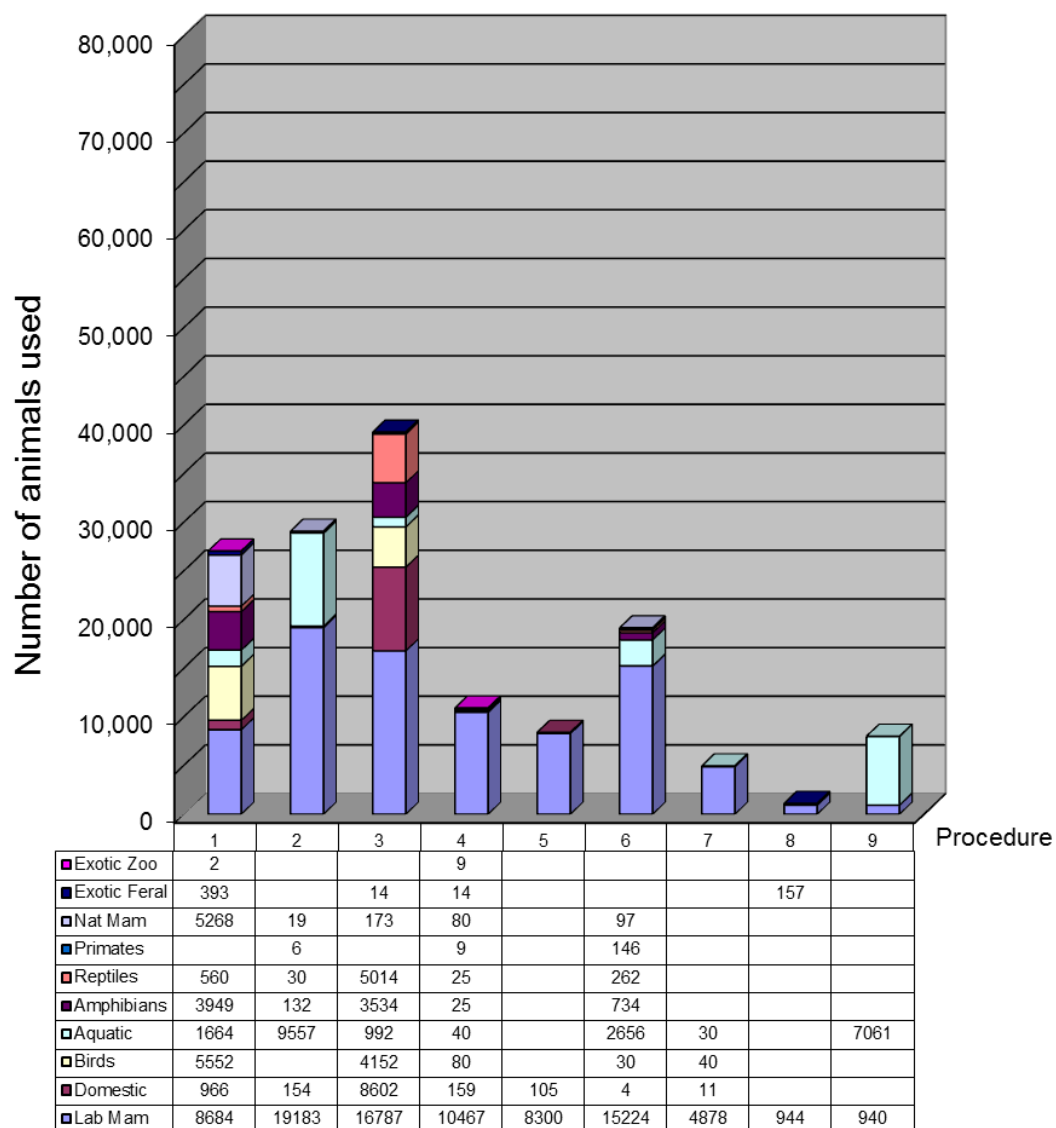


**Purpose: Education**  
Breakdown of Primate Species

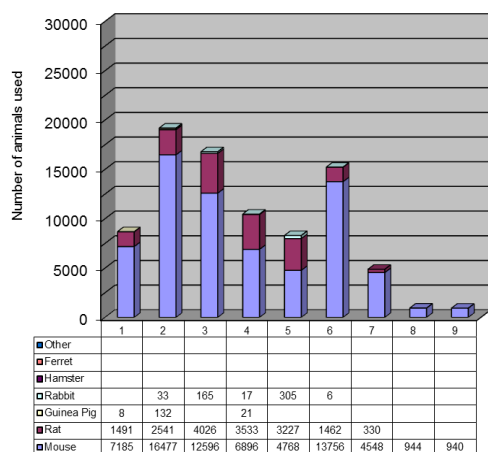


## Purpose: Research - Human or Animal Biology

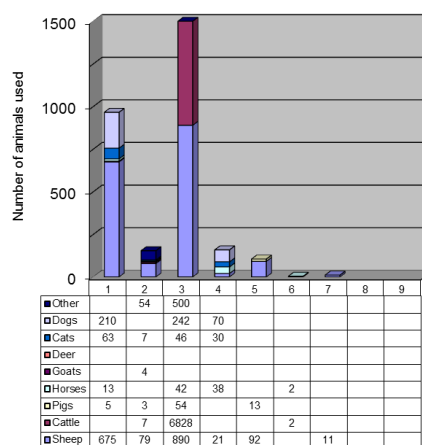
Research protocols which aim to increase the basic understanding of the structure, function and behaviour of animals, including humans, and processes involved in physiology, biochemistry and pathology.



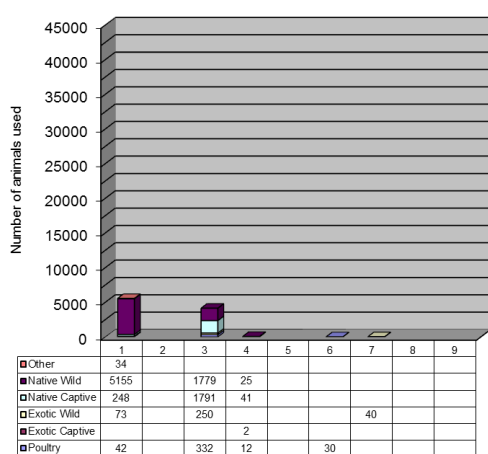
**Purpose: Research - Human or Animal Biology**  
*Breakdown of Laboratory Mammals Species*



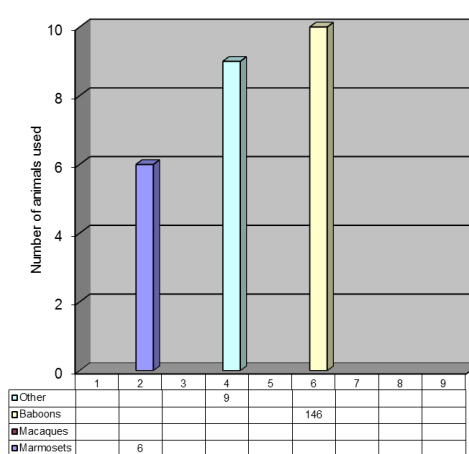
**Purpose: Research - Human or Animal Biology**  
*Breakdown of Domestic Mammals Species*



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

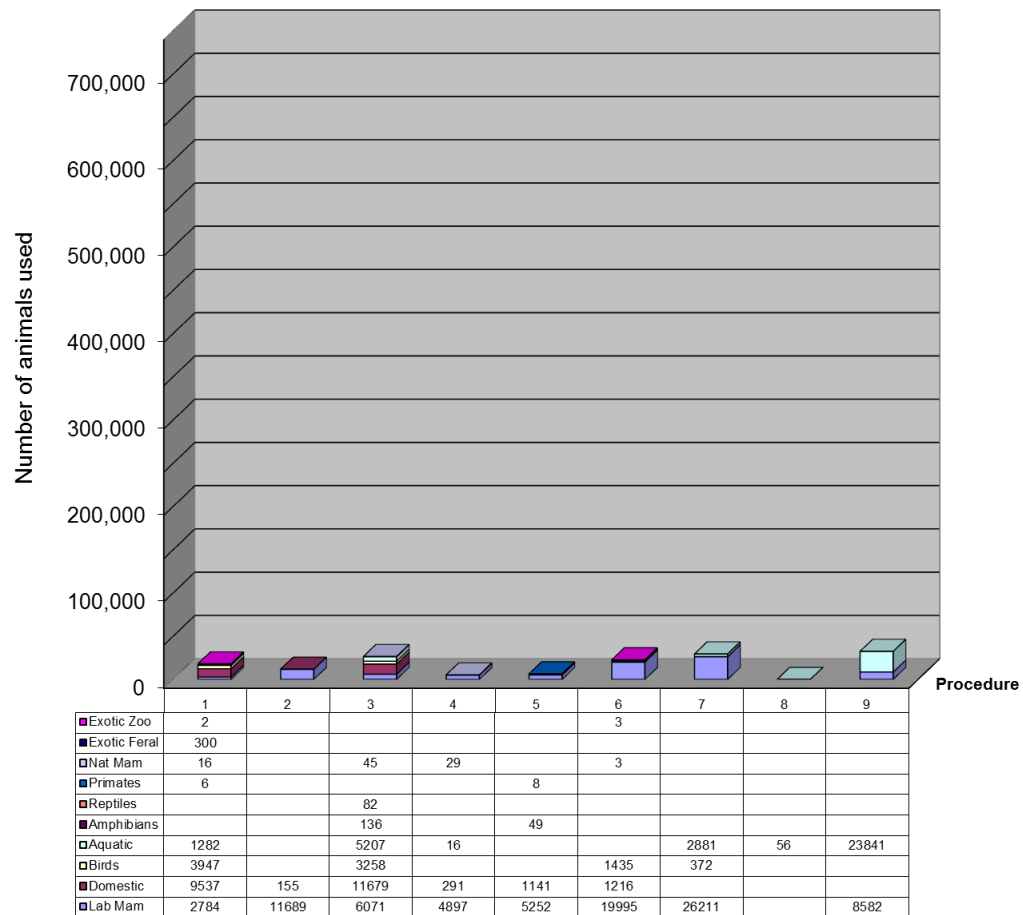


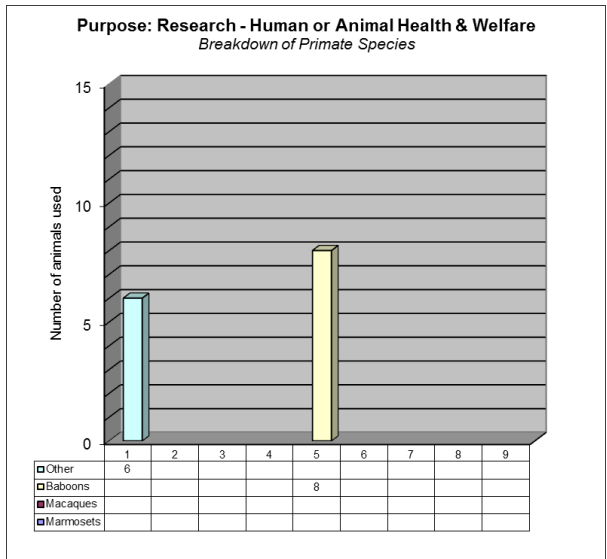
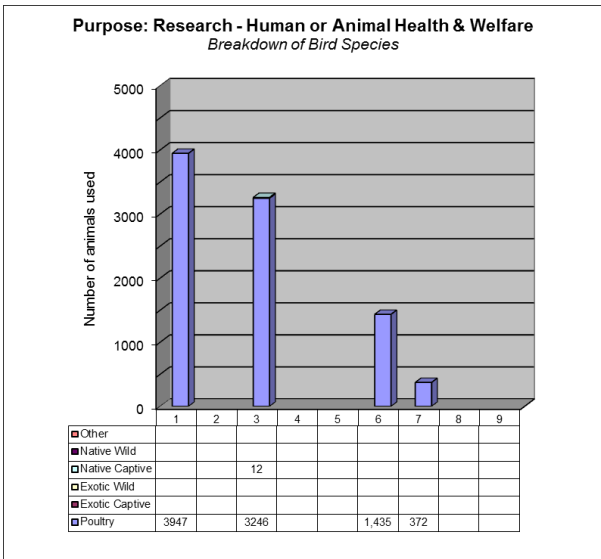
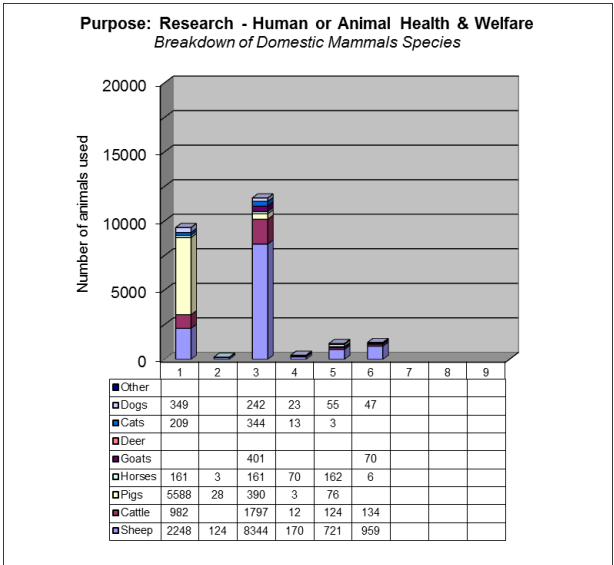
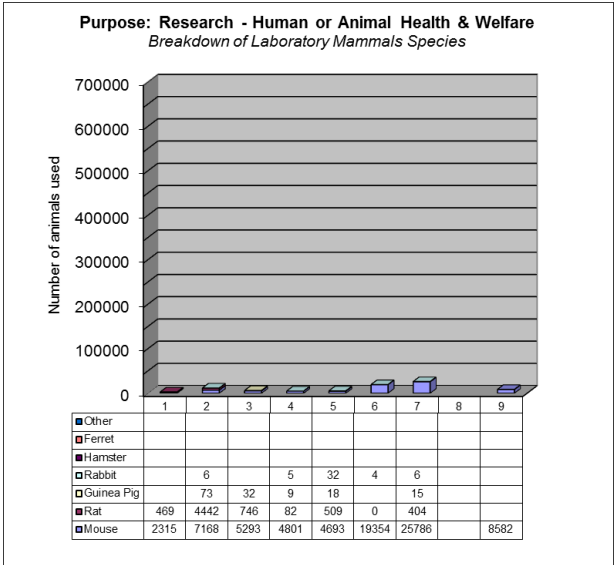
**Purpose: Research - Human or Animal Biology**  
*Breakdown of Primate Species*



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

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

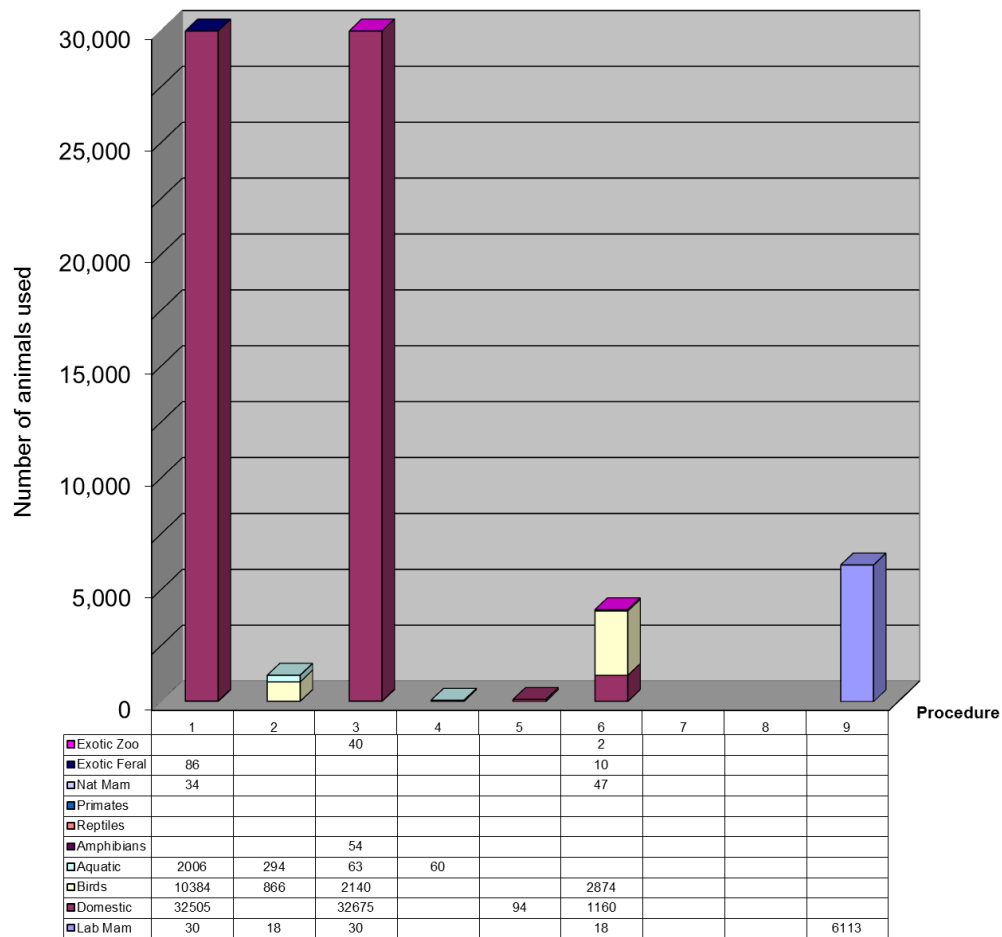




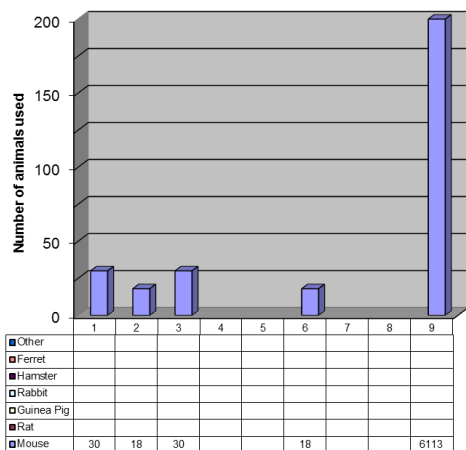


## Purpose: Research - Animal Management or Production

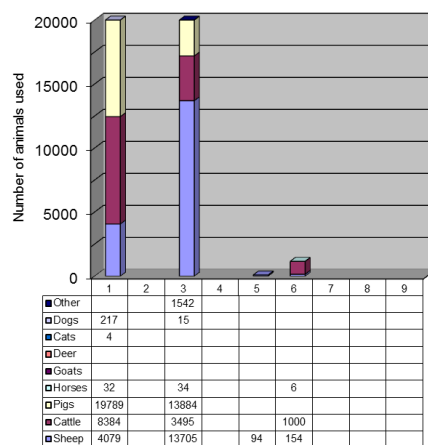
Research protocols which aim to produce improvements in domestic or captive animal management or production.



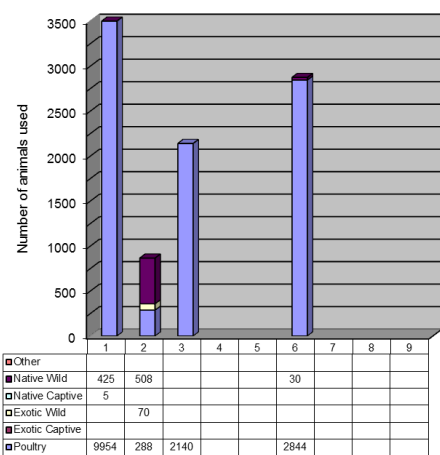
**Purpose: Research - Animal Management or Production**  
*Breakdown of Laboratory Mammals Species*



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

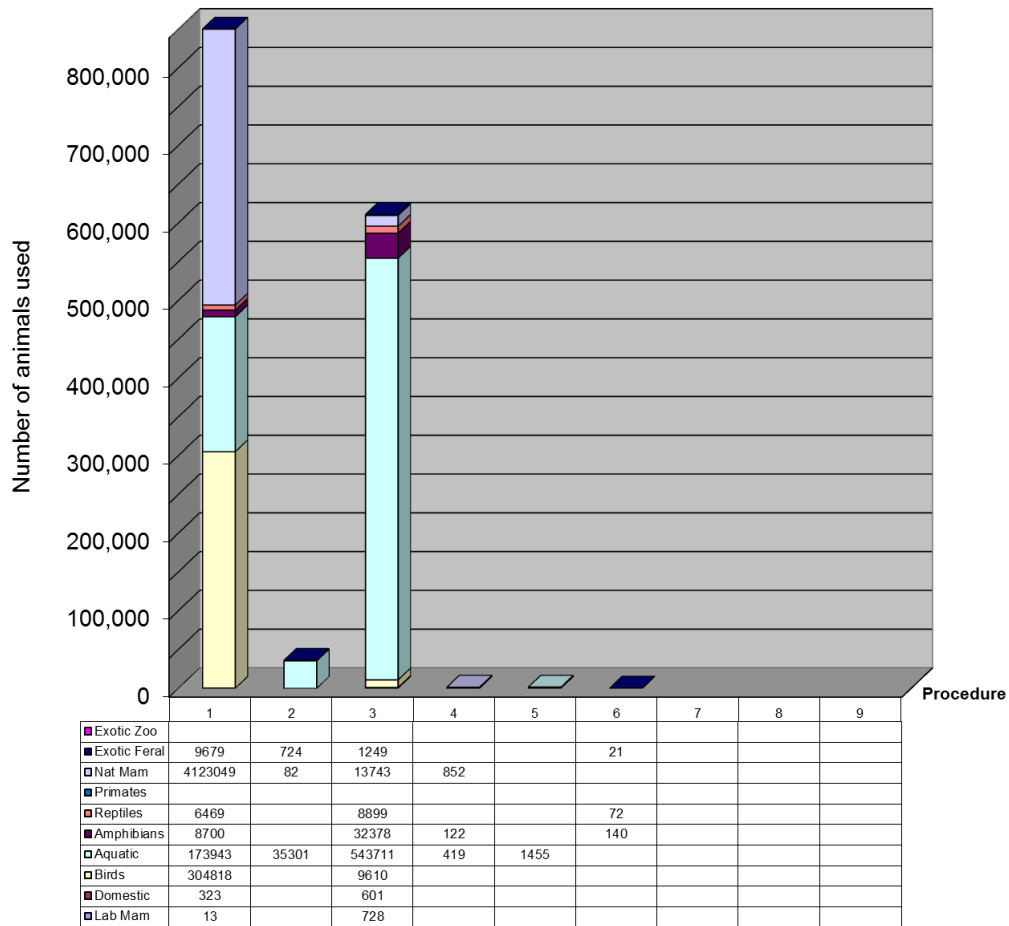


**Purpose: Research - Animal Management or Production**  
*Breakdown of Bird Species*

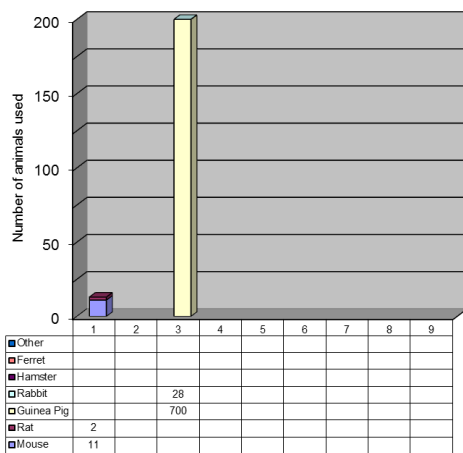


## Purpose: Research - Environmental Study

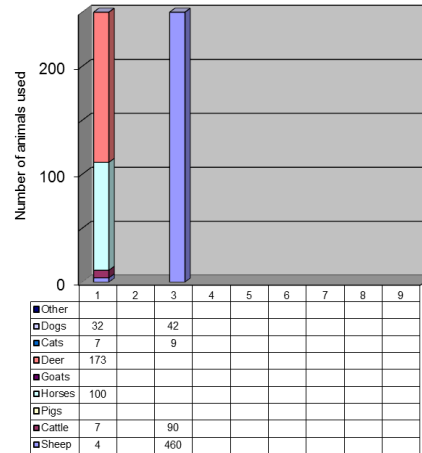
Research protocols which aim to increase the understanding of the animals' environment or its role in it, or that aim to manage wild or feral populations.



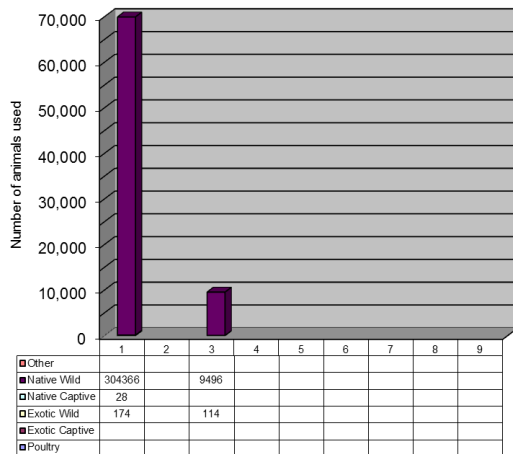
**Purpose: Research - Environmental Study**  
*Breakdown of Laboratory Mammals Species*



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

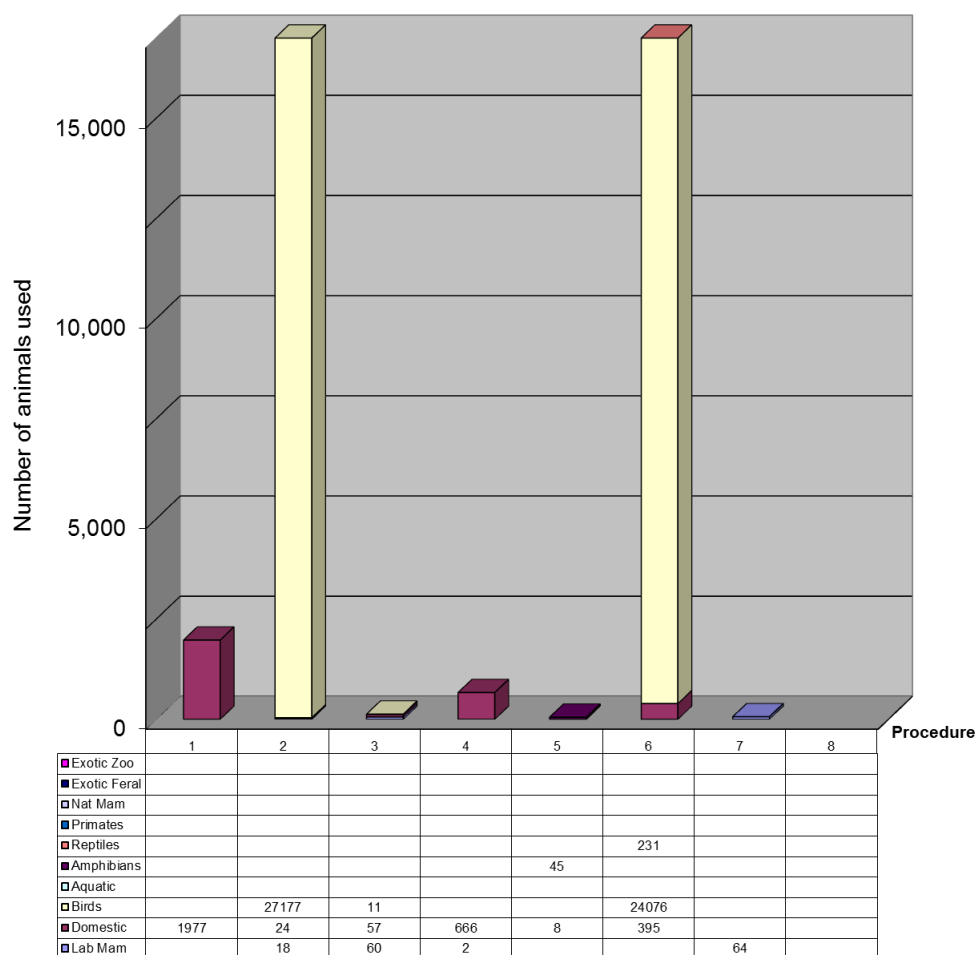


**Purpose: Research - Environment Study**  
*Breakdown of Bird Species*

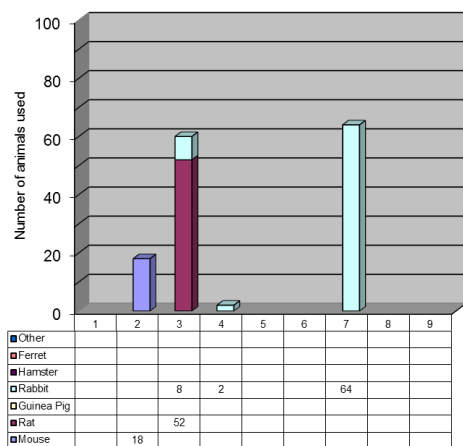


## Purpose: Production of Biological Products

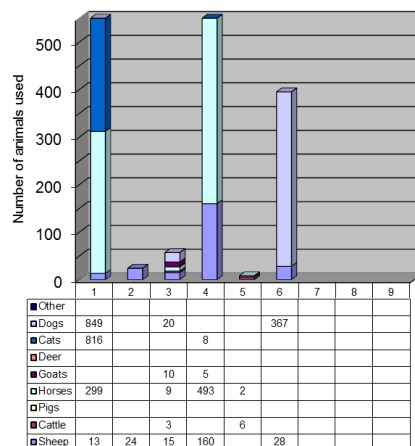
Use of animals to produce products (other than normal milk/meat/egg, etc).



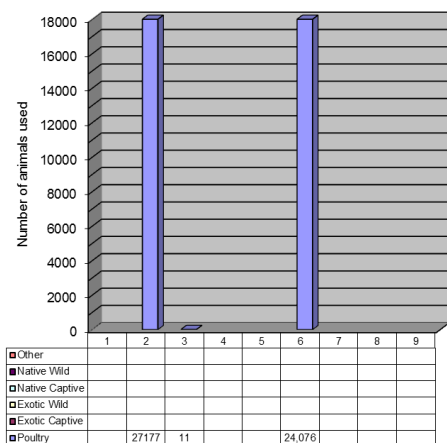
**Purpose: Production of Biological Products**  
*Breakdown of Laboratory Mammals Species*



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

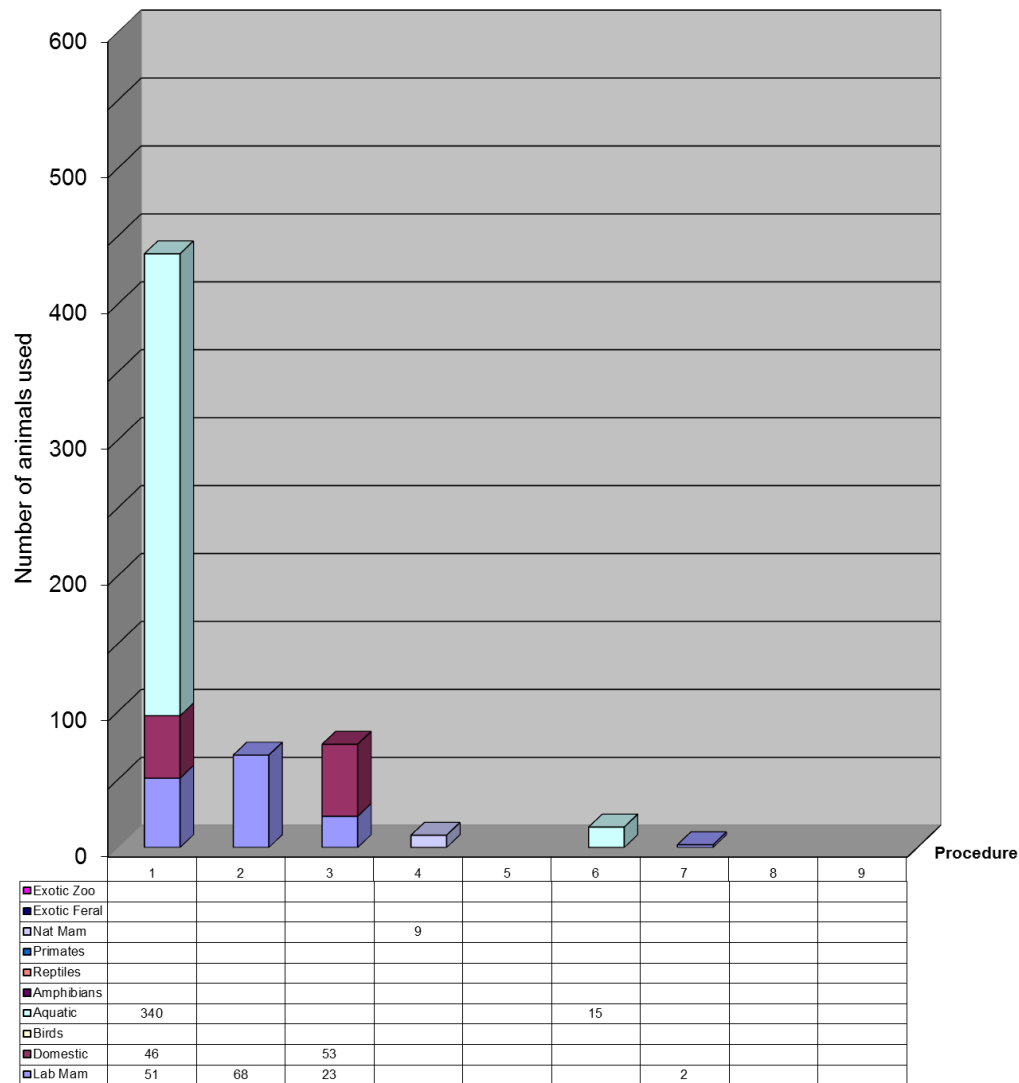


**Purpose: Production of Biological Products**  
*Breakdown of Bird Species*

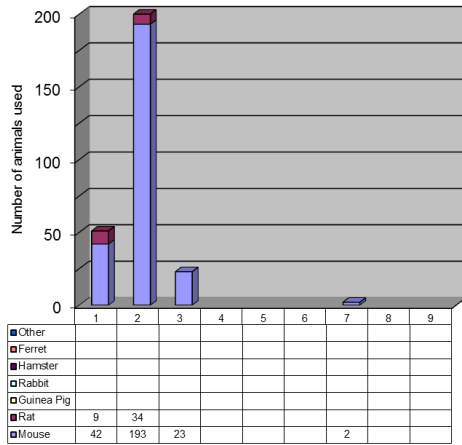


## Purpose: Diagnostic Procedures

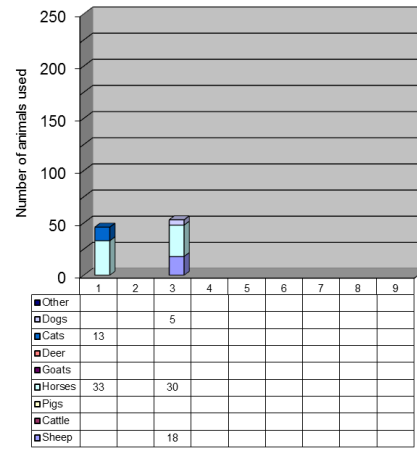
*Using animals directly as part of a diagnostic process.*



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



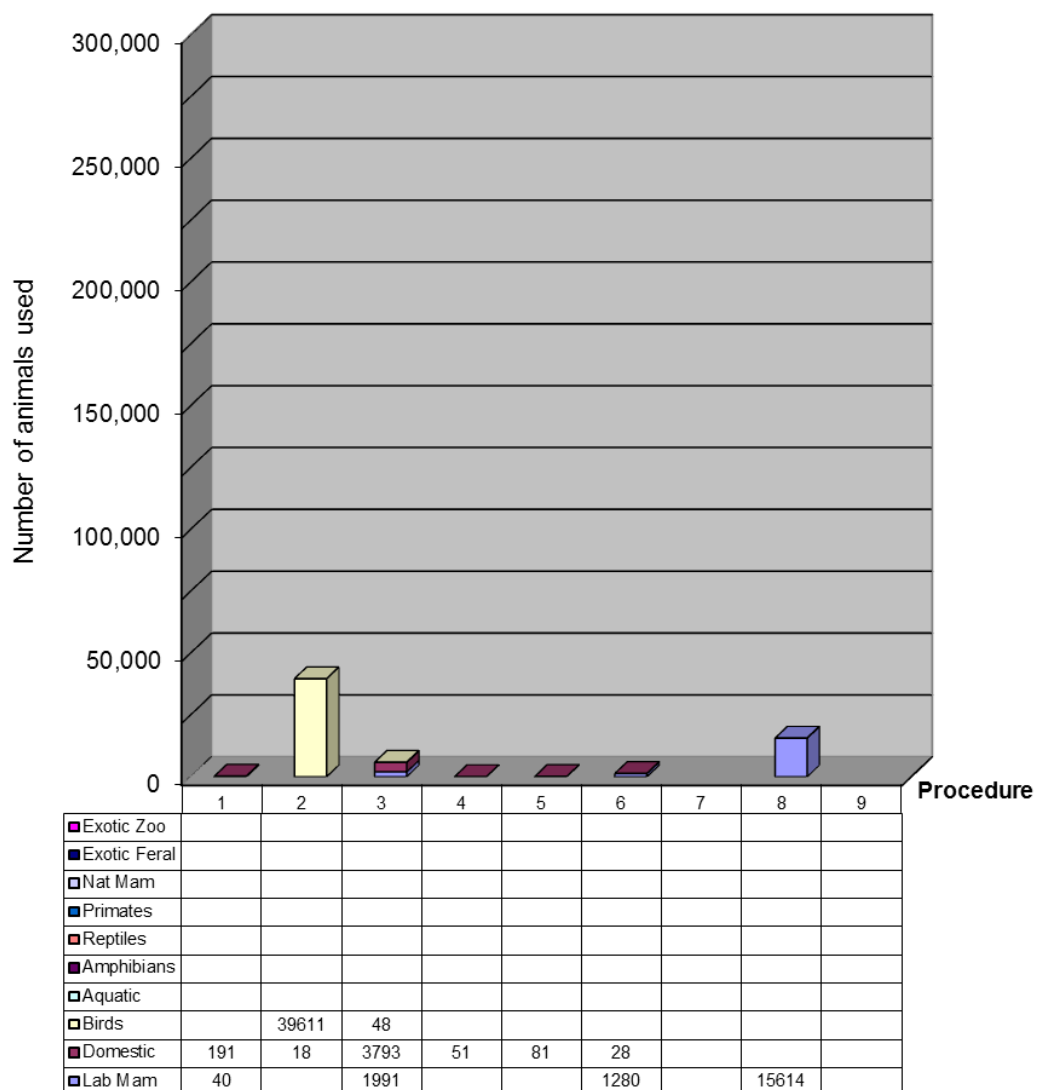
**Purpose: Diagnostic Procedures**  
*Breakdown of Domestic Mammals Species*

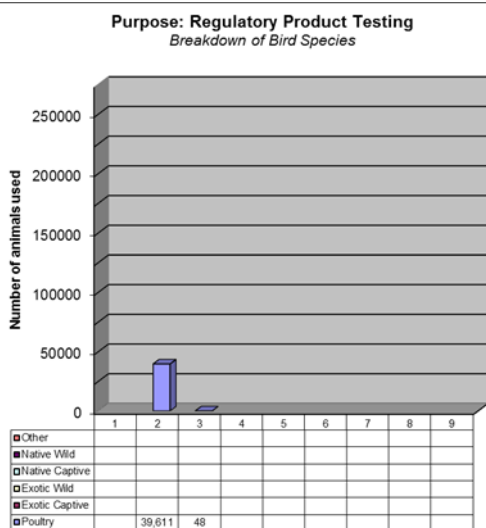
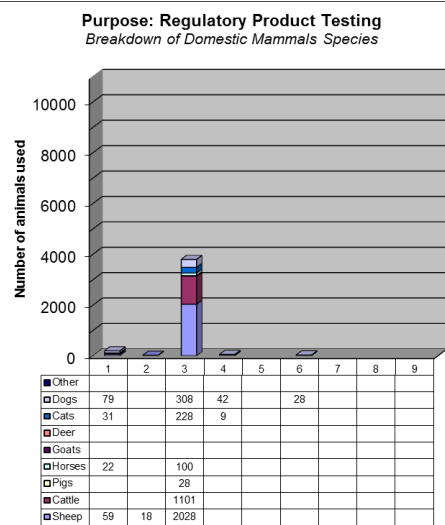
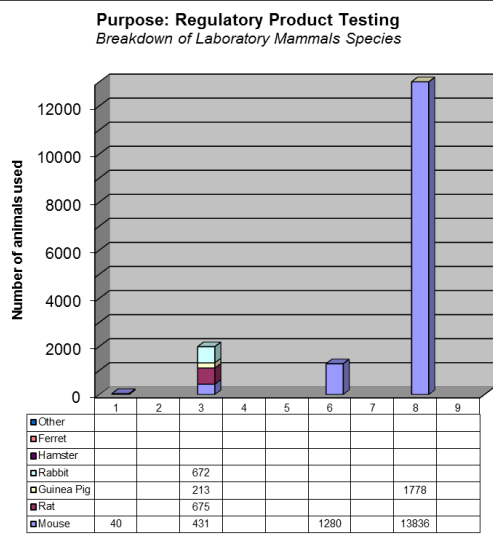




## Purpose: Regulatory Product Testing

*Protocols for the testing of products required by regulatory authorities.*





## LETHALITY TESTING – 2015

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 2015.

Species	Number used	Number died/ euthanased	Procedure	Justification	Alternatives
Guinea Pigs	1,827	375	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. There are no alternatives available at this time however the establishment has embarked on a long-term program to develop <i>in vitro</i> assays which may be used to replace existing <i>in vivo</i> assays subject to regulatory approval of these replacement assays.
Mice	1,544	1,619	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	This test is based upon regulatory requirements for the assessment of in-process products.  There are no alternatives available at this time however the establishment

					has embarked on a long-term program to develop in vitro assays which may be used to replace existing in vivo assays subject to regulatory approval of these replacement assays.
Mice	8,833	2,406	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 formulation.	<p>This test is based upon regulatory requirements for the assessment of in-process products.</p> <p>There are no alternatives available at this time however the establishment has embarked on a long-term program to develop in vitro assays which may be used to replace existing in vivo assays subject to regulatory approval of these replacement assays.</p>
Mice	4,380	2,322	Total Combining Power test in mice: Susceptible animals are challenged with test antigen/toxin/antibody dilutions to determine potency of antigen preparations.	In-process testing of vaccine constituents to allow evaluation of suitability for further manufacture.	<p>This test is based upon regulatory requirements for the assessment of in-process products.</p> <p>There are no</p>

					alternatives available at this time however the establishment has embarked on a long-term program to develop in vitro assays which may be used to replace existing in vivo assays subject to regulatory approval of these replacement assays.
Mice	160	80	Challenge of vaccinated mice with target organisms to demonstrate efficacy of vaccine.	Regulatory testing required to demonstrate efficacy (potency) of vaccines prior to release.	No alternatives available at this time.
Mice	166	162	<p>Study to potentially identify a novel therapeutic to prevent the development of invasive GAS disease in humanised plasminogen mice.</p> <p>Group A Streptococcus (<i>S.pyogenes</i>; GAS) is a significant human-specific pathogen that is responsible for a clinically diverse range of infections.</p> <p>GAS infections contribute to worldwide morbidity and mortality, with over 500,000 deaths reported each year (Carapetis et al., 2005).</p>	The contribution of specific virulence factors to the pathogenesis of microbial pathogens 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.	No current alternatives exist, which effectively mimic the mucosal and tissue barriers as well as a functioning immune system observed in live mammals.

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Mice	2	2	Diagnostic procedure	To identify the presence of algal toxins in potable water supplies that can be detrimental or dangerous to human health.	The establishment started trailing a new method of water testing called Abraxis Immunochromatographic Strip Test, which has proven to be effective. The establishment will no longer require the use of mice for testing. For further information on this method please see the link below:  <a href="http://www.abraxiskits.com/wpcontent/uploads/2015/08/Microcystins-Strip-for-Source-Drinking-Water-R082115.pdf">http://www.abraxiskits.com/wpcontent/uploads/2015/08/Microcystins-Strip-for-Source-Drinking-Water-R082115.pdf</a>
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## 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 2015 reporting year. They deal with '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, Reduction and Refinement

#### Reduction

- Use of tissue culture models as far as possible for mechanistic studies.
- Sharing tissues with other researchers at harvest. We will collect several tissues (e.g. fat, liver, muscle) from the same animals to allow a reduction in the total number of animals needed for these studies.
- Mouse numbers are based on power calculations and extensive experience with this model to ensure that sufficient numbers are used to obtain robust results while minimising un-necessary duplication. The minimum number of animals commensurate with a potentially statistically significant result will be used — usually 7-8 animals per group.

#### Refinement

- Use of heating pads, saline injections, and easy access to food to maintain healthy hydration and body weight and reduce mortality associated with neurotoxin use.
- 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. The animals used in the setting and testing of the aquatic system will be made available for researchers and the breeding program.
- It should be noted that the use of zebrafish in general can reduce the impact on sentient animals because much research is conducted on embryos before their nervous system has fully developed pathways for perception of pain or distress.
- Rats are handled regularly, which should reduce stress at the time of performing the procedures. During the procedure animals will be handled for as little time as possible to reduce any unnecessary stress.

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#### Reduction

- Control groups are shared whenever logistically possible and negative control groups are reused to reduce the number of chickens used.

#### Refinement

- Continuing experience in handling poultry which are particularly prone to stress. Staff enter bird houses and communicate in a quiet manner for the welfare of chickens.
- Use of foil blankets in transport tubs (transferring of eggs from incubator to Oocyst. Production Unit) have led to better hatching and less fluctuations in temperature.

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## Replacement

- The company conducts in-vitro assays, replacing the use of animals in early product development.

## Reduction

- Wherever possible the number of animals is reduced in a study, while maintaining statistical significance. The use of excessive animals is avoided. Pilot studies are conducted with a small number of animals to test unknown hypotheses, avoiding the use of large numbers of animals when outcomes are unknown or not guaranteed. One protocol included a spare group of 3 immune cats that may be used as replacements, should an untreated cat succumb to the disease, thereby reducing the need to conduct a repeat study, should inadequate data be collected following the removal of a cat(s).

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## Reduction

- We make available samples that are collected opportunistically from collection animals and wildlife under our care. Access to this important material reduces the need for additional interference with animals and has benefited many collaborative researchers through the years.

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## Reduction

- Extensive statistical analysis/justification is required in every application (including consultation with a statistician or statistical referencing) to ensure only the minimum number of animals are used. On occasion in the reporting period a number of Principle Investigators are asked to provide the AEC with further justification supporting the number of animals required.

## Refinement

- We are conscious of continued improvement in the techniques of handling and treating animals on trial. Rarely do the experiments conducted involve any procedure more invasive than blood sampling. The standard operating procedure for blood sampling is reviewed by research management staff, research technicians and the AEC to ensure that the procedure causes minimal distress to the animals.
- New thinner snare ropes were purchased for use to restrain smaller pigs for blood sampling.
- Some weighing systems have been redesigned to allow pigs to fit together in one group (pigs remain with their pen mates while weighing which reduces social stress) and to facilitate better pig flow during the weighing facility.
- Tattooing individual pigs is required for identification after slaughter and is part of the commercial pig production system (legislative requirement). The procedure is now conducted approx. 4 to 6 weeks prior to transport to meat processing. This reduces the handling of pigs around the time when pigs are being loaded for transport.
- The pig handling facilities have been redesigned so that pigs move single-file through a race way with their social group and pigs are individually tattooed. This reduces risk of injury to stock people and technicians and is a much calmer process.

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## Reduction

- The company began to re-home excess guinea pigs during 2015 which meets the criteria of reduction. An agreement was signed with the Research Animal Re-homing Service. 75 guinea pigs were re-homed via this service in 2015. All 75 were in excess of the research needs and had not had any scientific procedures performed on them.
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By giving them to the re-homing organisation, they were able to be placed as pets in suitable homes rather than being euthanized.

- The AEC and Animal Services department has an on-going action to investigate whether several of our animal tests can be reduced and refined. We eliminated the need for including additional rabbits on tests. The protocol for including 12 rabbits was reduced to 10 rabbits, saving 2 rabbits per test. This has resulted in a net saving of approximately 100 rabbits per year. Furthermore we also reduced the number of control guinea-pigs in one of our tests. Previously we have 2 control groups receiving different titrations of challenge spores. We have reduced this to the minimum prescribed and have therefore saved approximately 88 guinea pigs per year.

## **Refinement**

- The company invested in anaesthesia equipment for guinea-pigs and commissioned an external specialist trainer to train staff in using the equipment and bleeding guinea pigs while under anaesthetic. This refinement for guinea pigs reduces stress as they are unaware of being anaesthetised (as it is done by gas entering a box that the guinea pigs are placed in) and are not awake for the bleeding procedure.

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## **Reduction**

- Development of a mailing list to facilitate tissue sharing among researchers.
- Use of artificial models, e.g. Koken rat, for training.
- Use of videos and on-line resources for training.
- Transfer of excess animals from one project to another.
- Re-use of animals among multiple projects when ethically justified.
- Use of animals that were humanely killed under another approved project for training.
- Development of in vitro techniques to replace the use of animals.
- Use of ex vivo assays to minimise adverse impact on animals.
- Teaching projects utilising computer practicals to reduce the number of animals used.
- Pilot studies to ensure the least number of animals are used to obtain statistically valid data.
- Experimental results used for computational modelling.
- Combination of experiments so that only a single "control" group is used.

## **Refinement**

- Training of researchers in current best practise techniques.
- Improved peri- and post- operative analgesia to reduce pain from surgery.
- Use of modern trapping techniques and equipment to minimise potential for animal injury. Use of smaller, less invasive tags for identification.
- Use of in vivo imaging technology to perform repeated measurements on the same animal over the course of an experiment, resulting in a significant reduction of animals used.
- Increased awareness and use of environmental enrichment.

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## **Reduction**

- 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
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opportunity to re-use the animals for histological studies.

- Cryopreservation (sperm storage) of knock-out mice in breeding colonies was implemented in 2014 to secure lines in case of breeding difficulties, disease outbreak, emergency/disaster (e.g. fire etc.) and allows reduced numbers to be kept.
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## **Reduction**

- Request to use the ewes and newborn lambs to develop a new data key for a new version of a movement logger. By using lambs in this experiment was seen as a reduction in sheep numbers, as otherwise this work would have been undertaken on a new cohort of animals.
- An activity was coordinated so that only one group of animals was used to train several new staff in one session on one day, thus reducing the number of animals required for training.

## **Refinement**

- The use of poplar sticks for enrichment of animal house sheep included as part of the application was seen as a refinement.
  - A protocol change was made to the injection site for administering the vaccine, to via subcutaneous injection rather than using abomasal injections. There was also a request to reduce the amount of vaccine given. These changes were made to lessen the impact on the animals.
  - The use of experienced horse handlers (those which usually handle the animals) during study procedures, and the conduct of procedures in an environment in which the animal is familiar with, has reduced any pain or distress that the animals might otherwise have experienced.
  - The results of the first part of a study, from Day 0 to Day 56, showed that both the Control Product and the investigational Veterinary Product had adequately demonstrated the knock down effect on lice. The knock down effect is the effective removal of at least two life cycles post treatment represented by 0 lice counts at Day 56 according to the APVMA guidance. It was deemed unnecessary for the sheep in the Untreated Control (UTC) Group to be left untreated. The UTC Group was removed from the study and each animal was treated with a pour-on insecticide. The removal and treatment will reduce any distress or pain caused by lice that they may have experienced if they were to be left untreated for the remainder of the study.
  - Investigating retention at the same time as another factor under investigation will reduce the amount of handling for the cows and heifers. Handling cattle for multiple blood collections was conducted using a head-bail crush with the halter on the animals head to tie it to the side. It was found during practice run for baseline progesterone that a blind over the animal's eyes assisted to calm them down during this process.
  - Use of electronic scanner to read the identification of each heifer, so that the heifers were less distressed with handling, for example most heifers did not have to have their heads caught in the crush bail or their heads or ears handled, procedures cattle dislike.
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## **Reduction**

- A protocol about the transplantation of encapsulated Melligen Cells has completed exhaustive studies using liver cells in vitro. They have also used power analysis to derive the number of animals to ensure that the minimum number of animals can be used. They have also spent many years refining the procedures, anaesthesia protocol and analgesia in the previous protocols and in our previous experience in other protocols to ensure that the animals undergo minimal suffering.
  - A protocol on the development of odour mimics for training explosives detection
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canines is using multiple canines for multiple trials/experiments so that the number of repetitions per animal can be reduced. They are also ensuring constant communication with the dog handlers to ensure the safest and most effective methods of investigation are undertaken.

#### **Refinement**

- A protocol establishing a set of bioinformative DNA markers that will assist in the identification of individual echidnas will be collecting DNA only through trained veterinarians and animal care experts.

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#### **Reduction**

- In-vitro simulation of the equine metabolism of designer anabolic steroids using horse liver.

#### **Refinement**

- Accommodation of research horses in a large paddock on a professional horse spelling/pre-training farm.
- Rehoming of retired research horses to suitable new owners.
- Spontaneous collection of naturally voided urine for the purpose of drug analyses.

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#### **Replacement**

- Use of audio-visual material such as videos, slides, interactive computer.
- Use programs; of training models to teach techniques (e.g. latex rat for injections).
- Use of abattoir specimens and cadavers.
- Use of plant tissue as a replacement for animal tissue for certain enzymatic assays.
- Routine husbandry procedures to be performed on animals are coordinated with teaching activities.
- Use of animals killed in road accidents.
- Researchers moving away from primary cultures and using stem cell differentiation.

#### **Reduction**

- Sharing of tissue among researchers.
- Obtaining more data from the use of fewer animals by combining objectives.
- Incorporating animals from one project as breeding stock for subsequent project, rather than discarding.
- Use of the Braincubator to extend the life of neuronal tissue for electrophysiology and imaging.
- Use of organs collected from culled mice for in-vitro testing (e.g. gastrointestinal studies).

#### **Refinement**

- Improvements to animal housing and management (e.g. introduction of “buddy cages” to avoid single housing of mice).
- Training of researchers (animal monitoring and administration of injections).
- 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).
- Developing competency assessment procedures.

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#### **Replacement**

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- Studies are co-ordinated where possible to enable the sharing of tissues and surplus animals by other investigators or as a teaching resource.
  - Undertaking observational studies rather than capturing animals has proved useful in a number of instances.
  - Where applicable in vitro studies are used. Results from previous studies are used to reduce the number of animals required for some experiments.
  - Video recording of experiments, especially behavioural experiments, enables future use without the need to repeat the experiment.
  - Existing resources of other Universities, businesses and Institutions are used where possible.

## **Reduction**

- A tissue bank is maintained and, whenever possible, generated so that tissues not required for immediate use can be preserved for future use.
- Where animals are used in teaching, animals are allocated to small groups of students rather than to individual students.
- When designing a project, investigators often refer to previous or similar studies to ensure that work is not being unnecessarily duplicated.
- A pilot study or proof of concept study is often employed by an investigator before proceeding further.
- Investigators seek the advice of a biostatistician, where appropriate.
- Experiments are sometimes run in parallel using just one control group.
- Pooling of samples is undertaken whenever possible.
- The Committee requires studies to be concluded when sufficient data has been collected and not at the duration of the time approved or when the full allocation of approved animals has been exhausted.
- The minimum number of animals is used at each stage to provide statistical significance.
- It is common to undertake a literature review or use previous research data during the planning stage of the project.
- Animals not required are allocated to other projects, where possible.
- Animals are sometimes used as their own control, resulting in a greater statistical power and decreasing the number of animals required.
- Wildlife studies use traps that are appropriate for the size of the animal being studied, thereby reducing unwanted by-catch.
- Investigators share research information, results, models and methods to avoid repeating work and to ensure they are using the most appropriate methods that will lead to valid results while minimising the number of animals required.
- Some research projects are undertaken collaboratively with other institutions.

## **Refinement**

- Inexperienced personnel work under the direct supervision of experienced personnel until competent.
  - Pitfall traps are provided with shelter materials (sand, leaf litter, cloth and PVC piping) for animals awaiting release. Traps are checked early each morning and each evening to avoid animals spending more time than necessary in captivity.
  - Insect surface sprays are used around pitfall traps to reduce possible irritation from ants.
  - A number of experiments have been designed to measure physiological parameters employing minimal handling of animals, while others are purely observational or use infra-red cameras.
  - Where appropriate, animal behaviour is captured using motion detection cameras
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placed at a distance so as not to disturb animals.

- The AEC always tries to ensure that projects are designed to reduce the need for repeat procedures, and stress on animals.
  - Data loggers are used for data collection to avoid strict confinement of animals.
  - Use of captive wildlife is preferred to use of wild specimens as they are accustomed to human presence.
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## **Replacement**

Tissue Sharing:

- Samples collected under an ARA were properly stored and used years later for use in another project.
- Using control data across a number of related protocols.

*In vitro technology:*

- Immortalised cell lines were used instead of animals.
- In vitro drug testing demonstrated that drugs didn't perform as suggested in the literature and indicated that any animal work would have had uncertain interpretation, so did not commence.

## **Reduction**

- Animals that are scheduled for approved euthanasia are made available for tissue harvest, new technique training or post mortem technique training.
- At the conclusion of appropriate research protocols, some animals are retained for animal handling training.
- Researchers are encouraged to consult with statisticians to determine the minimum number of animals required for statistically valid and relevant results.

## **Refinement**

- The use of captive animals in place of wildlife.
  - Enrichment, Wood blocks, Seeds, Straws, Substrate maintenance.
  - Companionship provided by vasectomised or ovariectomised animals.
  - Wildlife enclosures are provided with a range of natural and man-made hides and basking spots.
  - Live insect prey/food provided to encourage natural behaviours.
  - Wildlife is rotated through indoor and outdoor enclosures whenever possible.
  - Animals individually identified e.g. with microchips or visually implanted elastomer to allow group housing.
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## **Replacement**

- 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.

## **Reduction**

The Committee has minimised animal usage by the following techniques:

- Careful scrutiny of the numbers of animals requested to ensure that sufficient numbers are used to provide a statistically valid result, thus preventing the need for
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repeat experiments and use of additional animals.

- Approval of new techniques for embryo freezing rather than continuous breeding to maintain lines.
- Re-use of animals, where appropriate, after extended recovery interval.
- Making surplus tissue available through a Biological Non-Human Tissue Database and seeking prior agreement from investigators to make surplus tissue available.
- Consolidating breeding protocols to ensure no over-breeding which in turn reduces the need for culling.
- Animal facilities optimise fostering process and thereby minimise the numbers of female mice used for fostering purposes.
- Training: Animal facilities use mice for training purposes that were identified with an undesired genotype (hence would have been euthanized regardless).
- Sharing: Where possible, mouse lines are shared between different research groups to avoid unnecessary breeding.

### **Refinement**

- The Committee continues to encourage researchers to undertake a pilot study if the impact of the proposed study interventions on animal health and well-being is unknown.
- Animal House veterinary managers review protocols with researchers in order to optimise anaesthesia protocols (including monitoring) and analgesia.
- Scoring systems for monitoring of experimental animals have been developed and refined, with the aim of minimising potential pain and distress that animals may experience as part of certain research related procedures.

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### **Reduction**

- To both reduce animal numbers and refine their use, we limited our bird sampling days to crucial stages within the first week post hatch, and at 28 and 40 days of age.
- As a standard practice, we conduct analyses as we proceed with data collection, and if we achieve the reacquired statistical power with lower sample sizes than expected, we are able to stop experiments at reduced sample sizes.
- We have chosen a repeated measures design in which each animal is exposed to multiple temperatures. This as opposed to only subjecting a single animal to one temperature. This approach is statistically more complicated but does dramatically reduce the number of animals needed.
- All mice used in one protocol were obtained from existing protocols and otherwise scheduled for culling (such as retired breeders, animals with non-useable genotype, excess stock, untreated controls from certain experiments etc.). The number of mice used has been kept to the minimum needed to achieve competency with the described techniques.
- We have developed a culturing technique which enables us to grow astrocytes from previously frozen cells. The technique has been expanded so that we have been able to create large amount of frozen cells which can then be used for experiments for a period of time without killing additional animals.

### **Refinement**

- Animals are kept in small paddocks in the company of other affected or unaffected animals to provide them with an enriched natural environment.
  - Rather than perfuse livers in-vivo with fixative prior to tissue collection we use ex-vivo fixation which means that the liver samples can be used for western blotting and qPCR as well as for histology and immunostaining, and that in addition to the liver we can obtain serum, spleen and draining lymph nodes for analysis.
  - In order to reduce the number of reproductive adult toads required, we have
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coordinated our experiments with the other researchers, which allow us to share clutches.

- We have used retinal fluorescein angiography to monitor changes in the retinal blood vessels in a real-time manner over different period after tamoxifen-induced metabolic gene knockdown in Muller cells. This technique allowed us to avoid euthanizing animals for histological examination of vascular changes in the retina.

## **Replacement**

- There has been approval by the faculty to purchase a Breeding Betsy. Breeding Betsy is an artificial cow that can be used to replace some live cow practicals in 2016. This artificial cow can be used for introductory practicals in pregnancy diagnosis as well as introductory artificial insemination in cows.
- We are utilizing a small stuffed toy for students to practice with to become familiar with the technique used to restrain birds. This 'dummy' bird has the same essential anatomical features of the real birds so that they can take time to perfect their technique prior to handling real birds.
- We have REPLACED a large amount of animal work using a cell culture system to screen for effective Chinese herbal chemicals (CHM).
- A very large proportion of the current project was performed on immortalised cultured cells expressing opioid receptors to precisely unravel the biochemical mechanisms that might be responsible for failure of opioid receptors to re-sensitize after chronic exposure to opioids.
- Students have access to narrated video footage that demonstrates basic horse handling techniques. Students are encouraged to view this material prior to and following the horse handling practical classes in the first year of the degree programme; as well as in subsequent years as revision prior to activities that require horse handling (other equine practical classes, extramural animal husbandry work and clinical rotations). This video footage, as well as previous practical classes in horse handling, provides a basis for safe interactions with live horses throughout the degree programme, including the topographical anatomy and clinical procedures practical classes. Students are encouraged to view this material prior to the topographical anatomy and clinical procedures practical classes.

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## **Replacement**

- In one study, the intact thorax of neonate piglets humanely killed to obtain pancreatic islet cell clusters were used in a study to assess and compare neonatal resuscitation equipment commonly utilised in birth centres.

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## **Replacement**

- Mannequins, audio-visual materials, photographs, taxidermised and preserved specimens were used as substitutes for live animals where the learning outcomes were able to be met by substitute means.
  - Injection and ear-tagging of sheep practiced on cardboard and leather.
  - Use of mechanical horse for horse riding and racing training.
  - Bandaging and health care procedures are performed on dummies.
  - Life size fiberglass replica of horse used for demonstrations.
  - Use of photos and wool samples to identify breeds of sheep.
  - Use of dog and cat cadavers for anatomy studies and injection practice.
  - Visit to zoos, aquariums and museums to familiarize students with a range of native animals, eliminating the need for field visits or trapping.
  - Use of case study data to eliminate need for live animal data.
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## Reduction

- Simulated penning of sheep by demonstration.
- Minimum number of animals used in teaching activities.
- Use of ultrasound equipment to capture images (cattle) for replay to students.
- The number of occasions that an animal is used is minimized e.g. lambs are tanned and drenched at the same time as normal management schedule.
- Working with university researchers and National Parks on native animal projects rather than duplicating own projects.
- Timetabling of classes is coordinated so that activities are spread over the semester, to avoid over-use of the same animal.
- Appropriate animal to student ratio.
- Native and feral fauna are only involved in limited field surveys under natural settings and no repeated exposure of any individual animal to survey techniques.
- Cattle and sheep are used on farm in industry environments. Animals are divided into groups and these groups are not reused for health applications and not more than twice for drafting.
- Students attend various workplaces to reduce the use of a particular mob of animals.
- Animals are placed on a rotation roster so they are not overused.
- Weighing and husbandry of cattle are carried out as part of their normal, regular commercial schedule.
- Use of a booking system and individual animal records to record animal use.
- Field work involving the trapping of animals is minimised and related to other contact with animals such as zoo visits.
- Maximum amount of data and student/animal contact is derived from each trapping in order to minimise trapping requirement.

## Refinement

- During shearing training the learner shearer begins by shearing only part of the sheep, with the professional shearer completing the task, to reduce handling time, injury and stress.
  - Horses are monitored for behavioral changes and replaced regularly. Horse usage is rotated to prevent overuse.
  - Using treats as substitution for medication.
  - Reduction of lamp size to less intense light; use of red light covers for spotlighting activities.
  - For native animals, handling is conducted by the licensed person only, with students observing the techniques.
  - Animals are given appropriate rest periods.
  - Designated animal carers attend class with animals to ensure the animals are not unduly stressed or over-used.
  - Use of instructional activities that maximise students' competence in handling animals.
  - Professional development for teachers to improve skills and knowledge.
  - Use of industry sites where animals are housed to minimise stress.
  - All fauna survey techniques follow guidelines approved by National Parks and Wildlife and Local Land Services.
  - Miniature pony used in place of foals for handling and health care procedures.
  - Uncomfortable procedures e.g. temperature taking only done once.
  - Keeping a diary of on-farm activities.
  - Students are referred to Standard Operating Procedures prior to animal use.
  - Training of teachers in recognition of signs of stress and distress in animals.
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## Replacement and Reduction

- An increase in pilot studies for field work projects, minimising the impact on larger groups of wild animals until critical information has been gathered and methods trialled in the pilot.
- Minimising the impact on endangered species by using captive populations where possible.
- Sharing of information with other research institutions or NGQs to prevent multiple interferences with the same animals in the wild.

## Refinement

- The use of topical analgesics and anti-microbials for application immediately post tissue sampling.
- Increased use in less invasive sampling for DNA, such as plucking hair or feathers or buccal swabbing over blood sampling, ear biopsy etc.
- Increased access to veterinary advice and support 24/7.
- The use of camera traps increases as does the use of GIS to minimise impact on wildlife in their natural habitat.

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## Reduction

- Re-use of animals - have transferred rabbits to other research institutes for possible future use. Goats have been used in 2 different projects. On termination of the protocol, goats were re-homed to a suitable new owner.
- Animals used in teaching are assigned to a group of students rather than a single individual.
- Pilot studies are often undertaken by investigators before proceeding further.
- 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.
- Similar studies have shared the same control animals.
- Environment enrichment has been introduced for pigs and rabbits.

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## Refinement

- Remote infrared cameras and acoustic and high frequency recorders are used where possible to record species' presence at a location. The organisation has been able to convince the regulator that intensive box trapping in that region does not produce useful results for pre-harvest surveys. They have been able to negotiate a monitoring program on some areas of their estate rather than pre-harvest surveys that are required in other Regions. The monitoring work uses the remote cameras/recorders. 11 out of the 16 projects include camera surveys.

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## Replacement

- Video and images for demonstration of fish disease management.
- Generation of anatomical 3D models for the zebrafish to replace use of live animals.
- Use of archival footage from documentaries and tour operators available on the web for behavioural studies on foraging behaviours of leopard seals.
- Development of Eco-App for student use on smart phones for bird identification.

## Reduction

- Continuous review of data obtained during experiments to refine our estimates of
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group variability and repeat power analysis to determine if sample size may be reduced in subsequent experiments.

- A number of researchers are utilising pilot studies to optimise animal numbers – often statistically significant results can be obtained with smaller numbers of animals.
- Data from previous studies are utilised to reduce the number of animals required.
- The establishment continues to encourage researchers to harvest and share tissues. In instances where animals have been humanely killed specimens are donated to the museum or other researchers.
- Sharing of tissues or storage of samples for re-use in future protocols where possible.
- Re-use of animals for research that would have been already in the laboratory for other research in order to reduce the number captured from the wild.
- Collection of samples such as hair, mouth/sternal gland/pouch swabs and blood from animals captured for other routine health checks minimising handling and use of wild animals.
- Re-use of animals from other previously approved projects where the animals are not allowed to be released back into wild and would otherwise be euthanased.
- Rehoming and re-use of 350 animals (lizards) with a long-term known pedigree from another tertiary Institution which would have otherwise been euthanased. These lizards have a long-term known pedigree and will provide researchers with access to both the parents and offspring for behavioural experiments. The level of background information provided is extremely rare and often takes years to obtain.
- Use of captive animals for observation and filming of feeding behaviours reducing use of wild animals.

## Refinement

- Use of Observational only applications.
  - Longer periods of acclimation for wild caught animals in facilities post capture and prior to performing experimental trials thus providing animals with the opportunity to rehydrate and increase body conditioning prior to experiments being conducted.
  - Non-invasive monitoring techniques such as use of cameras for identifying habitat use by animals in preference to traditional trapping methods this has minimised the need for animal handling.
  - Increasing use of targeted remote infra-red cameras to replace/supplement trapping for wildlife surveys and monitoring.
  - Utilisation of advanced technology which reduces size and weight of tracking devices.
  - Utilisation of remotely operated Unmanned Aerial Vehicles (UAV's) mounted with automatic camera system for use in seabird and shorebird surveys. These techniques allow birds to be counted from a distance and altitude that do not cause flushing so that the likelihood of disturbance is greatly reduced.
  - Location and sexing of free swimming adult turtles using unmanned aerial vehicles (drone copters) with cameras providing faster and less intrusive means of observation.
  - Individually housing wild caught animals collected from different sites to prevent negative interactions between animals from different locations/harems (Permit requirement).
  - Improvements to housing and segregation of animals captured from the wild, reducing the risk of introduction of potential pathogens to natural populations when animals are released back into the wild (respective government authorities permitting).
  - Refinement of anaesthetic agents used and dosage rates reducing recovery times and the risk of complications such as respiratory depression for animals where
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surgical procedures are conducted.

- Upgrades to animal housing facilities: Upgrades to Animal House Facility - use of a BAS system (Building automation system). The BAS system will be used for monitoring temperature set-points and other variables such as humidity within the rooms. Alarm notifications will be improved. Installation of RO water system to overcome issues with water quality and in particular issues with copper in the tap water.
  - Donation/Rehoming of animals unable to be returned to the wild to suitable organisations such as Zoos, Wildlife and Conservation Parks.
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### **Reduction**

- Continued use of remote controlled infrared digital cameras and acoustic recording.
- Testing marine radar as a monitoring/survey technique for micro bats.
- Testing of unmanned aerial vehicle (drone) for monitoring/surveying waterbirds on wetlands (unfortunately with limited success primarily due to low visual range and attack by bird of prey) devices instead of, or in addition to, trapping to detect species presence or absence.

### **Refinement**

- Ceased toe clipping in small mammals - replaced with temporary stock marker paint.
  - Ongoing use of secure outdoor enclosures furnished with native habitat for rearing endangered frogs in the location of their natural range instead of the artificial environment of indoor tanks at a breeding facility.
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### **Replacement**

- Continued use of replacement methods, such as ADInstruments and earthworms for teaching projects that previously used toad or rabbits.

### **Reduction**

- The University continues to encourage researchers to harvest and share tissues in instances where animals have been humanely killed.

### **Refinement**

- A rat general anaesthetic protocol was refined to improve the welfare on the animals.
  - For new procedures or high animal welfare impact procedures, the AEC requests the submission of a pilot study to be reviewed by the Committee prior to approval of the main study.
  - The AEC has continued request conditions of approval to include the presence of either the Animal Welfare Officer or Animal Facility Managers to oversee high impact or new scientific procedures.
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### **Replacement**

- Large photo cards have been used in practical classes instead of live animals to teach students how to identify freshwater fish species.
- Fish provided from other research projects can be used in place of wild-captured individuals for some species.

### **Reduction**

- Students work in groups to observe dissections of different fish while dissecting one of their own, gaining experiences in a variety of fish morphologies without the need to
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dissect each from themselves. However, the project will continue to require one fish per student, up to 12 individuals per species (less if more species are available).

### **Refinement**

- Fish are released within 20 minutes of capture at the same location as capture. Digital cameras are used to record images of fish in photo identification tanks that are then used to identify specimens.
- Fish are quickly removed from nets and those not required for class exercises are released immediately. The sampling site was slightly moved to avoid seagrass and anoxic muds that have caused oxygen stress to some species in the past.
- Close monitoring of fish (9 hours per day) during experiments meant no fatalities and found that feeding ceases at a temperature of 15 degrees Celsius.
- Daily monitoring of fish has been successful in maintaining healthy stock. This resulted in a 25% weight gain and fish showed no signs of disease or parasites.

### **Replacement**

- Use of video training tools for training in animal handling and injection techniques.
- Use of museum specimens in practicals.
- Use of deceased feral birds in a course and existing fur pelts for heat transference models.
- Use of cadavers for initial training in injection techniques and progression to training on live animals only once competent on cadavers.
- Use of anatomical models rather than live animals for blood collection.

### **Reduction**

- Sharing tissue from deceased rats and mice with other researchers e.g. 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 to train researchers in various techniques, thus minimising number of animals required in their research applications and providing Certificates of Competency as needed.

### **Refinement**

- Use of remote underwater video instead of trapping and releasing fish as a less intrusive research method.
- Uses of pilot studies to refine techniques before large numbers of animals are used.
- Rather than teaching researchers all techniques for handling and injection only training them in the procedures they will need.

### **Replacement**

- The use of existing data for additional retrospective analyses x 2 when additional research questions arose.
- The investigation of extracting and explanting cells from tissues collected from guinea pigs.
- The replacement of bat observations with electronic devices.
- The use of mouse lung primary fibroblasts for FBLN-1C inhibition firstly in order to optimize FBLN-1C AO concentration.
- The use of in vitro study rather than animal work.
- The use of a range of in vitro screening assays to identify candidates before moving on to animal based research.

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- The use of cell cultures as an alternative to animal work.

## Reduction

- Unused animals approved under a previous protocol were transferred to a current protocol to reduce the number of new animals required.
  - Making all of the organs besides those specifically used for a study available for use by other researchers.
  - The use of the female littermates of male mice in a stage of an experiment where sex was not critical rather than culling the females. This reduced animal wastage and increasing the efficiency with which the aims were achieved.
  - The use of existing data for additional retrospective analyses x 2 when additional research questions arose.
  - The use of the same animals (rats) to get tissue for both protein and mRNA analysis, by collecting one hemisphere of the brain for processing for protein, and the other half for processing for mRNA, effectively halving the required sample size.
  - The introduction of vaginal swabbing to determine the stage of oestrus cycle. Mating during pro-oestrus had been shown to produce more embryos. Vaginal swabbing allowed the researchers to better time the mating prior to the collection of embryos thereby reducing the amount of mice necessary.
  - Primary brain cell culture from neonatal mice used as an alternative to intact adult animals in a study focusing on how high concentrations of corticosterone alter the function of brain cells function.
  - Animals euthanased in such a way that tissues were used the most efficiently in the laboratory, thereby potentially reducing the number of total animals required.
  - Control animals from previous studies were used to substitute the need for repetition of such animals.
  - The use of 1 toad by 4 students rather than 1 toad being used by each student.
  - The use of a crossover design well accepted in medical science used 24 animals with repeated crossover measures rather than > 100 animals per treatment.
  - The measurement of multiple physiological variables within each animal reduced sample size.
  - A reduction in the replication of the control groups required to make valid comparisons was achieved by sharing control groups run in parallel where possible.
  - The re-use of control or unused animals from one treatment in subsequent studies using different treatments to minimise the number of new animals required.
  - Animals approved under an approved protocol being transferred to another protocol to reduce the number of new animals required.
  - Practicing on dead or culled animals to become competent with procedures, reduces animal numbers and decreased the stress caused to the animals in an experiment.
  - A drug being tested on every cell line in vitro first and only the cell lines that responded to the drug in vitro were moved onto the in vivo testing in mouse xenograft models.
  - Conducting RIP3 and MLKL knockout studies simultaneously. This allowed a common set of wild type control mice to be used thereby reducing the number of mice used.
  - The fixing of liver and hearts in 70% ETOH for potential future genetic analysis.
  - The number of animals used was reduced by using each rat on more than one test. For the offspring in the behaviour group, each rat was tested for their behaviour in the social interaction task, anxiety tests and pre-pulse inhibition of startle, thereby reducing the number of rats that would have been required from 320 to 80.
  - The number of rats needed was greatly reduced by performing as many molecular experiments as possible using the same animal. For instance, after euthanasia and dissection of the gastrointestinal system, intestines and stomach were carefully
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sectioned in two halves along all its extension so the same tissue for otherwise incompatible molecular techniques in terms of tissue processing could be used. This approach reduced the number of rats that would have been required from 800 to 400.

- A method for growing mouse uterine epithelial cells was developed. Growing cells in culture replaced the need to extract these cells from mice.
- Tumour burden was measured by callipers while restraining a mouse and therefore there was no need to euthanase mice to determine tumour volume.
- A study was designed so that each animal would be its own control with pre-supplement, supplement period and post-supplement measures taken. Using a within group design reduced the number of animals required.

## Refinement

- The use of testicular artery clamping rather than surgically-created testicular torsion reduced impacts on animal welfare, as testicular artery clamping is non-invasive and there is less potential for distress or discomfort to the animal.
  - Healthy reproductively inactive females were used to improve animal wellbeing by providing companions for singly housed male mice held on their own for extended periods of time. Hormonally inactive animals destined for culling were drawn from the breeding colony for this purpose.
  - The refinement of laparotomy on culled mice prior to commencing the technique on live mice.
  - The incorporation of Xenogen bioluminescent in vivo imaging allowed sequentially monitoring of tumour burden in animals without needing to euthanase the mouse. Prior to this imaging technique, additional mice would be needed in orthotopic models of cancer so they could be sacrificed for the sole purpose of measuring tumour burden.
  - The introduction of vaginal swabbing to determine the stage of oestrus cycle. Mating during pro-oestrus had been shown to produce more embryos. Vaginal swabbing allowed the researchers to better time mating prior to the collection of embryos.
  - Beach seining has often caught more species and individuals than required. In this instance, the catch was immediately put into a tub of ambient water. The target species and number of individuals were removed and all remaining species/individuals were released at the point of capture. Non-target fish were not removed from the water at any time. The seine net used had a soft mesh to reduce any adverse impacts during the capture process. All fish were kept within the water and within the seine net until being identified as a target species and removed using a dip net.
  - Only using compounds showing effective in vitro activity, low to no in vitro toxicity and low in vivo irritancy from previous studies being used in a project.
  - A substantial refinement of the methods used to induce myopia from commencing with occlusion for several months and concluding by inducing the required biological changes within days. In addition, the methods for lens-wear were refined so as to be less invasive for the animals.
  - The addition of a new technique to measure the diffusing capacity of the lungs of a mouse using a calibrated gas chromatograph. The new technique enabled the measurement of clinically relevant respiratory function in pulmonary fibrosis and respiratory infections, and provided a more complete picture of the extent of disease in other models.
  - Animals were transported in the cage in which they were housed which was covered to minimise exposure to environmental influences which may have distressed the mice.
  - In order to investigate the effects of circulating mitochondrial DNA on organ dysfunction, known concentrations of purified mitochondrial DNA were injected into
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rabbit circulation. This saved the rabbit from having to go through the trauma of shock and fracture.

- The design of a protocol to reduce distress through the performance of oral administration of drugs (gavage) under general anaesthesia.
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### **Replacement and Reduction**

- The company has been developing in vitro assays to replace in vivo assays that require animal use. Several other mass spectrometry assays have been developed to support the research stage projects. All these assays have real potential for further development to a stage where they could initially reduce, and then replace current animal testing at most process stages with better, more consistent assays.
  - For example the company has developed alternative tests to the L+ mouse toxicity assay using mass spectrometry and HPLC-based assays. At the R&D phase, scientists used these assays to quantify the amount of toxin in about 50 fermentation experiments. This approach resulted in the replacement of at least 2000 mice that would have been used in testing final toxin. Furthermore, these new assays were also used monitor toxin production over time. The results from these experiments would have required a total of over 8000 mice using the conventional L+ mouse toxicity assay demonstrating the potential reduction in animal testing going forward.
  - Another approach is refine and reduce animal numbers in a study is maximise the use of negative controls within the other treatment groups without impacting the scientific outcomes. For example, when efficacy of two vaccines is assessed in a study, one vaccine control group will serve as a negative for the second vaccine group and visa versa.
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### **Replacement and Reduction**

- Freshly dead specimens (road kill, beach wash, by-catch, and euthanasia) are utilised as much as possible. There is obviously a limit to this though, depending on the aims of the study, researchers need to ensure the cause of death has not biased the sampling. A 50:50 balance of live and dead birds assists in the practice of Replacement and Reduction. It limits the number of live animals being handled, while providing data on dead and live birds that may enable researchers to directly examine whether dead birds are indeed representative (evidence so far suggests they are not .for example, beach washed birds tend to be more emaciated and contain more plastic than birds selected at random In the colony, but this in itself is useful information).

### **Refinement**

- The operation of the backpack electro-fisher only by highly trained and experienced researchers. Also, in order to avoid any risk to non-target vertebrates, if any of these are seen in the sampling reach, electrofishing will cease until the area is clear of non-target animals.
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## Appendix I: Animal Research Review Panel expenses

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

Fees and retainers	<b>6,382</b>
Travel and subsistence	<b>380</b>
Stores (including catering) and printing	<b>1,725</b>
Freight and postage	<b>861</b>
<b>TOTAL</b>	<b>9,348</b>

## Appendix J: ARRPP policies and guidelines

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

### Policies

2. Payment of External Members of Animal Ethics Committees (revised 15/5/2009)
3. Procedures Prohibited under the NSW Prevention of Cruelty to Animals Act (revised 24/4/2009)
4. Non-Research Animals at Accredited Animal Research Establishments (revised 4/8/2010)
5. Annual Reporting by Animal Ethics Committees to Accredited Animal Research Establishments (revised 24/1/2014)
- 5A. Accredited Animal Research Establishment Support for Animal Ethics Committees (revised 8/5/2014)
6. Differentiation between animal research and veterinary treatment (revised 8/5/2014)
8. Establishment of Protocols for Grievance Procedures (revised 16/12/14)
9. Criteria for Assessment of Animal Ethics Committee Membership (revised 16/12/14)
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. The use of restricted drugs and the conduct of restricted acts of veterinary science in animal research (revised 27/2/2014)
15. Orientation of New Members of Animal Ethics Committees
16. Conflict of Interest with Membership of Animal Ethics Committees



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## **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 (revised 13/1/15)
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
24. Consideration of high impact projects by Animal Ethics Committees (December 2015)

## **Appendix K: Standard conditions for Accreditation and Animal Supply Licence**

The following are standard conditions that are placed on establishments Accredited as Animal Research Establishments and Licenced as Animal Suppliers, if relevant to their activities. Additional conditions are added on a case-by-case basis.

### **Accreditation**

That any site inspection is satisfactory.

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 Secretary, Department of Industry.

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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 for the Care and Use of Animals for Scientific Purposes* Clauses 3.1.5, 3.1.6, 3.2.13) (See ARRP Guideline 18: Guidelines for the Housing of Rabbits in Scientific Institutions (<http://www.animaethics.org.au/policies-and-guidelines/animal-care>))

Unless otherwise approved by the Animal Ethics Committee, animals should be housed in accordance with the ARRP guidelines on animal housing for specific species found at: <http://www.animaethics.org.au/policies-and-guidelines/animal-care>.

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.

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

The Establishment must comply with NHMRC Principles and guidelines for the care and use of non-human primates for scientific purposes. <https://www.nhmrc.gov.au/guidelines-publications/ea1511>

Housing for cats must include:

- A minimum floor area (not including shelves) of 1.5m<sup>2</sup>/ per cat and a minimum height of 2.0m.
- Shelves to enable cats to sit at varying heights must be provided.

In addition to these requirements, facilities for cats must at least meet the guidelines of the Council of Europe (2006) Appendix A. (<http://conventions.coe.int/Treaty/EN/Treaties/PDF/123-Arev.pdf> ).

Unless approved by the Animal Ethics Committee ducks must be provided with access to water to enable bathing behaviour (see Council of Europe (2006) Appendix A <http://conventions.coe.int/Treaty/EN/Treaties/PDF/123-Arev.pdf> ).

Unless approved by the Animal Ethics Committee, pigs should be provided with a solid floored area with bedding material for rooting and resting. (See Council of Europe Appendix A: <http://conventions.coe.int/Treaty/EN/Treaties/PDF/123-Arev.pdf> ).

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.animaethics.org.au/policies-and-guidelines/wildlife-research> .

Animals (other than exempt animals) may only be obtained from a licensed animal supplier (see <http://www.animaethics.org.au/policies-and-guidelines/animal-supply> ).

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*)

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*)

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## **Animal Supply Licence**

That any site inspection is satisfactory.

The documented procedures and methods of record keeping, as required under clauses 2.5.11, 2.5.12, 2.5.15 (vii) and 3.2.2 of the Australian Code for the Care and Use of Animals for Scientific Purposes, must be submitted by the supply unit to the AEC for approval.

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.

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.

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 2.4.26, 2.4.27 and 3.3.24 of the *Australian Code for the Care and Use of Animals for Scientific Purposes*.