



Animal Research Review Panel

New South Wales

Annual Report

2008 - 2009



Industry &  
Investment

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ISSN 0139-9402

Trim: 09/8337

Prepared by Janelle Townsend and Lynette Chave

May 2010



Industry &  
Investment

## ANIMAL RESEARCH REVIEW PANEL

The Hon Steve Whan MP  
Minister for Primary Industries  
Minister for Emergency Services  
Minister for Rural Affairs  
Level 33 Governor Macquarie Tower  
1 Farrer Place  
SYDNEY NSW 2000

Dear Mr Whan

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 2008 to 30 June 2009.

Yours sincerely

Professor Margaret Rose  
Chair, Animal Research Review Panel



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## SUMMARY

### The Animal Research Act 1985

The *Animal Research Act 1985* was introduced to protect and enhance the welfare of animals used in research. 'Research' includes teaching, testing, fundamental and applied research, and any other procedure, investigation or study using animals. The Act incorporates a system of enforced self-regulation, with community participation at the institutional and regulatory levels.

### The Code of Practice

Ultimate responsibility for animal care and use lies with those who use the animals: the researchers and teachers. This responsibility includes the need to comply with the National Health and Medical Research Council (NHMRC) *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*. This Code is incorporated in the Animal Research Regulation 2005. Adherence to the Code is achieved through a system of enforced self-regulation. Institutions must be accredited and individuals must be authorised to use animals. Failure to comply with the Act, Regulation or Code of Practice results in conditions being imposed on the accreditation or authority. For serious or repeated breaches, the accreditation or authority to conduct research may be withdrawn. Conducting animal research without appropriate authorisation is an offence with substantial custodial and financial penalties.

### The Animal Research Review Panel

The Animal Research Review Panel (ARRP) has responsibility for overseeing the effectiveness and efficiency of the legislation, investigating complaints, and evaluating compliance of individuals and institutions with the legislation. The constitution, membership and mode of operation of the ARRP are set out in the Act. The 12-member Panel has equal representation from industry, government and animal welfare groups. This allows community involvement in regulating the conduct of

animal research in New South Wales. Apart from developing overall policy on animal research issues, the ARRP is closely involved in the administration of the legislation. This is achieved through evaluating applications for accreditation and licences, conducting site visits to assess compliance, and investigating complaints. The ARRP also has a role in considering amendments to the Regulation. Industry & Investment NSW Animal Welfare Unit staff provide executive support for the ARRP.

### Animal Ethics Committees

Self-regulation operates through institutional Animal Ethics Committees (AECs), which must approve all animal research before it can commence. AECs are also responsible for monitoring research projects and providing recommendations to institutional management on matters relating to animal research. Under the legislation, AEC membership must include a veterinarian, a researcher, an animal welfare representative and an independent community representative. The animal welfare and independent members must be from outside the institution.

### Administration and planning

In 2008–09 there were 106 accredited animal research establishments and 34 holders of animal suppliers' licences.

### Inspections

In the 2008–09 year the ARRP carried out 15 inspections of accredited research establishments/animal suppliers and independent researchers. The inspections place a major focus on reviewing the operation of the AECs and ensuring that the AECs, investigators and institutions understand their responsibilities under the legislation and Code of Practice.

## **Support for Animal Ethics Committees**

Support for AECs is provided through site inspections; through publications including policies, guidelines and fact sheets; through maintaining a website dedicated to animal research issues; and through extension activities of Animal Welfare Unit staff and the ARRPP. Such activities in the 2008–09 year included conducting a meeting for members of AECs and releasing draft versions of evidence-based guidelines on mouse and sheep housing for comment. It is anticipated that the finalised versions of these guidelines will be available during the 2009–10 year. The preparation of these guidelines was part of the ARRPP's ongoing plan to develop evidence-based guidelines for the housing of animals in scientific establishments. Guidelines on the housing of rats, dogs, rabbits and guinea pigs have already been published. The ARRPP also revised its policy on AEC Annual Reports and provided feedback on 2007 AEC Annual Reports in order to assist Committees in conducting annual self-assessments of their establishment's compliance with the animal research legislation and to identify measures needed to ensure ongoing compliance.

## **Complaints**

The Animal Research Act establishes a mechanism for lodging formal complaints against institutions and individuals. The mechanism includes the proviso that these complaints must be referred to the ARRPP. One formal complaint and one informal complaint were received in 2008–09.

## **PART ONE: ORGANISATION**

### **1.1 The Animal Research Act 1985**

The NSW *Animal Research Act 1985* was the first piece of self-contained animal research legislation introduced in Australia. In introducing the legislation in 1985, the Hon. Kevin Stewart, Minister for Local Government, said that it was based on ‘the twin tenets of ... enforced self-regulation and public participation in the decision-making process’. It received bipartisan support in the Parliament when it was introduced in 1985 and continues to do so.

The primary aim of the legislation was to protect the welfare of animals used in teaching and research by ensuring that their use was justified, humane and considerate of their needs. The Act introduced a system of accreditation, licensing and authorisation of organisations and individual researchers, and established the Animal Research Review Panel (ARRP) to provide a mechanism for representatives of government, scientific and animal welfare groups to participate jointly in monitoring the effectiveness of the legislation.

The Act came fully into force in 1990, when the Animal Research Regulation was gazetted. The Regulation has subsequently been repealed and a new Regulation gazetted in 1995 and 2005. The *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* is included in the Animal Research Regulation. The Code provides guidance on day-to-day operations within research institutions.

### **1.2 The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes**

The *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (the Code of Practice) is a nationally accepted code and is included in NSW animal research

legislation as part of the Animal Research Regulation. The Code is reviewed regularly by the Code Liaison Group, which includes representatives from the National Health and Medical Research Council (NHMRC), the Commonwealth Scientific and Industrial Research Organisation, the Australian Research Council, the Australian Vice-Chancellors’ Committee, the State Government Ministries with responsibility for animal welfare, the RSPCA and Animals Australia. Members of the ARRP and the Animal Welfare Unit of Industry & Investment NSW are represented on the Code Liaison Group.

The ARRP has had significant input into successive revisions of the Code.

The Chairman of the ARRP attended a meeting of the Code Liaison Group in April 2009 to discuss revision of the 7th edition of the Code of Practice.

### **1.3 The Animal Research Review Panel**

#### **1.3.1 Mission statement**

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

The Animal Research Review Panel (ARRP) was created by the Act to provide a mechanism for representatives of the scientific and broader communities to participate in monitoring the self-regulatory process, which is established within institutions by the Act.

The strength of the ARRP lies in the diversity of expertise, opinions and ethical perspectives of its members. The development of cohesive and progressive policies has occurred as a result of this diversity. All members are employed in other fields and participate on a largely voluntary basis. Non-government



members are paid fees for attending formal meetings and participating in site inspections. Members are not paid for time spent preparing for meetings and inspections, for considering applications for accreditation or licenses, or for drafting discussion papers.

### 1.3.2 Functions of the ARRP

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

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

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

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

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

### 1.3.3 Membership

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

- New South Wales Vice-Chancellors' Committee: three nominees
- Medicines Australia Inc.: one nominee

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

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

During the 2008–09 period the membership of the ARRP was:

- Professor Margaret Rose (Chair) (nominated by Vice-Chancellors' Committee)
- Dr Regina Fogarty (Deputy Chair) (nominated by Minister for Primary Industries)
- Ms Stephanie Abbott (nominated by Animal Societies' Federation)
- Dr Magdoline Awad (nominated by RSPCA NSW)
- Mr Peter Batten (nominated by Minister for Education and Training)
- A/Professor Andrew Dart (nominated by Vice-Chancellors' Committee)
- Dr Mike Fleming (nominated by the Minister for the Environment)
- Dr Jason Grossman (nominated by Animal Societies' Federation)
- Professor Annemarie Hennessy (nominated by the Minister for Health)
- Dr Nicholas Malikides (nominated by Medicines Australia)

- Professor Robert Mulley (nominated by Vice-Chancellors' Committee)
- Mr David O'Shannessy (nominated by RSPCA NSW)

Information on members of the Animal Research Review Panel in 2008–09 is as follows:

**Professor Margaret ROSE (Chair) BVSc (University of Sydney), PhD (University of New South Wales).** Professor Rose has had a long-standing interest in the welfare of animals used in research and teaching. She chaired the committee of the Australian Veterinary Association that developed the proposal for the Animal Research Act, and since 1990 she has been closely involved in the revisions of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*. She was responsible for the development of the proposal to establish ANZCCART (Australian and New Zealand Council for the Care of Animals in Research and Teaching) and, as a member of the Board until 1994, was actively involved in its establishment. She is a member of the editorial board of two international journals devoted to the welfare of laboratory animals: *ATLA (Alternatives to Laboratory Animals)*, and the *Journal of Applied Animal Welfare Science*.

She has been involved in the development, delivery and assessment of courses on animal care and ethics in both the university and TAFE systems. Professor Rose holds the position of Area Director Research Governance in South Eastern Sydney and Illawarra Area Health Service, is a conjoint Professor at the University of New South Wales and Honorary Professor with the Centre for Values, Ethics and the Law in Medicine at the University of Sydney and a member of the Working Party on Harmonisation of the International Council for Laboratory animal Science.

Professor Rose joined the ARRPP in 1986 as a nominee of the NSW Vice-Chancellors'

Committee and has served as the ARRPP's Chair since that time.

**Dr Regina FOGARTY (Deputy Chair), BVSc, PhD (University of Queensland).** Dr Fogarty is the Director, Private Forestry and Resources at NSW Department of Primary Industries. Dr Fogarty has been actively involved in animal welfare issues in previous positions with the Department as Manager of NSW Agriculture's Animal Welfare Unit; as Program Leader, Intensive Livestock Products; and as Veterinary Officer (Pig Health). Dr Fogarty joined the ARRPP in 2003 as the nominee of the then Minister for Agriculture.

**Ms Stephanie ABBOTT, BA, LLB (University of Sydney).** Ms Abbott joined ARRPP in March 2004. She is a nominee of the Animal Societies Federation (NSW). She was the Vice Chair of the NSW Young Lawyers Animal Rights Committee from 2002-2006. Ms Abbott has a keen interest in animal law as well as in animal rights and welfare issues generally, and she seeks to apply her legal skills to improving the lives of animals. Ms Abbott is the principal of Kitsune Consulting.

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

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

Indigenous Dog Health Programs as well as the Pets of Older Persons Program (POOPS) for RSPCA NSW. She became a member of the ARRPP in 2008.

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

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

**Professor Andrew DART BVSc PhD Dip ACVS Dip ECVS**

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

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

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

**Dr Jason GROSSMAN, MA (Cantab) MPH (Sydney) PhD (Sydney).**

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

**Professor Annemarie HENNESSY**

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

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

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

held research, public health and clinical veterinary positions at Sydney University and has spent many years in mixed veterinary practice in Australia and the UK.

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

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

**Mr David O'SHANNESSEY, BSAgr.** Mr O'Shannessy is the nominee of the RSPCA (NSW). Since completing an Agricultural Science Degree he has been employed as an inspector with the RSPCA NSW and for a period of time was a sales representative for a veterinary pharmaceutical company. He was appointed RSPCA Chief Inspector in May 2005 and was appointed as a member of the ARRPP in January 2005.

## 1.4 Animal Ethics Committees

At the institutional level, Animal Ethics Committees (AECs) provide avenues for public participation in the regulation of animal research.

AECs are responsible for monitoring research within institutions, including inspections of animals and facilities. They must consider and evaluate applications to conduct research on the basis of the researchers' responses to a comprehensive set of questions, including their justification for the research, its likely impact on the animals, and procedures for preventing or alleviating pain or distress. On behalf of the institution, AECs have the power to stop inappropriate research and to discipline researchers by withdrawing their research

approvals. They can require that adequate care, including emergency care, is provided for animals. They also provide guidance and support to researchers on matters relevant to animal welfare, through means such as the preparation of guidelines and dissemination of relevant scientific literature. They are responsible for advising institutions on the changes to physical facilities that should be made to provide for the needs of the animals used.

The membership and duties of AECs are laid down in the NSW legislation and in the Code of Practice, which also provides guidance on how AECs should operate.

Committee membership must be as follows:

- Category A: a veterinarian
- Category B: an animal researcher
- Category C: a person with a demonstrated commitment to animal welfare who is not involved with the institution, animal research or the supply of animals for research
- Category D: an independent person who does not fit the requirements of the other categories and is not associated with the institution.

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

The criteria used by the ARRPP for assessment of AEC membership were clarified in an ARRPP policy document, *Policy 9: Criteria for the Assessment of Animal Ethics Committee Membership* (<http://www.animaethics.org.au/policies-and-guidelines/operation>). In examining applications from institutions for accreditation as animal research establishments, the membership of the AEC is assessed to ensure it is of acceptable composition and size. During audit

inspections, the ARRП assesses the operation of the AEC.

## **1.5 Accreditation and licensing**

The legislation requires that all applications for accreditation and animal supply licences be referred to the ARRП for consideration. The ARRП has established procedures to deal with the considerable workload this entails and has regularly reviewed and updated these procedures to take account of changes in needs and resources.

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

- 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 ARRП are referred to the Director-General of Industry & Investment NSW, who has statutory authority for the issue of accreditation and licences and for imposing, altering or removing conditions of accreditation or licence.

Accreditation and licences are usually issued subject to the condition that a site inspection is satisfactory and are subject to the reporting of changes in AEC membership to the Director-General of Industry & Investment NSW for approval. Other conditions may also be stipulated, as relevant to the operation of each institution. (See Appendix M for standard conditions on accreditation and licences).

### **1.5.1 Evaluation of written applications**

New and renewal applications for accreditation or licences are assessed by Animal Welfare Unit staff, according to criteria developed by the ARRП. Arising from these assessments, recommendations on the applications are made to the ARRП. The ARRП considers the recommendations and then makes recommendations on the applications to the

Director-General of Industry & Investment NSW.

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

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

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

Monitoring of animal care and use by the AEC and researchers is another vital area of assessment. Details of the type of monitoring undertaken must be provided. Questions on the source and destination of animals allow the ARRП to double-check compliance with the Act’s provisions relating to animal supply.

### **1.5.2 Conduct of site inspections**

Following the evaluation of written applications, the second phase of the process of assessing establishments is the site inspection. The aim of site inspections is to determine whether institutions and

individuals are complying with the legislation. The Code of Practice provides the criteria against which institutions are assessed. The range of items assessed includes: the membership, procedures and activities of the AEC; animal care procedures; animal research procedures; and the physical facilities for housing and using animals. An evaluation is also made of the wellbeing of the research or breeding animals.

Audit visits are arranged in advance and usually take from 1 to 4 days per site. Large establishments with multiple sites can take up to 2 weeks to inspect. Information about inspections conducted in the 2008–09 year is provided in Appendixes C and D. The dates provided represent days on site and do not include preparation and follow-up time, which is often considerable.

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

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

On the day(s) of the inspection the inspection team initially looks at the animals and the facilities and talks with researchers. This examination includes assessing a broad range of items such as the physical condition of animals, animal care and management, and records related to the animals held. After examining animals and facilities, the inspection team sits in on a scheduled meeting of the AEC, which allows it to view the operation of the AEC and the interaction of its members. At the end of the meeting, time is taken to discuss

with the AEC issues arising from the inspection and to solicit feedback from AEC members. Additional important considerations are how the committee liaises with researchers and whether it has developed its own policies or guidelines for procedures of particular concern, such as blood collection techniques, methodology for monoclonal antibody production, and standards for wildlife transportation and the recognition and relief of pain.

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

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

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

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

The ARRPP aims to carry out full audit visits for all institutions every 3 years, as well as unannounced visits by inspectors to follow up problems. In formulating its 2008–09 operational plan, the ARRPP again recognised that staff availability within the Animal Welfare Unit would mean that reinspections would mostly be conducted on a 3- to 4-yearly basis. Reinspections concentrate more on procedures rather than facilities, unless new facilities have been built. Announced and unannounced spot checks and visits to look at specific aspects of operation may be carried out between full visits.

## 1.6 The Animal Research Act in schools and TAFE

The Animal Research Act allows the use of animals for educational purposes when there is a demonstrated educational benefit, when there is no suitable alternative, and when the least number of animals is used, with the least impact on their wellbeing. Although animals are used for educational purposes in many situations, their use in schools and TAFE colleges presents special issues, such as mechanisms for approval and monitoring of animal use across the State. Their use also presents opportunities to promote in students an understanding of the ethical and technical issues involved with the use of animals.

## 1.7 Administration

The Animal Welfare Unit is a section within Industry & Investment NSW.

The functions of the Animal Welfare Unit cover:

- animal research issues under the *Animal Research Act*, including providing executive services to the ARRPP

- general animal care and cruelty issues under the *Prevention of Cruelty to Animals Act* (POCTAA), including the operation of the Animal Welfare Advisory Council (AWAC) under the Minister for Primary Industries
- animal display issues under the *Exhibited Animals Protection Act* (EAPA), including the operation of the Exhibited Animals Advisory Committee
- Departmental animal welfare activities.

The Animal Welfare Unit can be contacted at:

Animal Welfare Inspectorial Office  
Industry & Investment NSW  
95 Castle Hill Road  
WEST PENNANT HILLS NSW 2125  
Phone: (02) 9872 0571  
Fax: (02) 9871 6938

PO Box 100  
BEECROFT NSW 2119

or at the Industry & Investment NSW Head Office:

Animal Welfare Unit  
Industry & Investment NSW  
161 Kite Street  
Locked Bag 21  
ORANGE NSW 2800  
Phone (02) 6391 3149  
Fax (02) 6391 3570  
E-mail: [animal.welfare@industry.nsw.gov.au](mailto:animal.welfare@industry.nsw.gov.au)

In the 2008–09 financial year the following staff were assigned, at various times, to provide inspectorial and/or executive support to the ARRPP (amongst their other duties).

### Orange:

Ross Burton, BVSc, MVSc, Director, Animal Welfare  
Amanda Paul, BVSc, MACVSc (Animal Welfare), Veterinary Officer (part-time)  
Grace Cook, Licensing Clerk (part-time)  
Frances Kumbley, Clerical Officer

Tammy Kirby, Licensing Assessment Officer  
(part-time)

**Sydney:**

Lynette Chave, BVSc, Leader, Animal  
Research

Peter Johnson, BVSc, PhD, Veterinary Officer

Janelle Townsend, Clerical Officer (part-time)



## **PART 2: REPORT ON WORK AND ACTIVITIES**

### **2.1 Administration and planning**

Administrative functions have varied from activities such as assessments of licensing and accreditation to formulating the ARRPs operational plan for 2008–09. The appendixes to this annual report contain details of many of the operational and strategic functions of the ARRPs. These include the dates of, and attendance at, ARRPs meetings (Appendixes A and B); dates and attendance of ARRPs members at inspections of accredited research establishments and animal supply licence holders (Appendixes C and D); the ARRPs Strategic Plan 2008–11 (Appendix E) and Operational Plan for 2008–09 (Appendix F); and ARRPs operating expenses (Appendix I).

The ARRPs was pleased to welcome the Director-General of Industry & Investment NSW, Dr Richard Sheldrake to a meeting of the ARRPs. Dr Sheldrake reiterated the Department's support for the operation of the ARRPs.

#### **2.1.1 Strategic Plan 2008–11**

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

Details of the Plan are given in Appendix E.

#### **2.1.2 Operational Plan for 2008–09**

The ARRPs Operational Plan for 2008–09, including a performance review of each activity, is provided in Appendix F.

#### **2.1.3 Liaison with organisations, accredited establishments and authority holders**

The ARRPs liaised with several organisations, accredited establishments and animal research authority holders to offer advice and to facilitate the implementation of legislative requirements and adherence to replacement, reduction and refinement principles.

Examples of these activities include:

- \* Professor Margaret Rose (Chair, ARRPs) and Dr Regina Fogarty (Deputy –Chair, ARRPs) met with representatives of an educational institution to discuss progress made in addressing problems that had been identified at site inspection.
- \* Professor Rose accepted the invitation of an educational institution's AEC to attend an AEC meeting and give an overview of the activities of the ARRPs.
- \* An establishment looking at group housing rabbits was put in contact with other establishments that were successfully housing rabbits in groups in pens.
- \* Comments were provided by the ARRPs to the NHMRC on two documents that had been sent for public comment: "*A guide to the use of Australian native mammals in biomedical research*" and "*Policy on the care and use of non-human primates for scientific purposes*".

### **2.2 Assessment of applications**

During 2008–09 the ARRPs considered and made recommendations to the Director-General on :

- 11 new applications for accreditation
- 14 renewal applications for accreditation
- 8 new applications for animal suppliers' licences
- 28 renewal applications for animal suppliers' licences.

The ARRPs developed new standard conditions to be added, as applicable, to accredited animal research establishments. These conditions were:

*\* 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 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>*

A full list of standard conditions can be found at Appendix M.

### 2.2.1 LD50 testing

LD50 is a toxicity test used to determine the dose or concentration of a test substance—that is, the lethal dose—that is expected to kill 50% of the animals to which it is administered. For the purposes of the *NSW Animal Research Act, 1985* the definition of LD50 has been broadened. Included are all tests in which a potentially lethal dose of a substance will be administered and is expected to kill a proportion of the individuals in any group of animals to which it is given. In NSW such tests may be undertaken only under the approval of a properly constituted Animal Ethics Committee, with the concurrence of the Minister for Primary Industries. Applications for permission to conduct LD50 tests are evaluated by an ARRP subcommittee. Members of the subcommittee in 2008–09 were Mr Batten, A/ Professor Dart and Dr Malikides. The

subcommittee makes recommendations to the ARRP, which in turn advises the Minister.

In 2008–09 the subcommittee considered one application (6 tests) from an Accredited Research Establishment.

The testing is used in quality control during the manufacturing of vaccines and in the development of new vaccine formulations. The tests are related to the manufacture of equine salmonella vaccine and 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. The ARRP recommended to the Minister that he approve the application on the following conditions:

1. Data is provided in graphical form by 31 January 2010 with figures comparing 2007, 2008 and 2009 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 applicant. The measure should provide information on the trends in numbers of animals used over time.
  - b) The number of animals used for development and research over time, with an explanation of the purpose eg replacement of a test, refinement of a procedure.
  - c) The total number of animals produced in relation to numbers of animals actually used in tests.
  - d) The number of animals that die in tests and the number euthanased as an early end-point in tests.
2. Any application for Ministerial concurrence to conduct LD50 tests between April 2010 and April 2011 must be presented to the Animal Welfare Unit by 31 January 2010.
3. The company continues, in consultation with the AEC, to identify and implement refinements to lessen the impact of existing approved tests on animals and methods of reducing the numbers of animals used in existing approved tests with alternatives and reports upon these to the Animal Welfare Unit by 31 January 2010.

## 2.3 Assessment of changes to AEC membership

All establishments are required to advise the Director-General of Industry & Investment NSW of changes to AEC membership.

The ARRPP assesses and makes recommendations to the Director-General on the suitability of the qualifications of the new members for the categories of membership to which they are nominated.

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

In the 2008–09 year the ARRPP assessed and made recommendations to the Director-General on the appointment of 64 members of Animal Ethics Committees.

## 2.4 Assessment of accreditation and licensing responses

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

In the 2008–09 year the ARRPP made recommendations to the Director-General on responses from 37 accredited animal research establishments and licensed animal suppliers.

## 2.5 Subcommittees

The ARRPP appoints subcommittees to deal with particular issues. They explore issues in depth and have discussions with relevant members of the scientific and broader communities. Subcommittees provide reports

and recommendations to the full ARRPP for consideration. Membership of subcommittees is largely drawn from the ARRPP. External members of subcommittees are occasionally co-opted on a voluntary basis. Activities of subcommittees in the 2008–09 year include:

- Hosting of a meeting held in April 2009 for members and executive officers of AECs (Professor Rose, Dr Fogarty and Mr O'Shannessy).
- Evaluation of applications for LD50 testing (Mr Batten, A/Professor Dart and Dr Malikides).
- Development of a training package for AEC members (Professor Rose, Ms Abbott and Dr Awad).
- Development of training material for researchers / teachers (Professor Rose, Ms Abbott, Mr Batten, A/Professor Dart and Professor Mulley).

## 2.6 Statistics on animal use

The Animal Research Regulation 2005 requires accredited research establishments (other than schools) and animal research authority holders to record and submit information on the number of animals used in research each year.

The requirements for reporting on animal use provide data on the numbers of animals used in all research projects in NSW, reported against the purpose of the research and the types of procedures in which they were involved. The aim of collecting these statistics is to give some indication of the level of 'invasiveness' of the procedures on the animals and to provide data for inclusion in national statistics on the use of animals in research. Aspects of the system include:

1. the recording of an animal in all projects in which the animal is used
2. the recording of animals for each year in which they are held in long-term projects

3. the recording of the types of procedures used (giving an indication of the impact of procedures), combined with the recording of the purpose of the research.

The categories used are based on those planned to be used in a future national database. Figures are collected on a calendar year basis rather than by financial year.

Appendix G of this report summarises animal usage in 2008.

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 ARRPP recommended that the Annual Reports of AECs be submitted with the submission of annual statistics. The Code of Practice requires that each AEC must submit a written report on its activities at least annually to the governing body of the institution for which it acts (Clause 2.2.40). In the 2008-09 year, the ARRPP carried out its first assessment of these reports, at a supplementary meeting organised for this purpose, and provide 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 ARRPP. 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 ARRPP and the Animal Welfare Unit continue to use various means to support AECs in performing their duties. These means include the conducting of site inspections; the writing of policies, guidelines and fact sheets where a need is identified; the holding of meetings for AEC members; and the supply of advice over the telephone or by correspondence.

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

### **2.7.2 Meeting for members and executive officers of AECs**

In April 2009 a meeting for members and Executive Officers of AECs was held by the ARRPP in conjunction with the Animal Welfare Unit.

In an effort to ensure that the program for the meeting met the needs of AECs, comment was sought from all NSW AECs on topics they wished to discuss and the format for conducting the meeting. Valuable feedback was provided, and a program was structured accordingly. The members of the ARRPP subcommittee that worked on this project were Dr Fogarty, Mr O'Shannessy and Professor Rose. The Australian Catholic

University at its MacKillop Campus kindly hosted the meeting once again which was attended by almost 100 AEC members, representing 40 different Committees.

The programme was comprehensive, with presentations and discussions on Housing Guidelines, Wildlife Research and Hot Topics for AECs: “*Looking beyond application approvals*”.

Informative discussions by the keynote speakers were particularly well received. Dr Cullum Brown gave a fascinating presentation on fish welfare and A/Professor Paul McGreevy presented some illuminating insights into animal behaviour.

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

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

Reports from the meeting can be found at [www.animaethics.org.au](http://www.animaethics.org.au).

### **2.7.3 Seminar with Dr Clément Gauthier**

The ARRPP organised a seminar featuring Dr Clément Gauthier, Executive Director of the Canadian Council on Animal Care (CCAC).

The CCAC is responsible for setting and maintaining standards for the care and use of animals in science in Canada. Dr Gauthier has been Executive Director of the CCAC since 1999.

The seminar was well attended by AEC members who were given an outline by Dr Gauthier of the system governing the use of animals in research in Canada.

Dr Gauthier also attended a meeting of the ARRPP and met with staff of the Animal Welfare Unit which provided valuable opportunities for the exchange of ideas and

experiences in comparing the Canadian and NSW systems.

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

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

During the 2008-09 year, the Animal Ethics Infolink website underwent a complete upgrade and was re-launched to AECs at the meeting for members of AECs in April 2009. Publicity material on the website was developed and distributed. The material was designed to be able to be readily displayed and to act as an “easy access” prompt for use of the website.

The website has been developed and is maintained in conjunction with the Animal Welfare Unit. The Animal Ethics Infolink site is accessible at [www.animaethics.org.au](http://www.animaethics.org.au).

## **2.9 Site inspections**

A list of site inspections undertaken in 2008–09 is provided in Appendix C, and a list of ARRPP members attending is given in Appendix D. There were 15 inspections conducted over a period of 29 working days. The length of these inspections ranged from one day to six days. The inspections included AECs and the facilities of 15 accredited

animal research establishments /licensed animal suppliers.

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

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

## **2.10 Policies, guidelines and fact sheets**

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

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

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

The following guidelines were published for comment in 2008-09:

*ARRP Guideline 22: Draft guidelines for the housing of mice in scientific institutions*

*ARRP Guideline 23: Draft guidelines for the housing of sheep in scientific institutions*

These guidelines are comprehensive and based on information from the scientific literature.

The following policies were revised in 2008-09:

*ARRP Policy 2: Payment of external members of Animal Ethics Committees*

*ARRP Policy 3: Procedures prohibited under the NSW Prevention of Cruelty to Animals Act*

*ARRP Policy 5: Annual reporting by Animal Ethics Committees to accredited animal research establishments*

## **2.11 Initiatives in replacement, reduction and refinement**

Information collected from the 'Annual Return on Animal Use' submitted by each research establishment and independent researcher includes information on techniques developed or used by the establishment to replace, reduce and refine animal use in research and teaching. The adoption of such techniques is actively encouraged by the ARRPP. 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 Director-General of Industry & Investment NSW, who refers the complaint to the ARRPP for investigation. The ARRPP is bound to investigate formal complaints and to make recommendations to the Director-General for disciplinary action (if it is considered warranted) or dismissal of the complaint.

Both the complainant and the individual or institution being investigated have a right of appeal. There was one formal complaint received in the 2008–09 reporting period.

The ARRPP 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; ARRPP 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 ARRPP, or the Animal Welfare Unit. One informal complaint was received in the 2008–09 reporting period.

A summary of the complaints is as follows:

***Formal complaint:***

***Use of animals for tertiary teaching***

A formal complaint was received that animals were being used for a teaching project at a tertiary institution in contravention of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*. The basis of the complaint was an allegation that animals were being used for the teaching project when alternative teaching methods that did not use animals could have been used. The clauses of the Code of Practice on which the complaint was based were:

*1.8: Techniques that totally or partially replace the use of animals for scientific purposes must be sought and used wherever possible.*

*6.1.1: Animals are not to be used for teaching activities unless there are no suitable alternatives for achieving all of the educational objectives.*

The teaching project in question had approval of the establishment's AEC.

As is required by the Animal Research Act, the complaint was referred by the Director-General of Industry & Investment NSW to the ARRPP for investigation.

The ARRPP's investigation began with seeking written advice from the establishment on the reasons for approval of the use of animals in the teaching project.

Representatives of the ARRPP then met with representatives of the establishment's AEC and the Chief Investigator (teacher) to assess whether due process had been followed in approving the teaching project and to further explore the need to use animals rather than non-animal alternatives.

In the course of its investigation, the ARRPP was pleased to note that the teaching project had been modified to reduce negative impacts of procedures on the animals used.

Following its investigation, in accordance with the Act, the ARRPP provided a report to the Director-General. The determination of the Director-General on the complaint was that it be dismissed. This was based on evidence that the AEC followed due process in reaching a decision that the use of animals in the teaching project was justified. In light of the fact that the AEC of the establishment had recently been reconstituted, a request was also made that the teaching project be resubmitted to the AEC for review.

***Informal complaint:***

***Wildlife research – platypus***

An informal complaint was received alleging that wildlife research was being carried out involving the capture and killing of platypus. The investigation of this matter confirmed that this research had been carried out. The research had the approval of the establishment's AEC, but the establishment was based outside NSW and did not have accreditation as an animal research establishment in NSW.

The establishment was advised of its obligations under the NSW Animal Research Act and required immediately to cease animal research being carried out in NSW. The establishment did not subsequently seek accreditation as an animal research

establishment in NSW and therefore was not permitted to carry out any further animal research in NSW.

## **2.13 Attendance at other meetings**

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

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

1. *Australia's ethical framework for the use of animals in research and teaching.* Australian Animal Welfare Strategy, International Meeting, Gold Coast, 2008.

2. *International Guidelines on the Education and Training of Persons using Animals for Scientific Purposes.* Australian and New Zealand Laboratory Animal Association, Sydney, 2008

3. *Humane endpoints and genetically modified animals - challenges and opportunities.* Institute for Laboratory Animal Research, International Conference, National Academy of Sciences, Washington DC., 2008.

4. *Guidelines to promote the wellbeing of animals used for scientific purposes.* International conference on Laboratory Animal Science, Bangkok, 2009.

Members of the ARRP, Ms Stephanie Abbott and Dr Jason Grossman gave presentations at a symposium held in Sydney in 2008: *Australian alternatives to using animals in scientific and medical research.*



# APPENDIXES

## Appendix A: Dates of ARRP meetings 2008–09

Meeting number	Date of meeting
178	9 July 2008
179	8 October 2008
180	10 December 2008
180 (a) Supplementary Meeting	28 January 2009
181	25 February 2009
182	6 May 2009

## Appendix B: Members' attendances at ARRP meetings 2008–09

Member	Meeting number					
	178	179	180	180(a)	181	182
Professor M Rose (Chair)	*	*	*	*	*	*
Dr R Fogarty (Deputy Chair)	*	*	*	A	*	*
Ms S Abbott	*	A	*	*	*	*
Dr M Awad	-	*	*	*	*	*
Mr P Batten	-	*	*	*	*	*
A/Professor A Dart	-	*	*	*	A	*
Dr M Fleming	-	-	-	-	*	A
Dr J Grossman	*	*	*	A	A	-
Professor A Hennessy	-	*	*	A	*	A
Dr N Malikides	-	*	*	*	*	*
Professor R Mulley	-	A	*	*	*	*
Mr D O'Shannessy	*	*	*	*	*	*

\* = Present

A = Absent

– = Not applicable

## Appendix C: Inspections July 2008 – June 2009

Establishment	Date
EnGeneIc	1/7/2008
Sydney South West Area Health Service	21/7/2008 23-25/7/2008
Garvan	29/7/2008 9/6/2009
Centenary Institute of Cancer Medicine and Cell Biology	20/8/2008
ANSTO	11/9/2008
Sylvan Scientific	17/9/2008 18/2/2009
University of Sydney	9-10/10/2008 13-16/10/2008
NSW DPI – Forests	6/11/2008
Elanco	12/11/2008
Novogen	7/4/2009
Northern Sydney Central Coast Area Health Service	8-9/4/2009
University of NSW	27-28/4/2009 30/4/2009 1/5/2009 5/5/2009 22/6/2009
Children's Cancer Institute Australia	27/4/2009
South Eastern Sydney and Illawarra Area Health Service	27-28/4/2009 30/4/2009
University of Technology, Sydney	30/6/2009

**Appendix D: Attendance of ARRP members at site inspections 2008–09**

<b>Member</b>	<b>Number of days spent on site inspection</b>
Professor M Rose (Chair)	4
Dr R Fogarty (Deputy Chair)	5
Ms S Abbott	1
Dr M Awad	
Mr P Batten	1
A/Professor A Dart	
Dr M Fleming	
Dr J Grossman	5
Professor A Hennessy	
Dr N Malikides	1
Professor R Mulley	
Mr D O'Shannessy	6

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

\* Numbers in italics on right refer to items from 2008/2009 operational plan that address the strategies

### Goals and Strategies

#### **1. Effective and efficient implementation of the statutory requirements of the Animal Research Act 1985, the Animal Research Regulation 1995 and the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* .**

- |      |  |                          |
|------|--|--------------------------|
| 1.1  | Maintain a system to accredit all establishments and individuals in NSW conducting research and teaching using animals.  | <i>1.1</i>               |
| 1.2  | Maintain a programme of site visits to effectively monitor compliance with the legislation.  | <i>2</i>                 |
| 1.3  | Review the methods of conducting site visits and the documentation of these methods on a regular basis to help ensure high standards of efficiency, effectiveness and consistency.   | <i>2.6</i>               |
| 1.4  | Identify and implement adjuncts to inspections to better ensure compliance with the legislation.   | <i>2.6</i><br><i>3</i>   |
| 1.5  | Monitor compliance with the Act, Regulations and the Code with respect to the conduct of animal research and teaching and the supply of animals for research and teaching.   | <i>1</i><br><i>2</i>     |
| 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.   | <i>3.4</i><br><i>6.1</i> |
| 1.7  | Prepare an annual report to Parliament on the operations and achievements of the Animal Research Review Panel.   | <i>1.4</i>               |
| 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. | <i>1.5</i>               |
| 1.9  | Maintain a system for receiving and investigating complaints relating to the requirements of the legislation.  | <i>1.2</i>               |
| 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.   | <i>2</i><br><i>3.3</i>   |
| 1.11 | Maintain a system to consider and make recommendations on applications for permission to carry out LD50 tests.   | <i>1.3</i>               |

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

- |      |  |                        |
|------|--|------------------------|
| 2.1  | Promote an understanding of the roles and responsibilities of institutions in supporting the effective operation of their AECs.  | 2.6<br>3               |
| 2.2  | Promote an understanding of the roles and responsibilities of institutions in actively pursuing programmes for researchers and teachers that underpin their responsibilities under the Code.   | 3                      |
| 2.3  | Ensure there is effective participation by researchers and teachers, veterinarians, animal welfare representatives and independent representatives in a formal review of the justification and merit for all proposals for the use of animals for scientific purposes. | 2<br>3                 |
| 2.4  | Promote and foster interaction between AECs and researchers/teachers.  | 2<br>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<br>3<br>4            |
| 2.6  | Promote an understanding of the roles and responsibilities of AECs through encouraging participation in AEC training programmes.   | 2<br>3<br>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<br>3                 |
| 2.8  | Promote discussion and understanding of key technical and ethical issues and foster interaction between AECs by maintaining a programme of meetings of Chairs of AECs and participating in AEC meetings during site inspections.                                       | 2<br>3.2<br>3.3<br>3.4 |
| 2.9  | Review the membership and operation of individual AECs to ensure they are operating effectively.   | 1.1<br>2               |
| 2.10 | Develop and promulgate evidence-based guidelines to assist AECs, researchers and teachers to effectively implement the 3Rs.  | 4                      |
| 2.11 | Promote a critical review of the operation of AECs by the institution with a view to maximising their effectiveness.   | 2                      |

## **3. Researchers and teachers considering using animals are aware of and actively apply the principals set out in the Act, Regulation and the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*.**

- |     |   |   |
|-----|---|---|
| 3.1 | Promote an understanding of the roles and responsibilities of researchers/teachers through participation in | 3 |
|-----|---|---|

education programmes, to foster an awareness of ethical and scientific issues and the implementation of the 3Rs.	4
3.2 Maintain the “Animal Ethics Infolink” website as a resource for AECs, researchers and teachers and members of the community.	3.1

#### **4. Methods that complement or replace animal use are used wherever possible**

4.1 Encourage AECs critically to assess the adequacy of researchers’/teachers’ attempts to identify alternatives to animal use.	2 3
4.2 Encourage greater awareness of the use of alternatives to animals in research and teaching.	2 3
4.3 Collate and disseminate information on alternatives to animal use.	3.1
4.4 Promote consideration of funding for development and validation of alternatives.	

#### **5. Procedures involving animals are regularly reviewed and refined to minimise the number of animals required and to reduce the impact on individual animals**

5.1 Encourage a critical review of the design of experiments before protocols are submitted to AECs.	2
5.2 Ensure close scrutiny by AECs of breeding programmes to minimise overproduction of animals.	2 3
5.3 Ensure close scrutiny by AECs of the competence of researchers to carry out specific procedures	2 3
5.4 Promote the critical evaluation of the monitoring of animals being used in procedures.	2 3
5.5 Promote the critical evaluation by AECs and researchers of the impact of the type of housing / holding on experimental animals and awareness of its implications for experimental results.	2 3 4.1

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

6.1 Promote the implementation of strategies which will foster the well-being of animals and which will foster the development of appropriate risk management assessments related to pain and distress in animals.	2 3
6.2 Ensure that AECs and researchers/teachers focus on the possible impact of procedures at the planning stage and implement appropriate strategies for monitoring and alleviation.	2 3
6.3 Promote awareness by researchers / teachers and animal care staff of signs of well-being, pain and distress in animals.	2 3
6.4 Promote the use of appropriate analgesia and anaesthesia by facilitating access by researchers/teachers to	2

information resources.	3.1
	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
6.6 Monitor and identify deficiencies in anticipation, recognition and relief of pain and distress during site visits and ensure deficiencies are rectified, including by provision of pre-operative analgesia where appropriate.	2

## **7. High standards of housing and routine care are established for animals used in research and teaching**

7.1 Evaluate housing and routine care through the ongoing site visit programme.	2
7.2 Develop and disseminate evidence based guidelines for housing and routine care.	4.1
7.3 Actively participate in the development and review of appropriate national and international standards for housing and routine care.	

## **8. Animals used are supplied in accord with the legislation**

8.1 Identify areas of non-compliance through scrutiny of records during site visits and investigation of complaints.	1.2 2
8.2 Develop and disseminate appropriate educational material.	3

## **9. The community (research, teaching, veterinary, animal welfare and lay) has access to information about animal use for research and teaching in NSW**

9.1 Provide information in the annual report on ARRP activities and achievements, areas of concern to the Animal Research Review Panel and statistics on animal use.	1.4 1.5
9.2 Identify options for disseminating information about specific issues of interest and concern both broadly and to specific groups (researchers, teachers, veterinarians, animal welfare, lay).	3
9.3 Review and maintain a web site for the dissemination of information.	3.1
9.4 Provide opportunities for and encourage the community (researchers, teachers, veterinarians, animal welfare, lay) to have an input into legislative review, development of standards for housing and care and policy development.	4
9.5 Ensure that information about animal use provided by the Animal Research Review Panel is in lay terms where appropriate.	
9.6 Encourage institutions to provide information about their animal use direct to the general community.	

**10. The approach to administration of animal research and teaching is harmonised between State and Territory regulatory and funding bodies.**

10.1 Promote interaction between State and Territory regulatory and funding bodies.

6



## Appendix F: ARRP Operational Plan July 2008 – June 2009

Activity	Measure of Performance	Time Frame	Status
<b>1. Mandatory</b>			
1.1 Review incoming applications for accreditation and licence	Recommendation to Director-General	3 months (new) 2 months (renewal)	Applications processed and recommendations made to the Director-General
1.2 Investigate formal and informal complaints	Recommendation to Director-General	Interim or final recommendations within 3 months	1 formal and 1 informal complaint received and under consideration.
1.3 Review incoming applications to conduct LD50 tests	Recommendations to Minister	3 months	All applications reviewed and recommendations sent to the Minister.
1.4 Prepare annual report for 2007-2008	Report submitted to Minister	December 2008	Report prepared and submitted.
1.5 Prepare statistics on animal use for 2007	Statistics collated	December 2008	Statistics collated.
<b>2. Inspections</b>			
2.1 Conduct site visits of all accredited establishments on a 3 – 4 yearly basis	Number of establishments inspected.  Number of days for inspections  Total number of establishments not inspected within the last 4 years	Ongoing	15  29  5 (In-State / active/with own AEC)
2.2 Inspect new establishments applying for accreditation prior to or within 2 months of accreditation	Number of new establishments inspected  Number of new establishments not inspected	Ongoing	1 (In-State / active/with own AEC)  1 (In-State / active/with own AEC)
2.3 Conduct site visits of selected independent researchers with animal holding facilities	Number visited	Ongoing	0
2.4 Review and send inspection reports	Reports sent	Within 3 months of inspection	Reports sent
2.5 Follow up “problems” identified at inspection or on review of applications for accreditation or licence	Problems rectified	Within 12 months	Problems followed up as per “Accreditation/Site Inspection” section of ARRP agenda.
2.6 Assess AEC annual reports as adjunct to inspections	Assessment carried out	December 2008	2007 reports assessed and feedback provided to establishments.

<b>3. Education</b>			
3.1 Maintain ARRPs website	Site maintained	Ongoing	Website revised and publicity material about website distributed.
3.2 Finalise learning guide to accompany AEC learning package	Guide finalised	June 2009	Learning guide being finalised.
3.3 Meeting for members of AECs	Meeting held	April 2009	Meeting held April 2009
3.4 Facilitate access to education programmes by researchers and teachers (via Code Liaison Group)	Strategies developed	June 2009	Subcommittee established. Information sought from establishments on currently available education material.
<b>4. Policies and guidelines</b>			
4.1 Standards linked to performance criteria for rats, mice, guinea pigs and farm animals (sheep, cattle, pigs)	Draft of mouse document circulated for comment	July 2008	Draft circulated.
	Draft of sheep document circulated for comment	August 2008	Draft circulated.
	Revise rabbit guidelines	March 2009	No progress
	Draft cat guidelines	June 2009 (if staff resources available)	Staff resources not available
	Draft pig guidelines	June 2009 (if staff resources available)	Staff resources not available
4.2 Develop policies/ guidelines where strong need identified (maximum of 2 )	Developed as need identified	Ongoing	None identified for development (apart from housing guidelines)
4.8 Revise current policies and guidelines	Policies and guidelines revised	June 2009	Revision commenced.
<b>5. Legislation</b>			
<b>6. Additional</b>			
6.1 Continue liaison with NHMRC	Meeting held	Ongoing	Meeting with NHMRC (via Code Liaison Group) April 09.
6.2 Continue liaison with APVMA via the Animal Welfare Working Group	Contact with APVMA maintained	Ongoing	No action.
6.3 Refer items to AAWS Advisory Committee as necessary	Items referred	Ongoing	No items identified.
6.4 Prepare three year strategic plan for 08/11	Plan prepared	December 2008	Strategic plan prepared.

## Appendix G: Animal use statistics 2008

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

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

Some animals (e.g. those used to teach animal-handling techniques) are used in a number of projects. Animals that are re-used are counted in each project for which they are used. In welfare terms, this gives a more meaningful indication of animal use.

The system includes the collection of statistics on the observation of free-living animals. This causes a large number of animals to be recorded in procedure category 1 (‘observation involving minor interference’). For example, an aerial survey of birds can include many thousands of individual animals.

After the graphs, statistics are given on the lethality testing performed in 2008.

### Animal species categories used for collection of data

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

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

<b>PURPOSE</b>
<p><b>1. Stock breeding</b> Breeding protocols to produce new teaching or research stock. Include the animals used to produce progeny and any breeders or progeny culled in the process, NOT the final progeny themselves (as these will be counted under the protocol in which they go on to be used).</p>
<p><b>2. Stock maintenance</b> Holding protocols for animals maintained for use in other protocols. These animals may be maintained under an ethics authority because they require special management. If they are not held under an authority (e.g. normal stock animals kept mainly for commercial production, but occasionally used in research), then they are counted in the protocol only where they are used for teaching/research.</p> <p><i>Examples:</i> <i>Fistulated ruminants that are maintained under a holding protocol for use in other short-term feeding trial protocols</i> <i>A non-breeding colony of diabetic rats held for research in other protocols</i></p>
<p><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.</p> <p><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.</p> <p><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.</p> <p><i>Examples</i> <i>Use of a sheep flock to donate blood to produce microbiological media</i> <i>Production of commercial antiserum</i> <i>Production of products, such as hormones or drugs, in milk or eggs from genetically modified animals</i> <i>Quality Assurance testing of drugs</i></p>
<p><b>9. Diagnostic procedures</b> Using animals directly as part of a diagnostic process.</p> <p><i>Examples</i> <i>Inoculation of day-old chicks with Newcastle Disease virus to determine virulence</i> <i>Blue-green algae toxicity testing</i> <i>Water supply testing using fish</i></p>
<p><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.)</p> <p><i>Examples</i> <i>Pre-registration efficacy or toxicity testing of drugs and vaccines</i></p>

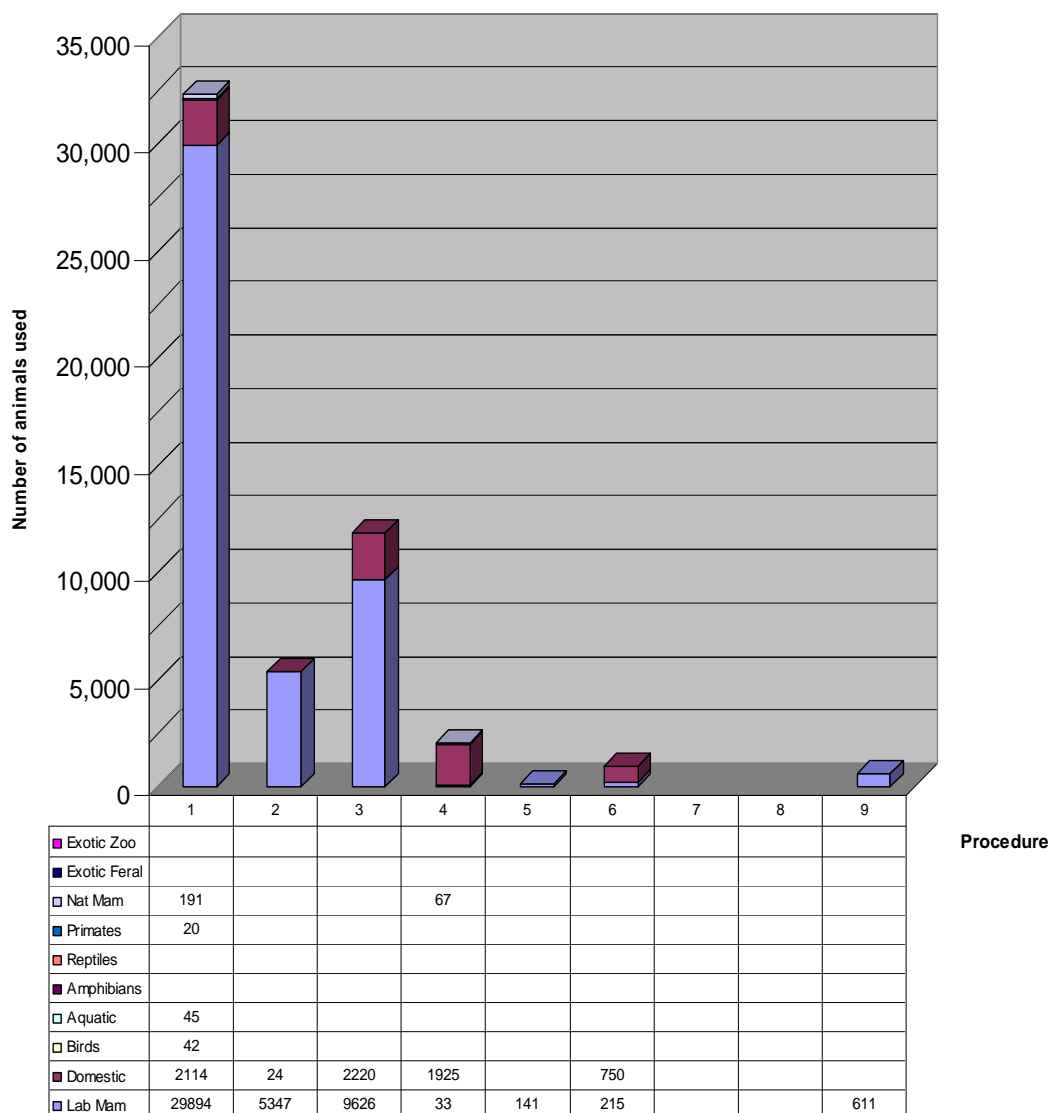
## Data collection: procedure categories and guidelines used for classification

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

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

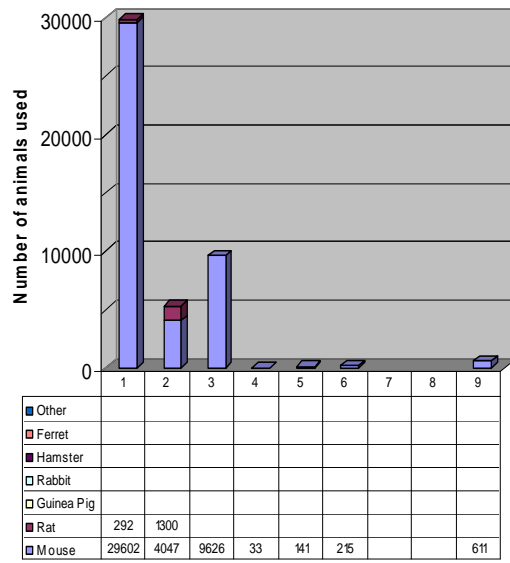
## Purpose: Stock Breeding

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

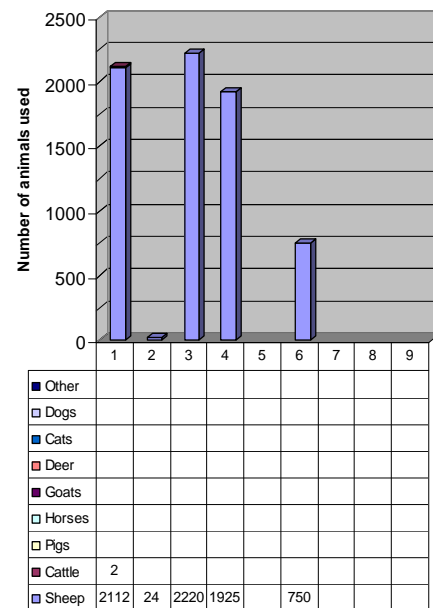


*Refer to following page for a further breakdown of species.*

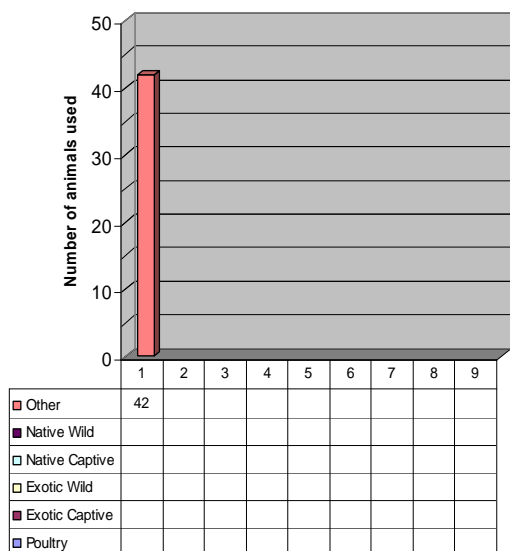
**Purpose: Stock Breeding**  
Breakdown of Laboratory Mammals Species



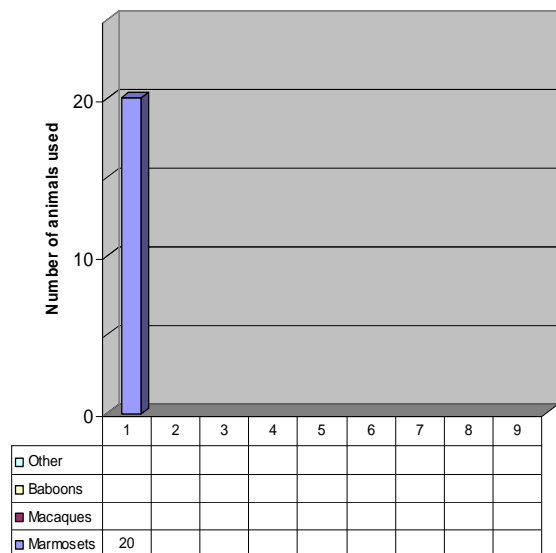
**Purpose: Stock Breeding**  
Breakdown of Domestic Mammals Species



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

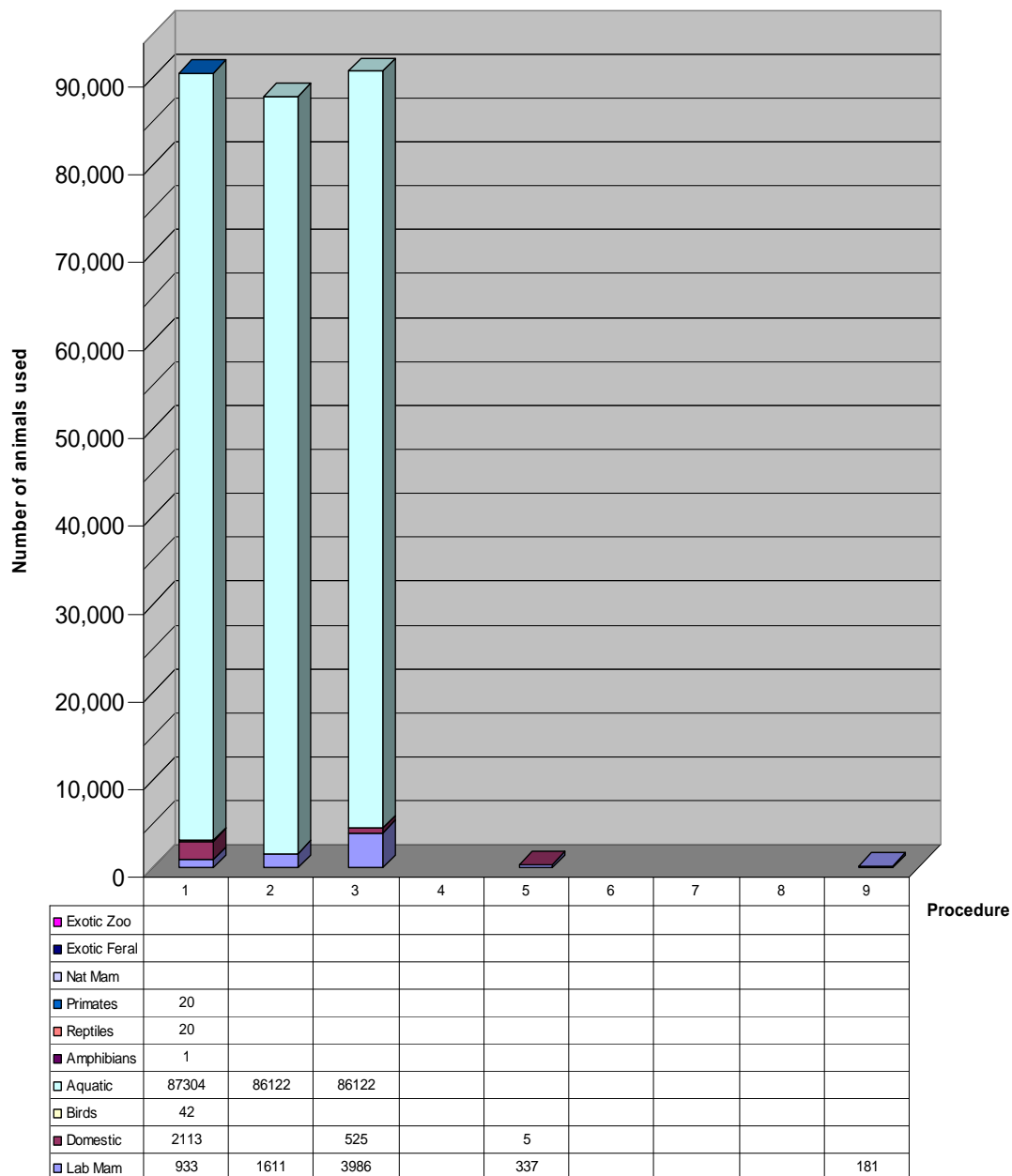


**Purpose: Stock Breeding**  
Breakdown of Primates Species



## Purpose: Stock Maintenance

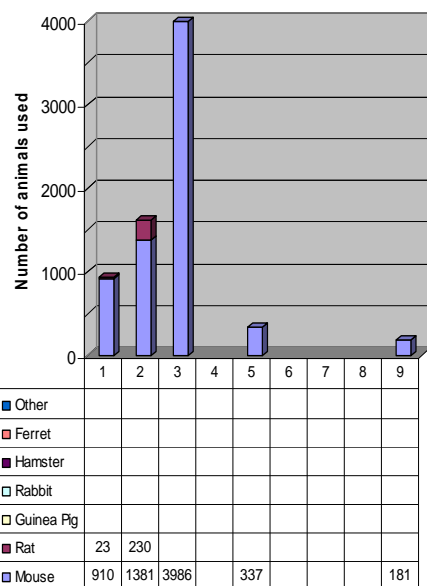
*Holding Protocols for animals maintained for use in other protocols .*



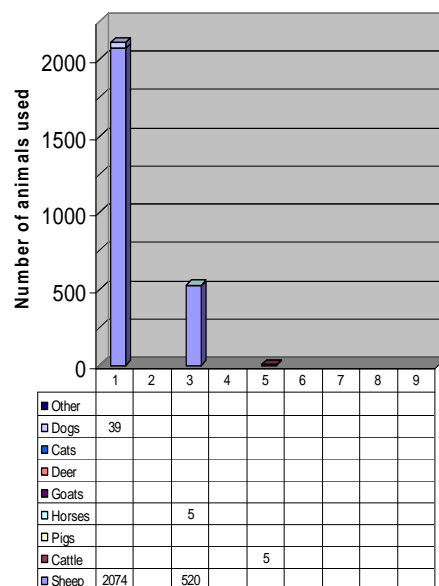
*Refer to following page for a further breakdown of species.*



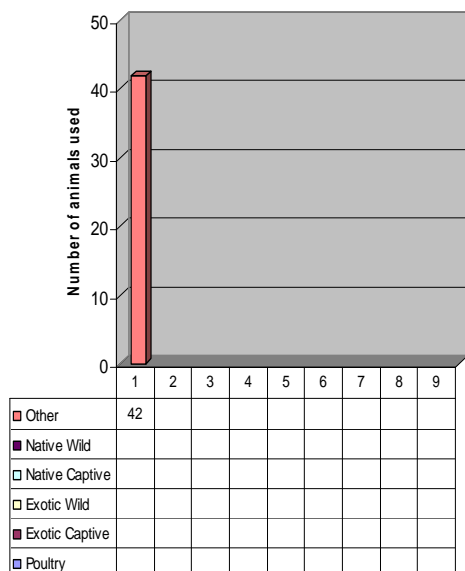
**Purpose: Stock Maintenance**  
Breakdown of Laboratory Mammals Species



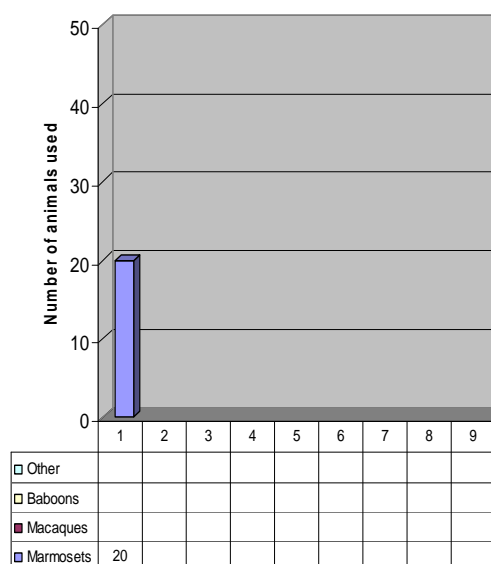
**Purpose: Stock Maintenance**  
Breakdown of Domestic Mammals Species



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

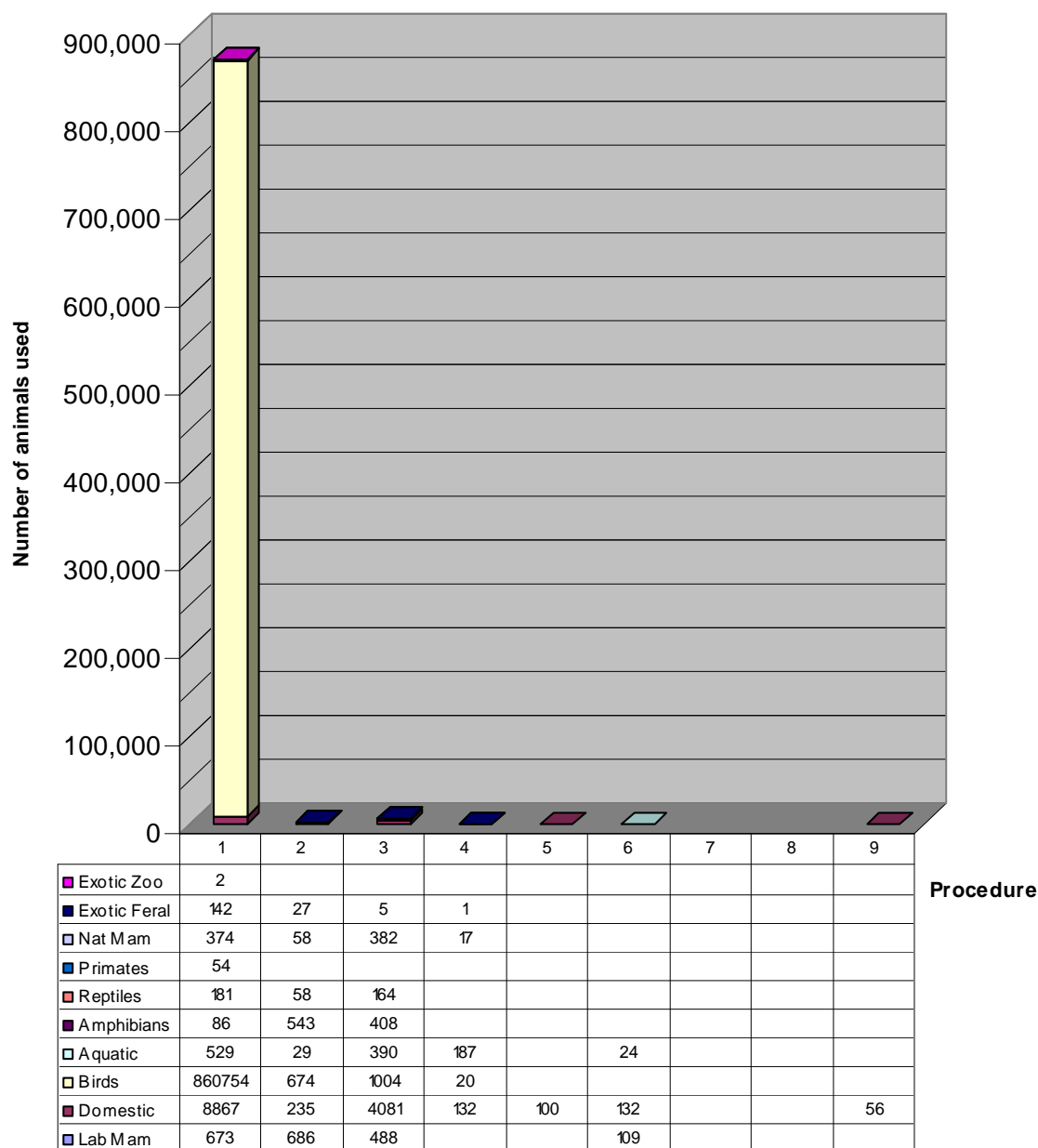


**Purpose: Stock Maintenance**  
Breakdown of Primates Species



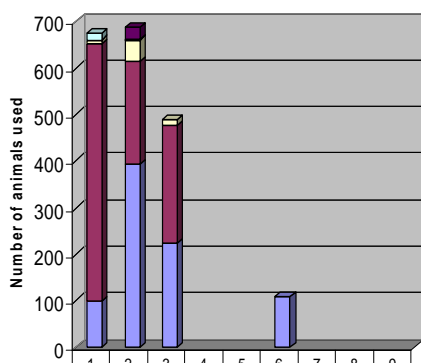
## Purpose: Education

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



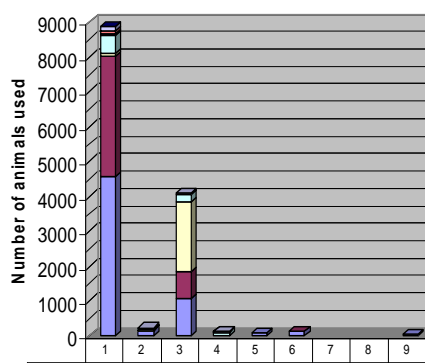
*Refer to following page for a further breakdown of species.*

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



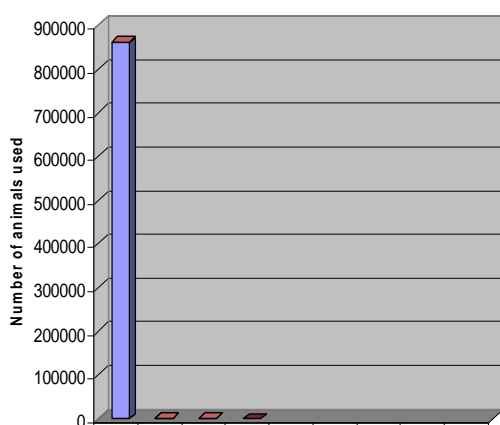
Other									
Ferret									
Hamster		24							
Rabbit	13	2							
Guinea Pig	8	46	12						
Rat	553	221	251						
Mouse	99	393	225			109			

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



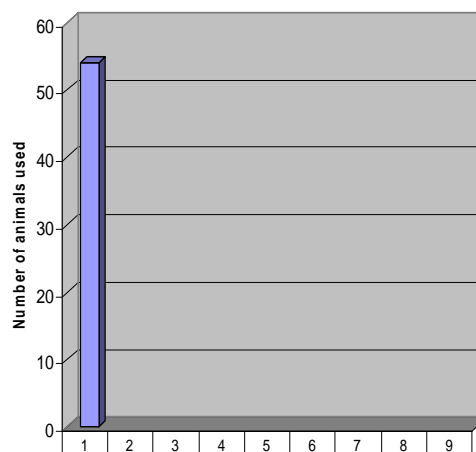
Other	11								
Dogs	116	36	16	20					
Cats	8		8						
Deer	85								
Goats	37								
Horses	508	11	226	112					
Pigs	80	38	1986						
Cattle	3473	1	760			8			
Sheep	4549	149	1085		100	124			56

**Purpose: Education**  
Breakdown of Bird Species



Other	894	29	29						
Native Wild									
Native Captive	17		40						
Exotic Wild	250								
Exotic Captive		220		20					
Poultry	859593	425	935						

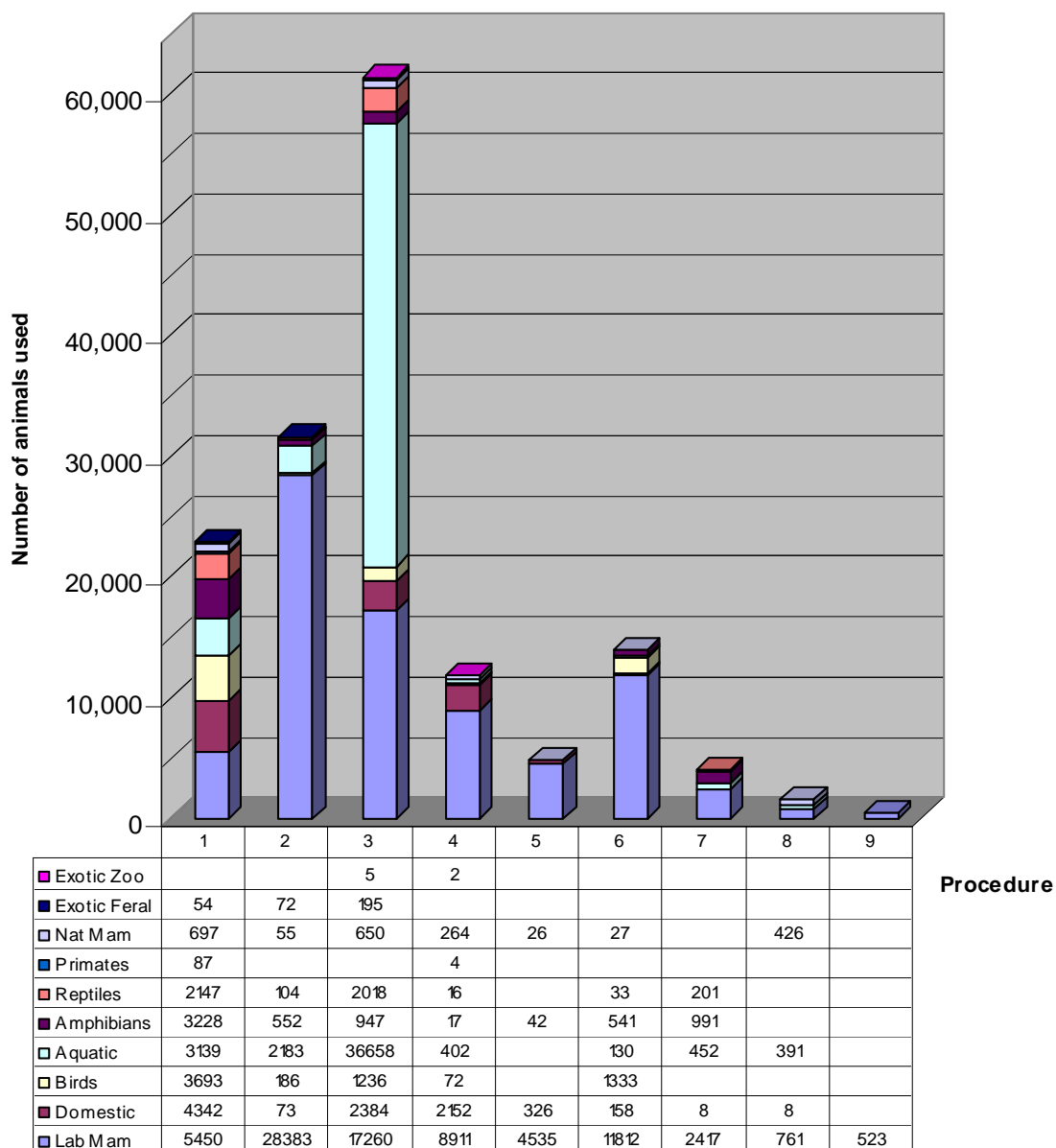
**Purpose: Education**  
Breakdown of Primate Species



Other									
Baboons									
Macaques									
Marmosets	54								

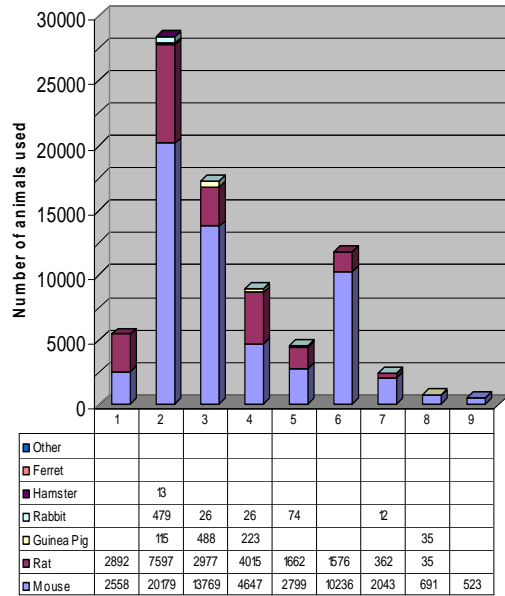
## Purpose: Research - Human or Animal Biology

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

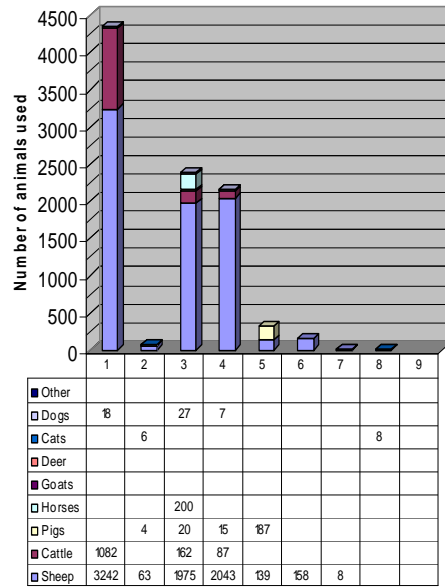


Refer to following page for a further breakdown of species.

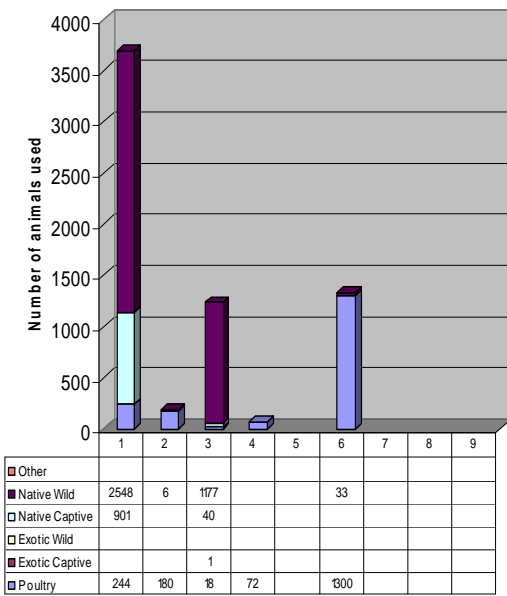
**Purpose: Research - Human or Animal Biology**  
Breakdown of Laboratory Mammals Species



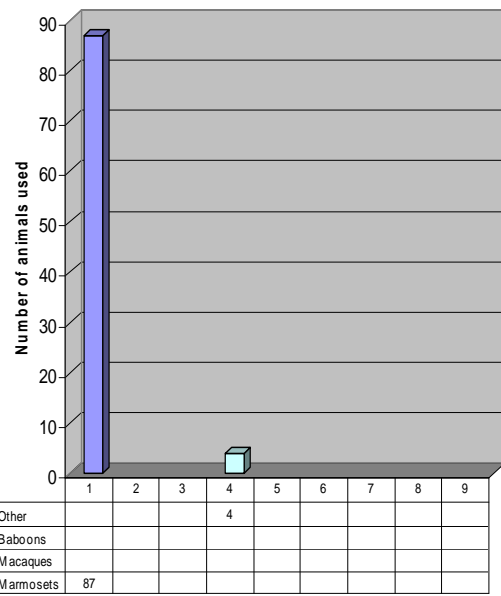
**Purpose: Research - Human or Animal Biology**  
Breakdown of Domestic Mammals Species



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

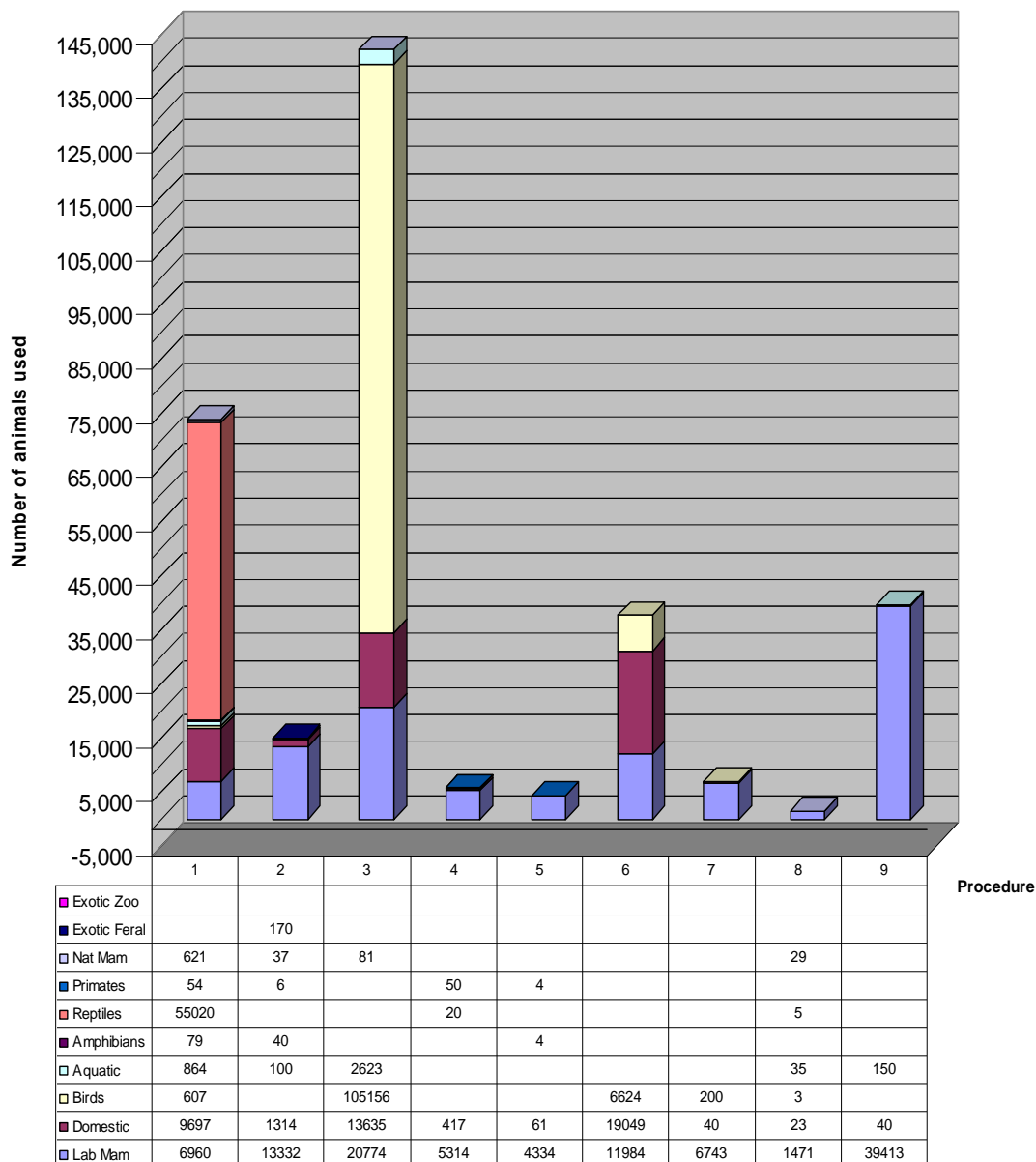


**Purpose: Research - Human or Animal Biology**  
Breakdown of Primate Species



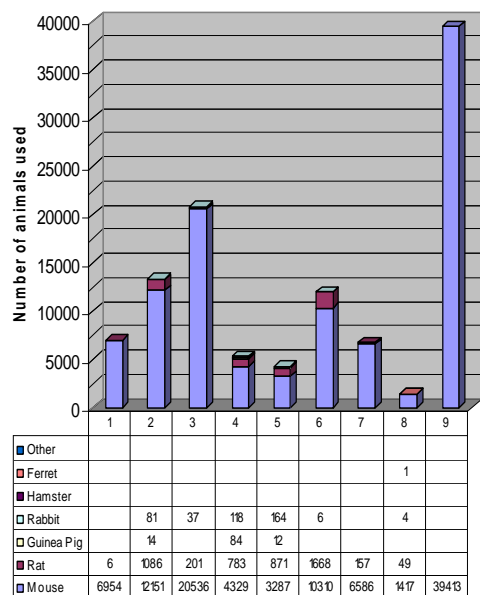
## Purpose: Research - Human or Animal Health & Welfare

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

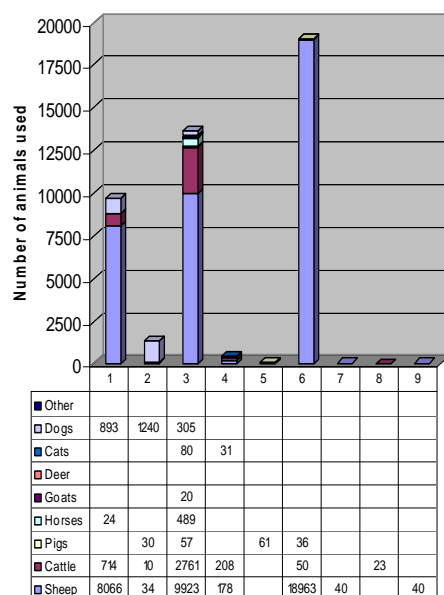


*Refer to following page for a further breakdown of species.*

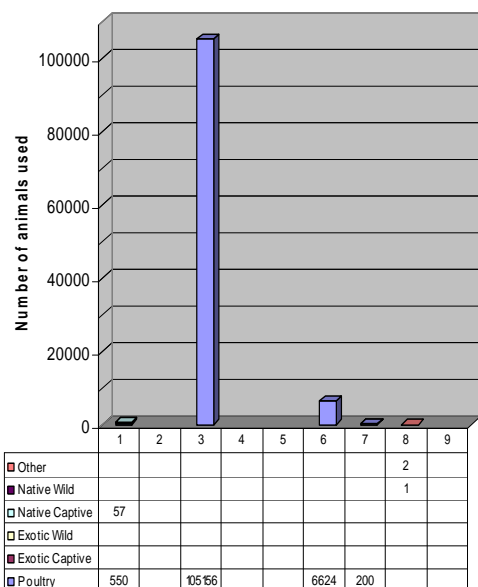
**Purpose: Research - Human or Animal Health & Welfare**  
*Breakdown of Laboratory Mammals Species*



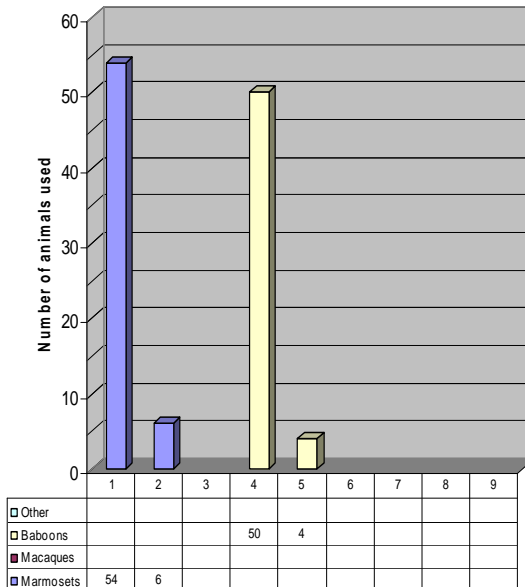
**Purpose: Research - Human or Animal Health & Welfare**  
*Breakdown of Domestic Mammals Species*



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

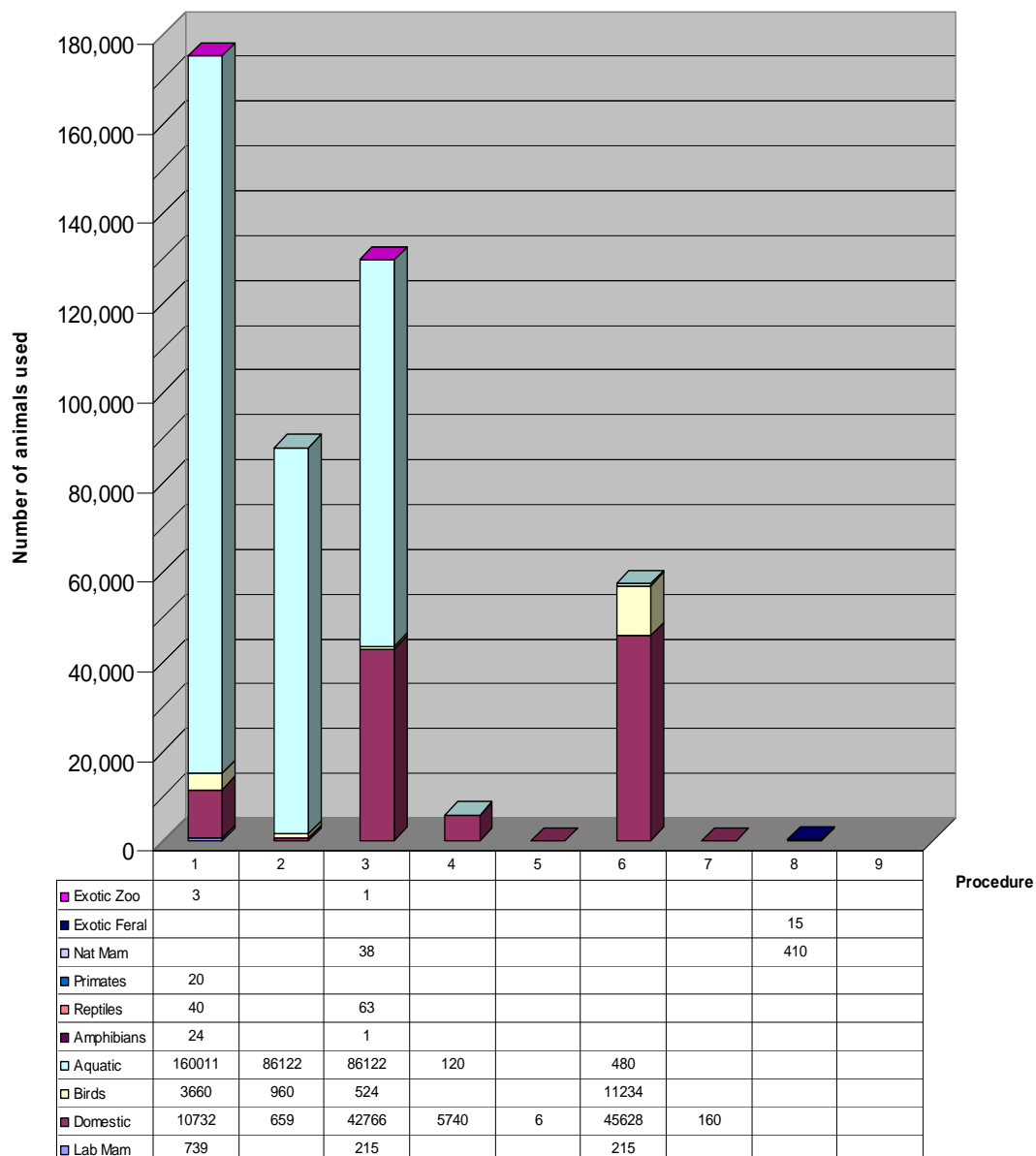


**Purpose: Research - Human or Animal Health & Welfare**  
*Breakdown of Primate Species*



## Purpose: Research - Animal Management or Production

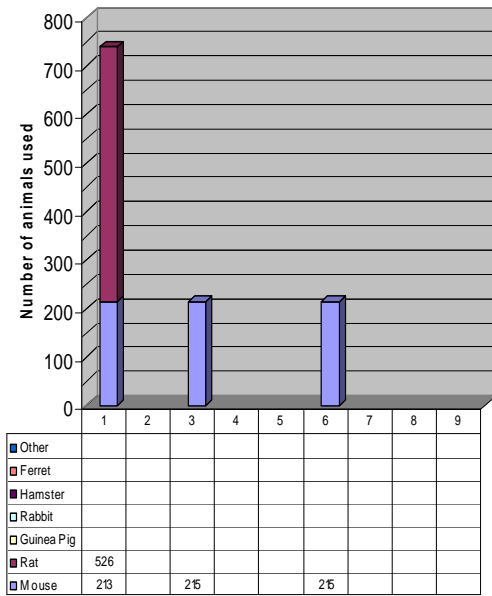
*Research protocols which aim to produce improvements in domestic or captive animal management or production .*



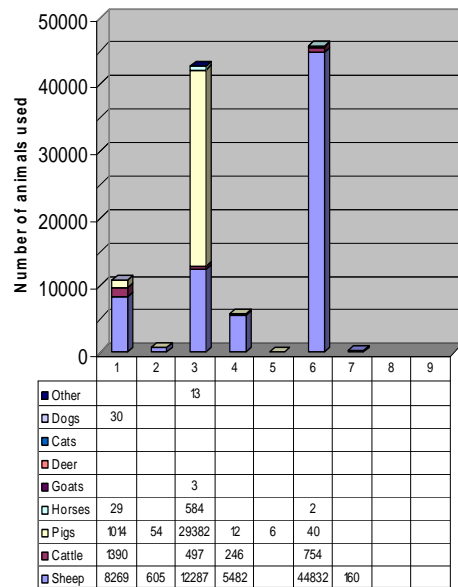
*Refer to following page for a further breakdown of species.*



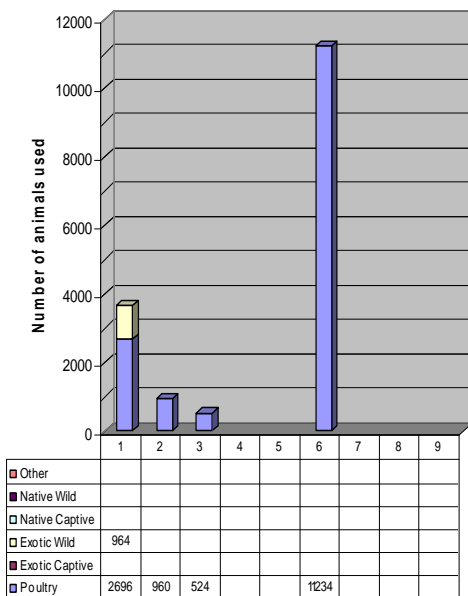
**Purpose: Research - Animal Management or Production**  
*Breakdown of Laboratory Mammals Species*



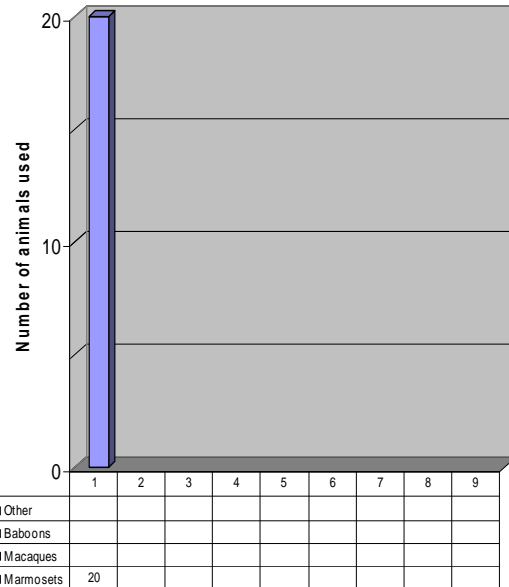
**Purpose: Research - Animal Management or Production**  
*Breakdown of Domestic Mammals Species*



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

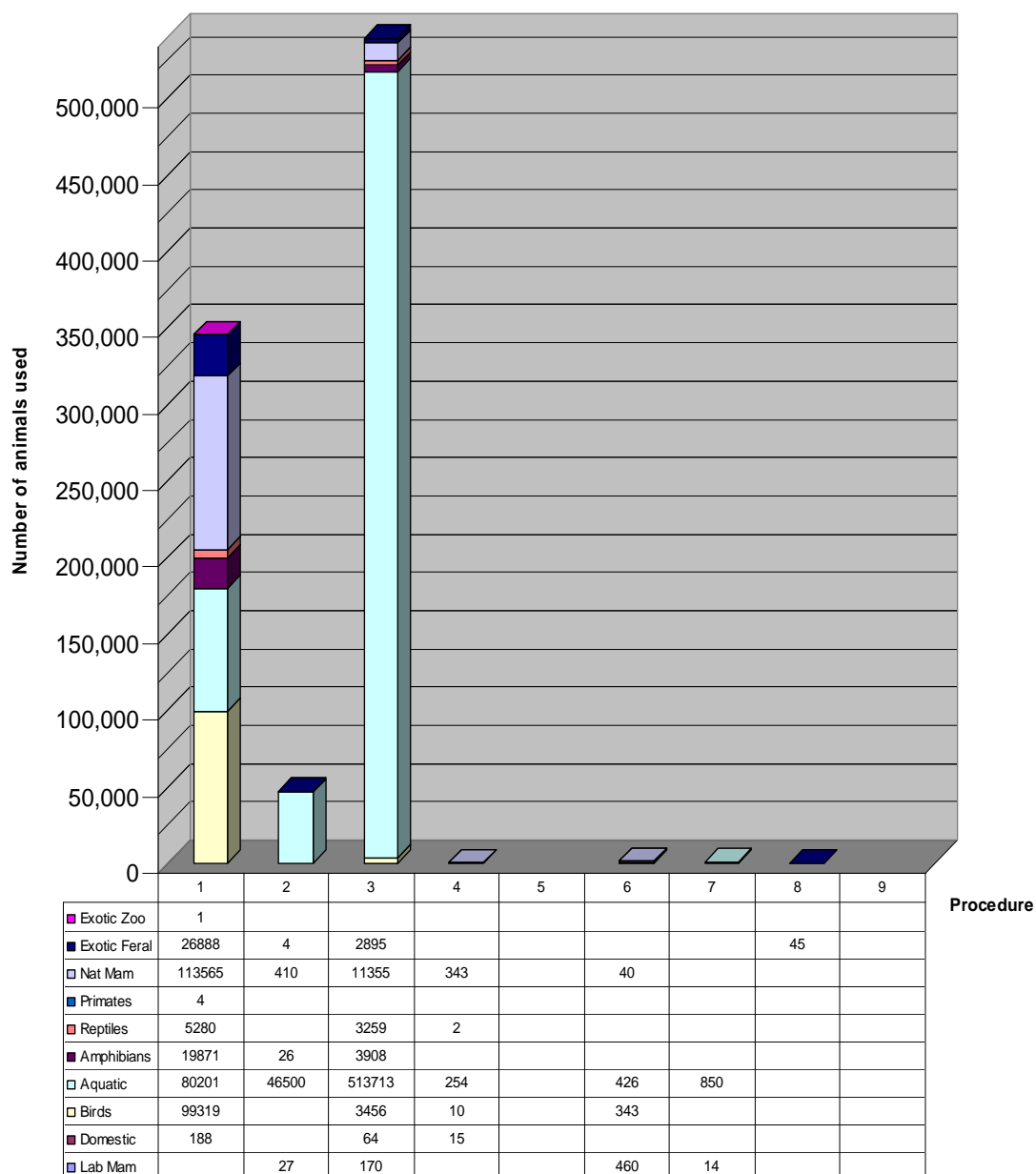


**Purpose: Research - Animal Management or Production**  
*Breakdown of Primate Species*



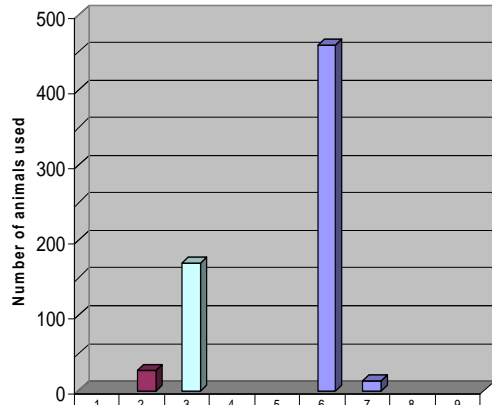
## Purpose: Research - Environmental Study

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



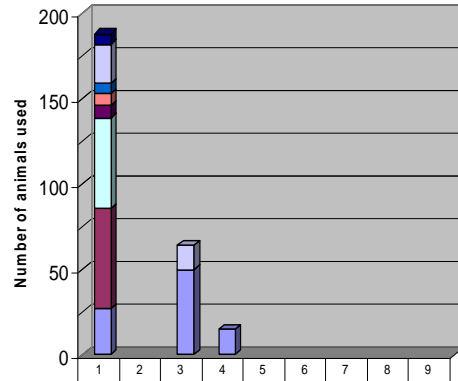
*Refer to following page for a further breakdown of species.*

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



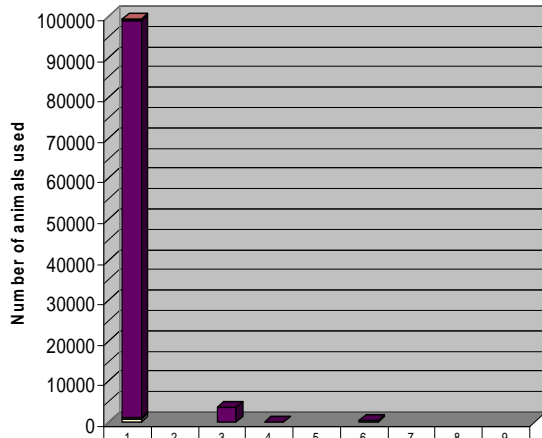
Other									
Ferret									
Hamster									
Rabbit			170						
Guinea Pig									
Rat		27							
Mouse						460	14		

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



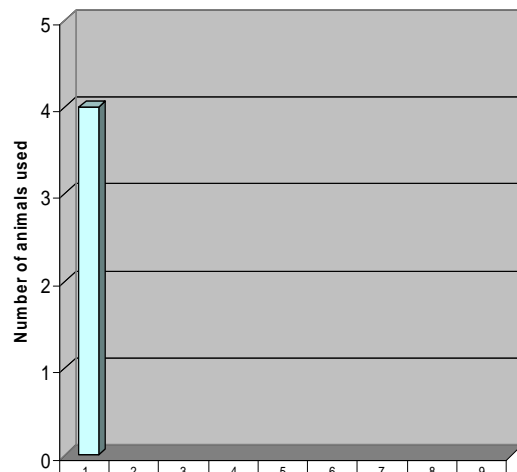
Other	6								
Dogs	23		14						
Cats	6								
Deer	7								
Goats	7								
Horses	53								
Pigs									
Cattle	59								
Sheep	27		50	15					

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



Other	268								
Native Wild	97848		3453	10		3			
Native Captive	332								
Exotic Wild	871		3						
Exotic Captive									
Poultry								340	

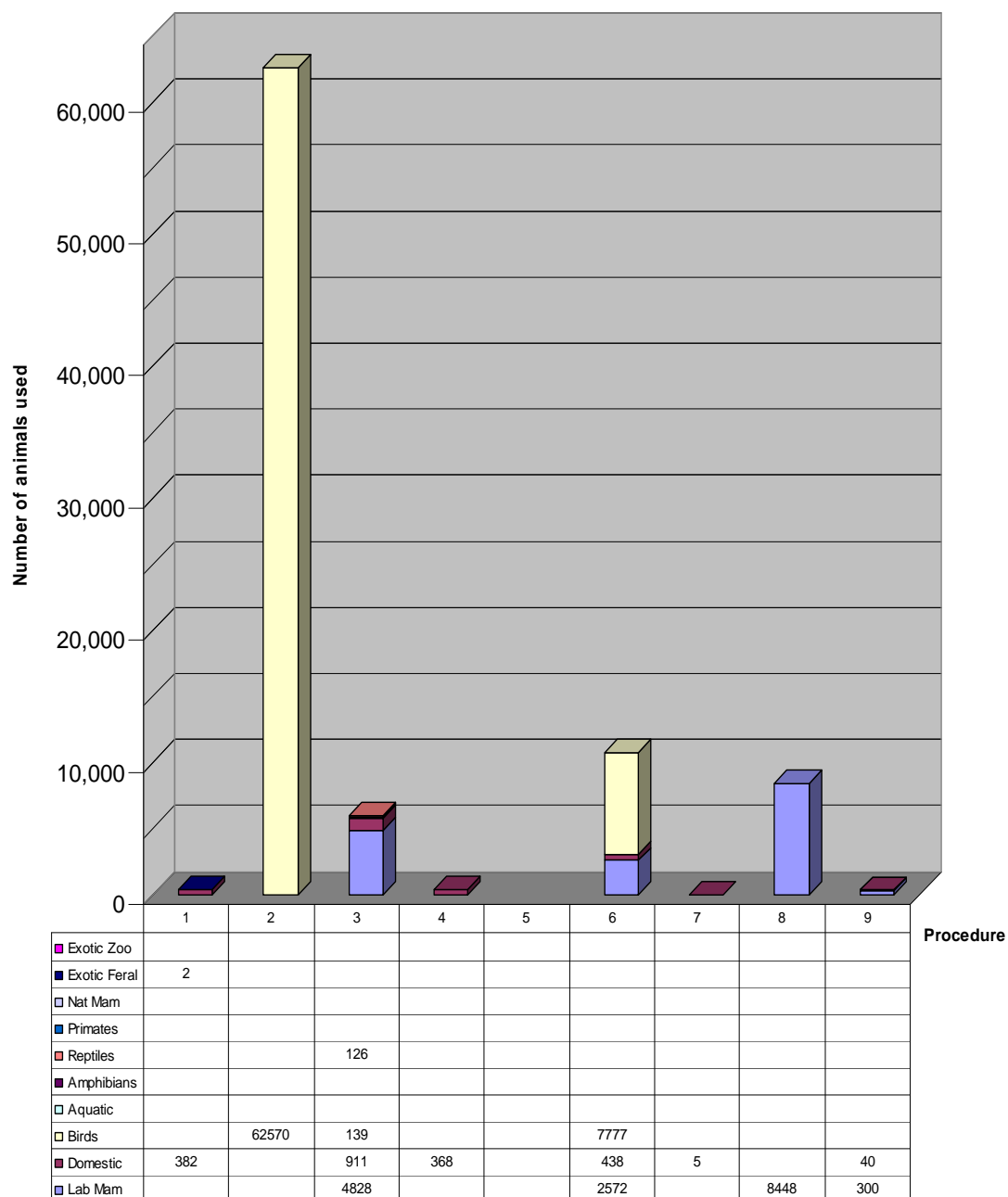
**Purpose: Research - Environment Study**  
Breakdown of Primate Species



Other	4								
Baboons									
Macaques									
Marmosets									

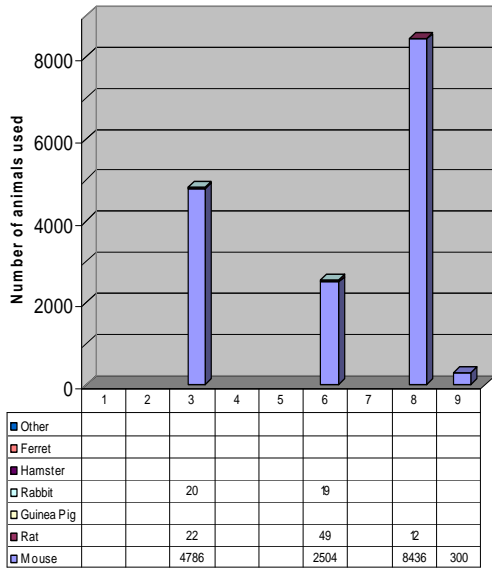
## Purpose: Production of Biological Products

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

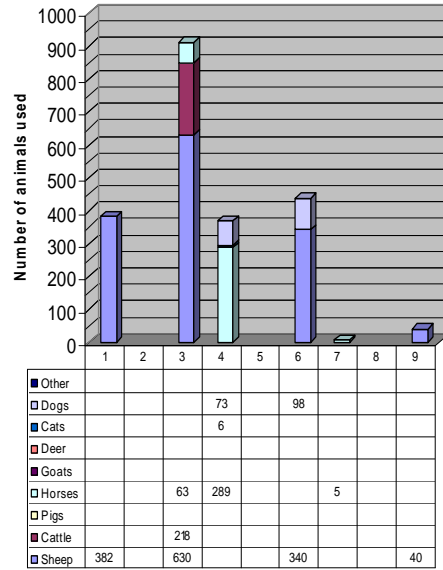


*Refer to following page for a further breakdown of species.*

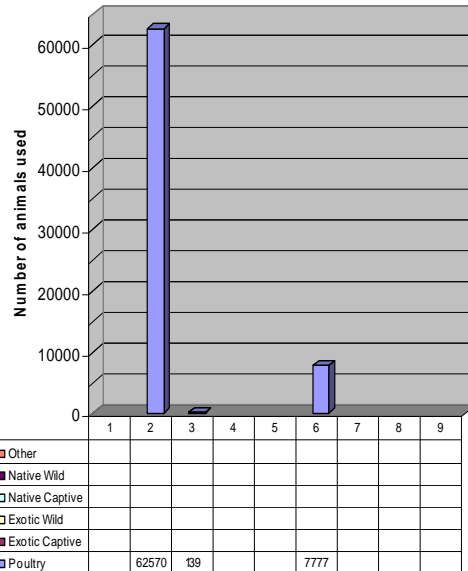
**Purpose: Production of Biological Products**  
Breakdown of Laboratory Mammals Species



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

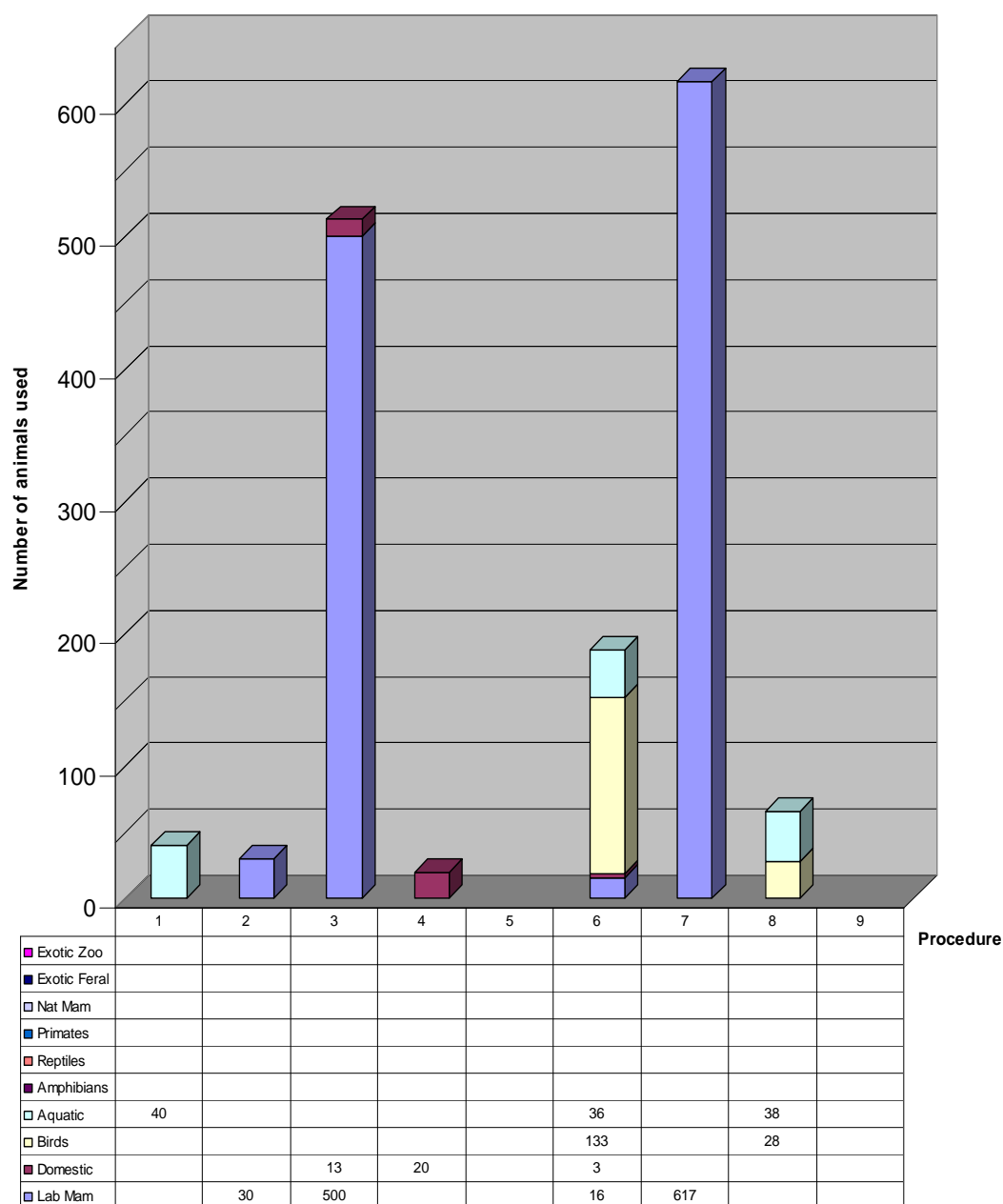


**Purpose: Production of Biological Products**  
Breakdown of Bird Species



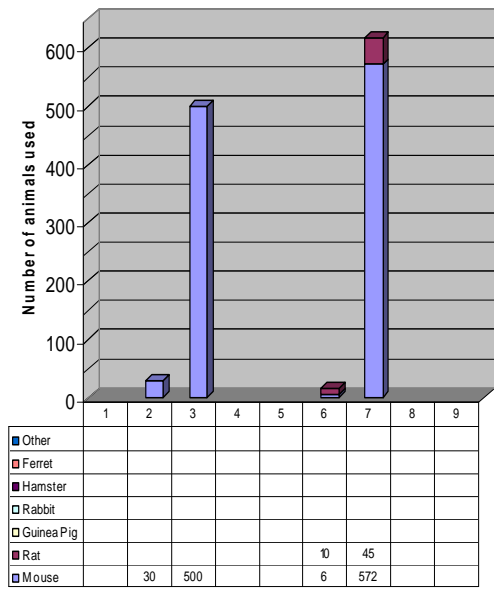
## Purpose: Diagnostic Procedures

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

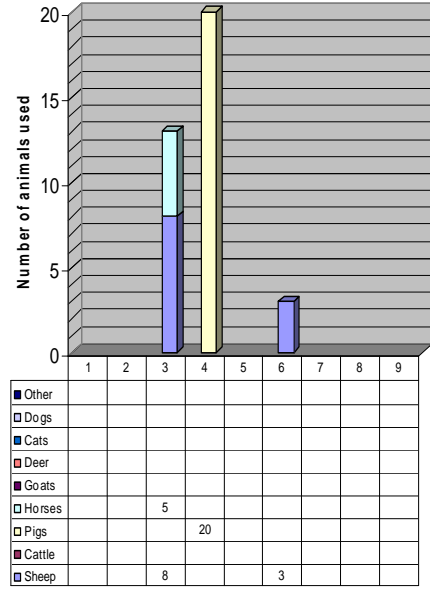


*Refer to following page for a further breakdown of species.*

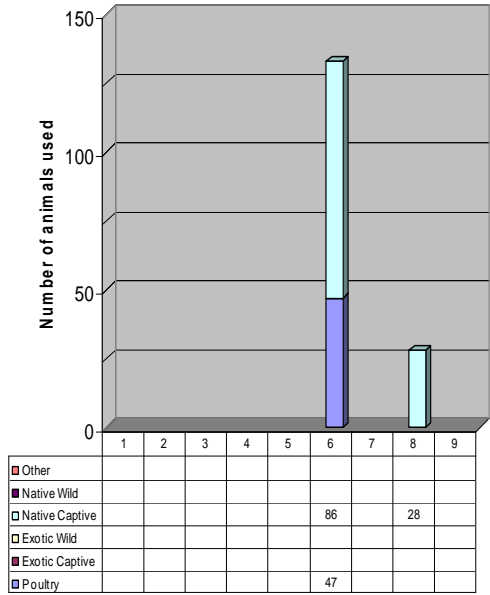
**Purpose: Diagnostic Procedures**  
*Breakdown of Laboratory Mammals Species*



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

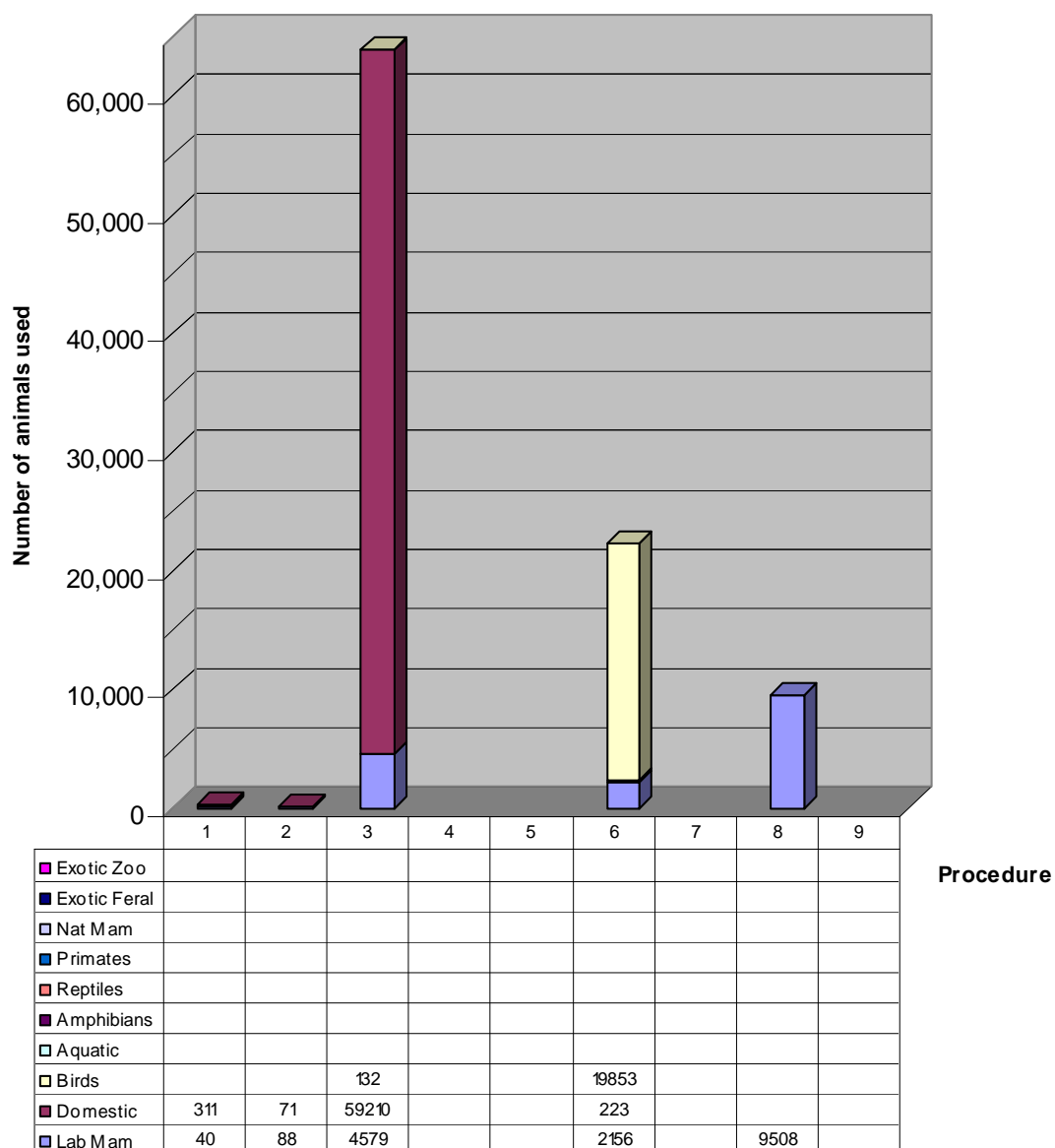


**Purpose: Diagnostic Procedures**  
*Breakdown of Bird Species*



## Purpose: Regulatory Product Testing

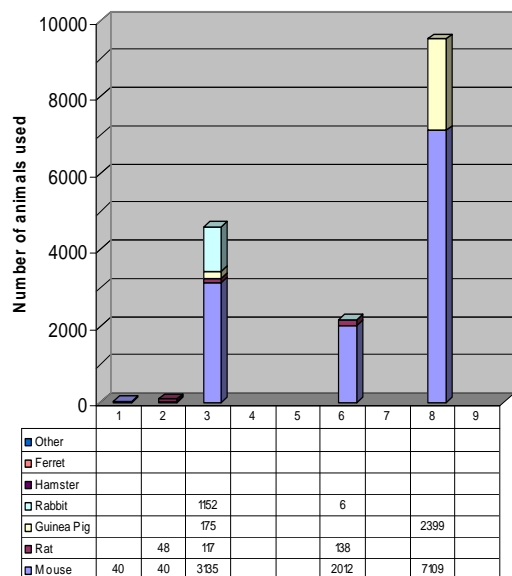
*Protocols for the testing of products required by regulatory authorities.*



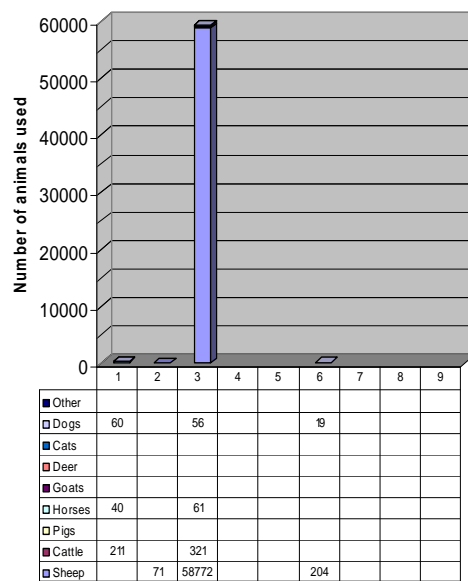
*Refer to following page for a further breakdown of species.*



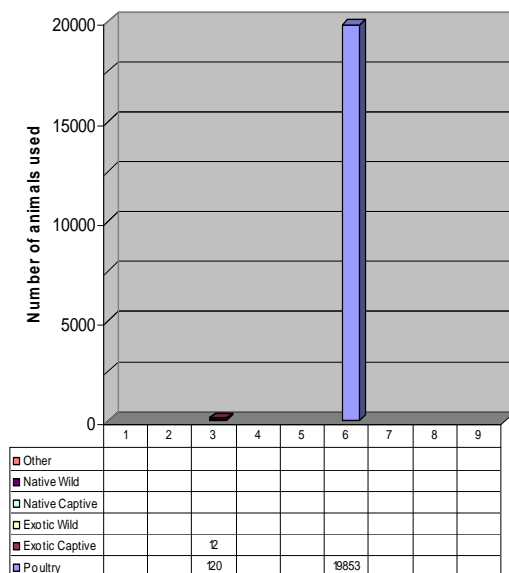
**Purpose: Regulatory Product Testing**  
*Breakdown of Laboratory Mammals Species*



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



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



## LETHALITY TESTING – 2008

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 2008.

Species	No. used	No. died/ euthanase	Procedure	Justification	Alternatives
Mice	120	56	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	6821	2014	Serum neutralisation test in mice: susceptible animals are challenged with test toxin/antibody dilutions to determine antibody titre.	Regulatory testing required to demonstrate efficacy (potency) of vaccines prior to release. Testing of stability batches and new product formulations.	This test is based on regulatory guidelines. No alternatives available at this time.
Mice	5024	2187	Total Combining Power test in mice: susceptible animals are challenged with test antigen/toxin/antibody dilutions to determine potency of antigen preparations.	In-process testing of vaccine constituents to allow evaluation of suitability for further manufacture.	No alternatives available at this time.
Mice	3292	1907	L+ titration in mice: susceptible animals are challenged with test toxin in order to determine potency of antigen preparation.	In-process testing of production and development antigen growths to allow stop/go decision during manufacturing process.	No alternatives available at this time.
Guinea Pigs	2554	1033	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.	No alternatives available at this time.
Dunnarts	37	3	Animals are trained to run on a treadmill while measuring their rate of oxygen consumption. Once repeatable performance is established, some are given a sublethal dose of fenitrothion, an organophosphate pesticide, and the control animals are given an equivalent volume of vehicle alone (oil). Treadmill performance is then evaluated over variable time periods following dosing to establish extent and duration of pesticide effects.	No current information exists on the effects of pesticide exposure to this species of dunnart.. This study will therefore inform on best practice pesticide use.	There is no available data regarding pesticide effects in dasyurid marsupials.
Zebra Finch, Budgerigar King Quail	7, 10, 11 (28 in total)	1, 4, 6 (11 in total)	Acute oral toxicity test procedures employed in this study follow the Up-and-Down protocol outlined in the OECD guidelines for testing of chemicals (OECD 2003; <a href="http://www.epa.gov/oppfead1/harmonization/">http://www.epa.gov/oppfead1/harmonization/</a> ). In summary, the first animal is administered an estimated sublethal	There is no research explaining the species-specific variability in sensitivity across the few species studied of fipronil, nor are there data assessing the toxic effects of fipronil in species that are at high risk of exposure	There is no alternative available a this time.

			dose as determined from available literature (175 mg/kg is the recommended default starting dose); if this animal survives, the dose administered to the next animal is increased by a factor identified from the OECD dose progression table (default 3.2); if it dies, the dose is decreased by the same factor. Birds are tested individually and observed routinely, for a minimum of 48 h after dose administration.		
Mice	185	185	We subcutaneously infected groups of 10 mice with knock out and wild type strains and monitored mice deaths over a course of 10 days to assess the contribution of the knocked out gene product to the virulence of <i>S.pyogenes</i> . At the end of 10 days, all remaining mice were euthanased.	The contribution of specific virulence determinants 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 alternatives exist, which effectively mimic the mucosal and tissue barriers as well as a functioning immune system observed in live mammals.
Mice	458	458	We vaccinated groups of 10 mice with antigens produced by <i>Streptococcus pyogenes</i> and then subcutaneously challenged vaccinated and control mice with a dose of <i>S. pyogenes</i> known to cause a lethal infection. We monitored mice deaths over a course of 10 days to assess the efficacy of vaccine antigens to protect mice. At the end of the 10 day experiment, all remaining mice were euthanased.	The contribution of specific virulence determinants 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 alternatives exist, which effectively mimic the mucosal and tissue barriers as well as a functioning immune system observed in live mammals.
Feral rabbits		45	Fumigation of burrows.	Improving pest management techniques leading to more humane killing methods.	No alternatives available at this time.

## 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 2008 reporting year. They are under the headings of ‘Replacement’ (of animals with other methods), ‘Reduction’ (in the number of animals used in specific protocols) and ‘Refinement’ (of techniques used to reduce the impact on animals).

Category	Comments
Replacement	<ul style="list-style-type: none"> <li>* We have established several cell culture <i>in vitro</i> assays, which has reduced the need for certain strains of fish.</li> <li>* We use more cell lines to minimise the use of animals.</li> <li>* To reduce the number of animals involved in transplant experiments we have developed a number of replacement strategies based upon <i>in vitro</i> and tissue culture assays designed to mimic the <i>in vivo</i> immunological pathways involved in islet graft destruction. We have further reduced the usage of animals by developing a number of tissue culture systems based upon available islet cells.</li> <li>* Development of relevant software.</li> <li>* Animal studies were used to support the use of an <i>in vitro</i> assay for vaccine potency and stability during storage. The <i>in vitro</i> assay will replace the need for animals.</li> <li>* Research groups adopted hybridoma technology which allows production of unlimited amounts of specific antibody <i>in vitro</i>, with use of only a small number of animals as immune spleen cell donors.</li> <li>* Extensive gene expression studies were carried out in cancer cell lines <i>in vitro</i>, prior to undertaking animal studies.</li> <li>* Extensive <i>in vitro</i> analysis of combined radiation and oncolytic virus treatment of cancer cell lines was performed to establish a “proof of concept” prior to analysis <i>in vivo</i> using mouse models.</li> </ul>
Reduction in numbers	<ul style="list-style-type: none"> <li>* The number of animals is always determined either by statistical analysis or the recommendations for the minimum number of animals required in a study to satisfy regulatory authorities for new products.</li> <li>* Statistical analysis is used to determine animal numbers.</li> <li>* Animal tissue can be shared with other researchers.</li> <li>* Thorough use of previous studies through literature analysis.</li> <li>* Pilot procedures using reduced animal numbers for new protocols to test viability.</li> <li>* Use of Biometrician’s comments prior to approval by AEC.</li> <li>* We obtained tissues from animals used by other groups within the lab – through the use of tissue sharing we have been able to minimise the number of animals required to fulfil the research goals of this project.</li> <li>* For all studies requiring surgical or drug interventions, a pilot study was performed to optimise experimental procedures and to ensure the minimum number of mice were used to obtain sufficient endpoints for data analysis.</li> <li>* In addition to measurements of physiological function with isolated rat hearts, heart tissue has been harvested at the end of the procedure for further molecular biology and immunohistochemistry studies. Therefore, compared to previous study protocols, we are more productive with using the same number of rats.</li> <li>* Because our experiments have generated significant data we have not had to repeat some of them, and our animal use is far less than expected.</li> <li>* The Committee has established 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.</li> </ul>

	<ul style="list-style-type: none"> <li>* Approval of new techniques for embryo freezing rather than continuous breeding to maintain lines</li> <li>* Consolidating breeding protocols to ensure no over-breeding which in turn reduces the need for culling</li> <li>* By simultaneously running investigations with similar studies, the total number of animals was decreased. This is the result of the sharing of data gathered from control groups.</li> <li>* Treatment of sheep for more effective use in parasite larvae production, which doesn't impact on the sheep, but reduces the need for additional animals.</li> <li>* Introduction of new more sensitive mass spectroscopy technology supported a reduction in the amount of material (and hence fewer animals) needed for analysis.</li> <li>* Opportunistic sampling has considerably reduced the number of animals required for blood samples in one project.</li> <li>* Extensive equipment testing on abattoir specimens to ensure equipment accuracy before live animals were used.</li> </ul>
Refinement of techniques	<ul style="list-style-type: none"> <li>* Development of pitfall trap with floating base plate to prevent captured animals from drowning.</li> <li>* The main initiatives during 2008 have focussed on the production of <i>Clostridium chauvoei</i> antigen for use in vaccines. The long-term benefit of improvements in production is that increased efficacy of the antigen manufacturing will ultimately lead to a reduction in the amount of testing required on a lot-by-lot basis. It is important to note that the regulatory pass criterion for the test of <i>Cl. Chauvoei</i> in vaccines is 90% survival of challenged vaccinates with 80% survival required for a repeat test. In real terms the death of 2 animals will result in a further 19 being required for repeat testing. Hence small improvements can result in significant reductions in animal usage. This project will remain as a focus activity during 2009.</li> </ul> <p>An ongoing focus area has been on the potency testing of multivalent clostridial vaccines containing combinations of additives such as moxidectin and selenium in laboratory animals which pose several difficulties in providing reliable and reproducible data required for regulatory release testing. A revised testing regime was developed which avoids exposing laboratory animals to the toxic effects of selenium whilst still providing sound efficacy data for the vaccine under-test. An added benefit is a reduction in repeat testing due to greater reliability of testing. Initial approval for this testing regime in selected products was received from the APVMA in 2007 with extensions covering additional product types being obtained during 2008. In addition, approval was received from the New Zealand authorities to adopt this regime for all applicable products sold in the New Zealand market.</p> <ul style="list-style-type: none"> <li>* Use of adjuvants known not to produce adverse reactions</li> <li>* Use of the saphenous vein method as the standard technique for blood collection in rodents.</li> <li>* The use of electronic feeders as a method of studying feed intake and efficiency response in group housed pigs between 45-100kg.</li> <li>* Introduced the mouse Local Lymph Node Assay to replace the Guinea Pig Maximisation Test for skin sensitisation. This assay uses fewer animals, is less invasive and does not use Freund's Adjuvant. The test is now accepted by regulator authorities world-wide.</li> <li>* We have optimised the endpoints of these experiments so that the mice are culled at a point when only a subset of mice have developed cancer, and before they do not get sick due to metastasis.</li> <li>* We have reduced the number of animals we immunise per target as we are finding we don't need to do as many fusions to generate good monoclonal antibodies.</li> <li>* We are using lower amounts of KRN serum, containing the arthritis-inducing autoantibodies, to reduce arthritis severity. We have found that in C57Bl6 mice, one quarter of the published amount was sufficient to produce the desired effect.</li> <li>* The first 60 mice were injected on a weekly basis. Subsequent mice were then fed an oral form of the drug, which was well tolerated by the mice and avoided the need for injections.</li> <li>* Introduction of a new product of insulin, which is now long acting, provides the mouse with longer and more stable coverage and keeps the blood glucose at a more consistent level.</li> <li>* The Bone Program has purchased a micro Computed Tomograph, enabling extremely detailed analysis of</li> </ul>

	<p>bone microstructure. This has enabled a reduction in animal requirements, most particularly in the examination of new models of treatment.</p> <ul style="list-style-type: none"> <li>* We have replaced subcutaneous injections with an osmotic pump, which means less handling and injection-related stress on the animals and less variability. This means we can reduce the number of animals per group and also the number of repeat experiments.</li> <li>* For monitoring of diabetes, we test for glucose levels in the urine instead of blood, which is less invasive than bleeding mice in incidence studies weekly.</li> <li>* Due to the high doses of irradiation needed to replace the bone marrow derived cells in NOD mice, we have implemented a protocol whereby irradiation is split into two half doses, with a two-hour rest in between. This decreases the impact of this level of irradiation on the mice.</li> <li>* Every drug and time course was first performed in cultured cells. Only the best antioxidants and time-points were used in mice and the minimal time-point for antioxidant treatment has worked, so this has reduced the number of times we need to inject mice.</li> <li>* A major focus for 2008 has been educating researchers in the AEC policy of requiring analgesic cover for 24-48 hr following all surgical procedures, including those that have previously been considered “minor”. The AEC requires analgesia unless the investigators can make a compelling case that it would interfere with the results of the experiments. We have also been having a fruitful dialogue with investigators on the importance of looking for specific signs that animals are in pain following treatments designed to produce effects in animal unrelated to nervous system injury. These include the induction of diabetes or administration of chemotherapeutic agents, both of which can cause long term neuropathic pain syndromes.</li> <li>* Wildlife Study – Edible bait to provide sustenance for animals after capture.</li> <li>* Wildlife Study – Trapping only when weather conditions optimal.</li> <li>* Wildlife Study – To deduce the risk of pathogen transfer between frogs: the use of disposable latex gloves and sterilisation of instruments.</li> <li>* The AEC reviewed the application of pain relief and decided to request that analgesics be used whenever possible as part of surgical procedures unless there was strong scientific evidence that the use could interfere with the research results.</li> <li>* Accommodation of research horses in a large paddock on a professional horse spelling/pre-training farm.</li> <li>* Rehoming of a retired research horse to suitable new owners and location.</li> <li>* Spontaneous collection of naturally voided urine for the purpose of drug analyses.</li> <li>* Rapid turn around time for faecal samples, ensuring that property owners were able to treat animals that did not respond to treatments, minimising risk of animals suffering from parasite associated disease.</li> <li>* Study conducted by dog owners at their own homes to minimise any possible distress for the dogs.</li> <li>* Animals were fed hay immediately following bleeding procedures which allowed the associate of the bleeding procedure with a positive reward, hence reducing stress on the animal.</li> <li>* Animals were kept together in an enclosure during the critical post dosing period. This ensured that any animals experiencing adverse clinical signs did not decline in health due to extremes in environment.</li> <li>* Young animals remained with their mothers at all times.</li> <li>* Euthanasia always occurred in a fixed location, which was visually and audibly blocked from other animals.</li> <li>* Fin pinching with forceps was found to cause small but definite tearing to fins if the fish moved suddenly whilst being grasped. The protocol was therefore modified to use the investigator’s fingers instead of forceps to evaluate withdrawal reflexes. This more sensitive method resulted in less or no trauma to the fins.</li> <li>* The research program has been undertaken to reduce the pain for the procedure known as surgical mulesing and replace with a procedure whereby an anionic surfactant is injected with a needleless applicator into the intradermal region of the tail and buttock of lambs which results in necrosis and eventual stretch of the skin increasing the bare area and reducing wrinkles with subsequent reduction in blow fly</li> </ul>
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	<p>strike. The anionic surfactants upon injection rapidly denature the neural bundles thereby minimising the pain of the procedure.</p> <ul style="list-style-type: none"> <li>* Use of osmotic mini-pumps instead of daily IP injections.</li> <li>* A number of researchers have adopted use of infra-red cameras. Some of these are focused on bait stations, others are placed near specific habitat features used regularly by animals eg quoll latrines. The cameras allow information to be gathered on presence, or identification of many small to medium wild animals and birds without the need for more invasive techniques, such as trapping.</li> <li>* Use of inhalation anaesthesia to reduce the stress of handling and injections in mice.</li> <li>* Use of photon imaging techniques to detect tumour growth in a quantitative manner allowing earlier endpoints and early detection of metastatic tumours.</li> </ul>
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## Appendix I: ARRP expenses

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

Fees and retainers	\$13,000
Travel and subsistence	\$6,748
Stores and printing	\$4,925
Freight and postage	\$1,025
<b>TOTAL</b>	<b>\$25,698</b>

## Appendix J: Abbreviations

AEC	Animal Ethics Committee
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARRP	Animal Research Review Panel
ATLA	Alternatives to Laboratory Animals
AWAC	Animal Welfare Advisory Council
CSIRO	Commonwealth Scientific and Industrial Research Organisation
EAPA	<i>Exhibited Animals Protection Act 1986</i>
NHMRC	National Health and Medical Research Council
POCTAA	Prevention of Cruelty to Animals Act
RSPCA	Royal Society for the Prevention of Cruelty to Animals
TAFE	Technical and Further Education
'3Rs'	Replacement, Reduction and Refinement in animal use



## Appendix K: ARRP policies and guidelines

(Available from <http://www.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 on Designated Land
5. Annual Reporting by Animal Ethics Committees to Accredited Animal Research Establishments (revised 17/2/2010)
- 5a. Institutional Support for Animal Ethics Committees
6. Differentiation Between Acts of Animal Research and Acts of Veterinary Treatment
7. Relationships Between Accredited Research Establishments and Licence Holders WITHDRAWN
8. Establishment of Protocols for Grievance Procedures
9. Criteria for Assessment of Animal Ethics Committee Membership
10. Emergency Procedures
11. Formal Agreements between Accredited Research Establishments sharing Animal Ethics Committees
12. Frequency of Animal Ethics Committee Meetings
13. Inspections by Animal Ethics Committees
14. Acts of Veterinary Science and the Use of Restricted Drugs
15. Orientation of New Members of Animal Ethics Committees
16. Conflict of Interest with Membership of Animal Ethics Committees

### Guidelines

1. Opportunistic Research on Free-Living Wildlife
2. Specific to Animal Ethics Committees Supervising Research on Captive Wildlife (additional to 1)
3. Individuals and Institutions Engaged in Collaborative Research
4. Animal Ethics Committees Considering the Use of Animals for Post-graduate Surgical Workshops
5. Collection of Voucher Specimens
6. Use of Pitfall Traps
7. The Use of Feral Animals in Research
8. Welfare Guidelines for Teaching Artificial Insemination and Pregnancy Testing in Cattle
9. Radio Tracking in Wildlife Research
10. Animal Care Guidelines for Wildlife Surveys
11. Guidelines for Tick Serum Producers
12. Animal Research Model Application Form
13. Guidelines for the Production of Monoclonal Antibodies
14. Guidelines for the Care and Housing of Dogs in Scientific Institutions
15. Blood Collection
16. Supervision of Animal Supply by Animal Ethics Committees
17. Training Personnel
18. Guidelines for the Housing of Rabbits in Scientific Institutions
19. Teaching Cervical or Vaginal Artificial Insemination of Sheep
20. Guidelines for the Housing of Rats in Scientific Institutions
21. Guidelines for the Housing of Guinea Pigs in Scientific Institutions
22. Draft Guidelines for the Housing of Mice in Scientific Institutions
23. Draft Guidelines for the Housing of Sheep in Scientific Institutions

## Appendix I: Animal Welfare Unit fact sheets

(Available from <http://www.dpi.nsw.gov.au/agriculture/livestock/animal-welfare/research-teaching> )

- Fact Sheet 1: The *Animal Research Act 1985*
- Fact Sheet 2: Applying for accreditation as a animal research establishment
- Fact Sheet 3: Animal Ethics Committees (AECs)
- Fact Sheet 4: Application for Accreditation as an Animal Research Establishment (Schools) Form D
- Fact Sheet 5: Animal Research Authorities
- Fact Sheet 6: Application—Animal Supplier’s Licence (Form J)
- Fact Sheet 7: The Animal Research Review Panel
- Fact Sheet 8: The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes
- Fact Sheet 9: Inspections under the Animal Research Act
- Fact Sheet 10: Draize Tests, LD50 tests and Lethality Tests Requiring Death as an Endpoint
- Fact Sheet 11: Independent and Welfare Members of Animal Ethics Committees Frequently Asked Questions
- Fact Sheet 14: Animal Research Review Panel Policy Statements and Guidelines
- Fact Sheet 15: Example of Fauna Emergency Procedures for Wildlife Researchers
- Fact Sheet 17: Summary of Amendments to the Animal Research Act Made in 1997
- Fact Sheet 19: Summary of Amendments to the Animal Research Act and Regulations Made in 1999

## Appendix M: Standard conditions for accreditation and animal supply licence

The following are standard conditions that are placed on establishments seeking accreditation as animal research establishments and licences as animal suppliers. Additional conditions are added on a case-by-case basis.

### Accreditation

1. That any site inspection is satisfactory.
2. Details of changes to Animal Ethics Committee membership (including the qualifications of new members and the categories to which they are appointed) must be provided to the Director-General of Industry & Investment NSW within 30 days of membership changes. The revised composition of the AEC must meet the approval of the Director-General.
3. Rabbits should be housed in groups in pens. Rabbits may only be housed in cages with the express permission of the AEC on the basis of compelling evidence for the need to use such housing. Lack of space or facilities for pens should not be considered sufficient justification for the use of cages. Where rabbits are held in cages, these cages should be enriched by methods such as pair housing in double cages. (*Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* Clause 4.4.19) (See ARRPP Guideline 18: Guidelines for the Housing of Rabbits in Scientific Institutions (<http://www.animaethics.org.au/reader/animal-care>))  
(*For establishments housing rabbits*)
4. Unless precluded by the requirements of specific projects, chickens should be provided with housing that meets their behavioural needs including straw or other suitable bedding to cover the floors of cages, perches and dust bathing substrate.  
(*For establishments housing chickens*)
5. Unless otherwise approved by the Animal Ethics Committee, animals should be housed in accordance with the ARRPP guidelines on animal housing for specific species found at: <http://www.animaethics.org.au/policies-and-guidelines/animal-care>.
6. Unless otherwise approved by the Animal Ethics Committee, wildlife studies should be carried out in accordance with the ARRPP guidelines on wildlife research found at: <http://www.animaethics.org.au/policies-and-guidelines/wildlife-research>.
7. 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>).
8. 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*)
9. A response to conditions {xx} of the inspection report of {date} must be provided to the Director-General of Industry & Investment NSW by {date}—within 3 months of inspection report being sent}.  
(*Added after inspection*)

### Animal Supply Licence

1. That any site inspection is satisfactory.
2. The documented procedures and methods of record keeping, as required under Clauses 4.5.7 and 4.5.8 of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*, must be submitted by the supply unit to the AEC for approval.
3. To assist in monitoring the management of breeding colonies, the supply unit must provide regular reports to the AEC, for review, on the fertility, fecundity, morbidity and mortality of all breeding colonies. The frequency of such reports should be at least 6 monthly and more often if determined necessary by the AEC.
4. To help ensure that overproduction is avoided, the supply unit must provide regular reports to the AEC, for review, on the number of animals culled and the reasons for these numbers. The frequency of such reports should be at least 6 monthly and more often if determined necessary by the AEC.

5. Any breeding which involves animals which have been the subject of genetic modification (involving the introduction of foreign DNA into cells or whole animals) must comply with Clauses 3.3.56 to 3.3.63 of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*.

