Animal Research Review Panel

New South Wales

Annual Report

2007 - 2008

NSW DEPARTMENT OF PRIMARY INDUSTRIES

DISCLAIMERS

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Prepared by Lynette Chave
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NSW DEPARTMENT OF PRIMARY INDUSTRIES

Animal Research Review Panel

161 Kite Street
Locked Bag 21
ORANGE NSW 2800

Telephone (02) 6391 3276
Facsimile (02) 6391 3570

Animal Ethics Infolink:
www.animalethics.org.au

The Hon Ian Macdonald MLC
Minister for Primary Industries
Minister for Energy
Minister for Mineral Resources
Minister for State Development
Level 33 Governor Macquarie Tower
1 Farrer Place
SYDNEY NSW 2000

Dear Mr Macdonald

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 2007 to 30 June 2008.

Yours sincerely

Professor Margaret Rose
Chair, Animal Research Review Panel

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 For serious or repeated breaches, the accreditation or authority to conduct research may be withdrawn.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. NSW Department of Primary Industries Animal Welfare Branch 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 2007–08 there were 101 accredited animal research establishments and 27 holders of animal suppliers' licences.

Inspections

In the 2007–08 year the ARRP carried out 21 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 Branch staff and the ARRP. Such activities in the 2007–08 year included releasing a revised version of evidence-based guidelines on rat housing. The revisions were based on comments received from user groups and people with internationally recognised expertise in rat care and management. The release of the rat housing guidelines was part the ARRP's ongoing plan to develop evidence-based guidelines for the housing of animals in scientific establishments. Guidelines on the housing of dogs, rabbits and Guinea pigs have already been published.

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 ARRP. No formal complaints were received in 2007–08. Two informal complaints were received and dealt with in the 2007–08 reporting period.

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 Branch of the NSW Department of Primary Industries 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 February 2008 to discuss matters related to the most recent (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 2007–08 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)
- Dr Barry Lowe (nominated by Medicines Australia)
- Ms Stephanie Abbott (nominated by Animal Societies' Federation)
- Dr Jason Grossman (nominated by Animal Societies' Federation)
- Dr Mark Lawrie (nominated by RSPCA NSW)
- Mr David O'Shannessy (nominated by RSPCA NSW)
- Associate Professor Ron Pirola (nominated by the Minister for Health)
- Dr Jack Baker (nominated by the Minister for the Environment)

- Dr Stephen Atkinson (nominated by Vice-Chancellors' Committee)
- Dr Philip Towers (nominated by Vice-Chancellors' Committee)
- The position of the nominee for the Minister for Education was vacant for the 2007-08 period.

Information on members of the Animal Research Review Panel in 2007–08 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 three international journals devoted to the welfare of laboratory animals: ATLA (*Alternatives to Laboratory Animals*), *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 of Research Management in South Eastern Sydney and Illawarra Area Health Service and is a conjoint Professor at the University of New South Wales.

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

Dr Regina FOGARTY (Deputy Chair), BVSc, PhD (University of Queensland). Dr Fogarty is the Director, Extensive Industries Development, 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). Before joining the Department in 1991, Dr Fogarty worked at the University of Queensland's Faculty of Veterinary Science in research, teaching and clinical veterinary practice. Dr Fogarty joined the ARRP in 2003 as the nominee of the then Minister for Agriculture.

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

Dr Steve ATKINSON, BVSc, MACVSc, DipContEd, CMAVA. Dr Atkinson is a nominee of the New South Wales Vice Chancellors' Committee and was appointed to the ARRP in 2005. He has a long-standing interest in the welfare of animals used in research and teaching. Over time he has been a member of four AECs. He edited the *Guidelines for the Use of Animals in NSW TAFE*. He has developed training programs for TAFE teachers who use animals in the delivery of their courses and has delivered training programs to managers within NSW TAFE to help them identify their responsibilities under the NSW Animal Research Act. He worked as Animal Welfare Manager at the CSIRO McMaster Laboratory

in Armidale and at the University of New England, caring for animals being used in research and assisting and training researchers in aspects of the care and welfare of research animals. He is currently a veterinary consultant in animal welfare and animal research ethics.

Dr Atkinson chairs the NSW Government's Animal Welfare Advisory Council, after previously being a member of that Council for 5 years. He is a Director of the Australian Veterinary Association and a member of the AVA Animal Welfare Advisory Committee and chairs their Animal Welfare Trust. He has been appointed to provide animal welfare advice to the national Technical Working Group advising the Committee developing the Australian Standards for the export of live animals from Australia. He is a member of the Animal Research and Teaching Working Group within the Australian Animal Welfare Strategy Implementation process, and is undertaking several projects within that implementation program.

Dr Jack BAKER, BSc, GradDipEd, BAppSc, PhD, JP. Dr Baker was the nominee of the Minister for the Environment in 2004. He is an employee of the Department of Environment and Climate Change, where he manages the Biodiversity Conservation Science Section. He has expertise in wildlife management and research.

Dr Jason GROSSMAN, MA (Cantab) MPH (Sydney) PhD (Sydney).
Dr Jason Grossman joined ARRP 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 is now 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.

Dr Mark LAWRIE, BVSc (University of Sydney), MACVSc (Animal Welfare), Chief Veterinarian, RSPCA. Dr Mark Lawrie was a member of the ARRP from July 1993 to August 1996. He was nominated by his employer, the RSPCA NSW, and rejoined the ARRP in August 2000. Dr Lawrie has been a member of three major institutional AECs. He has been a practising veterinarian in Australia and the United Kingdom and has worked as a volunteer in India, Nepal and Rarotonga. He is responsible for four veterinary clinics and 80 staff that provide shelter, welfare and private veterinary services. In July 2002 he assisted the RSPCA Papua New Guinea in restarting its veterinary clinic in Port Moresby. He worked for 6 months in 2003–04 as a veterinary consultant with the International Fund for Animal Welfare (IFAW) on projects in the South Pacific and South Korea. He was the President of the NSW Division of the Australian Veterinary Association (AVA) in 2005 and the Secretary of Animal Management in Rural and Remote Indigenous Communities (AMRRIC) from 2003-2007 and will be the National President of AVA in 2008.
He has particular interests in:

- the link between cruelty to animals and humans
- animal hoarders
- international animal welfare, especially companion animal population control

Dr Barry LOWE, BSc (University of Melbourne), BEd (University of Melbourne), PhD (University of Sydney).
Dr Lowe worked for Elanco Animal Health for 34 years until his retirement. He held an international position as Emeritus Director of Research and Development with Elanco Animal Health, the animal health division of Eli Lilly and Company. His fields of research were the external parasitology of farm and companion animals and the intra-ruminal controlled release of drugs in sheep and cattle. He was involved in research into the health and nutrition of farm animals for 30 years with the same company and was Chairman of the Elanco Animal Ethics Committee for 10 years.

Dr Lowe was appointed to the ARRP in 2002 after being nominated by Medicines Australia Inc.

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

Conjoint Associate Professor Romano (Ron) PIROLA, OAM, MBBS (University of Sydney), MD (University of New South Wales), FRACP. Associate Professor Pirola is the nominee of the Minister for Health and was appointed to the ARRP in May 2002. He has extensive experience in biomedical animal research. He is a consultant in Gastroenterology at the Prince of Wales Hospital, Randwick. He was formerly the elected staff representative on the Board of the Eastern Area Health Service and the Chairman of the Research Ethics Committee of the South-Eastern Area Health Service – Eastern Division.

Dr Philip A TOWERS, BSc(Hons) MAppSc PhD. Dr Towers was a 2004 nominee of the New South Wales Vice Chancellors' Committee. Dr Towers is a Senior Lecturer in Physiology at Charles Sturt University. He is an academic staff member of the University Council and has chaired the CSU Animal Care and Ethics Committee since 1997. Dr Towers has research interests in dietary effects on reproduction and reproduction in Australian wildlife.

1.3.4 Vale Dr Barry Lowe

Dr Barry Lowe died suddenly as a result of an accident on his property on 19th May 2008.

Dr Lowe had been a member of the ARRP, as nominee of Medicines Australia, since 2002. Dr Lowe was a valued member of the ARRP and actively contributed to its functions including frequent participation in site inspections and sitting on its LD50 and applications subcommittees.

Dr Lowe was instrumental in establishing the Elanco Animal Health Animal Ethics Committee in 1996 and was its Chair until the time of his death. He had worked for Elanco Animal Health for a period of 34 years and after his retirement held an international position as Emeritus Director of Research and Development.

His pragmatic approach and willingness to engage in debate made for some lively discussions which ultimately contributed to the strength of ARRP decisions. In addition to being an informed and committed member of ARRP, Barry was truly good company. He is very much missed.

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 ARRP for assessment of AEC membership were clarified in an ARRP policy document, *Policy 9: Criteria for the Assessment of Animal Ethics Committee Membership* (http://www.animalethics.org.au/reader/operation-aecs). In examining applications from institutions for accreditation as animal research establishments, the membership of the AEC is assessed to ensure it is of acceptable composition and size. During audit inspections, the ARRP assesses the operation of the AEC.

1.5 Accreditation and licensing

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

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

- consideration of a written application to determine whether the applicant is complying with a limited number of fundamental requirements of the legislation
- evaluation of the applicant at a site inspection, when a much broader approach is taken.

The recommendations of the ARRP are referred to the Director-General of NSW Department of Primary Industries, who has statutory authority for the issue of accreditation and licences and for imposing, altering or removing conditions of accreditation or licence.

Accreditation and licences are usually issued subject to the condition that a site inspection is satisfactory and are subject to the reporting of changes in AEC membership to the Director-General of NSW Department of Primary Industries 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 Branch staff, according to criteria developed by the ARRP. Arising from these assessments, recommendations on the applications are made to the ARRP. The ARRP considers the recommendations and then makes recommendations on the applications to the Director-General of NSW Department of Primary Industries.

The ARRP has 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 Branch for input by the Applications Subcommittee, recommendations are made by the Branch directly to the ARRP.

A small number of applications are also viewed directly and considered by the full

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

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

Monitoring of animal care and use by the AEC 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 ARRP to double-check compliance with the Act's provisions relating to animal supply.

1.5.2 Conduct of site inspections

Following the evaluation of written applications, the second phase of the process of assessing establishments is the site inspection. The aim of site inspections is to determine whether institutions and individuals are complying with the legislation. The 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 2007–08 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 Branch Veterinary Inspector and the ARRP members who have been nominated to participate in the inspection. This pre-inspection evaluation allows likely problem areas to be identified and a general idea to be gained of how the establishment is operating.

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

A meeting is usually held with the head of the institution at the beginning or end of the

inspection. Any serious concerns are immediately referred to the institution at the appropriate level. A letter is usually sent to the institution within a week of the visit, providing the general impressions of the site visit team and reinforcing the need to deal with any serious problems that may have been identified during the visit.

As soon as possible after the inspection, a detailed report is prepared. The report covers an evaluation of the AEC and an assessment of the animals' wellbeing, housing and holding, and their care and monitoring. Once the ARRP has considered the report, recommendations may arise to impose additional conditions on the accreditation or licence. For example, a condition may be that appropriate post-operative procedures must be implemented.

In addition to conditions for accreditation or licence (which are mandatory and must be implemented), the ARRP report usually contains a number of recommendations—for example, for more effective operation of the AEC, for improvement of the management of research within the institution, or for improvement of the animal facilities. Implementation of recommendations is not mandatory, but the institution is required to advise on how it has responded to the recommendations. If the recommendations have not been implemented, then the reasons for this must be explained.

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

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

The ARRP aims to carry out full audit visits for all institutions every 3 years, as well as unannounced visits by inspectors to follow up problems. In formulating its 2007–08 operational plan, the ARRP again recognised that staff availability within the Animal Welfare Branch 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 Branch is a section within NSW Department of Primary Industries.

The functions of the Animal Welfare Branch cover:

- animal research issues under the *Animal Research Act*, including providing executive services to the ARRP
- general animal care and cruelty issues under the *Prevention of Cruelty to Animals Act* (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 Branch can be contacted at:

Animal Welfare Inspectorial Office
NSW Department of Primary Industries
95 Castle Hill Road
WEST PENNANT HILLS NSW 2125
Phone (02) 9872 0570
Fax (02) 9871 6938

PO Box 100
BEECROFT NSW 2119

or at the NSW Department of Primary Industries' Head Office:

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

In the 2007–08 financial year the following staff were assigned, at various times, to provide inspectorial and/or executive support to the ARRP (amongst their other duties).

Orange:

Ross Burton, BVSc, MVSc, Director, Animal Welfare
Amanda Paul, BVSc, MACVSc (Animal Welfare), Veterinary Officer (part-time)
Angela Thompson, BLMgt, Leader, Animal Welfare Standards (part-time)
Grace Cook, Licensing Clerk (part-time)
Frances Kumbley, Clerical Officer
Natasha Coker, Clerical Officer (part-time)
Jeynelle Hughes, Clerical Officer (part-time)

Sydney:

Lynette Chave, BVSc, Leader, Animal Research
Peter Johnson, BVSc, PhD, Veterinary Officer
Ann Sullivan, Clerical Officer (part-time)
Sue Mifsud, Clerical Officer (part-time)
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 ARRP's operational plan for 2007–08. The appendixes to this annual report contain details of many of the operational and strategic functions of the ARRP. These include the dates of, and attendance at, ARRP meetings (Appendixes A and B); dates and attendance of ARRP members at inspections of accredited research establishments and animal supply licence holders (Appendixes C and D); the ARRP Strategic Plan 2005–08 (Appendix E) and Operational Plan for 2007–08 (Appendix F); and ARRP operating expenses (Appendix I).

2.1.1 Strategic Plan 2005–08

During 2005 the ARRP revised its 3-year strategic plan. The plan identifies the primary goals of the ARRP and strategies for achieving these goals. In developing the plan the ARRP identified four priority areas:

- training of Animal Ethics Committee members
- promoting education of researchers and teachers
- ongoing review and maintenance of the ARRP website 'Animal Ethics Infolink' (http://www.animalethics.org.au)
- promoting alternatives to the use of animals in research and teaching.

Details of the Plan are given in Appendix E.

2.1.2 Operational Plan for 2007–08

The ARRP Operational Plan for 2007–08, including a performance review of each activity, is provided in Appendix F.

2.1.3 Liaison with organisations, accredited establishments and authority holders

The ARRP 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.

2.2 Assessment of applications

During 2007–08 the ARRP considered:

- 6 new applications for accreditation
- 28 renewal applications for accreditation
- 6 new applications for animal suppliers' licences
- 21 renewal applications for animal suppliers' licences.

2.2.1 LD50 testing

LD50 is a toxicity test used to determine the dose or concentration of a test substance—that is, the lethal dose—that is expected to kill 50% of the animals to which it is administered. For the purposes of the NSW *Animal Research Act 1985* the definition of LD50 has been broadened. Included are all tests in which a potentially lethal dose of a substance will be administered and is expected to kill a proportion of the individuals in any group of animals to which it is given. In NSW such tests may be undertaken only under the approval of a properly constituted Animal Ethics Committee, with the concurrence of the Minister for Primary Industries. Applications for permission to conduct LD50 tests are evaluated by an ARRP subcommittee. Members of the subcommittee in 2007–08 were Dr Fogarty and Dr Lowe. The subcommittee makes recommendations to the ARRP, which in turn advises the Minister.

In 2007–08 the subcommittee considered two applications (7 tests) from Accredited Research Establishments.

Application A

The testing was required to produce a dose curve to determine challenge dose of Group A Streptococcus organisms in mice. The ARRP recommended to the Minister that he approve the application on the following conditions:

1. That a report is provided to the Animal Welfare Branch NSW Department of Primary Industries documenting:

    1.1 Consideration of the use of an earlier endpoint (eg body temperature reduction) See: Olfert ED and Godson DL 2000. Humane Endpoints for Infectious Disease Animal Models. ILAR Journal V41 (2) http://dels/nas.edu/ilar_n/ilarjournal/41_2/Infectious.shtml

    1.2 The number of animals used in determining the dose response curve.

    1.3 The number of animals that died in the test and the number humanely killed at the conclusion of the procedure.

    1.3 A description of the experimental outcomes.

2. Any application for Ministerial concurrence to conduct further LD50 tests under the project Group A Streptococcus vaccination and challenge protocols must be presented to the Animal Welfare Branch.

In making its recommendation for approval, the ARRP noted that an alternative statistical approach may be possible to reduce the number of animals used (Reference supplied: ILAR V43 (4) 2002. Experimental Design and Statistics in Biomedical Research http://dels/nas.edu/ilar_n/ilarjournal/43_4/index.shtml).

The ARRP also made note to the applicant that the conduct of LD50 tests had serious implications for animal welfare which highlighted the imperative for the researchers to engage closely with the AEC.

Application B

The testing was required as part of the registration process for biological agents. 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 2009 with figures comparing 2006, 2007 and 2008 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 2009 and April 2010 must be presented to the Animal Welfare Branch.

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 and reports upon these to the Animal Welfare Branch.

In making its recommendation for approval, the ARRP noted that it would appreciate being kept informed of technical developments that lead directly to reductions in the need for animal based tests and in

particular advances that increase the antigen production per batch, thus reducing the number of batch tests required.

The ARRP also noted that the use of an alternative statistical method (sequential design) was being considered and requested comment.

2.3 Subcommittees

The ARRP appoints subcommittees to deal with particular issues. They explore issues in depth and have discussions with relevant members of the scientific and broader communities. Subcommittees provide reports and recommendations to the full ARRP for consideration. Membership of subcommittees is largely drawn from the ARRP. External members of subcommittees are occasionally co-opted on a voluntary basis. Activities of subcommittees in the 2007–08 year include:

- hosting of a meeting to be held in 2009 for members and executive officers of AECs (Professor Rose, Dr Fogarty and Mr O'Shannessy)
- evaluation of applications for LD50 testing (Dr Fogarty and Dr Lowe).

2.4 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 protocols 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 2007.

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

As an additional means of monitoring accredited animal research establishments, the ARRP recommended that the Annual Reports of AECs be submitted with the submission of annual statistics. The 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). The ARRP intends to carry out an assessment of these reports and provide feedback to the AECs and institutions.

2.4.1 Lethality testing

Accredited research establishments must keep figures on lethality testing and submit these to the ARRP. Lethality testing is defined as 'any animal research procedure in which any material or substance is administered to animals for the purpose of determining whether any animals will die or how many animals will die'. Figures on lethality testing are included in Appendix G of this report.

2.5 Support for Animal Ethics Committees

The ARRP and the Animal Welfare Branch 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 ARRP is used as a reference source by the State's AECs, for example as a source of information on successful policies developed at other institutions.

All establishments are required to advise the Director-General of NSW Department of Primary Industries of changes to AEC membership. The ARRP advises the Director-General on the suitability of the qualifications of the new members for the categories of membership to which they are nominated.

2.5.1 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 ARRP suggested the establishment of a register of AEC members interested in joining other AECs. The Animal Welfare Branch 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.

2.5.2 Meeting for members and executive officers of AECs

During the 2007-08 year, an ARRP sub-committee commenced preparations for a meeting for members and Executive Officers of AECs. The meeting is planned to be held by the ARRP in April 2009.

2.6 Website: Animal Ethics Infolink

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

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

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2.7 Site inspections

A list of site inspections undertaken in 2007–08 is provided in Appendix C, and a list of ARRP members attending is given in Appendix D. There were 21 inspections conducted over a period of 23 working days. The length of these inspections ranged from one day to two days. The inspections included AECs and the facilities of 24 accredited institutions/licensed animal suppliers.

The ARRP 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 ARRP places a major focus on reviewing the operation of AECs, to ensure that AECs, investigators and institutions understand their

responsibilities under the Animal Research Act and the Code of Practice. The conduct of research procedures and the conditions in which animals are held also receive close scrutiny during site visits.

2.8 Policies, guidelines and fact sheets

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

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

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

The following guideline was finalised in 2007–08:

ARRP Guideline 20: Guidelines for the housing of rats in scientific institutions. The revision of an extensive guideline on rat housing was finalised for publication. A draft of the guideline was developed, based on information from the scientific literature. The draft was sent out for comment, including user groups, animal welfare organisations and international experts. Very favourable responses were received, including from the international reviewers, and the guidelines were revised on the basis of the comments received.

2.9 Initiatives in replacement, reduction and refinement

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

2.10 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 NSW Department of Primary Industries, who refers the complaint to the ARRP for investigation. The ARRP is bound to investigate formal complaints and to make recommendations to the Director-General for disciplinary action (if it is considered warranted) or dismissal of the complaint. Both the complainant and the individual or institution being investigated have a right of appeal. There were no formal complaints received in the 2007–08 reporting period.

The ARRP also has a policy of responding to informal complaints. These may involve varying degrees of investigation, from formal interviews to requests for documents or unannounced visits to animal holding facilities. Complaints may arrive from a variety of sources: the RSPCA may refer matters that fall outside its jurisdiction; ARRP members may raise matters brought to their attention by members of the community; public concern may be expressed in the media; and complaints may be raised in direct correspondence to the Minister for Primary Industries, the ARRP, or the Animal Welfare Branch. Two informal complaints were received in the 2007–08 reporting period.

A summary of the informal complaints is as follows:

Change of AECs
A complaint was received that a researcher had put an application to one AEC and, prior to approval, had put the application to another AEC without informing either AEC. The concern was that this could represent "shopping around" for an AEC that would approve the project. After communication with the researcher and the AECs it was established that there were no animal welfare implications. The principal investigator on the project was cautioned about the responsibilities of investigators under the legislation.

Daytime use of Elliot traps
A complaint was received that Elliot traps had been found open during the day. The use of Elliot traps is a common means of conducting fauna surveys. The traps consist of a rectangular metal box. They are baited with a food attractive to target species and animals are trapped when they enter the trap to get the food. The animal welfare issue of leaving the traps open during the day is the possibility that animals caught during the day may be subjected to heat stress. After communication with the person responsible for setting the traps it was apparent that they had been deliberately left open to try to catch animals that were active during the day (diurnal), and that this had not been reflected in the application to the AEC for this study. The researcher advised he had not experienced any cases of injury or mortality as a result of leaving traps open during the day. The organization was advised of the responsibilities of individuals and corporations under the Animal Research Act and the particular action to be taken as a result of the complaint investigation - including that daytime use of Elliot traps may only be undertaken with the approval of the AEC.

2.11 Attendance at other meetings

The Chair of ARRP, Professor Margaret Rose, attended the following (the costs for attendance at these meetings was not met from ARRP expenses):
•*Governance of the Use of GM Animals In Australia.* ICLAS Workshop on Harmonisation, Como, Italy, 2007.

• *Genetically Modified Animals in the Biomedical Sciences: the challenge of rapid advances & ethical demands.* World Congress on Alternatives and the Use of Animals in the Life Sciences, Tokyo, 2007.

• *Public Participation in Decisions relating to the Use of Animals for Scientific Purposes: A Review of 20 years experience in Australia.* World Congress on Alternatives and the Use of Animals in the Life Sciences, Tokyo, 2007.

• *The Development of National Guidelines to Promote the Wellbeing of animals Used for Scientific Purposes.* World Congress on Alternatives and the Use of Animals in the Life Sciences, Tokyo, 2007.

•*Research Governance*. National Ethics Meeting, NHMRC, Melbourne, 2007.

APPENDIXES

Appendix A: Dates of ARRP meetings 2007–08

Meeting number	Date of meeting
173	15 August 2007
174	17 October 2007
175	12 December 2007
176	20 February 2008
177	7 May 2008

Appendix B: Members' attendances at ARRP meetings 2007–08

	Meeting number				
Member	173	174	175	176	177
A/Professor M Rose (Chair)	*	*	*	*	*
Dr R Fogarty (Deputy Chair)	*	*	*	*	*
Ms S Abbott	*	A	*	*	A
Dr S Atkinson	A	A	*	*	-
Dr J Baker	*	A	*	A	-
Dr J Grossman	*	*	*	*	*
Dr M Lawrie	*	A	*	*	-
Dr B Lowe	*	*	A	*	*
Mr D O'Shannessy	*	*	*	*	*
A/Professor R Pirola	*	A	*	A	-
Dr P Towers	*	A	*	*	-

* = Present

A = Absent

– = Not applicable

Appendix C: Inspections July 2007 – June 2008

Establishment	Date
Baiada Poultry	17 July 2007
Zootechny	17 July 2007
Engeneic	26 July 2007
ICP Firefly – Meadowmist	31 July 2007
Agrisearch	3 August 2007
Sydney West Area Health Service	23-24 August 2007
The Children's Hospital at Westmead	23 August 2007
NSW DPI Fisheries	5 September 2007
Nestle Purina	6 September 2007
University of Western Sydney	12-13 September 2007
Children's Medical Research Institute	8 October 2007
NSW DPI – EMAI	9 October 2007
Sally Colgan Equine Consulting	9 October 2007
Southern Cross University	6 November 2007
Bioquiv	12 November 2007
QAF Meat Industries	19 November 2007
Vision CRC	10 December 2007
Macquarie University	12-13 March 2008
Garvan Institute of Medical Research	11, 14 April 2008
St Vincent's Hospital	11, 14 April 2008
Victor Chang Cardiac Research Institute	11, 14 April 2008
University of New England	5-6 May 2008
Veterinary Health Research	5 May 2008
Bioniche	6 May 2008
Fort Dodge Australia Pty Ltd	25 June 2008

Appendix D: Attendance of ARRP members at site inspections 2007–08

Member	Number of days spent on site inspection
A/Professor M Rose	3
Ms S Abbott	-
Dr S Atkinson	4
Dr J Baker	-
Dr R Fogarty	6
Dr J Grossman	3
Dr M Lawrie	1
Dr B Lowe	2
Mr D O'Shannessy	7
A/Professor R Pirola	-
Dr P Towers	-

Appendix E: Animal Research Review Panel strategic plan July 2005 – June 2008

Priority items are numbers 2.5, 3.1, 3.2, 4.2 and 9.3.

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.

1.2 Maintain a program of site visits to effectively monitor compliance with the legislation.

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.

1.4 Identify and implement adjuncts to inspections to better ensure compliance with the legislation.

1.5 Monitor compliance with the Act, Regulations and the Code with respect to the conduct of animal research and teaching and the supply of animals for research and teaching.

1.6 Active participation in national reviews of the Code to ensure that it is effective in regulating the conduct of animal research and teaching and the supply of animals for research and teaching.

1.7 Prepare an annual report to Parliament on the operations and achievements of the Animal Research Review Panel.

1.8 Maintain and review the system for collection and analysis of statistics on animal use for research and teaching, to ensure that it provides useful information which accurately reflects the use of animals, without imposing an undue administrative burden on institutions or Government.

1.9 Maintain a system for receiving and investigating complaints relating to the requirements of the legislation.

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.

1.11 Maintain a system to consider and make recommendations on applications for permission to carry out LD50 tests.

2. The principles, processes and responsibilities in the Code are actively embraced wherever animals are used, principally through Animal Ethics Committees

2.1 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.

2.2 Promote support for AECs within institutions.

2.3 Promote and foster interaction between AECs and researchers/teachers.

2.4 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.

2.5 Promote an understanding of the roles and responsibilities of AECs through encouraging participation in AEC training programs. ***(Priority item)***

2.6 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.

2.7 Promote discussion and understanding of key technical and ethical issues and foster interaction between AECs by maintaining a program of meetings of Chairs of AECs and participating in AEC meetings during site inspections.

2.8 Review the membership and operation of individual AECs during site visits to ensure that all categories of membership are able to contribute effectively to discussions, decisions and activities of the AEC.

2.9 Develop and promulgate guidelines to assist AECs to evaluate protocols effectively.

2.10 Conduct ongoing monitoring of TAFE, schools and Director-General's AECs to identify any special needs.

2.11 Promote a critical review of the operation of AECs with a view to maximising their effectiveness.

3. Researchers and teachers using animals actively support the principles set out in the Act, Regulation and *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 encouraging participation in education programs, to foster an awareness of ethical and scientific issues and the implementation of the 3Rs. ***(Priority item)***

3.2 Maintain the 'Animal Ethics Infolink' website as a resource for AECs, researchers and teachers and members of the community. ***(Priority item)***

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.

4.2 Encourage greater awareness of the use of alternatives to animals in research and teaching. ***(Priority item)***

4.3 Collate and disseminate information on alternatives to animal use.

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.

5.2 Ensure close scrutiny by AECs of breeding programs to minimise overproduction of animals.

5.3 Ensure close scrutiny by AECs of the competence of researchers to carry out specific procedures.

5.4 Promote the critical evaluation of the monitoring of animals being used in procedures.

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.

6. Pain or distress in animals used in research and teaching is anticipated, promptly recognised and relieved.

6.1 Promote the use of appropriate analgesia and anaesthesia by facilitating access by researchers/teachers to information resources.

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.

6.3 Promote awareness by researchers/teachers and animal care staff of signs of pain or distress in animals.

6.4 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.

6.5 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.

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 program.

7.2 Develop and disseminate policies and/or guidelines for housing and routine care.

7.3 Actively participate in the development and review of appropriate national 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.

8.2 Develop and disseminate appropriate educational material.

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.

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).

9.3 Review and maintain a web site for the dissemination of information (including the publication of a newsletter). ***(Priority item)***

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.

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 is harmonised between State and Territory regulatory and funding bodies.

10.1 Promote interaction between State and Territory regulatory and funding bodies as issues are identified.

Appendix F: ARRP operational plan July 2007 – June 2008

Activity	Measure of Performance	Time Frame	Status
1. Mandatory			
1.1 Review incoming applications for accreditation and licence	Recommendation to Director-General	3 months (new) 2 months (renewal)	Applications (62) 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	2 informal complaints considered and recommendations made. (Starrate prosecution (successful) finalised August 07)
1.3 Review incoming applications to conduct LD50 tests	Recommendations to Minister	3 months	All applications (7) reviewed and recommendations sent to the Minister.
1.4 Prepare annual report for 2006-2007	Report submitted to Minister	December 2007	Report prepared and submitted.
1.5 Prepare statistics on animal use for 2006	Statistics collated	December 2007	Statistics collated.
2. Inspections			
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	24 23 2 (In-State/active/with own AEC) Impact of Equine Influenza on inspectorial staff available.
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	0 (In-State / active/with own AEC) 0 (In-State / active/with own AEC)
2.3 Conduct site visits of selected independent researchers with animal holding facilities	Number visited	Ongoing	0

2.4 Review and send inspection reports	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	June 2008	Reports for 2007 collected for assessment.
3. Education			
3.1 Maintain ARRP website	Site maintained	Ongoing	Website maintained.
3.2 Finalise learning guide to accompany AEC learning package	Guide finalised	December 2007	Finalisation of guide with external contractor. Reasons for delay being followed up.
3.3 Meeting for members of AECs	Meeting held	December 2008	Meeting planned for April 2009.
3.4 Facilitate access to education programmes by researchers and teachers (via Code Liaison Group)	Plan to facilitate access developed.	December 2008	Issue raised with Code Liaison Group.
4. Policies and guidelines			
4.1 Standards linked to performance criteria for rats, mice, guinea pigs and farm animals (sheep, cattle, pigs)	Finalise revision of rat document	October 2007	Finalised.
	Draft of mouse document circulated for comment	March 2008	Draft document published and circulated.
	Draft of sheep document progressed	December 2007	Draft document published and circulated.
	Revise rabbit guidelines	June 2008	Revision to begin if resources (staff) available.
4.2 Develop policies/ guidelines where strong need identified (maximum of 2)	Developed as need identified	Ongoing	None identified for development.
4.8 Revise current policies and guidelines	Policies and guidelines revised	June 2008	Revisions to commence 2008.
5. Legislation			
6. Additional			
6.1 Continue liaison with NHMRC	Meeting held	Ongoing	Meeting with NHMRC (via Code Liaison Group) February 2008.
6.2 Continue liaison with APVMA via the Animal Welfare Working Group	Contact with APVMA maintained	Ongoing	Workshop on alternatives in animal testing proposed.
6.3 Refer items to AAWS Advisory Committee as necessary	Items referred	June 2008	Referred proposal for a workshop on alternatives.

Appendix G: Animal use statistics 2007

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 2007.

Animal species categories used for collection of data

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

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

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

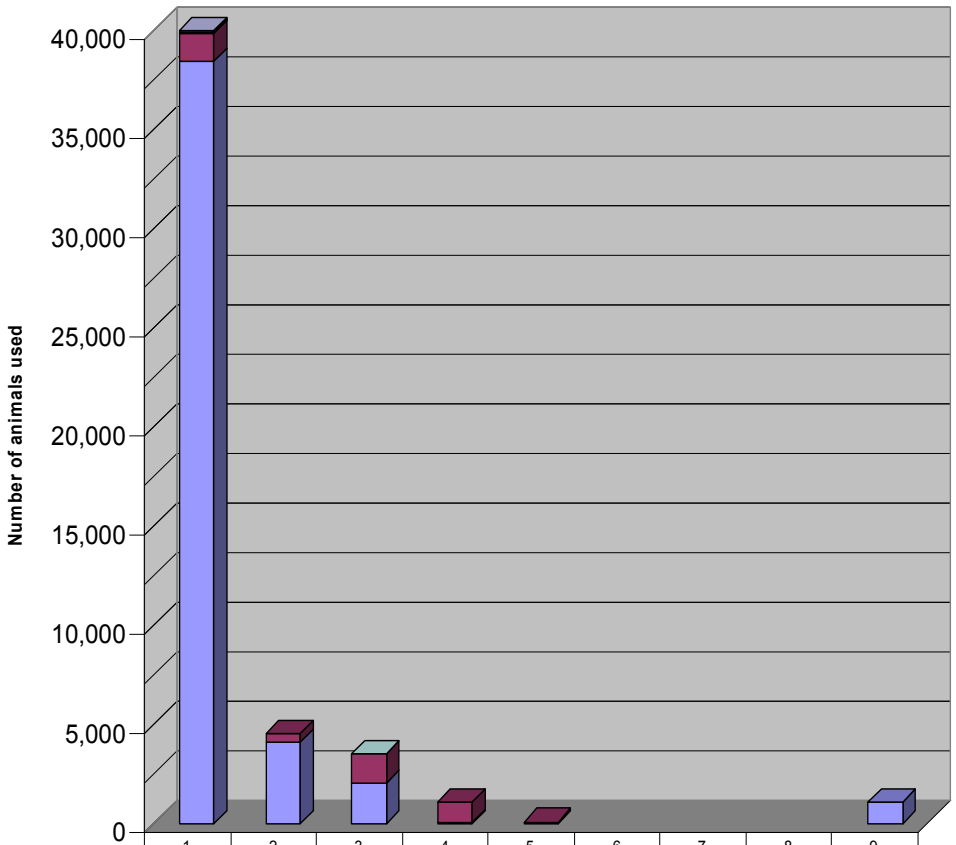
Data collection: procedure categories and guidelines used for classification

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

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

Purpose: Stock Breeding

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



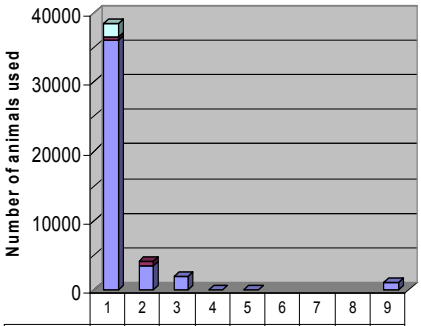
	1	2	3	4	5	6	7	8	9
Exotic Zoo									
Exotic Feral									
Nat Mam	87								
Primates	22								
Reptiles									
Amphibians									
Aquatic			29						
Birds	42								
Domestic	1415	420	1473	1000	50				
Lab Mam	38397	4092	2012	69	27				1057

Procedure

Refer to following page for a further breakdown of species.

Purpose: Stock Breeding

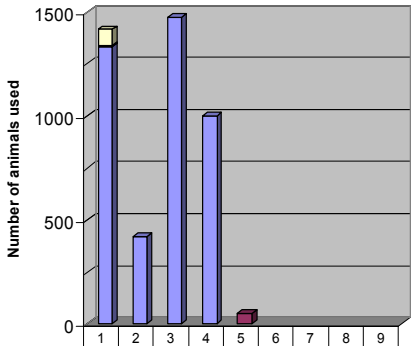
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit	1999								
Guinea Pig									
Rat	285	648							
Mouse	3611	3444	2012	69	27				1057

Purpose: Stock Breeding

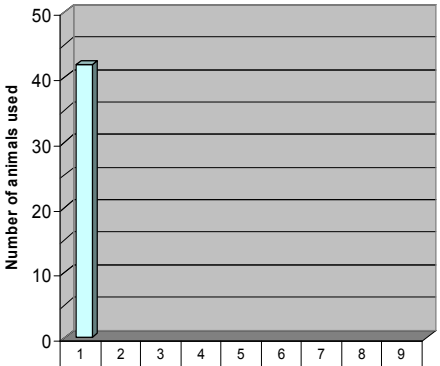
Breakdown of Domestic Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Dogs									
Cats									
Deer									
Goats									
Horses									
Pigs	80								
Cattle	4				50				
Sheep	1331	420	1473	1000					

Purpose: Stock Breeding

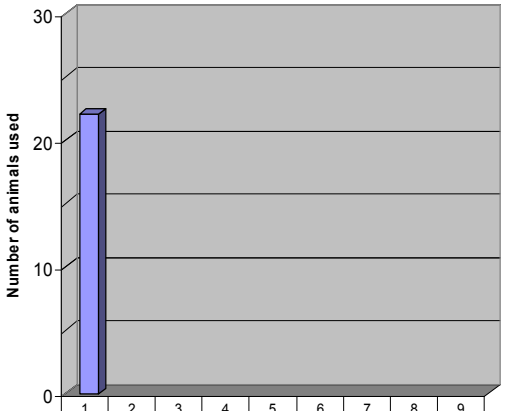
Breakdown of Bird Species



	1	2	3	4	5	6	7	8	9
Other									
Native Wild									
Native Captive	42								
Exotic Wild									
Exotic Captive									
Poultry									

Purpose: Stock Breeding

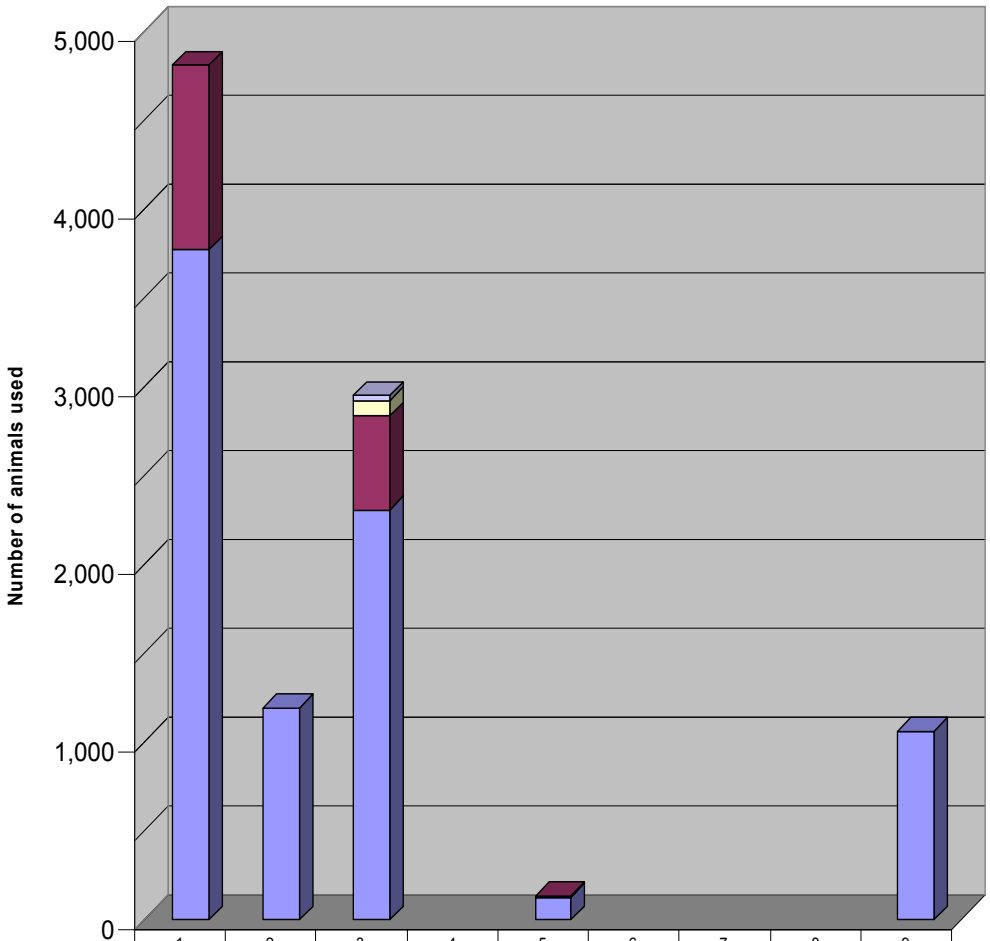
Breakdown of Primates Species



	1	2	3	4	5	6	7	8	9
Other									
Baboons									
Macaques									
Marmosets	22								

Purpose: Stock Maintenance

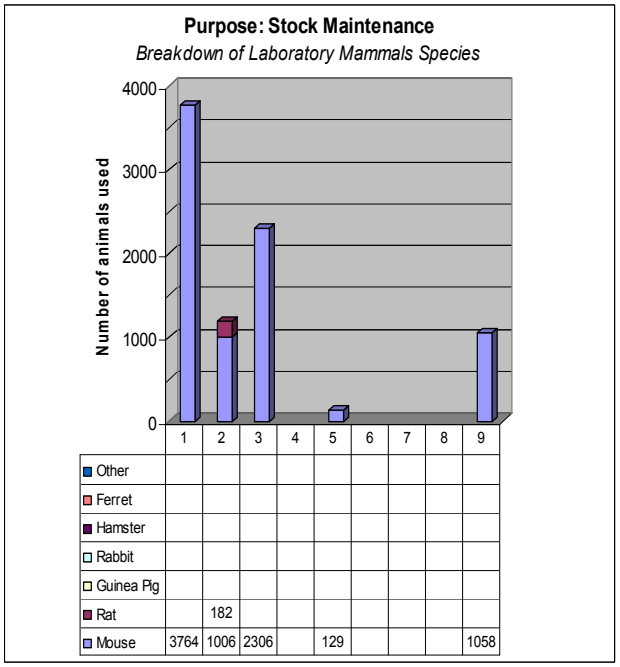
Holding Protocols for animals maintained for use in other protocols .

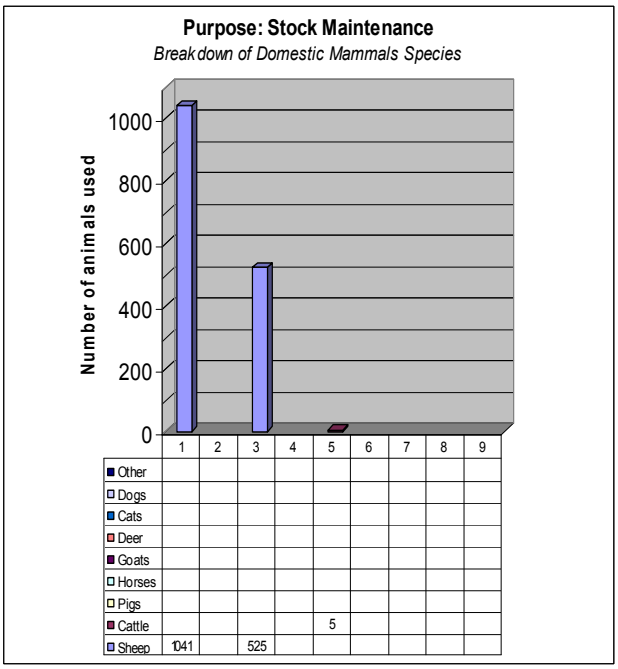


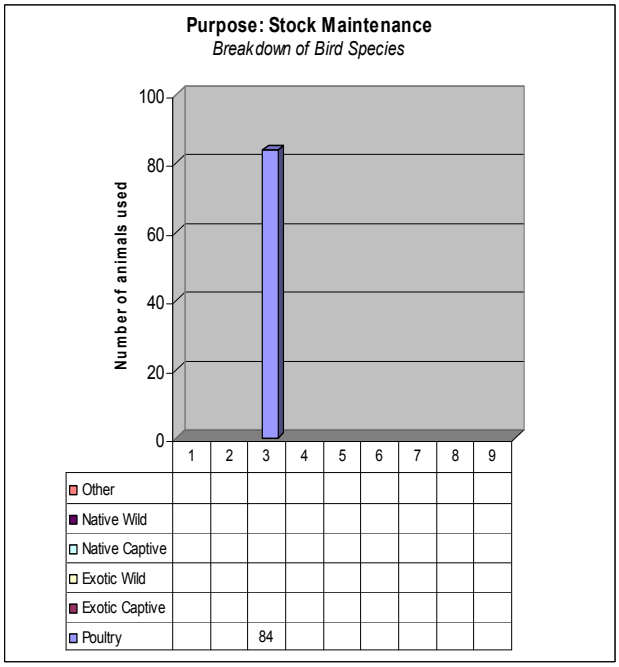
	1	2	3	4	5	6	7	8	9
Exotic Zoo									
Exotic Feral									
Nat Mam			30						
Primates									
Reptiles									
Amphibians									
Aquatic									
Birds			84						
Domestic	1041		525		5				
Lab Mam	3764	1188	2306		129				1058

Procedure

Refer to following page for a further breakdown of species.

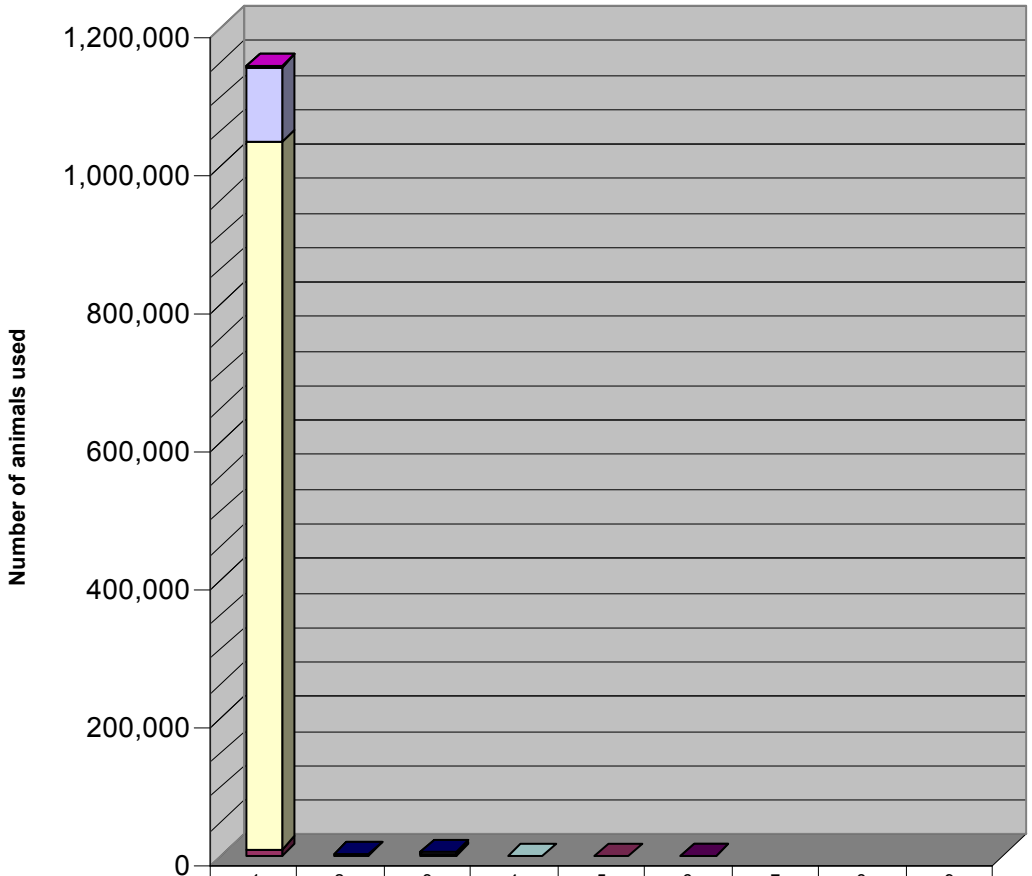

Purpose: Stock Maintenance
Breakdown of Laboratory Mammals Species
Number of animals used
4000
3000
2000
1000
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit
Guinea Pig
Rat 182
Mouse 3764 1006 2306 129 1058


Purpose: Stock Maintenance
Breakdown of Domestic Mammals Species
Number of animals used
1000
800
600
400
200
0
1 2 3 4 5 6 7 8 9
Other
Dogs
Cats
Deer
Goats
Horses
Pigs
Cattle 5
Sheep 1041 525


Purpose: Stock Maintenance
Breakdown of Bird Species
Number of animals used
100
80
60
40
20
0
1 2 3 4 5 6 7 8 9
Other
Native Wild
Native Captive
Exotic Wild
Exotic Captive
Poultry 84

Purpose: Education

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



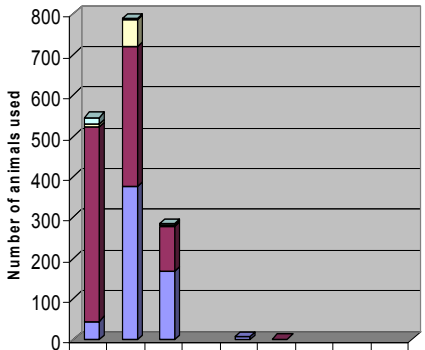
	1	2	3	4	5	6	7	8	9
Exotic Zoo	5								
Exotic Feral	60	124	109						
Nat Mam	109036	45	444						
Primates	21								
Reptiles	177		23						
Amphibians	297	1089	5			2			
Aquatic	282	20	310	63		22			
Birds	1022885	194	672			123			
Domestic	9964	323	3624	315	100	5			
Lab Mam	546	789	284		7	2			

Procedure

Refer to following page for a further breakdown of species.

Purpose: Education

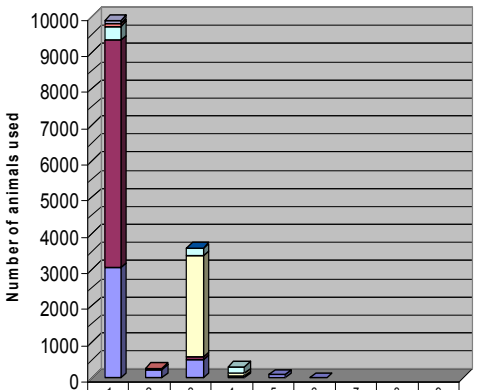
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit	15	4	3						
Guinea Pig	9	67	4						
Rat	476	342	109			2			
Mouse	46	376	168		7				

Purpose: Education

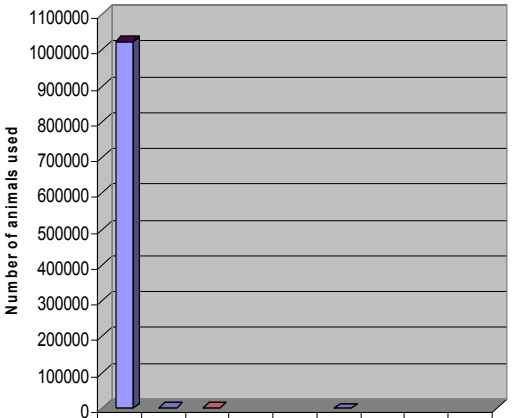
Breakdown of Domestic Mammals Species



	1	2	3	4	5	6	7	8	9
Other	90								
Cats	11		7						
Deer	72	1							
Goats	8	4	4						
Horses	377	13	225	187					
Pigs	7	32	2794	84					
Cattle	6283	1	83						
Sheep	3050	225	490	44	100	5			

Purpose: Education

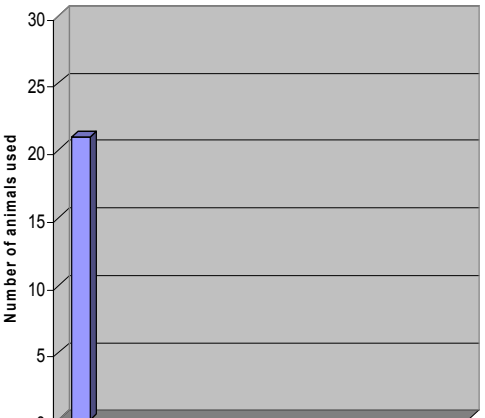
Breakdown of Bird Species



	1	2	3	4	5	6	7	8	9
Other			80						
Native Wild	906		4						
Native Captive	108								
Exotic Wild									
Exotic Captive									
Poultry	1021916	194	588			123			

Purpose: Education

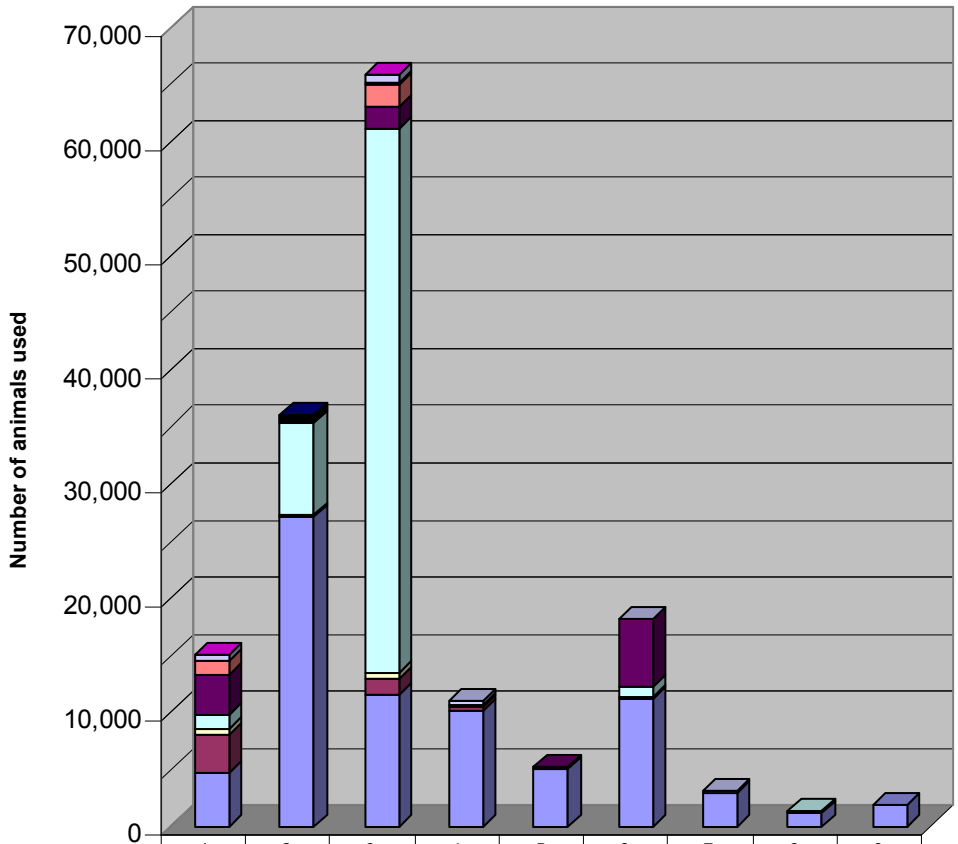
Breakdown of Primate Species



	1	2	3	4	5	6	7	8	9
Other									
Baboons									
Macaques									
Marmosets	21								

Purpose: Research - Human or Animal Biology

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



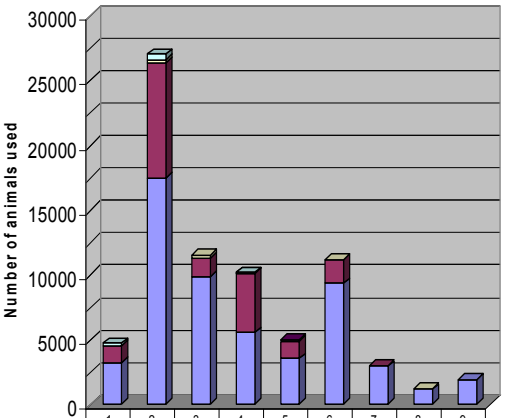
	1	2	3	4	5	6	7	8	9
Exotic Zoo	10		54						
Exotic Feral		150							
Nat Mam	412	109	720	353		21	7		
Primates	21		16						
Reptiles	1208	255	2026	12		85			
Amphibians	3589	179	1921		40	5950			
Aquatic	1117	7962	47544	78		808	142	65	
Birds	537	241	569	3		17			
Domestic	3369	92	1389	360	182	149		6	
Lab Mam	4721	27041	11567	10190	5036	11231	3037	1248	1945

Procedure

Refer to following page for a further breakdown of species.

Purpose: Research - Human or Animal Biology

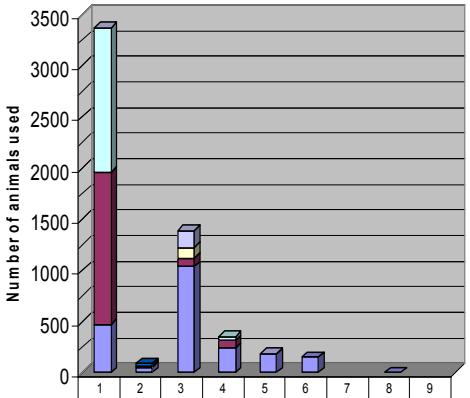
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster					46				
Rabbit	138	370		42	117				
Guinea Pig		281	269	29		26		9	
Rat	1297	8915	1446	4573	1321	1841	90	54	
Mouse	3286	17475	9852	5546	3552	9364	2947	1185	1945

Purpose: Research - Human or Animal Biology

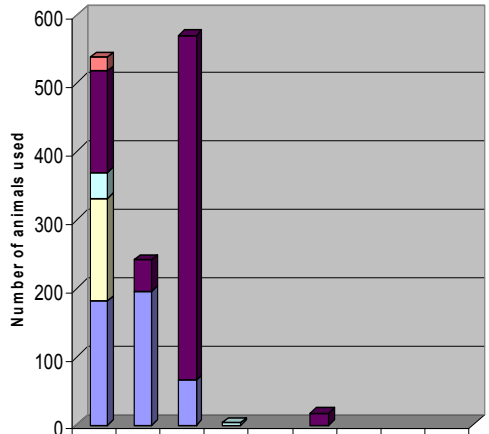
Breakdown of Domestic Mammals Species



	1	2	3	4	5	6	7	8	9
Other	2		163		2				
Cats		23			5				
Deer									
Goats									
Horses	1407		4	35					
Pigs		14	102						
Cattle	1487		86	79					
Sheep	473	55	1034	239	182	149		6	

Purpose: Research - Human or Animal Biology

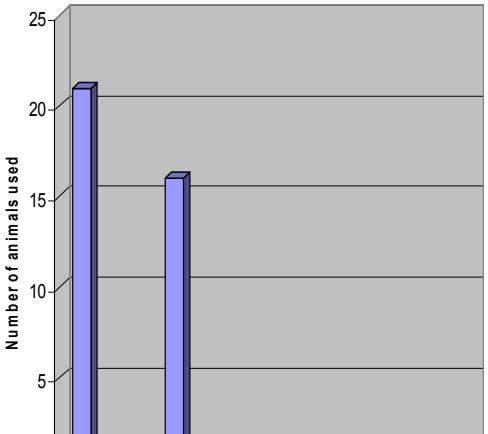
Breakdown of Bird Species



	1	2	3	4	5	6	7	8	9
Other	20								
Native Wild	148	46	504			17			
Native Captive	38			3					
Exotic Wild	150								
Exotic Captive									
Poultry	181	195	65						

Purpose: Research - Human or Animal Biology

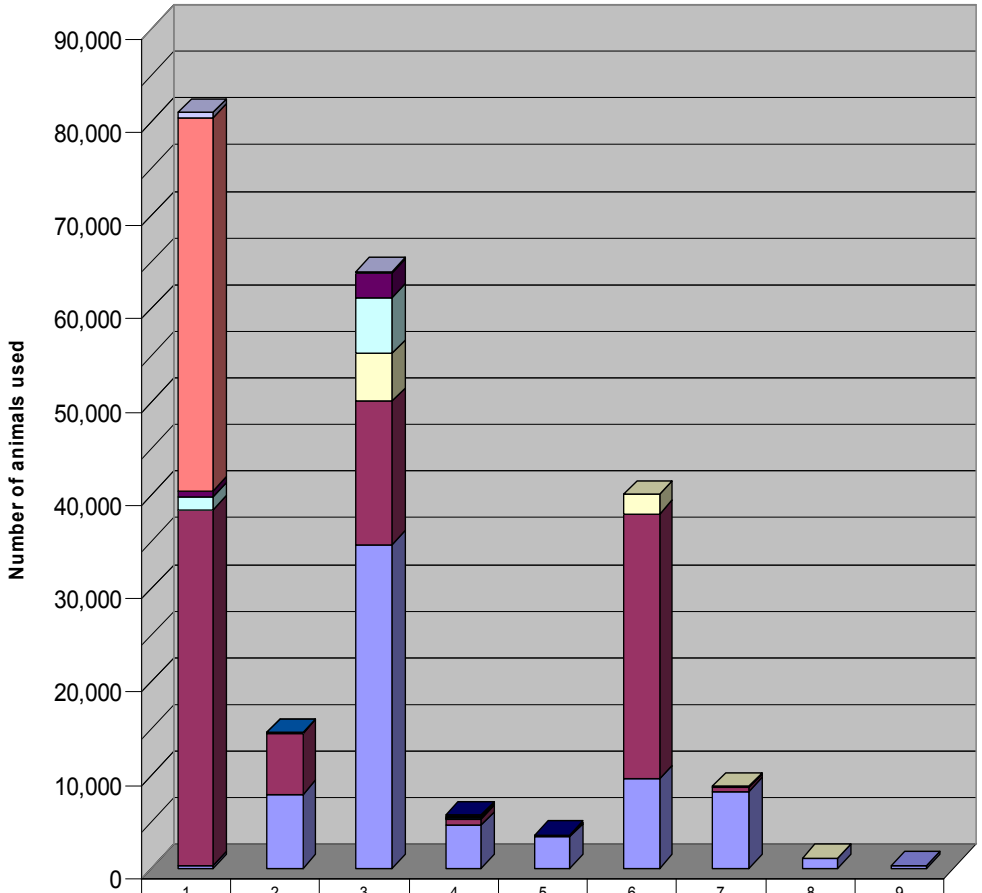
Breakdown of Primate Species



	1	2	3	4	5	6	7	8	9
Other									
Baboons									
Macaques									
Marmosets	21		16						

Purpose: Research - Human or Animal Health & Welfare

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

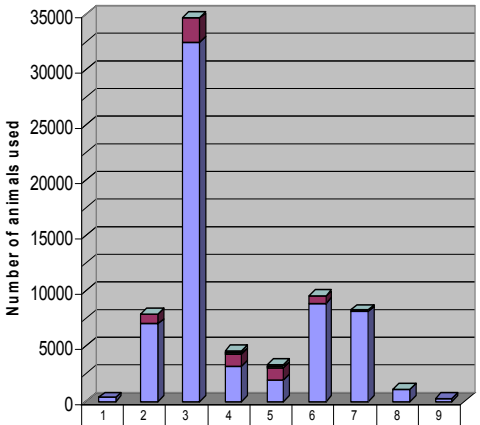


	1	2	3	4	5	6	7	8	9
Exotic Zoo									
Exotic Feral				185	3				
Nat Mam	478		144	200	11				
Primates	7	5		41	14				
Reptiles	40042				2				
Amphibians	633		2695		24				
Aquatic	1396	96	5966						
Birds	2	0	5132		3	2105	165	26	
Domestic	38070	6505	15362	736	187	28418	393		
Lab Mam	366	7958	34709	4576	3336	9559	8286	1112	314

Refer to following page for a further breakdown of species.

Purpose: Research - Human or Animal Health & Welfare

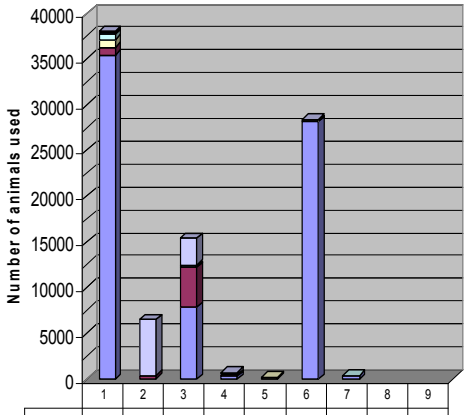
Breakdown of Laboratory Mammals Species



	1	2	3	4	5	6	7	8	9
Other									
Ferret									
Hamster									
Rabbit		20	68	216	194	11	6	4	
Guinea Pig				79	45	24			
Rat		909	2181	1082	1154	612	175		
Mouse	366	7029	32460	3199	1943	8912	8105	1108	314

Purpose: Research - Human or Animal Health & Welfare

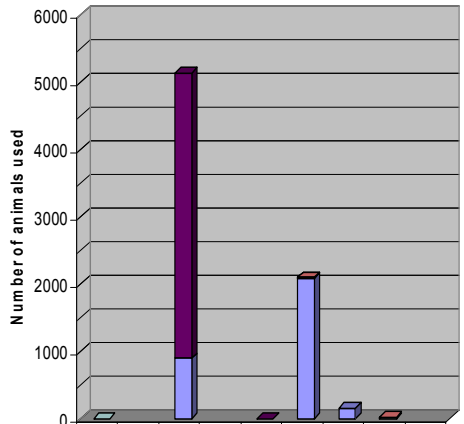
Breakdown of Domestic Mammals Species



	1	2	3	4	5	6	7	8	9
Dogs	236	6120	2939	240		74			
Cats	180		97	37					
Deer									
Goats									
Horses	519	20	104	12			14		
Pigs	846	7			157	184			
Cattle	884	346	4371	207					
Sheep	35405	12	7851	240	30	28160	379		

Purpose: Research - Human or Animal Health & Welfare

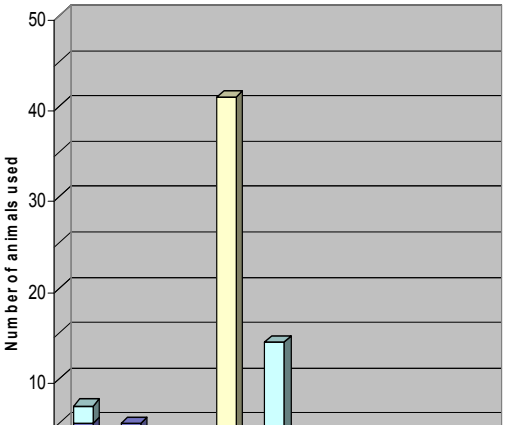
Breakdown of Bird Species



	1	2	3	4	5	6	7	8	9
Other						15		9	
Native Wild			4228		2			2	
Native Captive	2							15	
Exotic Wild					1				
Exotic Captive									
Poultry			904			2090	165		

Purpose: Research - Human or Animal Health & Welfare

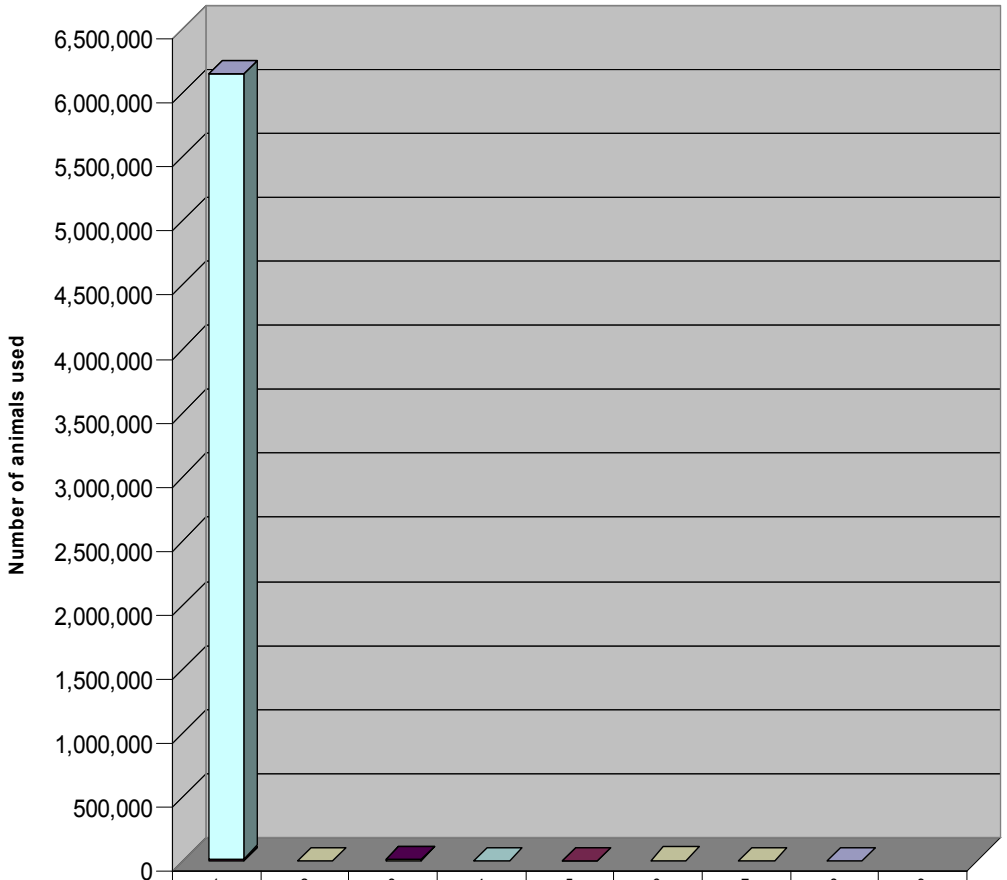
Breakdown of Primate Species



	1	2	3	4	5	6	7	8	9
Other	2				11				
Baboons				41	3				
Macaques									
Marmosets	5	5							

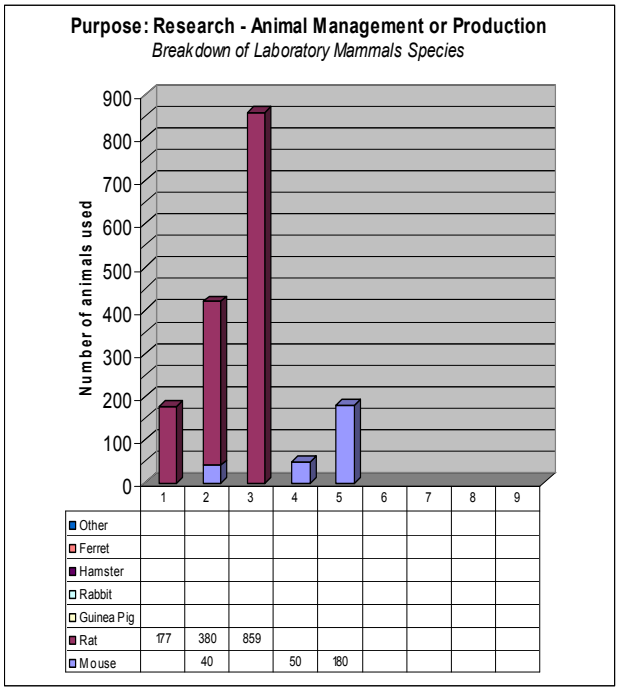
Purpose: Research - Animal Management or Production

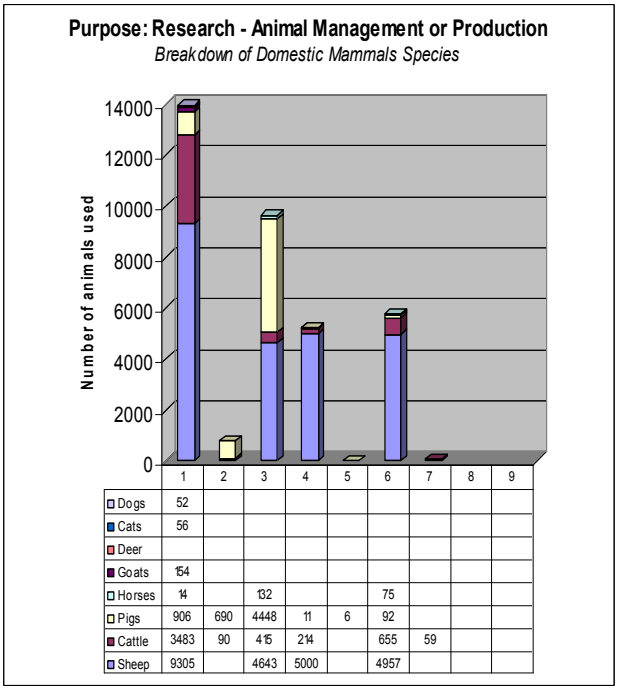
Research protocols which aim to produce improvements in domestic or captive animal management or production .

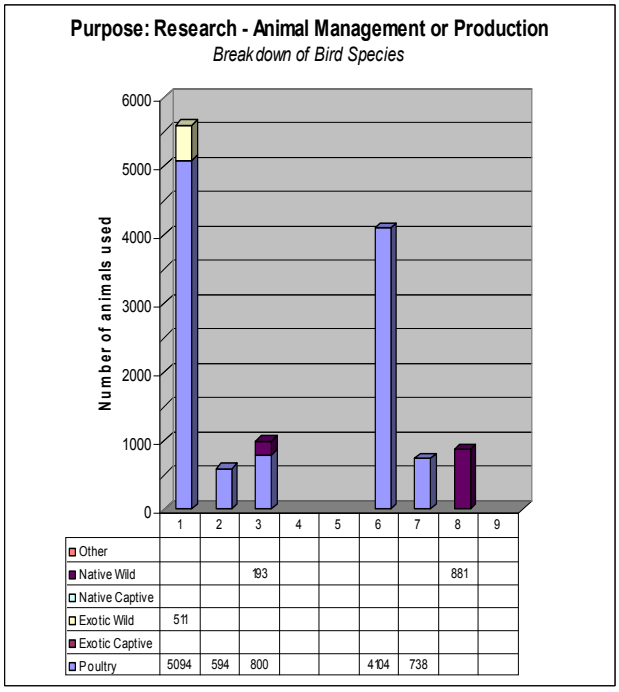


	1	2	3	4	5	6	7	8	9
Exotic Zoo									
Exotic Feral									
Nat Mam	7							410	
Primates									
Reptiles									
Amphibians			300						
Aquatic	6129320			249					
Birds	5605	594	993			4104	738	881	
Domestic	13970	780	9651	5225	6	5779	59		
Lab Mam	177	420	859	50	180				

Refer to following page for a further breakdown of species.

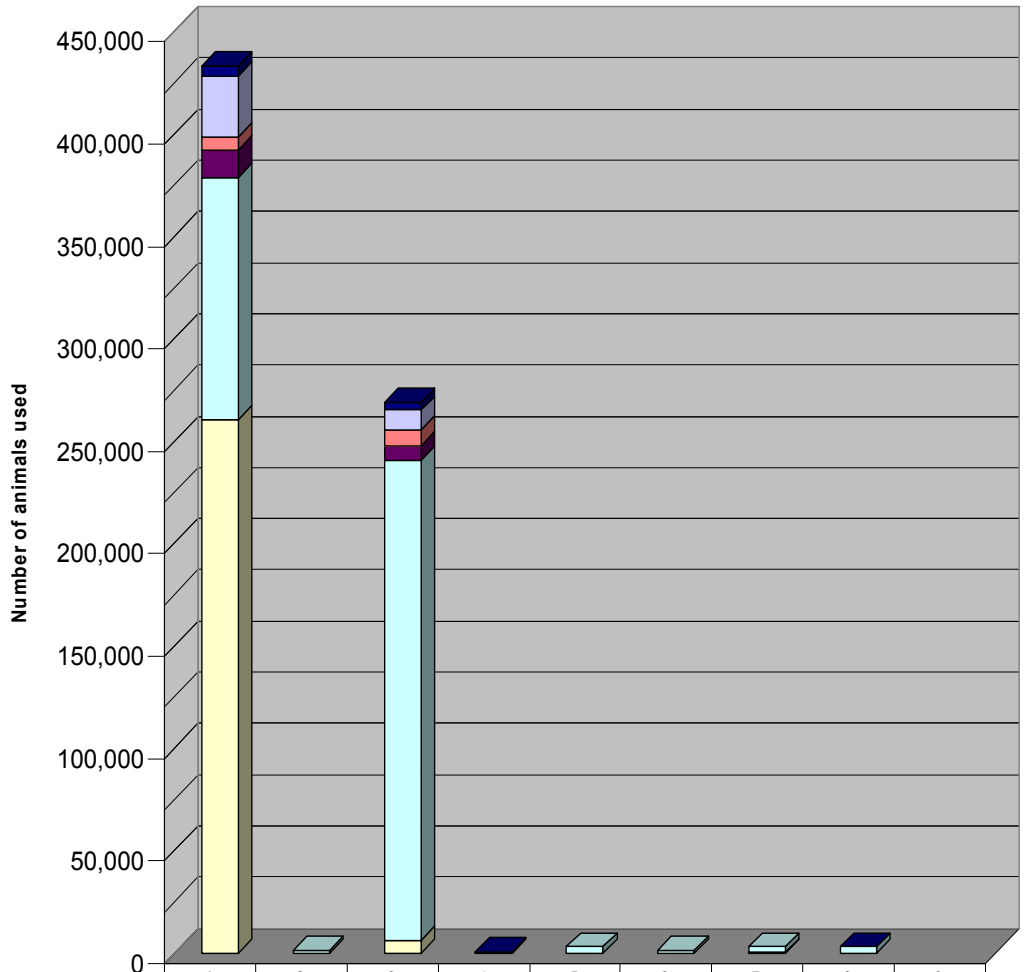

Purpose: Research - Animal Management or Production
Breakdown of Laboratory Mammals Species
Number of animals used
900
800
700
600
500
400
300
200
100
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit
Guinea Pig
Rat 177 380 859
Mouse 40 50 180


Purpose: Research - Animal Management or Production
Breakdown of Domestic Mammals Species
Number of animals used
14000
12000
10000
8000
6000
4000
2000
0
1 2 3 4 5 6 7 8 9
Dogs 52
Cats 56
Deer
Goats 154
Horses 14 132 75
Pigs 906 690 4448 11 6 92
Cattle 3483 90 415 214 655 59
Sheep 9305 4643 5000 4957


Purpose: Research - Animal Management or Production
Breakdown of Bird Species
Number of animals used
6000
5000
4000
3000
2000
1000
0
1 2 3 4 5 6 7 8 9
Other
Native Wild 193 881
Native Captive
Exotic Wild 511
Exotic Captive
Poultry 5094 594 800 4104 738

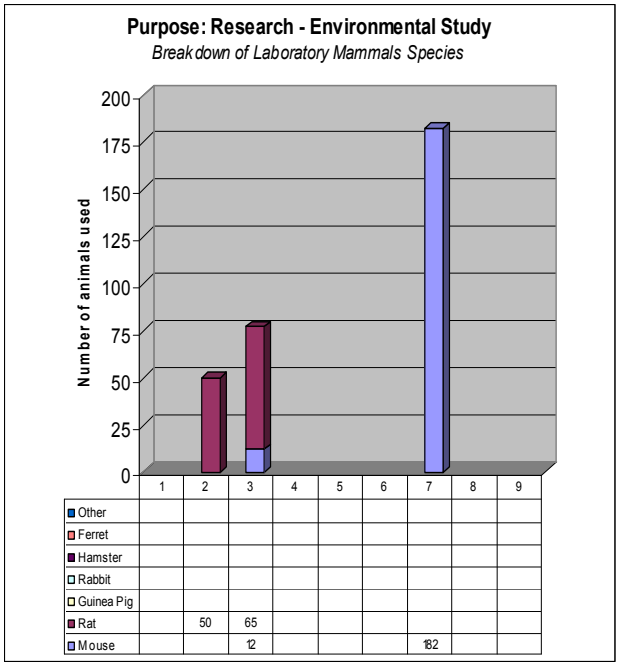
Purpose: Research - Environmental Study

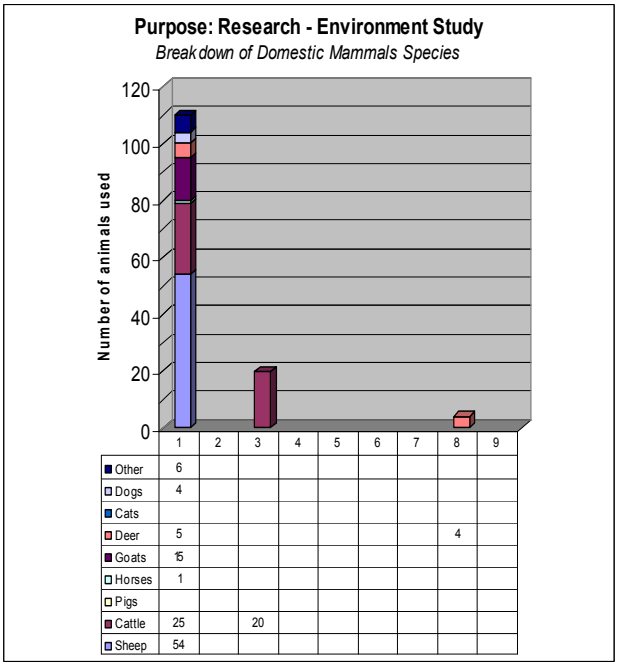
Research protocols which aim to increase the understanding of the animals' environment or its role in it, or that aim to manage wild or feral populations .

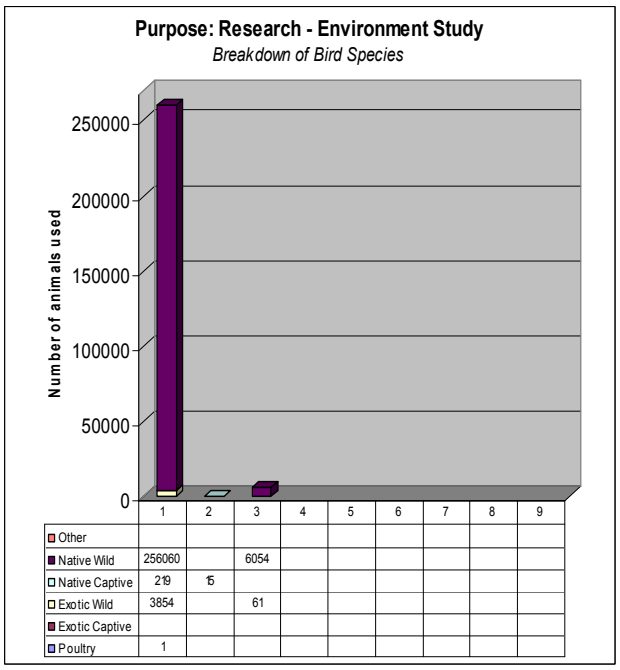


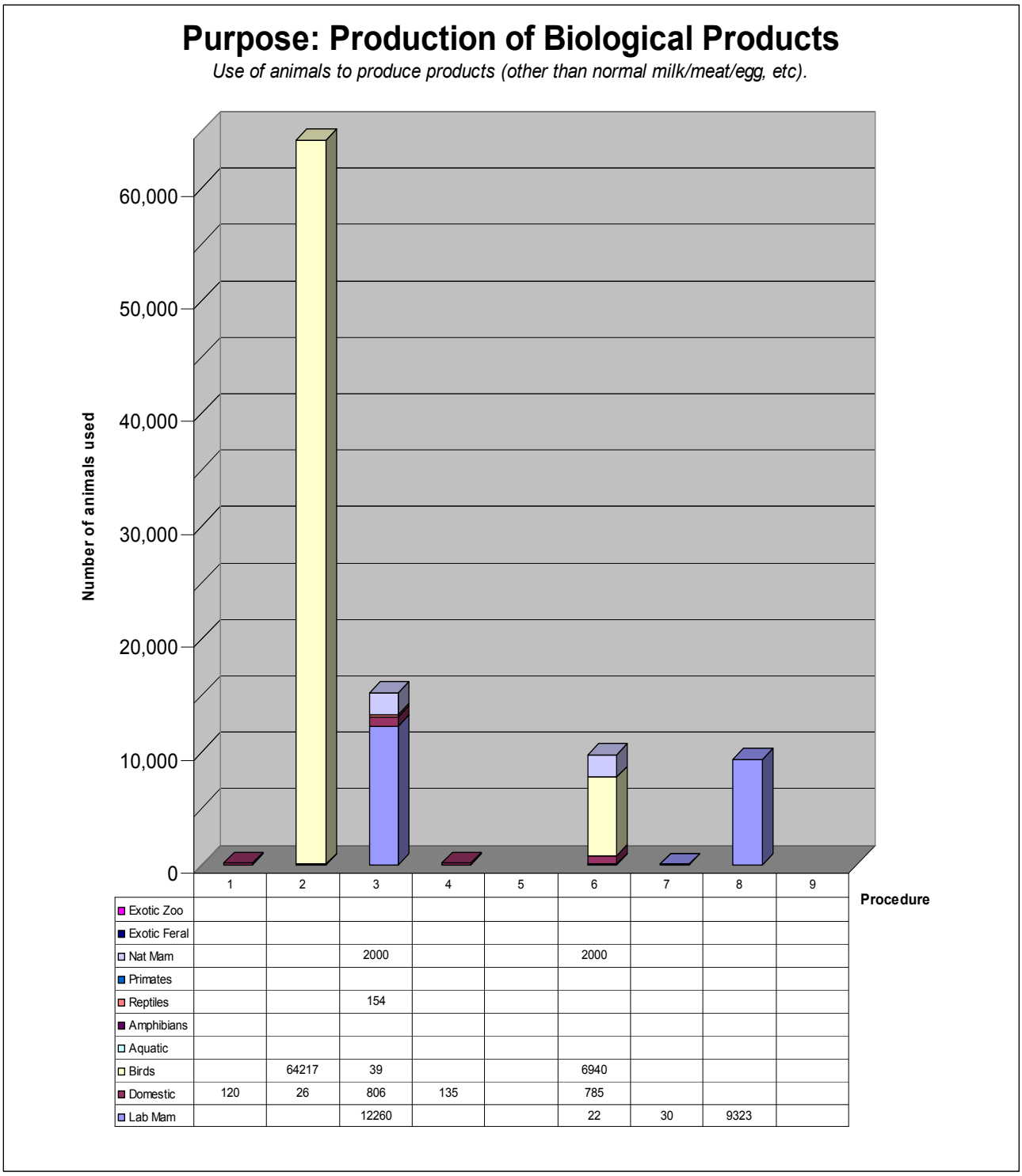
	1	2	3	4	5	6	7	8	9
Exotic Zoo									
Exotic Feral	5009		3907	28				45	
Nat Mam	29727		9511	244					
Primates									
Reptiles	6312		7646	2					
Amphibians	13369		7478					11	
Aquatic	118294	1268	234115	105	3100	1124	2840	3082	
Birds	260134	15	6115						
Domestic	110		20					4	
Lab Mam		50	77				182		

Refer to following page for a further breakdown of species.


Purpose: Research - Environmental Study
Breakdown of Laboratory Mammals Species
Number of animals used
200
175
150
125
100
75
50
25
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit
Guinea Pig
Rat 50 65
Mouse 12 182

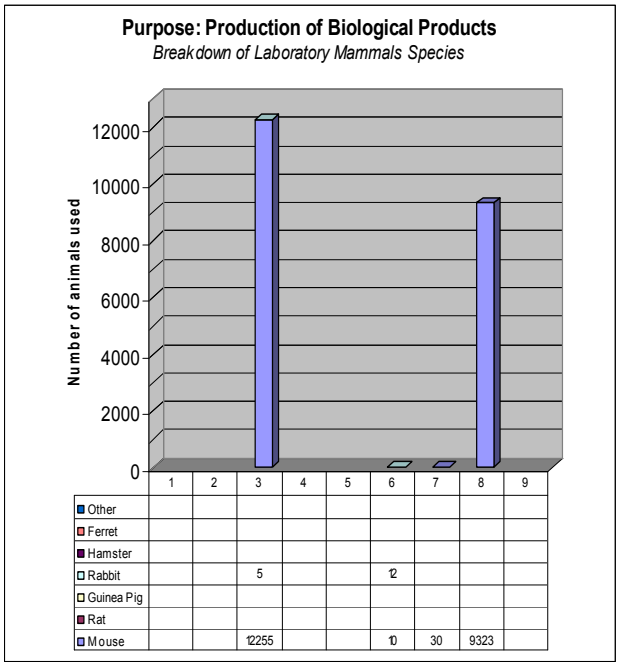

Purpose: Research - Environment Study
Breakdown of Domestic Mammals Species
Number of animals used
120
100
80
60
40
20
0
1 2 3 4 5 6 7 8 9
Other 6
Dogs 4
Cats
Deer 5 4
Goats 15
Horses 1
Pigs
Cattle 25 20
Sheep 54

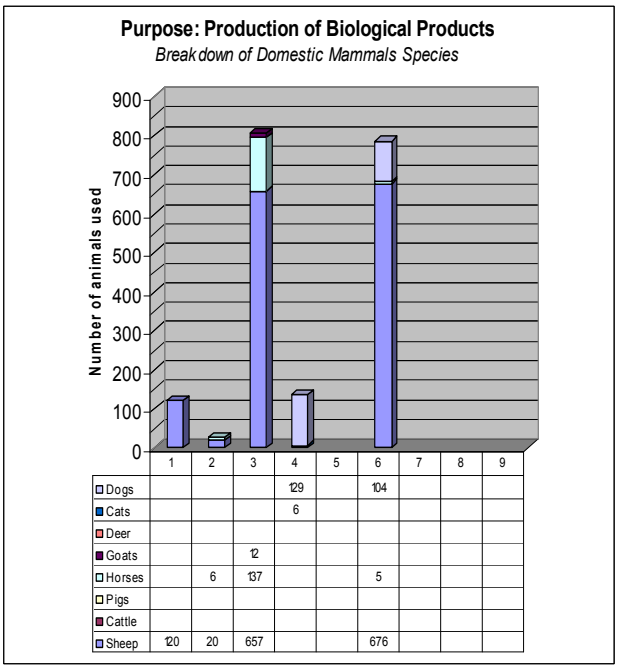

Purpose: Research - Environment Study
Breakdown of Bird Species
Number of animals used
250000
200000
150000
100000
50000
0
1 2 3 4 5 6 7 8 9
Other
Native Wild 256060 6054
Native Captive 219 15
Exotic Wild 3854 61
Exotic Captive
Poultry 1

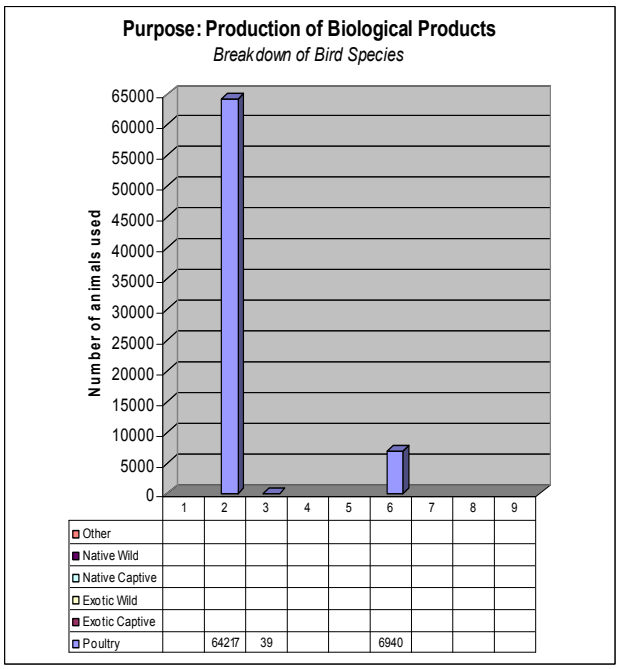


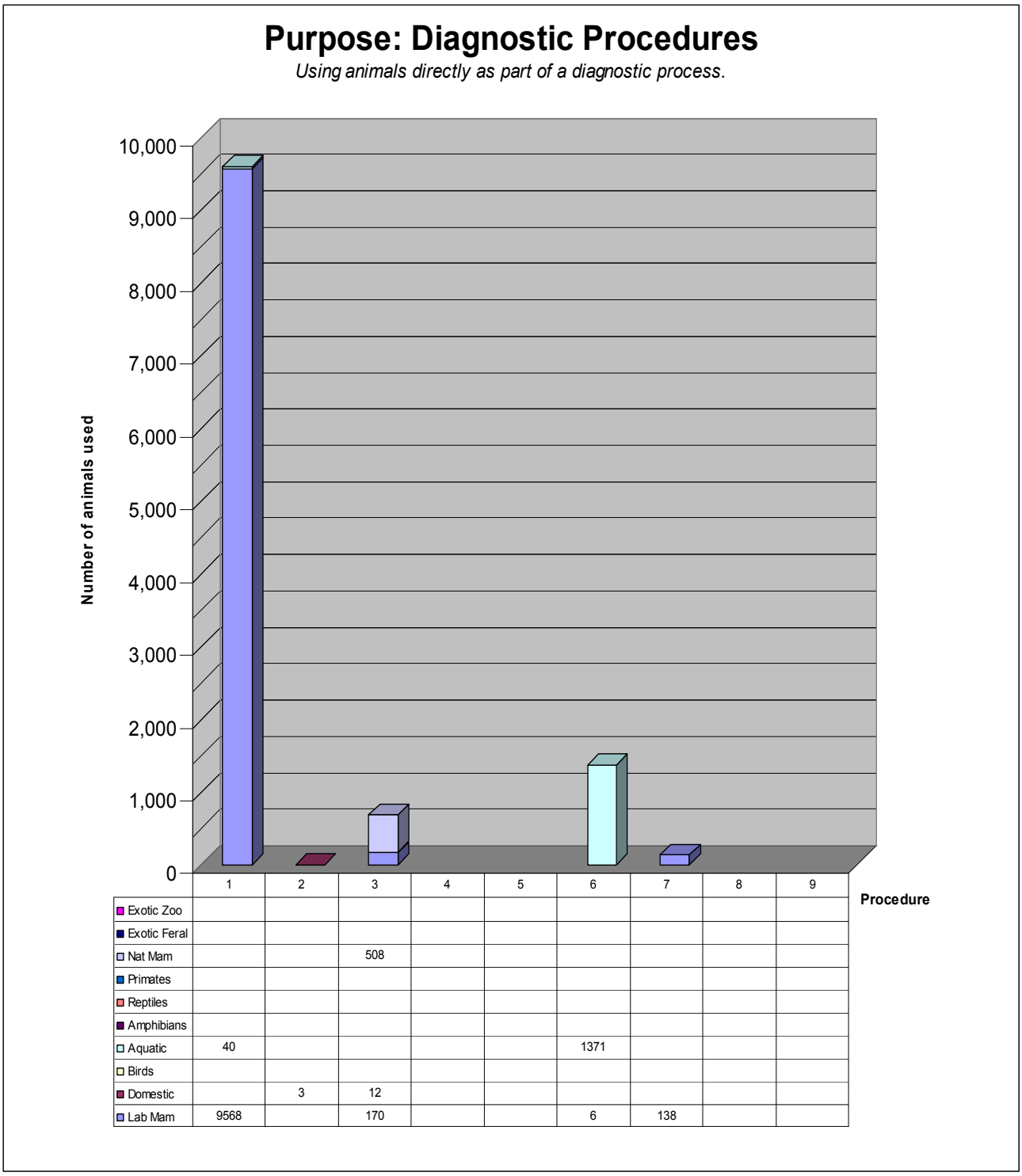
	1	2	3	4	5	6	7	8	9
Exotic Zoo									
Exotic Feral									
Nat Mam			2000			2000			
Primates									
Reptiles			154						
Amphibians									
Aquatic									
Birds		64217	39			6940			
Domestic	120	26	806	135		785			
Lab Mam			12260			22	30	9323	

Refer to following page for a further breakdown of species.

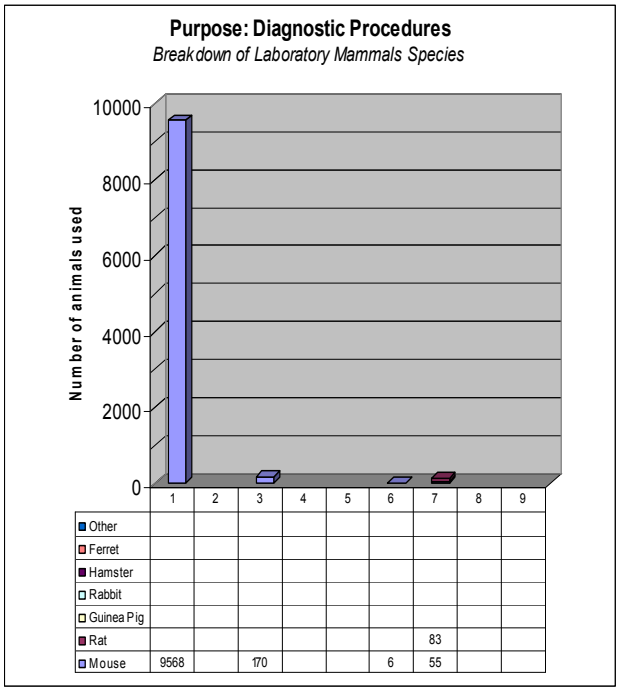

Purpose: Production of Biological Products
Breakdown of Laboratory Mammals Species
Number of animals used
12000
10000
8000
6000
4000
2000
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit 5 12
Guinea Pig
Rat
Mouse 12255 10 30 9323

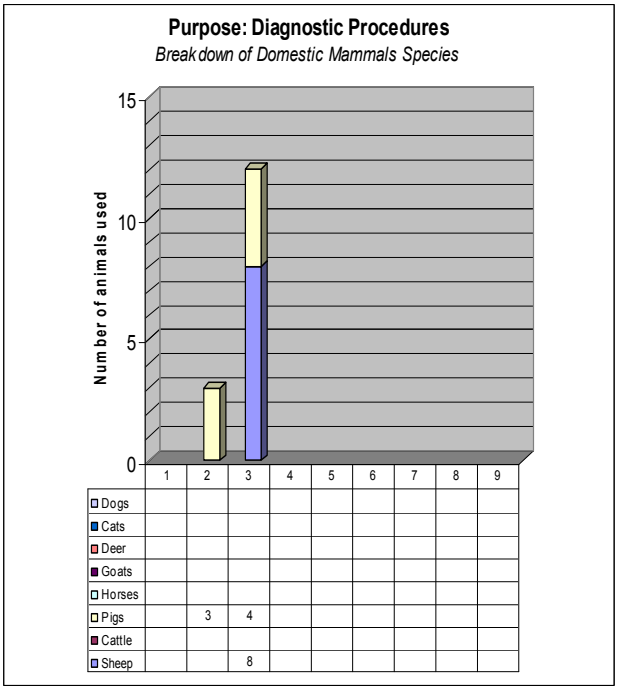

Purpose: Production of Biological Products
Breakdown of Domestic Mammals Species
Number of animals used
900
800
700
600
500
400
300
200
100
0
1 2 3 4 5 6 7 8 9
Dogs 129 104
Cats 6
Deer
Goats 12
Horses 6 137 5
Pigs
Cattle
Sheep 120 20 657 676


Purpose: Production of Biological Products
Breakdown of Bird Species
Number of animals used
65000
60000
55000
50000
45000
40000
35000
30000
25000
20000
15000
10000
5000
0
1 2 3 4 5 6 7 8 9
Other
Native Wild
Native Captive
Exotic Wild
Exotic Captive
Poultry 64217 39 6940



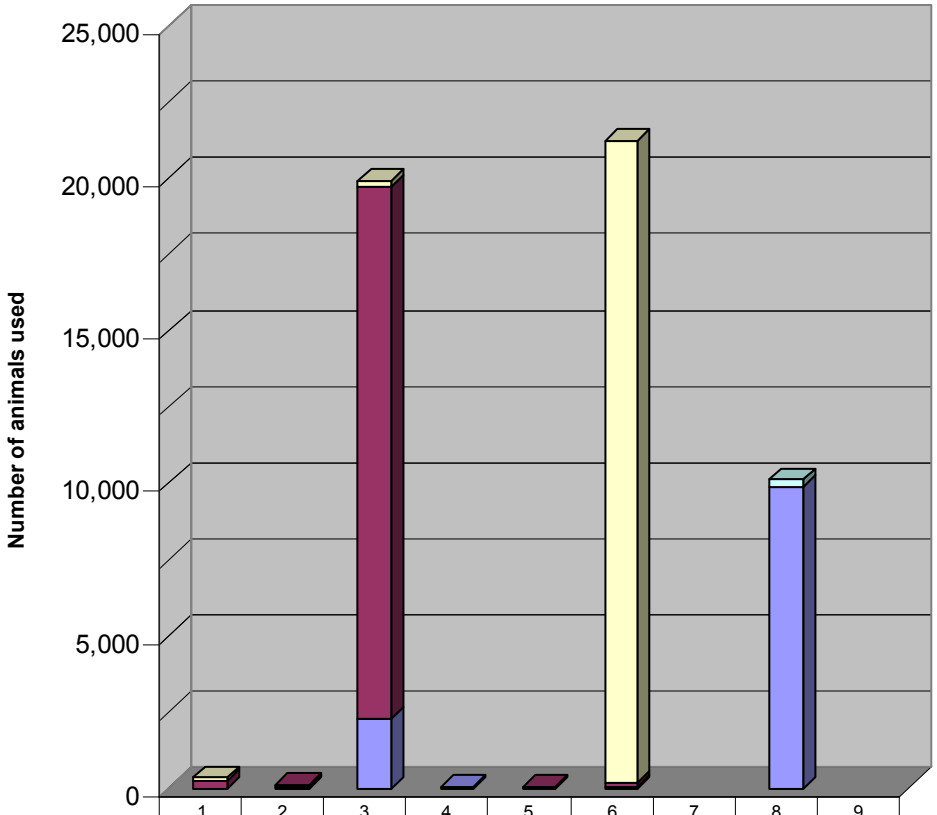
Refer to following page for a further breakdown of species.


Purpose: Diagnostic Procedures
Breakdown of Laboratory Mammals Species
Number of animals used
10000
8000
6000
4000
2000
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit
Guinea Pig
Rat 83
Mouse 9568 170 6 55


Purpose: Diagnostic Procedures
Breakdown of Domestic Mammals Species
Number of animals used
15
10
5
0
1 2 3 4 5 6 7 8 9
Dogs
Cats
Deer
Goats
Horses
Pigs 3 4
Cattle
Sheep 8

Purpose: Regulatory Product Testing

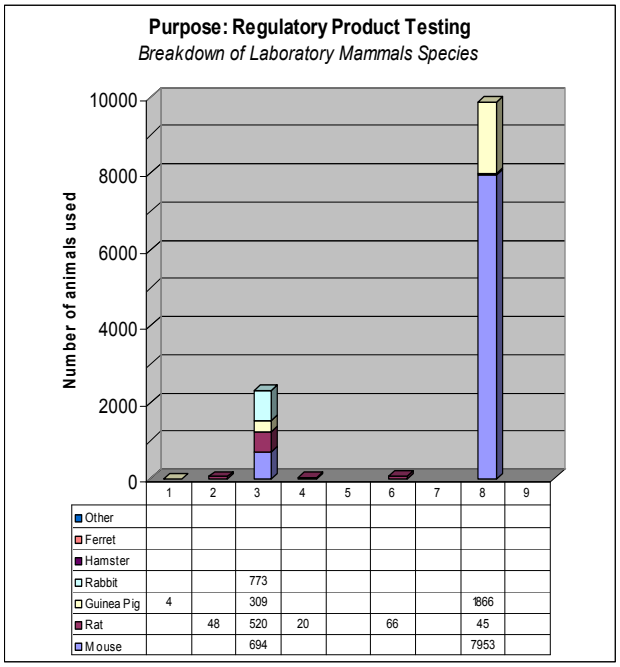
Protocols for the testing of products required by regulatory authorities.

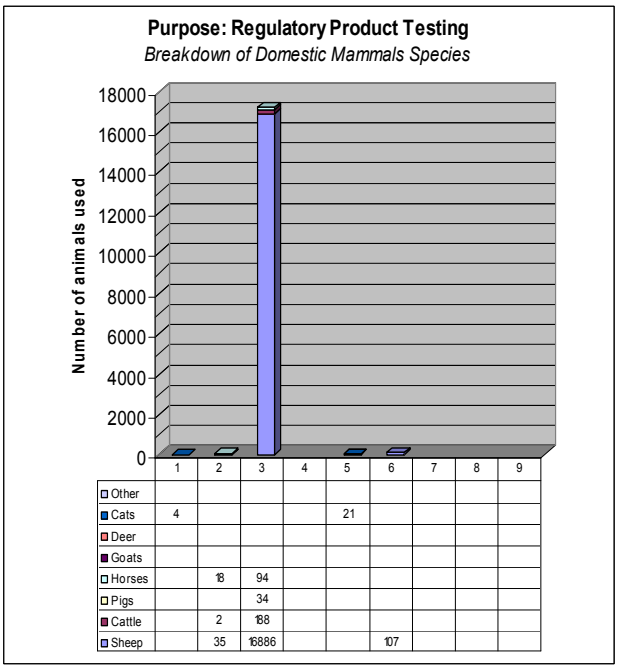


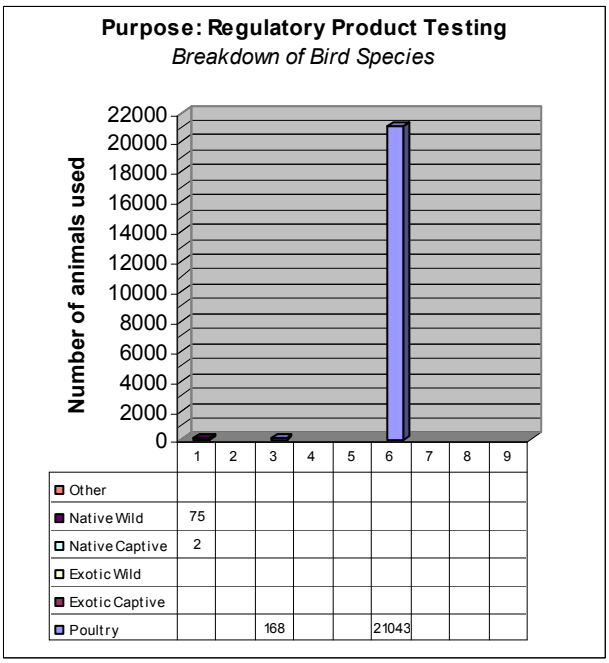
	1	2	3	4	5	6	7	8	9
Exotic Zoo									
Exotic Feral									
Nat Mam									
Primates									
Reptiles									
Amphibians									
Aquatic								240	
Birds	77		168			21043			
Domestic	255	55	17420		40	127			
Lab Mam	4	48	2296	20		66		9864	

Procedure

Refer to following page for a further breakdown of species.


Purpose: Regulatory Product Testing
Breakdown of Laboratory Mammals Species
Number of animals used
10000
8000
6000
4000
2000
0
1 2 3 4 5 6 7 8 9
Other
Ferret
Hamster
Rabbit 773
Guinea Pig 4 309 1866
Rat 48 520 20 66 45
Mouse 694 7953


Purpose: Regulatory Product Testing
Breakdown of Domestic Mammals Species
Number of animals used
18000
16000
14000
12000
10000
8000
6000
4000
2000
0
1 2 3 4 5 6 7 8 9
Other
Cats 4 21
Deer
Goats
Horses 18 94
Pigs 34
Cattle 2 188
Sheep 35 16886 107


Purpose: Regulatory Product Testing
Breakdown of Bird Species
Number of animals used
22000
20000
18000
16000
14000
12000
10000
8000
6000
4000
2000
0
1 2 3 4 5 6 7 8 9
Other
Native Wild 75
Native Captive 2
Exotic Wild
Exotic Captive
Poultry 168 21043

LETHALITY TESTING – 2007

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'*.

The following are the figures reported on animal use for lethality testing in 2007.

Species	No. used	No. died/ euthanase	Procedure	Justification	Alternatives
Stripe-faced dunnart	14	8	Determination of effects of exposure to pesticide to performance and/or immune function in small marsupials	Lack of toxicity data for endemic Australian species	Alternatives available for the determination of acute oral toxicity use more animals per test substance than what has been used in this procedure.
Zebra Finch	15	6	Determination of effects of exposure to pesticide to natural immunity and hormonal indicators of seasonal change in Australian native birds.	No current data exists assessing the toxic effects of pesticide in species that are at high risk of exposure.	None available.
King Quail	10	5	Determination of effects of exposure to pesticide to natural immunity and hormonal indicators of seasonal change in Australian native birds.	No current data exists assessing the toxic effects of pesticide in species that are at high risk of exposure.	None available.
Mice	40	40	Lethal dose of Streptococcus pyogenes	Develop a vaccine for human use	No
Rattus rattus (wild black rat)	10	10	Lethabarb injection	Palatability and efficacy for regulatory bodies must be performed on the target animal wild black rats	Lethality tests must be performed on rats in order to meet regulatory guidelines for registration of products.
Mice	6980	3434	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	7138	3382	Serum neutralisation test in mice: Susceptible animals are challenged with test toxin/antibody dilutions to determine antibody titre.	Regulator testing required to demonstrate efficacy (potency) of vaccines prior to release. Testing of stability batches and new product formulations.	This test is based upon regulatory guidelines. No alternatives available at this time.
Mice	2202	1090	L+ titration in mice: Susceptible animals are challenged with test toxin in order to determine potency of antigen preparation.	In-process testing of production and development antigen growths to allow stop/go decision during manufacturing process.	No alternatives available at this time.
Mice	160	78	Challenge of vaccinated mice with target organisms to demonstrate efficacy of vaccine.	Regulatory testing required to demonstrate efficacy (potency) of vaccines prior to release.	No alternatives available at this time.
Guinea Pigs	1770	760	Vaccinated animals are challenged with test organism in order to demonstrate protection and hence vaccine efficacy.	Regulatory testing required to demonstrate efficacy (potency) of vaccines prior to release. Assessment of in-process or development material to determine suitability for further manufacture.	This test is based upon regulatory guidelines. No alternatives available at this time.

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 2007 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	* Our laboratory scientists are continuing to work hard to replace laboratory animal testing with bench top assays wherever practical and possible. The clostridial tests that were traditionally conducted in lab animals (to assess the antibody levels present in target species) for septicum, tetani, perfringens type D, and novyi type B have now been replaced with benchtop assays. When we run studies with the intention of assessing the antibody levels to these antigens in target species the blood is assessed by these assays routinely now. * We have now finished our virtual atlas of zebrafish development from embryo to adult – this online atlas will reduce the need for direct histological analyses of zebrafish and will be generally available to the whole zebrafish community. The development of our virtual fish atlas is the best possible mechanism of replacement. * To reduce the number of animals involved in transplant experiments, we have developed a number of replacement strategies. These are based upon in vitro and tissue culture assays designed to mimic the in vivo 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 cell lines. * The AEC was active in relation to the replacement of animals in teaching and training. * Use of videos, DVDs and CD ROMs to replace or supplement the use of animals in teaching protocols. * Use of audio-visual material such as videos, slides, interactive computer programs. * Use of plant tissue as a replacement for animal tissue for certain enzymatic assays. * Promotion of the use of artificial serum as a replacement for Fetal Calf serum in tissue culture.
Reduction in numbers	* Use of GLP and GLP Standards ensures a high standard of research minimising the need for greater numbers of sheep. * The Committee has instigated the consolidation of breeding protocols to ensure no over-breeding which in turn reduces the need for culling. * Data on experimental block used to determine plot boundaries. The reduced variability of plot enabled lower numbers of animals to be used without reducing the power of the experiment to determine differences in treatment affects. * We have used a common 'control' group of sheep when conducting two similar types of study therefore reducing the number of sheep required. * In the early discovery phase of product development where the treatment has not yet demonstrated proof of principle, we are electing to run small pilot studies to effectively refine the formulation selection before proceeding with a larger study. This effectively results in the utilisation of fewer animals over the course of a project (with minor costs with respect to time in most cases). * Increased statistical analysis of data aims to minimise number of animals involved in trials. * We have a biometrician review all planned studies to be conducted in animals to ensure they are powered appropriately to get the desired statistical outcomes. * We refined the research procedures by performing a number of pilot studies using a small number of animals to determine appropriate dosing regimes. * Numbers have been substantially reduced as pilot data showed that statistically significant results were

	obtainable with smaller numbers. * Small scale pilot trials allowed for greater controlled pivotal studies. * We have considerably reduced the number of animals used this year because of our increased use of cell lines. * Use of tissues obtained from a single animal by multiple research groups to reduce to overall number of animals used. * When animals are used as a source of tissues for subsequent *in vitro* studies, blood and tissues that were not immediately needed were routinely collected and stored for possible future use. * Tissue and blood samples are harvested from experimental animals (once time-point is reached) and used for other research. For example, spleens are supplied to a researcher from animals culled under a different experimental protocol, thus reducing animal numbers. * Use of abattoir specimens. * Routine husbandry procedures to be performed on animals coordinated with teaching activities. * Obtaining more data from the use of fewer animals by combining objectives. * Ex-breeder mice are assigned to non-recovery or non-invasive studies in order to reduce number of animals bred for experimental purposes. * Similar studies were combined to share control animals. * If relevant, Chief Investigators are encouraged to make videos to use at a future date. * Using SPF eggs instead of clean commercial eggs giving higher fertility therefore less eggs used.
Refinement of techniques	* The AEC is proactive in ensuring that, unless a very strong case can be made to the contrary, analgesics are used in all animal procedures. * All animals given appropriate anaesthesia, local anaesthesia, analgesia and sedation for procedures that warrant it. * Refinement of pain models through the use of analgesia. * Introduction of the use of ketoprofen and Marcaine as a post-operative analgesics. * In projects where it is difficult to entirely eliminate the possibility of pain or stress to an animal, the AEC will closely monitor the progress of the projects with the assistances of the animal facility manager, and periodical reporting will be required form the Chief Investigator to the AEC. * On-going mentoring/training of animal handling staff was implemented to ensure their handling techniques remain current. * An Animal Welfare Introduction Manual has been written for new employees. This will assist in increasing a better understanding about animals in research, resulting in improved study plans and animal welfare. * Developing an Animal Handling Policy with Standardised Operating Procedures to ensure that new researchers are trained in animal handling technique. * Introduction of a training/information package for all researchers using animals. Provides advice on species, monitoring, signs of distress and animal care. * Yearly training courses for Masters, Honours and PhD students and staff to ensure the correct use of techniques. * All Masters, Honours and PhD Students are required to be supervised at all times by the Chief Investigator when they are involved with the care of animals. * On-going mentoring/training of animal handling staff was implemented to ensure their handling techniques remain current. * Distribution of a generic monitoring check list to all investigators. Requirement to keep the check list in

	animals monitoring folder. * Development of monitoring checklists to identify, action and report adverse events. * Attachment of the document "assessment of the impact on animal well being" (from ARRP Model Form) to the AEC application. * Proposal to introduce an annual 'Animal Welfare Award' to recognise and award achievements in the 3Rs. A working party was established to develop guidelines for the implementation and administration of the proposed award. * Additional mouse enrichment is being utilised, ie autoclaved cardboard tubing which is replaced at each weekly cage clean. * Increased awareness and use of environmental enrichment. * Improved environmental enrichment for rodents. Paper towels, toilet rolls and packaging added to caging. * Continued development of roughage feeding for housed experimental sheep. This was shown by us to reduce oral stereotypy and the results published for the information of other researchers and institutions. * Relocation of research horses to a farm setting. * Retirement of a research horse to pasture, with ongoing care and supervision. * Spontaneous collection of naturally voided urine for the purpose of drug analysis. * There have been several initiatives during 2007 which have focused on the sourcing and testing of *Clostridium chauvoei* and *Clostridium botulinum* antigens for use in vaccines. The potential long-term benefits of these initiatives are that increased efficacy of antigens manufactured will ultimately lead to reduction in the amount of testing required on a lot by lot basis. A key focus area with regard to animal usage and welfare 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. Laboratory animals are known to be susceptible to the toxic effects of these vaccine additives and as a consequence their presence may interfere with the outcome of compendial potency tests. A study was performed to examine the potency of samples drawn from different states in the manufacture of these clostridial vaccines. The objectives of the trial were to develop a test minimising the potential for adverse effects on test animals. On the basis of the results obtained, applications were made to the relevant regulatory authorities requesting that the potency testing of vaccines containing selenium be performed using samples drawn from the final blend immediately prior to the addition of selenium. This testing regime will avoid exposing laboratory animals to the toxic effects of selenium whilst still provide sound efficacy data for the vaccine under test. To date, approval has been received from the APVMA for modified testing on one group of products and it is anticipated that further approvals will be granted during the course of 2008. * Use of adjuvants known not to produce adverse reactions. * Use of TiterMax rather than Freund's adjuvant for polyclonal antibody production. * The development of a minimally invasive laparoscopic technique for abomasal injections in sheep, representing a considerable refinement of previous approaches. * XYZ transgenic mice have a low tolerance to stress and display a sudden death phenotype, which can be induced by animal handling or mating. We have modified our animal handling procedures to utilise an animal handling 'pouch', which greatly minimises stress and premature death. Since implementation of this new procedure, no mice have died due to handling. * We now use saline/fluid injections, as well as analgesia, as this contributes to a more rapid postsurgery recovery rate. * We shortened the experimental time point to reduce the chance of lymphomas developing during the experiment. * Surgical techniques have been optimised to improve recovery and thread sutures have been replaced with

	clips, avoiding the mice chewing or scratching open their wounds. * We have refined group numbers and monitored blood glucose values in diabetic-prone mice so that the majority of mice can be euthanased prior to development of overt diabetes. * Adverse effects are minimised through the use of narrow gauge needles, by rotating injection sites when multiple injections are given and by anaesthetising the animals when bleeding. * 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. * Replacement of a surgical procedure with a less invasive non-surgical procedure. * Use of osmotic mini-pumps instead of daily IP injections. * Positive rewards (eg food) were offered to study animals to reduce stress. * A number of studies were conducted with the assistance of animal owners at their homes to minimise any possible distress. * Young animals remained with their mothers at all times during studies and twins remained with their siblings. * Bedding changed from wood shavings to fibresorb which provides greater absorbency and more comfort for diabetic rats. * Purchase of an anaesthetic machine using isoflurane which provides a more reliable anaesthetic than injectables and a smoother recovery. * Development of a dedicated animal procedures room so that procedures did not need to be performed within an animal room. Development of a dedicated surgery. * Introduced humidity sprays to chicken hatching room reducing cull rate by 3-4%. * Wildlife Study: Anaesthetic regimes in the field eg portable isoflurane administration. Veterinarian included for anaesthetic administration and any necessary veterinary interventions. Edible bait to provide sustenance for animals after capture. Trapping only when weather conditions optimal. To reduce the risk of pathogen transfer between frogs: the use of disposable latex gloves and sterilisation of instruments. * The stress of trapping will be minimised by the provision of bedding material, adequate food and weather-proofing over the trap. Animals will be released within 2 hours of sunrise. Traps will not be left open during the day particularly in summer months. Trapping will not be carried out during inclement weather. All animals are released on the morning of capture and at the location where they are caught. Animals with pouch young will be immediately released without further handling to minimise the chances of any young becoming detached. Trapping is avoided where possible during known period where pouch young would be small. Where necessary small mammals will be handled with bare hands to eliminate the risk of a compression injury to the animal. Most often the small mammals are placed in a cloth bag for identification. Larger mammals such as possums or bandicoots are not handled. * Traps are insulated with Dry leaf litter and Dupont Hollofill to provide warmth and shelter. Traps are set at dusk and checked at dawn to reduce sun exposure and heat related illness. Trapping is not conducted when wet weather is forecast. Traps are covered in a plastic cover to protect them from rain. Traps will be cleared and/or closed in the event that illness or injury removes the investigator from the field. Trapping will occur on a maximum of three consecutive nights at a single site. * Remote release radio-tracking collars used on deer to avoid recapture.

Appendix I: ARRP expenses

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

Fees and retainers	$9,429
Travel and subsistence	$5,619
Stores and printing	$888
Freight and postage	$1294
TOTAL	**$17,230**

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	*Exhibited Animals Protection Act 1986*
NHMRC	National Health and Medical Research Council
NSW DPI	New South Wales Department of Primary Industries
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.animalethics.org.au)

Policies

2. Payment of External Members of Animal Ethics Committees
3. Procedures Prohibited under POCTAA
4. Non-Research Animals on Designated Land
5. Annual Reporting by Animal Ethics Committees to Accredited Establishments

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
17. Training Personnel

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 Involved in the Care and Use of Animals for Scientific Purposes
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 l: Animal Welfare Branch 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 16: Guidelines for Minimum Standards for Keeping Horses in Urban Areas
- 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
- Fact Sheet 20: Protecting the Welfare of Horses Competing in Bush Races in NSW

Appendix M: Standard conditions for accreditation and animal supply licence

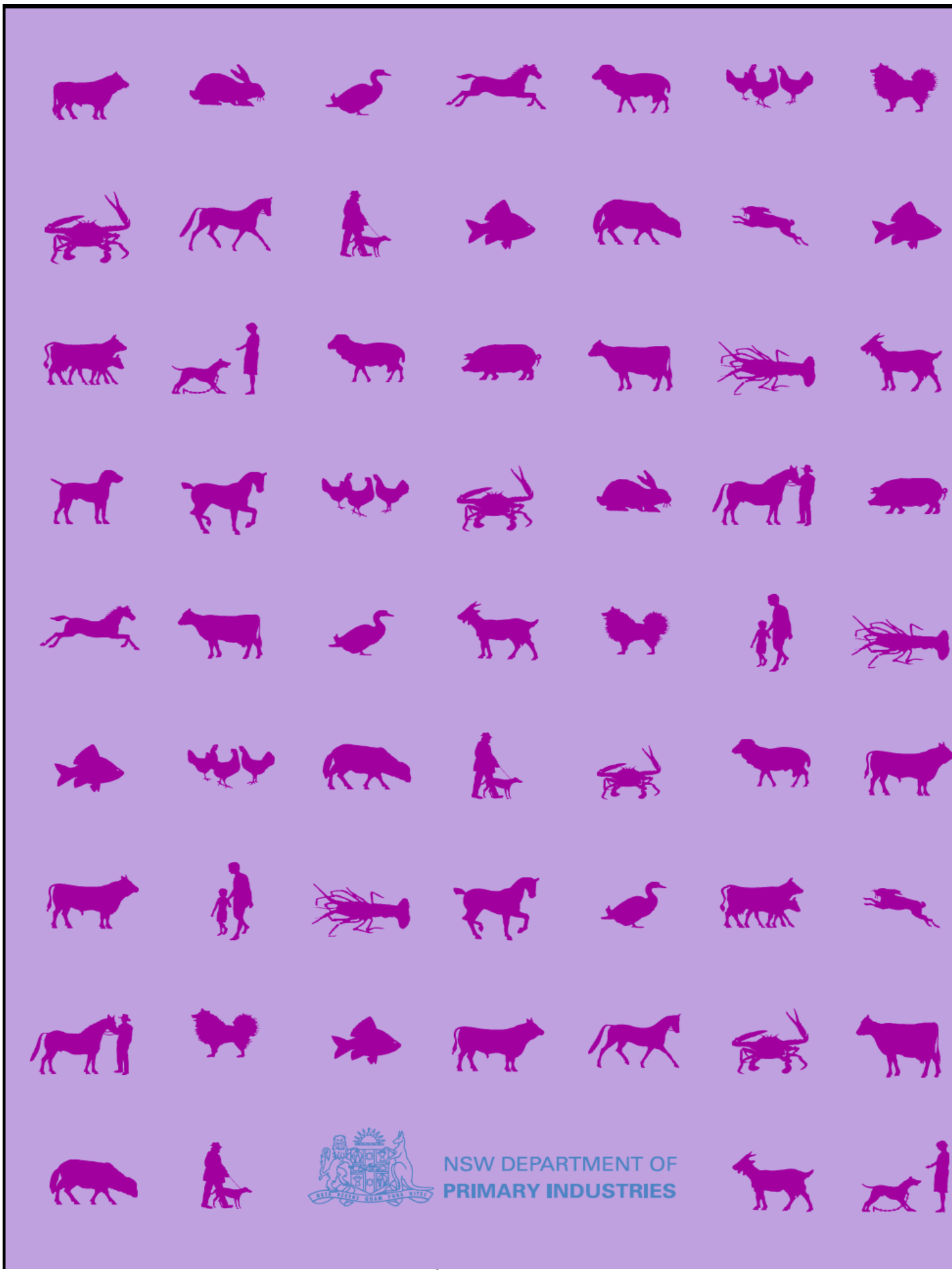
The following are standard conditions that are placed on establishments seeking accreditation as animal research establishments and licences as animal suppliers. Additional conditions are added on a case-by-case basis.

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 NSW Department of Primary Industries within 30 days of membership changes. The revised composition of the AEC must meet the approval of the Director-General.
3. Rabbits should be housed in groups in pens. Rabbits may only be housed in cages with the express permission of the AEC on the basis of compelling evidence for the need to use such housing. Lack of space or facilities for pens should not be considered sufficient justification for the use of cages. Where rabbits are held in cages, these cages should be enriched by methods such as pair housing in double cages. (*Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* Clause 4.4.19) (See ARRP Guideline 18: Guidelines for the Housing of Rabbits in Scientific Institutions (http://www.animalethics.org.au/reader/animal-care))
   (For establishments housing rabbits)
4. Unless precluded by the requirements of specific projects, chickens should be provided with housing that meets their behavioural needs including straw or other suitable bedding to cover the floors of cages, perches and dust bathing substrate.
   (For establishments housing chickens)
5. 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)
6. A response to conditions {xx} of the inspection report of {date) must be provided to the Director-General of NSW Department of Primary Industries by {date—within 3 months of inspection report being sent}.
   (Added after inspection)

Animal Supply Licence

1. That any site inspection is satisfactory.
2. The documented procedures and methods of record keeping, as required under Clauses 4.5.7 and 4.5.8 of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*, must be submitted by the supply unit to the AEC for approval.
3. To assist in monitoring the management of breeding colonies, the supply unit must provide regular reports to the AEC, for review, on the fertility, fecundity, morbidity and mortality of all breeding colonies. The frequency of such reports should be at least 6 monthly and more often if determined necessary by the AEC.
4. To help ensure that overproduction is avoided, the supply unit must provide regular reports to the AEC, for review, on the number of animals culled and the reasons for these numbers. The frequency of such reports should be at least 6 monthly and more often if determined necessary by the AEC.
5. Any breeding which involves animals which have been the subject of genetic modification (involving the introduction of foreign DNA into cells or whole animals) must comply with Clauses 3.3.56 to 3.3.63 of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*.


NSW DEPARTMENT OF
PRIMARY INDUSTRIES