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# **ANIMAL RESEARCH REVIEW PANEL**

7 December 2011

The Hon Katrina Hodgkinson MP Minister for Primary industries Minister for Small Business Level 30 Governor Macquarie Tower 1 Farrer Place SYDNEY NSW 2000

Dear Ms Hodgkinson

In accordance with Section 11 of the Animal Research Act 1985, the Animal Research Review Panel presents its annual report covering the period 1 July 2010 to 30 June 2011.

Yours sincerely

Professor Andrew Dart

Chair, Animal Research Review Panel

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### PART ONE: ORGANISATION

### 1.1 The Animal Research Act 1985

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

The primary aim of the legislation is to protect the welfare of animals used in research and teaching by ensuring that their use is justified, humane and considerate of their needs. The Act incorporates a system of enforced self-regulation, with community participation at the institutional and regulatory levels.

The Act establishes a system of accreditation, licensing and authorisation of organisations and individual researchers. The Act also establishes the Animal Research Review Panel (ARRP) to provide a mechanism for representatives of government, scientific and animal welfare groups to participate jointly in monitoring the effectiveness of the legislation.

The Act creates offences for conducting animal research without appropriate authorisation, with substantial custodial and financial penalties.

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

The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (the Code of Practice) is a nationally accepted code and is included under the Animal Research Regulation. The Code is reviewed regularly by the Code 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.

# 1.3 The Animal Research Review Panel

The Animal Research Review Panel (ARRP) has responsibility for overseeing the effectiveness and efficiency of the legislation, investigating complaints, and evaluating compliance of individuals and institutions with the legislation. The constitution, membership and mode of operation of the ARRP are set out in the Act. The 12-member Panel has equal representation from industry, government and animal welfare groups. This allows community involvement in regulating the conduct of animal research in New South Wales. Apart from developing overall policy on animal research issues, the ARRP is closely involved in the administration of the legislation. This is achieved through evaluating applications for accreditation and licences, conducting site visits to assess compliance, and investigating complaints. The ARRP also has a role in considering amendments to the Regulation. Staff of the Animal Welfare Unit (the Department of Primary Industries) provide executive support for the ARRP.

### 1.3.1 Mission statement

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

The strength of the ARRP lies in the diversity of expertise, opinions and ethical perspectives of its members. The development of cohesive and progressive policies has occurred as a result of this diversity. All members are employed in other fields and participate on a largely voluntary basis. Non-government members are paid fees for attending formal meetings and participating in site inspections. Members are not paid for time spent preparing for meetings and inspections, for considering applications for accreditation or licenses, or for drafting discussion papers.

# 1.3.2 Functions of the ARRP

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

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

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

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

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

# 1.3.3 Membership

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

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

All members of the ARRP are part-time and are normally appointed for a term of 3 years. The 3 year term of appointment expired on 30 September 2010 and the Minister subsequently appointed and re-appointed members for the 3 year term to 30 September 2013.

During the 2010–11 period the membership of the ARRP was:

- Professor Margaret Rose (Chair) (nominated by the NSW Vice-Chancellors' Committee). Retired August 2010
- A/Professor Andrew Dart (Chair) (nominated by the NSW Vice-Chancellors' Committee). Appointed Chair December 2010
- Dr Regina Fogarty (Deputy Chair) (nominated by the Minister for Primary Industries)
- Ms Stephanie Abbott (nominated by Animal Societies' Federation NSW). Retired May 2011
- Dr Magdoline Awad (nominated by RSPCA NSW)
- Mr Peter Batten (nominated by the Minister for Education and Training)
- Ms Celeste Black (nominated by Animal Societies' Federation)
- Dr Mike Fleming (nominated by the Minister for the Environment)
- Dr Craig Godfrey (nominated by the Minister for Health). Appointed December 2010
- Professor Annemarie Hennessy (nominated by the Minister for Health). Retired December 2010
- Professor Robert Mulley (nominated by Vice-Chancellors' Committee)
- Mr David O'Shannessy (nominated by RSPCA NSW)
- Professor Jacqueline Phillips (nominated by the NSW Vice-Chancellors' Committee)

Dr Peter Rolfe (nominated by Medicines Australia)

Information on members of the Animal Research Review Panel in 2010-11 is as follows:

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

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

Professor Rose joined the ARRP in 1986 as a nominee of the NSW Vice-Chancellors' Committee and has served as the ARRP's Chair since that time until August 2010.

# Professor Andrew DART(Chair) BVSc PhD Dip ACVS Dip ECVS

Dr Dart is Professor of Equine Veterinary Science and Director of the Research and Clinical Trials Unit of the Faculty of Veterinary Science, the University of Sydney. He has held positions as Director of the Veterinary Teaching Hospital and Deputy Chair and Acting Chair of the Animal Ethics Committee of the University of Sydney. Dr Dart is a Registered Specialist in Equine Surgery and has spent time in private practice and as a Clinical Academic. Professor Dart was appointed as Chair of the ARRP in December 2010.

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

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 principal of Kitsune Consulting.

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

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

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

Mr Peter Batten is Director of the TAFE NSW – Training and Education Support – Industry Skills Unit – Orange and Granville. Peter has 30 years experience in vocational education and training with TAFE NSW including positions dealing with the welfare of animals in teaching including Program Manager Extensive Agriculture, Industry Specialist

Livestock Production and Wool and Teacher of Agriculture. Peter joined the ARRP in 2008 as the nominee of the Minister for Education and Training.

Ms Celeste BLACK BA (Harvard), JD (University of Pennsylvania), LLM (Hons) (University of Sydney)

Ms Black joined the ARRP in March 2010 on nomination by the NSW Animal Societies Federation. She is a Senior Lecturer and currently the Associate Dean (Learning and Teaching) at the Faculty of Law, University of Sydney, where she developed and teaches the undergraduate law elective Animal Law. Ms Black is an executive and founding member of the Human Animal Research Network at the University of Sydney.

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

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

### Dr Craig Godfrey BVSc

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

### **Professor Annemarie HENNESSY**

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

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

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

# Mr David O'SHANNESSY, BSAgr.

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

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

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

### Dr Peter ROLFE BVSc. PhD

Dr Rolfe is a nominee of Medicines Australia. He is an employee of Novartis Animal Health.

# 1.3.4 Retirement of Professor Margaret Rose

The ARRP was formed in 1986 and Professor Margaret Rose has been the Chair since that time until her retirement from the ARRP in August 2010

Professor Rose was instrumental in the development of the Animal Research Act 1985. In introducing the legislation in 1985, the Hon Kevin Stewart noted 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. At the time of its introduction, the legislation was seen as innovative. It embodied the notion of a duty of care and respect for animals, which was a significant extension of the legal concept of protection from cruelty.

The achievements of the ARRP since its inception have been manifold and driven in large part by the vision and efforts of Professor Rose. Some of the achievements of the ARRP over this time include:

- \* A strong influence on the nationally implemented *Australian Code of Practice for the Care and use of Animals for Scientific Purposes.* The Panel's revision of an existing Commonwealth code was the catalyst for the development of the nationally accepted Code in 1990. The Panel's major influence was recognised by the Senate Select Committee in its 1989 report on Animal Experimentation. The ARRP has continued to have a major input into content of Code via Professor Rose's membership of the body responsible for Code revisions (the Code Liaison Group and more recently the Code Reference Group).
- \* The development of accreditation and licensing systems and procedures for the regulation of animal research establishments.
- \* The development and implementation of inspection processes for animal research establishments.
- \* The development of a system for the use of animals for teaching in schools. This was the first time in Australia that the use of animals in schools was addressed in a comprehensive way. Ongoing work with the Schools system has resulted in outcomes such as improved monitoring by the Schools Animal Ethics Committee and improved communication with teachers. The model is now being emulated in other States.
- \* The development of a system for the collection and publication of statistics on animal use in research.
- \* The development, in consultation with user and interest groups, of an extensive set of policies and guidelines on the use of animals in research and teaching.
- \* The development of comprehensive guidelines on wildlife research. These were created well ahead of moves in other States to consider the use of animals in wildlife research.
- \* The development of evidence-based guidelines for the housing of animals in scientific institutions. The guidelines have been developed as a result of significant input from Professor Rose. They have received international recognition and commendation by groups such as the Canadian Council on Animal Care, the RSPCA UK and the International Council for Laboratory Animal Science.
- \* The development of a dedicated website, Animal Ethics Infolink, (<a href="http://www.animalethics.org.au/">http://www.animalethics.org.au/</a>) as a comprehensive source of information. The development of the website was at the instigation of Professor Rose and the content primarily created by her.
- \* Meetings for members of Animal Ethics Committees (AECs). These meetings were instigated to help provide information for, and contact with, AEC members. They have proved over the years to be a very valuable resource for AECs.
- \* Various workshops have been held in addition to meetings for members of AECs:
  - Alternatives to the use of animals in education
  - Animal Welfare and independent AEC members
  - Farm animals in research
  - Monitoring
  - Researcher training
- \* Continued liaison with an establishment carrying out LD50 tests (tests which involve deaths of a percentage of animals and which require Ministerial concurrence). As a result, successful replacements, reductions and refinements of animal use have been implemented.
- \* A training package for AEC members is under development.
- \* Training material for researchers using animals is under development.

In recognition of her achievements, in July 2010 Professor Rose was made an inaugural Life Member of the Australian and New Zealand Council for the Care of Animals in Research and Teaching.

Although she will no longer be a member of the ARRP, Professor Rose has agreed to continue to Chair the ARRP subcommittee responsible for developing training material for researchers.

### 1.4 Animal Ethics Committees

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

AECs are responsible for approving and monitoring research within institutions, including inspections of animals and facilities. No animal research may be carried out without AEC approval. AECs must consider and evaluate applications to conduct research on the basis of the researchers' responses to a comprehensive set of questions, including their justification for the research, its likely impact on the animals, and procedures for preventing or alleviating pain or distress. On behalf of the institution, AECs have the power to stop inappropriate research and to discipline researchers by withdrawing their research approvals. They can require that adequate care, including emergency care, is provided for animals. They also provide guidance and support to researchers on matters relevant to animal welfare, through means such as the preparation of guidelines and dissemination of relevant scientific literature. They are responsible for advising institutions on the changes to physical facilities that should be made to provide for the needs of the animals used.

The membership and duties of AECs are laid down in the NSW legislation and in the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*, which also provides guidance on how AECs should operate.

Committee membership must include members as follows:

- Category A: a veterinarian
- Category B: an animal researcher
- Category C: a person with a demonstrated commitment to animal welfare who is not involved with the institution, animal research or the supply of animals for research
- Category D: an independent person who does not fit the requirements of the other categories, is not associated with the institution and who has never been involved in the use of animals for research.

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

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

# 1.5 Accreditation and licensing

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

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

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

The recommendations of the ARRP are referred to the Director-General of the Department of 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 the Department of Primary Industries for approval. Other conditions may also be stipulated, as relevant to the operation of each institution. (See Appendix L for standard conditions on accreditation and licences).

# 1.5.1 Evaluation of written applications

New and renewal applications for accreditation or licences are assessed by Animal Welfare Unit staff, according to criteria developed by the ARRP. Arising from these assessments, recommendations on the applications are made to the ARRP. The ARRP considers the recommendations and then makes recommendations on the applications to the Director-General of the Department of Primary Industries.

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

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

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

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

# 1.5.2 Conduct of site inspections

Following the evaluation of written applications, the second phase of the process of assessing establishments is the site inspection. The aim of site inspections is to determine whether institutions and individuals are complying with the legislation. The *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* provides the criteria against which institutions are assessed. The range of items assessed includes: the membership, procedures and activities of the AEC; animal care procedures; animal research procedures; and the physical facilities for housing and using animals. An evaluation is also made of the wellbeing of the research or breeding animals.

Audit visits are arranged in advance and usually take from 1 to 4 days per site. Large establishments with multiple sites can take up to 2 weeks to inspect. Information about inspections conducted in the 2010–11 year is provided in Appendixes C and D. The dates provided represent days on site and do not include preparation and follow-up time, which is often considerable.

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

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

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

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

As soon as possible after the inspection, a detailed report is prepared. The report covers an evaluation of the AEC and an assessment of the animals' wellbeing, housing and holding, and their care and monitoring. Once the ARRP

has considered the report, recommendations may arise to impose additional conditions on the accreditation or licence. For example, a condition may be that appropriate post-operative procedures must be implemented.

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

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

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

The ARRP aims to carry out full audit visits for all institutions every 3 years, as well as unannounced visits by inspectors to follow up problems. In formulating its 2010–11 operational plan, the ARRP again recognised that staff availability within the Animal Welfare Unit would mean that reinspections would mostly be conducted on a 4-yearly basis. Reinspections concentrate more on procedures rather than facilities, unless new facilities have been built. Announced and unannounced spot checks and visits to look at specific aspects of operation may be carried out between full visits.

# 1.6 The Animal Research Act in schools and TAFE

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

### 1.7 Administration

The Animal Welfare Unit is a section within the Department of Primary Industries. The functions of the Animal Welfare Unit cover:

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

The Animal Welfare Unit can be contacted at: Animal Welfare Inspectorial Office Department of Primary Industries

95 Castle Hill Road

WEST PENNANT HILLS NSW 2125

Phone: (02) 9872 0571 Fax: (02) 9871 6938

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Animal Welfare Unit 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@industry.nsw.gov.au

In the 2010–11 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) Grace Cook, Licensing Clerk (part-time) Frances Kumbley, Branch Support Officer Tammy Kirby, Licensing Assessment Officer (part-time)

# Sydney:

Lynette Chave, BVSc, Leader, Animal Research Peter Johnson, BVSc, PhD, Veterinary Officer Janelle Townsend, Branch Support Officer (part-time)

### PART 2: REPORT ON WORK AND ACTIVITIES

# 2.1 Administration and planning

Administrative functions have varied from activities such as assessments of licensing and accreditation to formulating the ARRP's operational plan for 2010–11. 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 2008–11 (Appendix E) and Operational Plan for 2010–11 (Appendix F); and ARRP operating expenses (Appendix I).

### 2.1.1 Strategic Plan 2008-11

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

Details of the Plan are given in Appendix E.

# 2.1.2 Operational Plan for 2010-11

The ARRP Operational Plan for 2010–11, including performance status for each activity, is provided in Appendix F.

# 2.1.3 Liaison with organisations and individuals

The ARRP liaises with organisations and individuals to offer advice and to facilitate the implementation of legislative requirements and adherence to replacement, reduction and refinement principles.

During the 2010-11 year the main method of liaison was via discussions during, and feedback after, site inspections. Additionally recommendations were made in the process of assessing Accreditation and Licence applications.

# 2.1.4 Revision of Accreditation and Animal Supply Licence application procedures

In the 2010-11 period, a major revision of the application forms for Accreditation as an Animal Research Establishment and Licence as an Animal Supplier was carried out. A new form was developed which combined into one form the previous two separate application forms. This was with the aim of reducing the duplication of information requested in the two forms as well as better targeting information required to assess the suitability of applicants.

In addition to this, a revision was undertaken of the ARRP criteria for assessment of applications, and new criteria were developed.

The ARRP reviewed its procedures for assessing applications and agreed to continue with the system in place (see item 1.5.1: Evaluation of written applications)

In an effort to reduce administrative burdens that were not contributing to animal welfare, an amendment to the Animal Research Act 1985 was made, to allow Animal Supply Licences to be granted for a period up to 3 years. Previously the licences needed to be renewed annually. The 3 year period is in accord with the period for Accreditation and has the added advantage for establishments of enabling application for Accreditation and Animal Supply Licence to be made at the same time.

# 2.2 Assessment of applications

In 2010–11 there were 121 accredited animal research establishments and 42 holders of animal suppliers' licences.

During 2010-11 the ARRP considered and made recommendations to the Director-General on:

- 8 new applications for accreditation
- 32 renewal applications for accreditation
- 6 new applications for animal suppliers' licences

- 32 renewal applications for animal suppliers' licences.
- 6 extensions to existing accreditations and/or animal suppliers' licences.

### 2.2.1 LD50 testing

LD50 is a toxicity test used to determine the dose or concentration of a test substance—that is, the lethal dose—that is expected to kill 50% of the animals to which it is administered. For the purposes of the NSW *Animal Research Act, 1985* the definition of LD50 has been broadened. Included are all tests in which a potentially lethal dose of a substance will be administered and is expected to kill a proportion of the individuals in any group of animals to which it is given. In NSW such tests may be undertaken only under the approval of a properly constituted Animal Ethics Committee, with the concurrence of the Minister for Primary Industries. Applications for permission to conduct LD50 tests are evaluated by an ARRP subcommittee. Members of the subcommittee in 2010–11 were Mr Batten and Professor Dart. The subcommittee makes recommendations to the ARRP, which in turn advises the Minister.

In 2010–11 the subcommittee considered one application (6 tests) from an Accredited Animal Research Establishment.

The testing is used in quality control during the manufacturing of vaccines and in the development of new vaccine formulations. The majority of the tests are related to the manufacture of clostridial vaccines, used to protect livestock and companion animals against tetanus, enterotoxaemia, black leg and black disease that are rapidly fatal if contracted by unvaccinated animals. One of the tests is required for quality control of batches of equine salmonella vaccine, used to protect horses against salmonellosis. The ARRP recommended to the Minister that he approve the application on the following conditions:

- 1) Data is provided in graphical form <u>by 31 January 2012</u> with figures comparing 2009, 2010 and 2011 calendar years on the following:
  - a) The number of animals used for each quality control test in relation to a relevant measure to be determined by the company. The measure should provide information on the trends in numbers of animals used over time.
  - b) The number of animals used for development and research over time, with an explanation of the purpose eg replacement of a test, refinement of a procedure.
  - c) The total number of animals produced in relation to numbers of animals actually used in tests.
  - d) The number of animals that die in tests and the number euthanased as an early end-point in tests.
- 2) Any application for Ministerial concurrence to conduct LD50 tests between April 2012 and April 2013 must be presented by the company to the Emergencies and Animal Welfare Branch by 31January 2012.
- 3) The company continues, in consultation with the AEC, to identify and implement refinements to lessen the impact of existing approved tests on animals and methods of reducing the numbers of animals used in existing approved tests or replacing animal tests with alternatives and reports upon these to the Emergencies and Animal Welfare Branch by 31 January 2012.

### 2.3 Assessment of changes to AEC membership

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

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

In the 2010–11 year the ARRP assessed and made recommendations to the Director-General on the appointment of 70 members of Animal Ethics Committees.

# 2.4 Assessment of accreditation and licensing responses

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

In the 2010–11 year the ARRP made recommendations to the Director-General on 41 responses from accredited animal research establishments and licensed animal suppliers.

# 2.5 Subcommittees

The ARRP appoints subcommittees to deal with particular issues. They explore issues in depth and have discussions with relevant members of the scientific and broader communities. Subcommittees provide reports and recommendations to the full ARRP for consideration. Membership of subcommittees is largely drawn from the ARRP. External members of subcommittees are occasionally co-opted on a voluntary basis. Activities of subcommittees in the 2010–11 year included:

- Evaluation of applications for LD50 testing (Professor Dart and Mr Batten)
- Development of training material for researchers / teachers (Professor Rose)
- Preparation for a 2011 seminar for AEC members and executive officers (Professor Dart, Dr Fogarty and Ms Abbott).

# 2.6 Statistics on animal use

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

The requirements for reporting on animal use provide data on the numbers of animals used in all research projects in NSW, reported against the purpose of the research and the types of procedures in which they were involved. The aim of collecting these statistics is to give some indication of the level of 'invasiveness' of the procedures on the animals and to provide data 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 2010.

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

As an additional means of monitoring accredited animal research establishments, the ARRP recommended that the Annual Reports of AECs be submitted with the submission of annual statistics. The *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* requires that each AEC must submit a written report on its activities at least annually to the governing body of the institution for which it acts (Clause 2.2.40). In the 2010-11 year, the ARRP carried out an assessment of these reports, and provided feedback to the AECs and institutions.

# 2.6.1 Lethality testing

Accredited research establishments must keep figures on lethality testing and submit these to the ARRP. Lethality testing is defined as 'any animal research procedure in which any material or substance is administered to animals for the purpose of determining whether any animals will die or how many animals will die'. Lethality tests include, but are not limited to, LD50 tests (see item 2.2.1). Figures on lethality testing are included in Appendix G of this report.

# 2.7 Support for Animal Ethics Committees

The ARRP and the Animal Welfare Unit continue to use various means to support AECs in performing their duties. These means include the conducting of site inspections; the writing of policies, guidelines and fact sheets where a need is identified; the holding of seminars for AEC members; the maintenance of a website dedicated to animal research issues (Animal Ethics Infolink) and the supply of advice over the telephone or by correspondence.

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

Examples of these activities in the 2010-11 year are:

- \* The holding of a seminar for members of AECs (see item 2.7.2)
- \* The holding of a meeting of the ARRP Education Steering Committee
  On 26 August 2010 the ARRP held a meeting of its Education Steering Committee. Members of this committee
  included members and Executive Officers of Animal Ethics Committees. The purpose of the meeting was to further
  progress the development of training material for personnel involved in the use of animals for research.

In view of progress with the review of the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, which would have implications for the content of training material, further action on this initiative was put on hold until completion of the Code review.

# 2.7.1 Register of candidates for AEC membership

Finding interested and suitable members has been a problem experienced by a number of AECs. Categories C (Animal Welfare) and D (Independent) have presented the most difficulty. To help AECs to maintain the required membership, the ARRP suggested the establishment of a register of AEC members interested in joining other AECs. The Animal Welfare Unit has established a list of names, contact details and the categories that individuals believe they can represent. This list is available to all NSW AECs.

### 2.7.2 Seminar for members and executive officers of AECs

In April 2011 a seminar for members and executive officers of AECs was held by the ARRP in conjunction with the Animal Welfare Unit.

In an effort to ensure that the programme for the meeting met the needs of AECs, comment was sought from all NSW AECs on topics they wished to discuss and the format for conducting the meeting. Valuable feedback was provided and was used, in conjunction with comments gathered from evaluation forms completed at previous meetings, to structure a programme accordingly. The members of the ARRP subcommittee that worked on this project were Ms Abbott, Professor Dart and Dr Fogarty. The Australian Catholic University at its MacKillop Campus kindly hosted the meeting once again which was attended by almost 90 AEC members, representing 30 different Committees.

The programme was comprehensive, with presentations and discussions on AEC Annual Reports, Electronic Meetings & Systems used by AECs, and an update on the development of an education package for researchers. A major section of the day was devoted to discussions on weighing ethical decisions against the benefits of research. These discussions were led by Dr Simon Bain, who also made a significant contribution of time and expertise in the planning of this session. Breakout groups, examining case studies on this topic, provided the opportunity for interaction amongst attendees.

Some informative presentations on animal behaviour were also given, including the research of Professor Chris Evans and Dr K-lynn Smith on poultry behaviour and Dr David Slip on marine mammal training and behaviour. Ms Donnalee Taylor also shared the findings of her research on the behaviour of sheep.

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

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

Information on the meeting presentations can be found at the Animal Ethics Infolink website at www.animalethics.org.au .

### 2.8 Website: Animal Ethics Infolink

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

The website has been developed and is maintained in conjunction with the Animal Welfare Unit. The Animal Ethics Infolink site is accessible at <a href="https://www.animalethics.org.au">www.animalethics.org.au</a>.

# 2.9 Site inspections

A list of site inspections undertaken in 2010–11 is provided in Appendix C, and a list of ARRP members attending is given in Appendix D. There were 18 inspections conducted over a period of 19 working days. The length of these inspections ranged from one day to three days. The inspections included AECs and the facilities of 18 accredited animal research establishments /licensed animal suppliers.

The ARRP aims to carry out a routine inspection of each accredited animal research institution approximately every 4 years to maintain personal contact with institutions, AECs and researchers, and to carry out a complete audit of institutional operation under the *Animal Research Act 1985*.

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

# 2.10 Policies, guidelines and fact sheets

The ARRP and Animal Welfare Unit produce policies, guidelines and fact sheets to aid researchers, AECs, research establishments, animal suppliers and members of the broader community to understand and comply with the requirements of the animal research legislation. These documents can be found by following the links from the ARRP's website, Animal Ethics Infolink, <a href="www.animalethics.org.au">www.animalethics.org.au</a> (see Appendix J for a list of guidelines and policies).

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

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

The following policy was revised in 2010-11:

ARRP Policy 4: Non-research animals at Accredited Animal Research Establishments <a href="http://www.animalethics.org.au/policies-and-guidelines/information">http://www.animalethics.org.au/policies-and-guidelines/information</a>

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

A review of the 7<sup>th</sup> edition of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* was progressed by the NHMRC in the 2010-11 year. The Animal Research Review Panel had provided a submission to the initial targeted request from the NHMRC for comments.

# 2.12 Initiatives in replacement, reduction and refinement

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

# 2.13 Complaints

A formal process for making specific complaints about animal research is set out in sections 22, 28 and 42 of the *Animal Research Act 1985*. The process allows any person to make such a formal complaint. The complaint must be made in writing to the Director-General of the 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. No formal complaints were received in the 2010–11 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 Unit. Two informal complaints were received in the 2010–11 reporting period.

A summary of the complaints is as follows:

# Informal complaint:

# Treatment of a cat at a teaching establishment

An enquiry was received regarding the treatment of a cat at a teaching establishment. The issue related to whether there were suitable facilities for housing cats overnight and procedures for monitoring of animals if held overnight. The matter was referred to the responsible Animal Ethics Committee for investigation. The outcome was that the cat had been brought to the establishment for the purpose of rehoming, and had not been used for teaching, nor held at the premises overnight.

### Informal complaint:

### Cattle at an agricultural research establishment

A complaint was received about the condition and housing of cattle at an agricultural research establishment. The complainant was concerned that the cattle, which had had surgical implants carried out some years ago (rumen fistulae) may be experiencing pain and distress and that the paddock housing was not appropriate for them.

An investigation was carried out by the responsible Animal Ethics Committee and included an assessment of the cattle by an independent veterinarian. The cattle were found to be in excellent condition with no evidence of pain or distress. The housing of the animals in paddocks was appropriate and to be encouraged as a means of meeting the physical and behavioural needs of the cattle (as compared to intensive indoor housing).

The investigation did reveal some deficiencies in the routine monitoring of the cattle and the documentation of monitoring. As an outcome of the investigation, these deficiencies were rectified.

### 2.14 Attendance at other meetings

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

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

Animal welfare and science: an evolving construct. Keynote, ANZCCART Annual Conference, Hobart July 2010

# **APPENDIXES**

Appendix A: Dates of ARRP meetings 2010-11

Meeting number	Date of meeting
188	28 July 2010
189	6 October 2010
190	8 December 2010
191	23 February 2011
192	11 May 2011

Appendix B: Members' attendances at ARRP meetings 2010–11

Meeting number					
Member	188	189	190	191	192
Professor Margaret Rose (Chair)	*	*	-	-	-
Professor Andrew Dart (Chair)	*	*	Α	*	*
Dr Regina Fogarty (Deputy Chair)	*	*	*	*	*
Ms Stephanie Abbott	*	*	Α	*	-
Dr Magdoline Awad	*	Α	*	*	Α
Mr Peter Batten	*	Α	*	*	*
Ms Celeste Black	*	*	*	*	*
Dr Mike Fleming	*	*	*	*	*
Dr Craig Godfrey	-	-	-	*	*
Professor Annemarie Hennessy	Α	Α	Α	-	-
Professor Robert Mulley	Α	*	*	*	Α
Mr David O'Shannessy	*	*	*	*	*
Professor Jacqueline Phillips	-	-	-	Α	*
Dr Peter Rolfe	Α	*	*	*	Α

\* = Present

A = Absent

– = Not applicable

Appendix C: Dates of Inspections July 2010 – June 2011

Date
12/07/10
20/07/10
11/08/11
19/08/10, 8-9/09/10
14/09/10
11/10/10
11/10/10
8/11/10
9/11/10
10/11/10
28/03/11
30/03/11
13/04/11
17/05/11
31/05/11
02/06/11
14/06/11
28/06/11

Appendix D: Attendance of ARRP members at site inspections 2010–11

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

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

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

# **Goals and Strategies**

# 1. Effective and efficient implementation of the statutory requirements of the Animal Research Act 1985, the Animal Research Regulation 2005 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.
  1.1
- 1.2 Maintain a programme 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. 2.6

3

- 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.

  3.4
  6.1
  - 1.7 Prepare an annual report to Parliament on the operations and achievements of the Animal Research 1.4 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 2 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 1.3 out LD50 tests.

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

2.1 Promote an understanding of the roles and responsibilities of institutions in supporting the effective operation of their AECs.

2.2	Promote an understanding of the roles and responsibilities of institutions in actively pursing programmes for researchers and teachers that underpin their responsibilities under the Code.	3
2.3	Ensure there is effective participation by researchers and teachers, veterinarians, animal welfare	2
	representatives and independent representatives in a formal review of the justification and merit for all proposals for the use of animals for scientific purposes.	3
2.4	Promote and foster interaction between AECs and researchers/teachers.	2
0.5		3
2.5	Promote an appreciation of the ethos underpinning the Code through visits and all communications from the Animal Research Review Panel to institutions, AECs, researchers/teachers and animal care	2
	staff.	4
2.6	Promote an understanding of the roles and responsibilities of AECs through encouraging participation	2
	in AEC training programmes.	3
		4
2.7	By identifying problems and suggesting remedies, provide assistance to institutions, AECs and	2
	researchers/teachers to ensure that the principles, processes and responsibilities in the Code are actively embraced.	3
2.8	Promote discussion and understanding of key technical and ethical issues and foster interaction	2
	between AECs by maintaining a programme of meetings of Chairs of AECs and participating in AEC meetings during site inspections.	3.2
		3.3
2.9	Review the membership and operation of individual AECs to ensure they are operating effectively.	1.1 2
	Develop and promulgate evidence-based guidelines to assist AECs, researchers and teachers to ctively	4
	implement the 3Rs.	
2.11	Promote a critical review of the operation of AECs by the institution with a view to maximising their effectiveness.	2
3. R	esearchers and teachers considering using animals are aware of and actively apply the	
prin	cipals set out in the Act, Regulation and the Australian Code of Practice for the Care and	
Use	of Animals for Scientific Purposes.	
3.1	Promote an understanding of the roles and responsibilities of researchers/teachers through participation in education programmes, to foster an awareness of ethical and scientific issues and the implementation of the 3Rs.	3 4
3.2	Maintain the "Animal Ethics Infolink" website as a resource for AECs, researchers and teachers and members of the community.	3.1

4. M	ethods that complement or replace animal use are used wherever possible	
4.1	Encourage AECs critically to assess the adequacy of researchers'/teachers' attempts to identify alternatives to animal use.	2 3
4.2	Encourage greater awareness of the use of alternatives to animals in research and teaching.	2
		3
4.3	Collate and disseminate information on alternatives to animal use.	3.1
4.4	Promote consideration of funding for development and validation of alternatives.	
5. Pr	rocedures involving animals are regularly reviewed and refined to minimise the number of	
anin	nals required and to reduce the impact on individual animals	
5.1	Encourage a critical review of the design of experiments before protocols are submitted to AECs.	2
5.2	Ensure close scrutiny by AECs of breeding programmes to minimise overproduction of animals.	2
		3
5.3	Ensure close scrutiny by AECs of the competence of researchers to carry out specific procedures	2
		3
5.4	Promote the critical evaluation of the monitoring of animals being used in procedures.	2
		3
5.5	Promote the critical evaluation by AECs and researchers of the impact of the type of housing / holding on experimental animals and awareness of its implications for experimental results.	2 3
		4.1
	hen animals are used in research and teaching, their well-being is promoted and there is the antic npt recognition and alleviation of pain and distress.	ipation,
6.1	Promote the implementation of strategies which will foster the well-being of animals and which will foster the development of appropriate risk management assessments related to pain and distress in animals.	3
6.2	Ensure that AECs and researchers/teachers focus on the possible impact of procedures at the	2
	planning stage and implement appropriate strategies for monitoring and alleviation.	3
6.3	Promote awareness by researchers / teachers and animal care staff of signs of well-being, pain and	2
	distress in animals.	3
6.4	Promote the use of appropriate analgesia and anaesthesia by facilitating access by	2
	researchers/teachers to information resources.	3.1
6.5	Promote awareness of the effects of handling and other interactions with humans on levels of pain	2
	and distress and the use of strategies to minimise adverse impacts.	2

6.6	Monitor and identify deficiencies in anticipation, recognition and relief of pain and distress during site visits and ensure deficiencies are rectified, including by provision of pre-operative analgesia where appropriate.	2	
7. Hi	gh standards of housing and routine care are established for animals used in research and		
teac	hing		
7.1	Evaluate housing and routine care through the ongoing site visit programme.	2	
7.2	Develop and disseminate evidence based guidelines for housing and routine care.	4.1	
7.3	Actively participate in the development and review of appropriate national and international standards for housing and routine care.		
8. A	nimals 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	1.2	
com	plaints.	2	
8.2	Develop and disseminate appropriate educational material.	3	
	ne community (research, teaching, veterinary, animal welfare and lay) has access to information al nal use for research and teaching in NSW	oout	
9.1	Provide information in the annual report on ARRP activities and achievements, areas of concern to the	1.4	
9.1	Animal Research Review Panel and statistics on animal use.	1.5	
9.2	Identify options for disseminating information about specific issues of interest and concern both broadly and to specific groups (researchers, teachers, veterinarians, animal welfare, lay).	3	
9.3	Review and maintain a web site for the dissemination of information.	3.1	
	Provide opportunities for and encourage the community (researchers, teachers, veterinarians, animal welfare, lay) to have an input into legislative review, development of standards for housing and care and policy development.	4	
9.5	Ensure that information about animal use provided by the Animal Research Review Panel is in lay terms where appropriate.		
9.6	Encourage institutions to provide information about their animal use direct to the general community.		
10. The approach to administration of animal research and teaching is harmonised between State and Territory regulatory and funding bodies.			
	Promote interaction between State and Territory regulatory and funding bodies	6	

Appendix F: ARRP Operational Plan July 2010 – June 2011

Activity	Measure of Performance	Time Frame	Status		
1. Mandatory					
1.1 Review incoming applications for accreditation and licence	Recommendation to Director-General	3 months (new) 2 months (renewal)	Applications processed and recommendations made to the Director-General.		
			Additional: Revision of application forms and criteria for assessment of applications.		
1.2 Investigate formal and informal complaints	Recommendation to Director-General	Interim or final recommenda tions within 3 months	2 informal complaints received and finalised.		
1.3 Review incoming applications to conduct LD50 tests	Recommendations to Minister	3 months	All applications reviewed and recommendations sent to the Minister.		
1.4 Prepare annual report for 2009- 2010	Report submitted to Minister	December 2010	Report prepared.		
1.5 Prepare statistics on animal use for 2009	Statistics collated	December 2010	Statistics collated.		
2. Inspections	2. Inspections				
2.1 Conduct site visits of all accredited establishments on a 3 – 4 yearly basis	Number of establishments inspected.	Ongoing	18		
	Number of days for inspections		19		
	Total number of establishments not inspected within the last 4 years (in-State, active, with own AEC)		5		
2.2 Inspect new establishments applying for accreditation prior to or within 2 months of accreditation (for those establishments in-State, active and with own AEC)	Number of new establishments inspected	Ongoing	1		
2.3 Conduct site visits of selected independent researchers with animal holding facilities	Number visited	Ongoing	2		

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 "Site Inspection /Accreditation Responses" section of ARRP agendas.	
2.6 Assessment of AEC annual reports	Assessment carried out	December 2010	2009 reports assessed and feedback provided to establishments.	
3. Education				
3.1 Maintain ARRP website	Site maintained	Ongoing	Website maintained.	
3.2 Develop training material for researchers/teachers via reference group	Reference group meetings held	June 2011	Meetings held. On hold pending review of the Code of Practice.	
3.3 Consider content of AEC learning package in light of researcher training material developed.	Content considered	After development of researcher training material.	Await development of researcher training package.	
3.4 Hold meeting for members of AECs	Meeting held	June 2011	Meeting held April 2011.	
4. Policies and guidelines				
4.1 Finalise housing guidelines	Draft of mouse document finalised	March 2011	Guidelines finalised.	
4.2 Develop policies/ guidelines where strong need identified (maximum of 2)	Developed as need identified	Ongoing	None identified.	
4.3 Revise current policies and guidelines	Policies and guidelines revised	June 2011	Revision in progress.	
5. Legislation				
5.1 Consider requirements of Government Information (Public Access) Act 2009	GIPA Act considered	March 2011	Determined no action necessary.	
6.1 Continue liaison with NHMRC	Contact with NHMRC maintained	Ongoing	Liaison via Code Reference Group meetings.	
6.2 Continue liaison with APVMA via the Animal Welfare Working Group	Contact with APVMA maintained	Ongoing	No action.	
6.3 Refer items to AAWS Advisory Committee as necessary	Items referred	Ongoing	No items identified.	

# Appendix G: Animal use statistics 2010

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 2010.

# 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.)

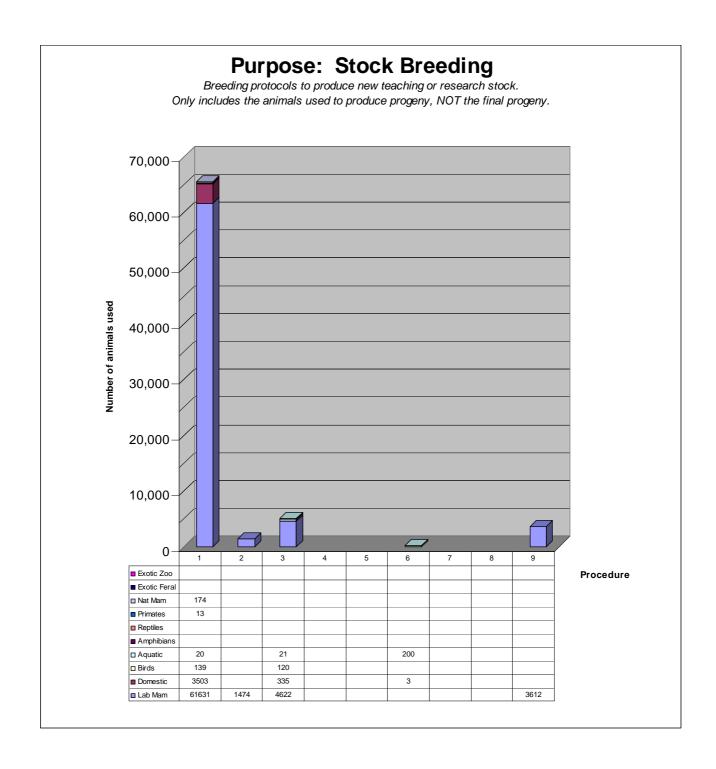
Examples

Pre-registration efficacy or toxicity testing of drugs and vaccines

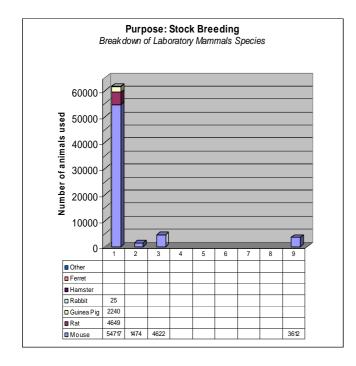
# Data collection: procedure categories and guidelines used for classification

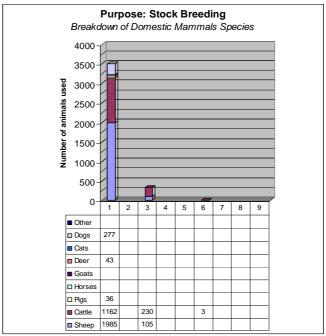
1. Observation involving miner interference	C. Miner physiological shallower
1: Observation involving minor interference	6: Minor physiological challenge
Animals are not interacted with, or, where there is interaction, it would not be expected to compromise the animal's welfare any more than normal handling, 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.	

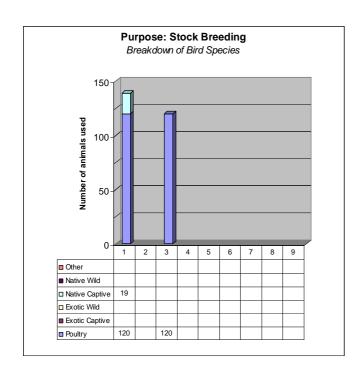
The following graphs (one for each purpose) show the numbers of animals used against the category of procedure (Categories 1 to 9).

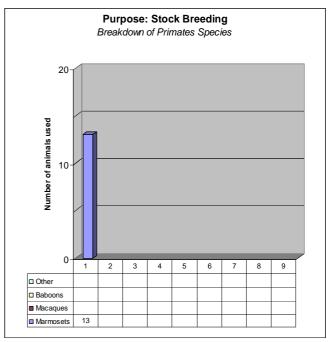


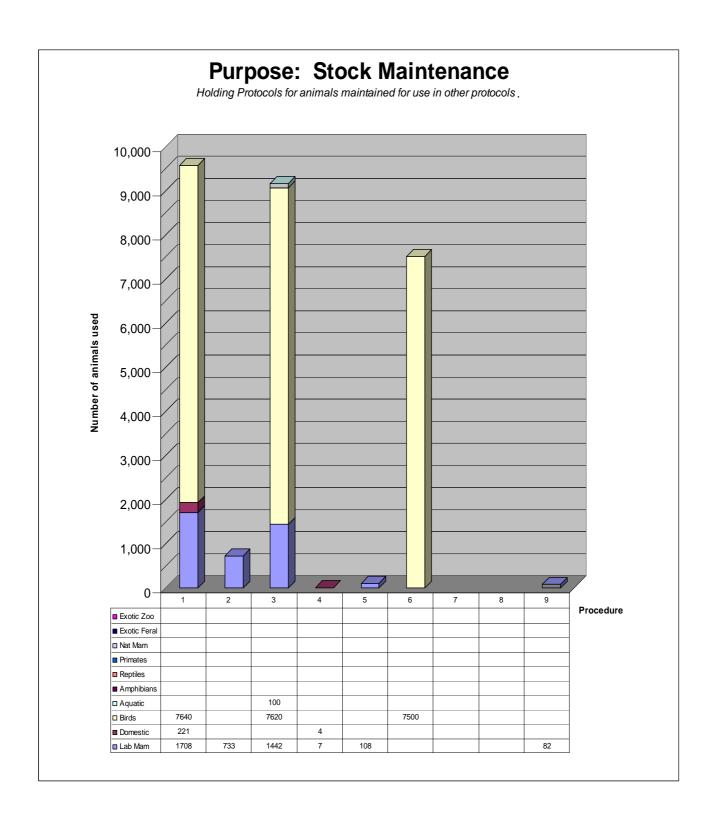
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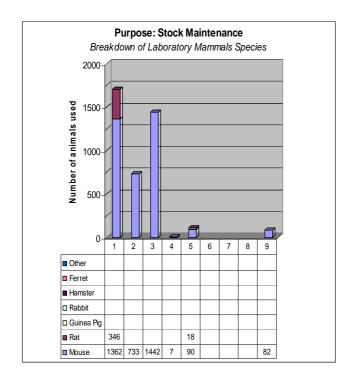


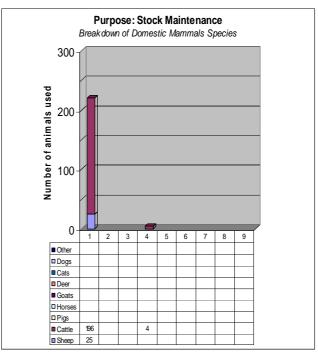


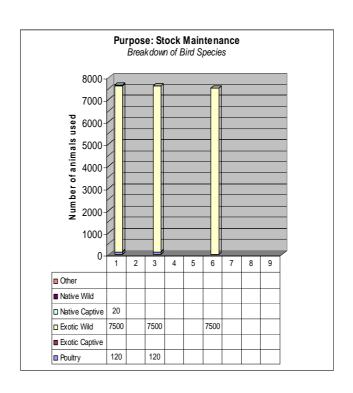


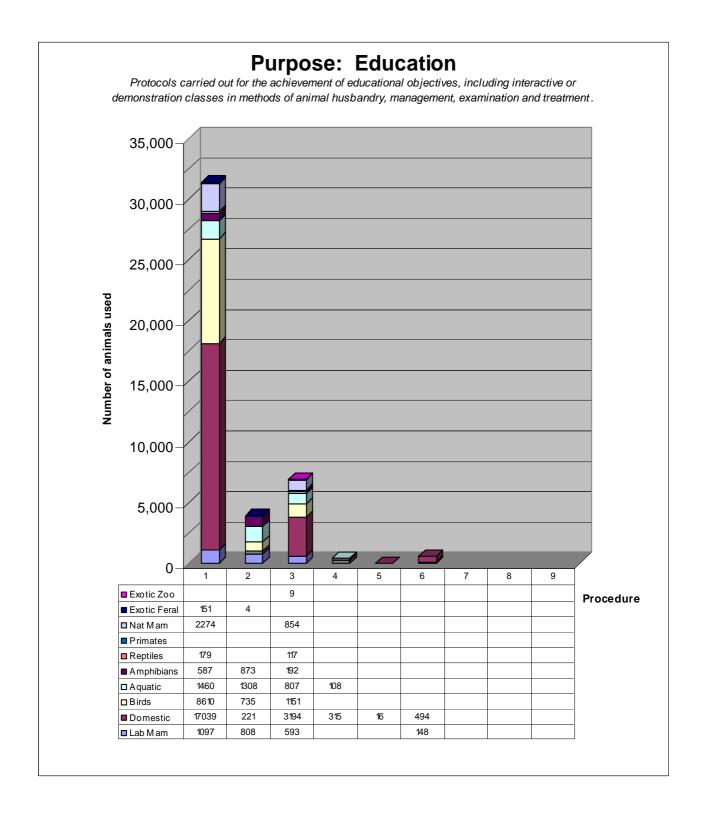


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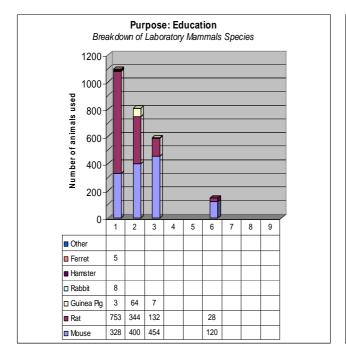


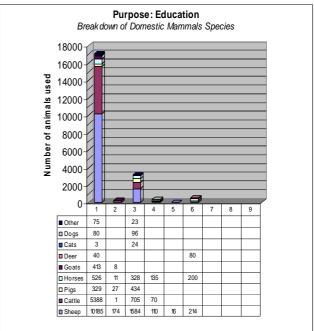


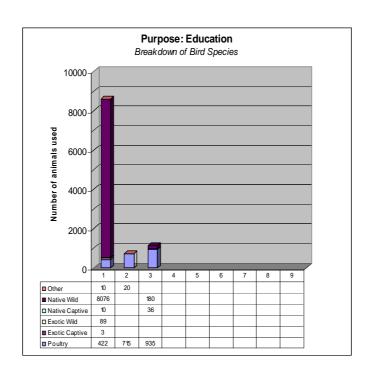


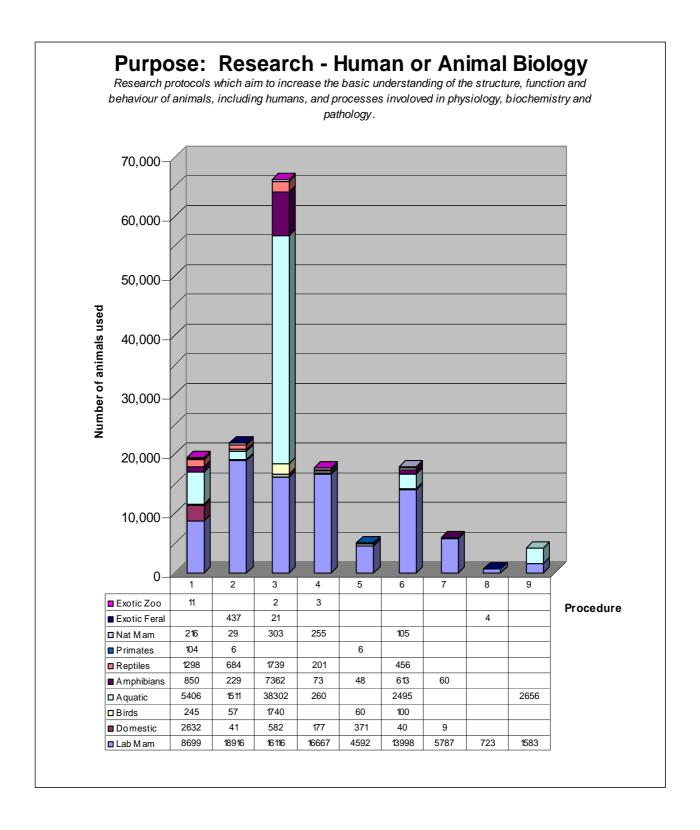


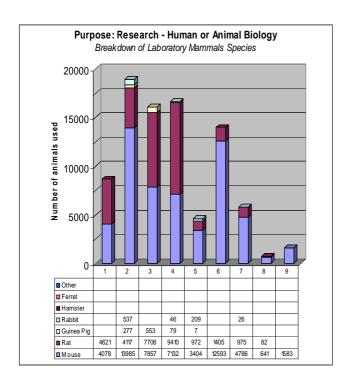
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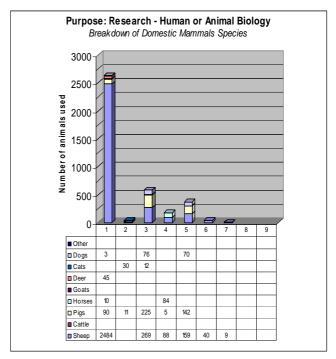


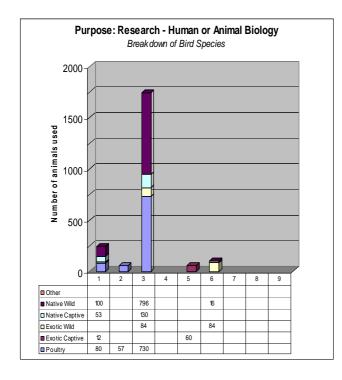


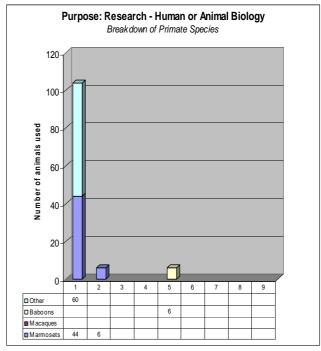


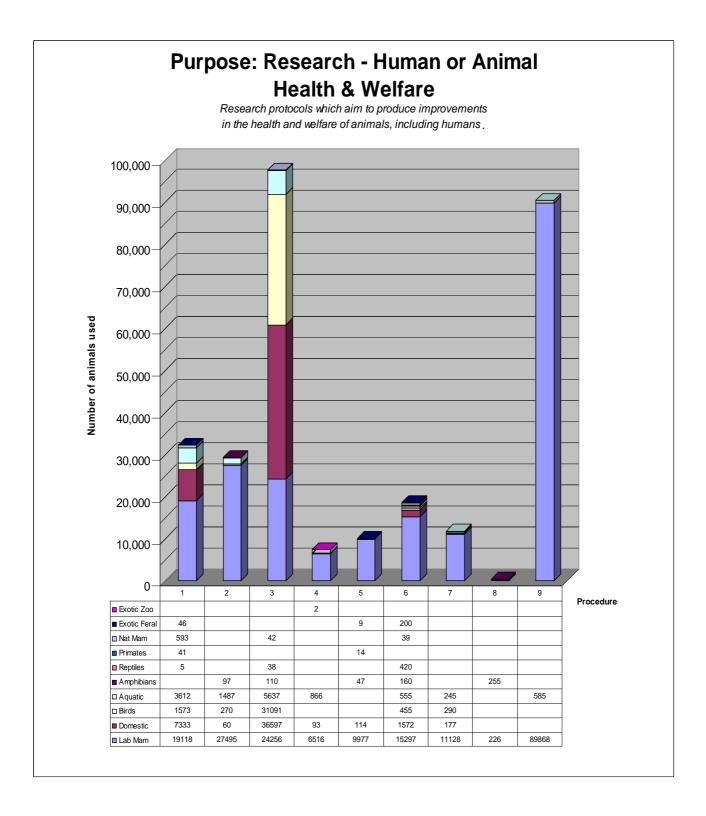


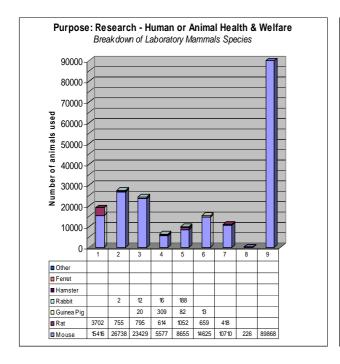


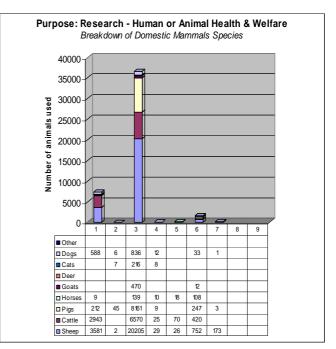


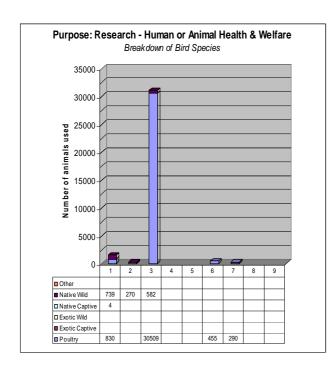


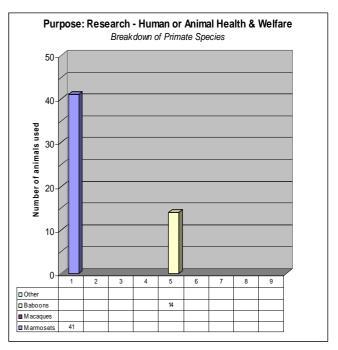


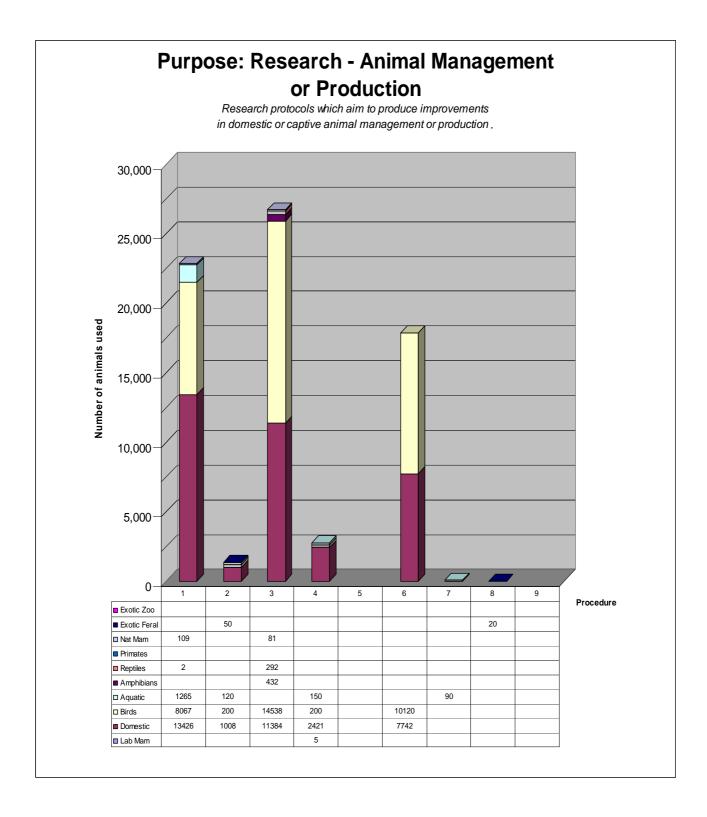


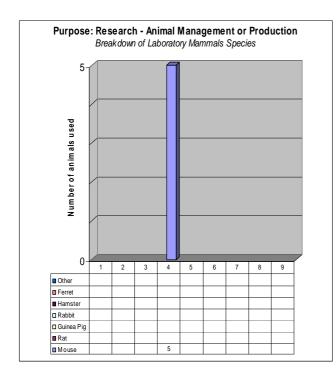


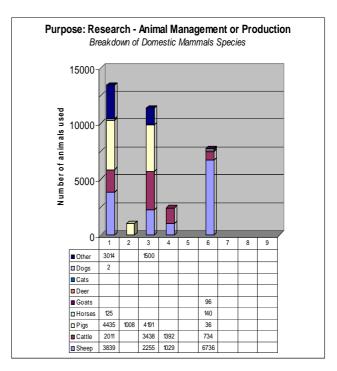


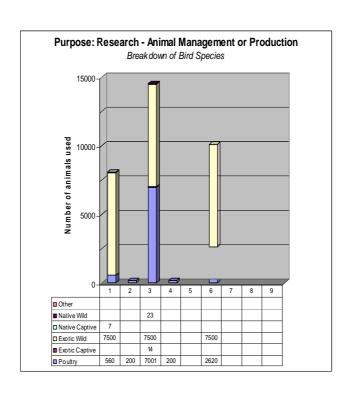


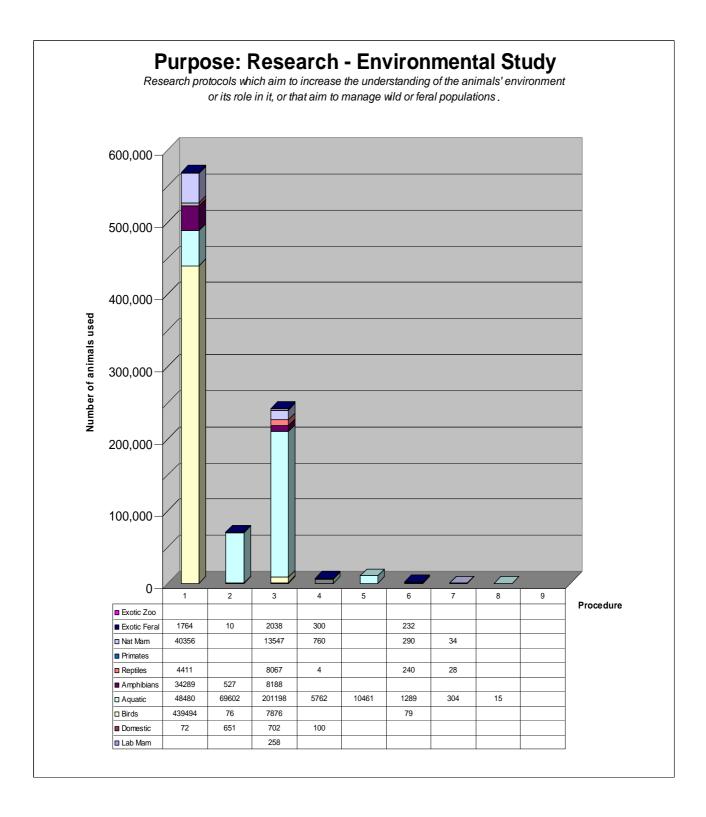


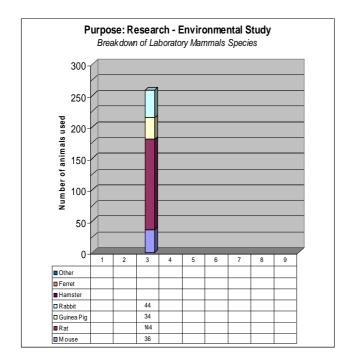


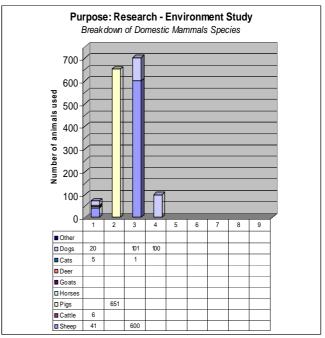


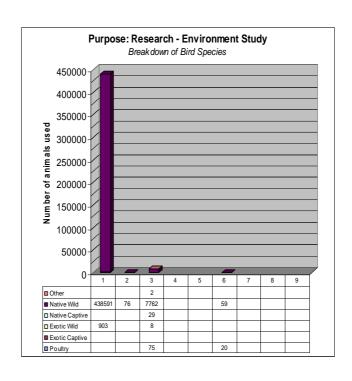


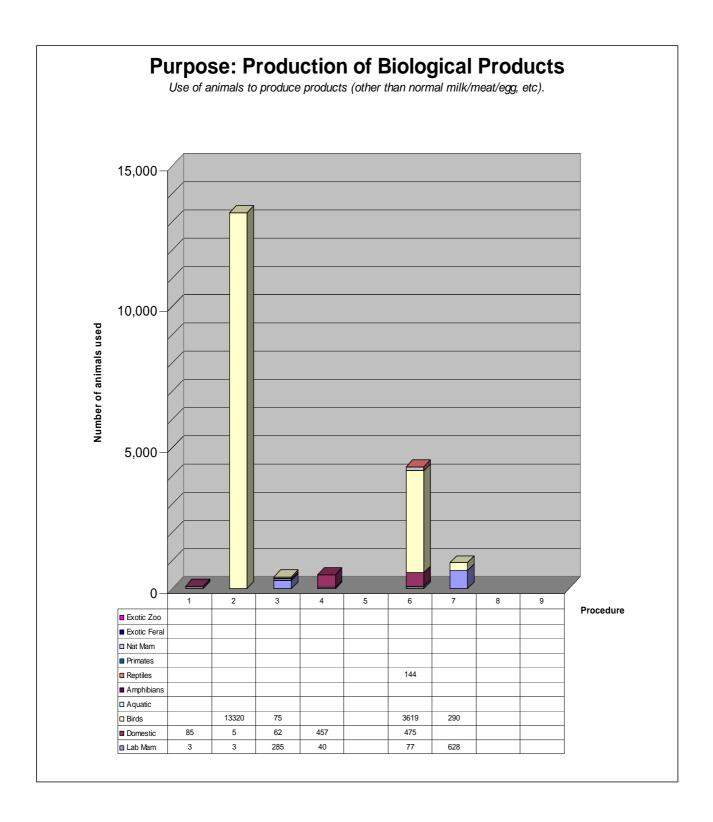


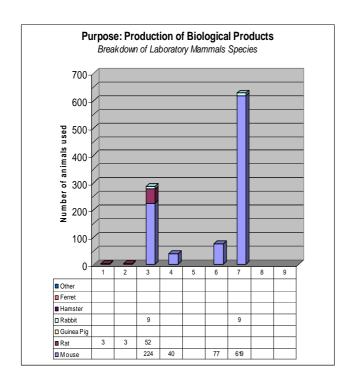


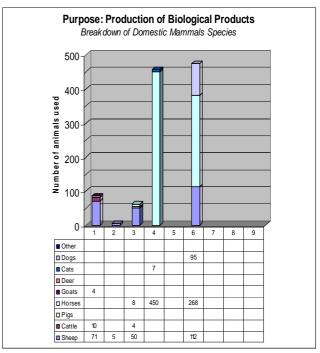


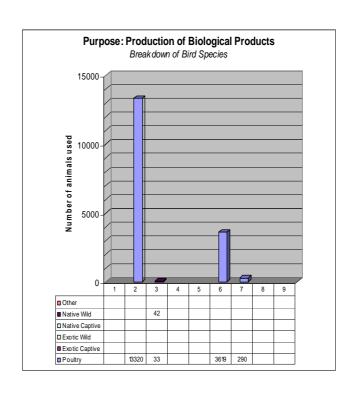


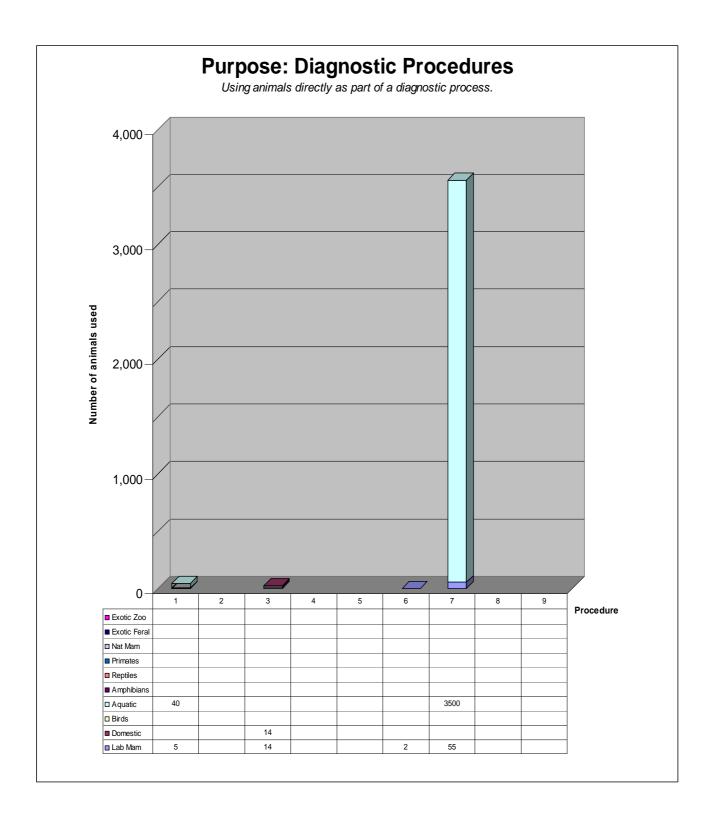


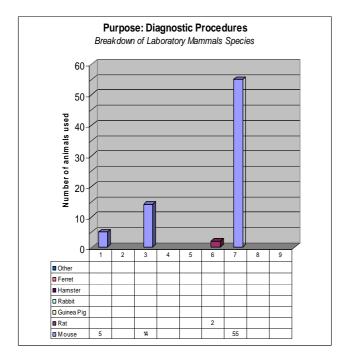


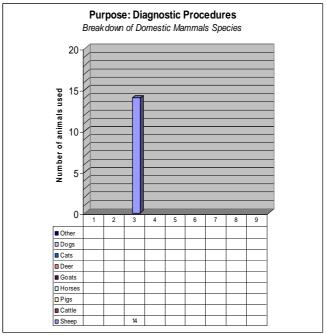


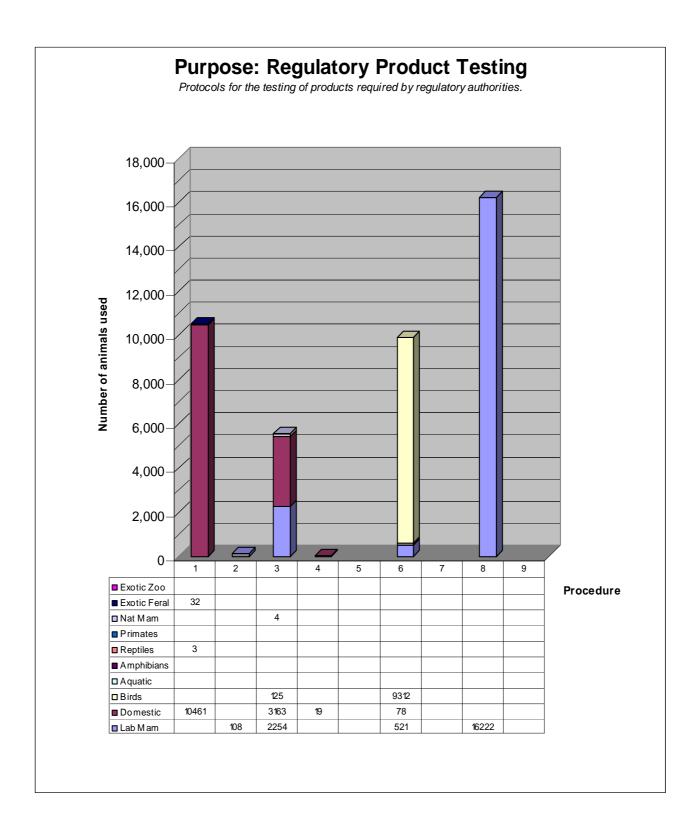


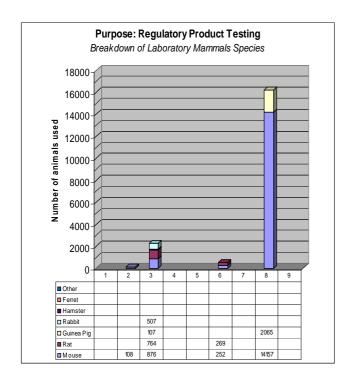


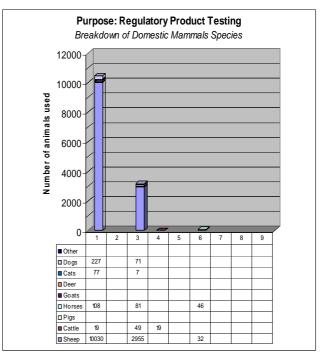


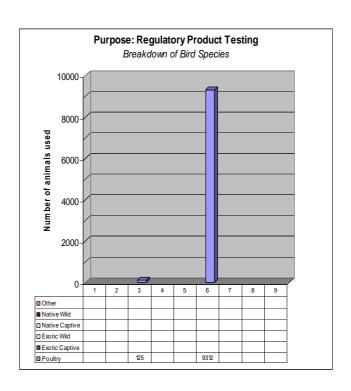












# **LETHALITY TESTING – 2010**

The Animal Research Act 1985 defines a 'lethality test' as 'an animal research procedure in which any material or substance is administered to animals for the purpose of determining whether any animals will die or how many animals will die'. Lethality tests include, but are not limited to, LD50 tests.

The following are the figures reported on animal use for lethality testing in 2010.

Species	No. used	No. died/ euthanased	Procedure	Justification	Alternatives
Mice	4194	1674	Serum neutralisation test in mice: Susceptible animals are challenged with test toxin/antibody dilutions to determine antibody titre.	Regulatory testing is 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	2310	1051	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 decisions during manufacturing process.	No alternatives available at this time.
Mice	120	61	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	2060	524	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 inprocess or development material to determine suitability for further manufacture.	This test is based upon regulatory guidelines. No alternatives available at this time.
Mice	7155	3618	Total Combining Power test in mice: Susceptible animals are challenged with antigen/toxin/antibod y 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.
Northern Trout Gudgeon	5	5	Exposure to dry cane toad skin.	Assessing the toxicity of dead cane toads.	There will be no further lethality tests needed to assess toxicity of dead cane toads.

### 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 2010 reporting year. They are under the headings of 'Replacement' (of animals with other methods), 'Reduction' (in the number of animals used in specific protocols) and 'Refinement' (of techniques used to reduce the impact on animals).

#### Replacement

Use of cadavers - leg parts of horses were sourced from local abattoir for use in shoeing and/or hoof health in equine studies.

Mannequins, audio-visual materials, taxidermy substitutes for live animals where trainees were inexperienced and the learning outcomes able to be met by substitute means.

Ear-tagging of sheep was practised on cardboard and leather.

Injection pads were used to practise medication injection for a range of species.

Prior to field work activities, students were familiarised with both the animals and the handling techniques to be used. This included visits to zoos, aquaria and museums to become familiar with the animals, demonstrations of the use of equipment and DVDs showing the use of research methods. Actual field work was kept to a minimum.

Many experiments were replaced with in-vitro experiments using immortalised cell lines

When possible, in-vitro studies are performed prior to research on animals.

Oocytes for training purposes are collected from the abattoir.

Researchers have moved towards donated human tissue - reducing the number of mice required.

Devices used for surgical training for vascular anastomosis as an alternative to using rats.

Use of a 'dummy' cow to conduct rainfastness studies by sourcing cattle hides from the abattoir, fastening them to a wooden cow shape, treating with product, expose to 'rain' or U/V then analyse result.

Use of cadavers for training in surgery or other invasive procedures.

The adoption, where possible, of an alternative approach to using live animals to gather the required data for a project by opportunistically collecting road-killed individuals fresh enough to provide viable samples for DNA and/or morphological analyses. Thereby reducing the total numbers of live individuals that needed to be captured and handled in the field.

We have been successful in setting up sources of human adipose tissue from human liposuction clinics within Sydney. This gives us regular access to fresh adipose tissue and has largely replaced the use of rats within our research program.

More tissue culture work (in vitro) being used routinely and less mouse inoculation.

Use of audio-visual material such as videos, slides, interactive computer programs.

Use of abattoir specimens and cadavers.

Use of plant tissue as a replacement for animal tissue for certain enzymatic assays.

Due to regulations on monoclonal antibody production and the necessity for researchers to investigate alternative methods to ascites model using in vitro techniques such as bioreactors, wave bags etc we have seen a large reduction in the number of animals for these purposes.

Reduction of the use of animals for surgical training purposes through the development of the pig 'mannequin'.

The use of computer simulation in teaching subject in place of cane toads.

### Reduction

Statistically based sampling that determines the minimum number of units required for 95% confidence of

detecting a significant difference.

Close scrutiny of the number of animals requested and Biometrician's comments reviewed to ensure numbers are adequate to obtain the desired statistical outcomes, to minimise the number of animals involved in trials and to ensure that trials do not have to be repeated unnecessarily.

Similar studies have shared the same control animals.

Continued improvement in statistical analysis for the use of the minimal number of animals.

Keeping the number of animals kept on campus to the minimum required to simulate a mini colony.

New and improved technology has continued to be developed during the year, in an attempt to improve the efficiency of stored serum processing to hopefully reduce the numbers of animals used in the production process.

As several people in our department work with this line of mice we coordinate our experiments so that we can share organs for several different experiments.

Tissue sharing was utilised to minimise the number of mice needed.

We have reduced numbers by tissue sharing and monitoring immune cells from blood rather than taking other tissues.

The use of a new flow cytometer allows more immunological parameters to be studied per sample of cells, allowing for less animals to be used.

This year we have reduced the number of animals as there seemed to be less variations in disease at earlier time-points, allowing us to gain statistical significance with smaller numbers.

The culturing technique has been refined to improve the numbers of surviving and proliferating cells in culture, which has meant that fewer animals are required per experiment to obtain sufficient numbers of stem cells

Pilot studies were performed that indicated that some of the full studies would not be worthwhile, or to modify the study to a smaller cross-sectional analysis, resulting in less mice being used.

We have a policy where we always test our hypotheses *in vitro* prior to live mouse experiments as if the *in vitro* method does not work, it is often unlikely that the *in vivo* method will.

We are developing techniques for primary and immortalised cell lines from our GM animals for our signalling studies. This will ultimately reduce animal usage.

We introduced the use of cell lines to perform validation of scientific methods and for optimising techniques.

Used surplus material for second experimental procedure.

Immortalisation of ovine intestinal and abomasal epithelial cells from neonatal lambs.

Developing cell lines to be used as models, thereby decreasing the number of animals required.

Comparison of different methods for transformation of bovine cells to create bovine germs line cell lines for experimentation in vitro.

A calf that died in the animal house required a post mortem and was used in the post mortem training and techniques workshop, while the sheep used in the workshop were going to be euthanized as a part of another experiment.

Maintain an ongoing program aimed at rationalising testing which has focussed on eliminating Quality Control testing which is not essential to meet product release requirements. This program covers both lethal and non-lethal testing. In addition, in all cases where clear test outcomes are not obtained upon initial testing, a critical assessment is made to confirm the necessity to perform repeat testing before retesting occurs. It should however be noted that whilst progress has been made in this regard, there remains a minimum amount of testing necessary to meet regulatory requirements for the assessment of in-process and final product prior to release.

A researcher indicated that their teaching activities were placed in separate semesters to allow for the reuse of animals and to avoid excessive handling of individual animals. The minimum number of animals required to meet APVMA guidelines is always used.

The AEC is proactive in requesting pilot studies to refine numbers of animals used where there is a real expectation of gain in clarifying research outcomes or numbers of animals used as a result of doing a pilot study. Reports of study outcomes can then be used to reduce or refine animals numbers in subsequent research.

The presence of a biostatistician on the AEC has enabled the AEC to provide refinement of statistical approach to researchers in a number of protocols, thus reducing the risk of wastage due to invalidity of data necessitating repeating of experiments.

The introduction of a new teaching protocol reducing the overall number of animals needed for research purposes.

Filming of procedures for teaching purposes to reduce the number of live animals required.

Rats re-homed to for use as breeding and education animals for training animal science students.

Tissue sharing both within the institution and externally with other institutions.

Breeding programs are designed and maintained to produce stock for orders only to reduce numbers and overproduction.

Genetically modified animals are bred as the desired genotype as far as possible to reduce numbers.

Animals used for courses are shared between multiple participants to achieve the best learning outcome whilst reducing overall numbers of animals used.

Increasing ability to conduct 'cross-over' studies by using the same animals after a wash-out period. This takes a little longer but reduces the numbers of animals required.

Early stage discovery models can potentially use smaller groups of animals.

Keep records on palatability of products which may alleviate need for separate study.

In 2010, fewer animals were used in teaching projects with one of the animal facilities electing to use excess stock humanely killed from in-house breeding colonies for teaching purposes. In addition, Investigators are also encouraged to harvest and share tissues in instances where animals have been humanely killed.

Recommendation to researchers to only request minimum number of matching timed-mated outbred female mice to avoid any surplus.

Use of surplus males for other scientific purposes, either as stud males or vasectomised males for use in production of pseudo pregnant females.

Archiving by cryopreservation for genetically modified mouse lines no longer required or seldom used.

Monthly breeding meetings are held with research groups to allow breeding to be adjusted promptly to avoid unnecessary litters being produced.

Mice with an unrequired genotype throughout the facility are utilised as either: control mice for experiments, tissue sharing, cryo-preservation or training where possible.

Drawing on previous experimental data to determine the number of animals required for new projects.

The use of power and sample size calculation (PS power and samples size software) with reference to the parameters of the project to determine the number of animals in each group to determine the percentage difference between the control and treatment groups.

The use of pilot studies to reduce the overall number of animals needed for studies by, for example, carrying out repeated measures of blood flow over the 24 hours of interest on a small number of animals to initially characterise this flow, the most physiologically relevant time points and those which show the greatest difference between groups can then be selected in order to reduce overall animal numbers in subsequent studies.

Use of serial sections to allow work up of multiple immunohistochemical techniques from single animals.

Accessing tissues in the Australian Wildlife Tissue Collection (SA Museum).

Fetal brains used for the assessment of neurosteroidogenesis and preterm birth and tissues and fluids will be available for use in other projects investigating aspects of labour. Project designed so that tissues and EMG recordings from these animals may be used as controls for subsequent studies involving therapeutic treatments.

The use of animals to their full potential with numerous tissues being collected at postmortem for subsequent analysis. These include brain, lungs, heart, liver, kidneys, spleen, skin, vessels, adrenal glands, placenta, umbilical cord, uterine tissues and fetal membranes.

The use of a seine net and limiting its deployment to ensure than no more than a limited number of fish were taken.

Sections of tissue frozen for subsequent protein analyses.

The use of Spontaneously Hypertensive Rats (SHR) shown to produce the most consistent sized infarcts in other stroke models, thereby reducing the number required to determine statistical significance.

Undertaking in vitro studies prior to sonothrombolysis experiments to determine the optimum parameters for ultrasound prior to working in the rat model.

The use where appropriate of animals that had been hormonally primed so as to maximise the number of oocytes that could be recovered.

By recording from targeted orexin neurons in mice it was anticipated that the numbers of rats needed for these studies will ultimately be reduced. Although some follow-up studies in rats may be necessary, this approach should dramatically improve the recordings from confirmed orexin cells and reduce overall rat numbers.

The testing of a hypotheses using two cohorts of animals made possible through the use of state-of-the-art technology that achieves multiple measurements on one sample and a design that enables multiple parameters to be assessed in one animal.

Trialled use of older SPF birds to produce Eimeria oocysts resulting in much higher yields (2 to 10 fold) with corresponding reduction in bird numbers in 2011 year expected.

Many animals euthanized after reaching a pre-determined study end point have had tissues taken for histological studies different to the primary study in which the animal was used. Cadavers are kept frozen/formalin preserved for 1-2months following euthanasia for the opportunity to re-use the animals for histological studies.

The Committee continues to maintain a Biological Non-Human Tissue Database through which researchers are able to share excess tissue, thus replacing the use of live animals with the use of stored tissue. In addition, to make these tissues more widely available, the Committee has joined the Ethitex tissue sharing database which facilitates tissue sharing throughout Australia.

Approval of new techniques for embryo freezing rather than continuous breeding to maintain lines.

The Committee has minimised animal usage by consolidating breeding protocols to ensure no overbreeding which in turn reduces the need for culling.

We have adapted our methodology around target animal safety testing with novel vaccines to potentially reduce the number of animals used. Instead of enrolling 10 animals per vaccine group up front, we now enrol 5 per group and only if the safety parameters are met are the second 5 animals enrolled in the study. This procedure was undertaken for a novel vaccine safety and efficacy study in sheep in 2010 and several vaccine groups were excluded after the first phase of the study, reducing the use of sheep by 5 animals per group.

Routine husbandry procedures to be performed on animals coordinated with teaching activities.

Sharing of tissue among researchers.

Obtaining more data from the use of fewer animals by combining objectives.

The introduction of a Bio-Statistician to our Committee 2 years ago has paid demonstrable dividends. He has been able to work directly with Principal Investigators and help design efficient and effective Protocol Applications that reflected minimal use of animals while maintaining meaningful statistical numbers.

The committee has focused strongly on experimental plans throughout the reporting period and has

required researchers to supply statistical evidence to determine animal numbers that are involved in experiments. This has led to both refinement of experiments and a reduction in total numbers used. In addition AEC are encouraging researchers to develop projects in a staged process, where results are presented to the AEC at the completion of a stage prior to the commencement of the next stage. This prevents projects from moving forward with undue haste which might involve unnecessary use of animals.

9 Shared Tissue Notifications were received ie notices of sharing tissue from deceased rats and mice with other researchers eg blood, skin, brains, lenses, livers and hearts.

Transfer of unused animals between protocols instead of ordering additional animals.

Data from previous studies were used to reduce the number of animals used.

Pilot procedures using reduced animal numbers for new protocols to test their validity.

Analysis of previous studies via literature analysis.

Power analyses are often submitted as part of the applications, which demonstrate how researchers and teachers calculate the most suitable numbers of animals required to give valid data.

This study was conducted on commercial pasture beef properties. Protocol design included a statistical power calculation that dictated the minimum number of animals to ensure statistical validity of the data.

This study was conducted to satisfy a regulatory requirement. This was a companion animal product field efficacy study and was conducted in the minimum number of households to satisfy Regulatory requirements. Careful screening of households was conducted prior to the study to ensure that households met study criteria.

Research involving the use of dogs in NSW was undertaken in association with active Veterinary cases and utilised excess from routine samples as far as possible. In this way reducing both use and impact on animals.

Utilising the animal tissue from euthanized fish to conduct post mortem to collect other useful data, such as internal effects of the fish of hook ingestion and other environmental indicators from the fish.

We obtain animal eyes from other labs when they are euthanasing animals. The use of these eyes means we do not need live animals for that project.

Reduction of animal usage numbers by use of each animal as its own control.

Reduction in animal usage numbers through protocol design which required fewer animals per study group for later time points as animals grew and were able to provide more tissue for study.

Reduction in animal usage by the sharing of tissue from euthanased animals (both diabetic and control) at the conclusion of this almost 20 year study.

### Refinement

Close monitoring of animals and development of monitoring checklists to identify adverse reactions in animals. The AEC will place conditions on projects at the approval stage to ensure that any pain or distress to animals is alleviated quickly in projects where it is impossible to eliminate this completely.

Use of experienced veterinarians and other staff.

Restraint time and dose rates kept to a minimum.

Use of adjuvants known not to produce adverse reactions.

Procedures used routinely so that animals become accustomed.

Close scrutiny of the volume of blood collected.

Use of the saphenous vein method as the standard technique for blood collection in rodents.

A number of studies conducted on animals at the owner's property to minimise any possible stress.

Appropriate training in handling & reduction in the number of blood samples taken on individuals.

The number of occasions that an animals is handled was minimised eg lambs are tagged and drenched at the same time to avoid having to recapture.

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

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

Use of Thermal Threshold Technology to assess pain in animals. This is a non invasive technique using technology developed in the UK and replaces other technology such as hot plates and carrageenan injections.

We have refined our research procedures to include daily and twice daily monitoring of animals receiving neurotoxins, injecting animals with saline to ensure adequate hydration, the use of heating pads to aid body temperature regulation.

We have been able to decrease the strength of streptozotocin to minimise the severity of induced diabetes. We also realise that two blood glucose readings above 16.7mmol/L are adequate as an endpoint, as opposed to three.

We observed that injecting the tumour cells into anaesthetised mice provided less stress for the animals and easier handling for the researcher.

Smaller minipumps were implanted in the mice to administer the drugs, since we were able to dissolve the drugs in a more concentrated solution, with no adverse effects.

We have developed a very robust transplantable cell line model whose cells are Luciferase and GFP labelled, so tumour burden can be tracked in-vivo via a luminescence imaging machine. This allows us to carefully track disease burden.

We refined our research procedures to reduce the amount of trauma during surgery by reducing the size off the incision, perfecting the dose of anaesthetic and by reducing the total time of surgery.

Accommodation of research horses in a large paddock on a professional horse spelling/pre-training farm.

Re-homing of retired research horses to suitable new owners.

Spontaneous collection of naturally voided urine from horses for the purpose of drug analysis.

Animals showing undue distress or pain that cannot be alleviated by treatment and analgesia are euthanased immediately.

Cats, rabbits and guinea pigs are group housed in pen/rooms ie. not caged.

Improved peri-and-post operative analgesia to reduce pain from surgery.

Increased awareness and use of environmental enrichment.

The refinement of bone marrow chimera model procedure to reduce the dose of irradiation required by about 50% of the chimera host mice.

Replacement of live traps with a more appropriate methodology, track plates.

A novel route of self administration of petrol fumes via olfactometer apparatus, which removed the need for forced administration typical of psychopharmaceutical research.

A new computer imaging techniques were developed, therefore, removed the requirement to place fluorescent cable ties around a rat's neck to visualise them in the apparatus. This made procedures considerably less stressful for the rats and streamlined experimental procedures.

The development of an overall cattle teaching protocol has allowed the use of individual animals to be better monitored. The teaching activities require the use of living animals, but are non-invasive. Skeletal and diagrammatic material was used to supplement live animal exercises. Videos have been provided for the students to view before the classes to ensure their handling of animals was appropriate and they are familiar with procedures. This was aimed to minimise risk or harm to themselves and distress of discomfort of the cows.

During wildlife field studies, researchers ensured that all animals were released at their exact point of capture within a few minutes of the initial captures; this reduced handling time, and therefore, any potential distress experienced by the animals.

We have refined procedures used in wool residue studies to reduce the time an animal spends in a study.

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.

The AEC is proactive in advising on appropriate anaesthesia agents and routes, and also on the most appropriate and humane method of euthanasia.

Standard Operating Procedures now updated ie removed SOPs that are no longer applicable, updated remaining SOPs, added any new SOPs and review all SOPs on annual basis. This is in line with our policy with being proactive in ensuring SOPs are current and up-to-date.

Required improved housing and husbandry of pigs during the conduct of trials.

At the Annual training program for investigators explanation of the importance of the 3 Rs was emphasised when planning work whether for teaching or research.

AEC development of a Monitoring Sheet template and 44 SOPs, now available from the AEC website for investigators to apply to projects in order to reduce impact of any adverse consequences.

Outdoor housing in large, well-equipped aviaries for finches and bantams.

The introduction of 'puppy pre-school' and 'kitten kindy' as a regular event involving all staff, up to twice per week to familiarise puppies/dogs and kittens/cats to procedures that may be required in studies eg sitting quietly for examinations, blood sampling, flea controlling etc.

Dog food (kibble) is now scattered on the floor. This slows down consumption, takes more time to eat and appears to make them less aggressive towards each other at feeding times.

Providing chopped fruit and vegetables for the dogs and cats as enrichment approx once per week.

With the construction of a custom-built aviary facility, the establishment has employed a veterinarian with a specialised interest in avian medicine and surgery to ensure the optimal health and welfare of the birds being used in research. This full-time position will also provide additional support to Animal Welfare Officers and offer greater opportunities for researchers to consult with veterinarians on refining procedures and the health needs of research animals.

During 2010, the AEC implemented the 3Rs through the modification of the SOPs. The modifications designed to replace, reduce and refine use of animals include:

- \* Additional of surveillance cameras the establishment has recently purchased several surveillance cameras, considered to be non-invasive for fauna, to implement the three R's. This technique has been successful in reducing the risk to fauna while maintaining the integrity of research results.
- \* Modification of hair tubes followed by removal of this technique from the SOPs previous concerns about the potential impact of hair tubes on reptiles resulted in the trial of a new hair tube design. This design has a smaller area of glue water that is located only on the top of the trap. Testing of this design has shown that adverse incidents involving reptiles are still occurring with the new design. Based on a number of adverse incidents that have been reported, hair tubes have been removed from the SOPs. Where State Government methodology requires the use of hair tubes, this will be negotiated with the relevant agency on a project by project basis. If hair tubes are required for the project, then a high risk procedure application will be submitted to the AEC for approval. It is expected that in cooler months when reptile activity is reduced, the use of hair tubes for targeted surveys will be approved. Possibility of incidents related to hair tubes may also vary according to location and subsequent variation in environmental conditions.

Use of multimodal analgesia for even analgesic dosing e.g. after abdominal surgery, buprenorphine SC is given followed by carprofen in drinking water.

Regular provision of pre-emptive analgesia for mice undergoing embryo transfer and vasectomy.

Only use unilateral transfer of embryos so only one skin incision per mouse, and size of incision kept to minimum.

If genotyping needs to be performed past weaning age, ear notching is recommended as an alternative to tail biopsies.

Minimize bleeding from the ovarian bursa by applying a vasoconstrictor prior to accessing the infundibulum during oviduct transfers.

Cross-fostering of genetically modified pups when applicable for increased chances of survival.

Some GM lines are maintained as homozygotes where no adverse phenotype is observed.

For those GM lines maintained as heterozygotes, researchers, whenever this is possible, are using non-GM mice as experimental controls; also, to avoid wastage, mice that have not integrated the transgene are used as controls or for the provision of tissues.

Samples collected for genotyping purposes are through ear notching to prevent multiple manipulations needing to be performed on animals to allow for genotyping and identification purposes.

All dogs enrolled in Phase 1 of the study were handled by their owners, therefore reducing the stress related to administering tablets. In addition, the tablets were to be freely accepted rather than forced administration.

The Thermal Threshold Testing Device reduced stress on animals, whilst validating the analgesic properties of methadone HCI. The animals were free to exhibit normal behaviour during testing, such as eating, drinking and roaming. The device inflicts brief stimulus to invoke a response from the animal, but this is transient. No skin lesions were observed throughout, and up to 24 hours after testing. This is a refinement over other procedures to investigate analgesic properties that involve surgery, or injecting noxious substances into tissues to inflict pain.

Training in the surgical techniques to be used is obtained from veterinary staff prior to the initiation of studies, to ensure competence.

Selection of tissue collection time points based on extensive searches of the literature and previous investigation to minimise number of time points needed.

The release of animals unharmed at the site of their capture on the same night.

The use of camera stations to remove the need for animals to be physically captured.

The re-use of wallabies to reduce the need to capture additional male animals from breeding yards or import wild caught animals. Familiarity of these animals to capture is expected to help minimise their stress response to experimental use, and therefore reduce the possibility of capture myopathy.

An improved technique to attach radio tagging of green and golden bell frogs. Instances where frogs are negatively affected by the radio transmitter or instances where frogs lose their transmitter were likely to be minimized.

Wildlife Study: veterinarian included for anaesthetic administration and any necessary veterinary interventions.

Wildlife Study: edible bait to provide sustenance for animals after capture.

Wildlife Study: trapping only when weather conditions optimal.

Wildlife Study: to reduce the risk of pathogen transfer between frogs: the use of disposable latex gloves and sterilisation of instruments.

The Committee encourages researches to undertake a pilot study if the impact of the proposed study interventions on animal health and well-being is unknown.

We have distributed the publication by DB Morton (1999) "Humane endpoints in animal experimentation for biomedical research: ethical, legal and practical aspects" which provides criteria for decision-making in euthanasia of unwell animals, to researchers and animal house managers.

In future to reduce the number of fatalities, a new approach will be adopted; the researcher has resolved that they may completely replace the cage traps in which the potoroo was captured in this survey with automated cameras, so that no trapping occurs of these larger mammals. This is an emerging survey technique and will be useful to allow students exposure to a further survey technique.

Improvements to animal housing and management.

Training of researchers.

Use of monitoring checklists to identify, action and report adverse events.

Increased awareness and use of environmental enrichment.

Use of an Observational Only -Field Research Form (No Trapping, Handling or Spotlighting) to maximise oversight of the committee of field research.

Increasing use of remote controlled infrared digital cameras instead of or in addition to other methods to detect species presence or absence.

Limited use of hair tubes to reduce impact on target and non-target species, particularly small reptiles. Hair tubes limited to cooler months when reptiles are less active. Encouraging use of alternatives such as tracking tubes.

Targeted poison delivery systems are under development for humane pest control and minimisation of non-target impacts.

Although research involving invertebrates does not require AEC approval advice has been given where wet pitfall traps for invertebrates are to be used in order to minimise vertebrate by-catch (eg size of container for target invertebrates, weather considerations).

Improved peri and post-operative analgesia to reduce pain from surgery.

Increased awareness and use of environmental enrichment materials, such as igloos and nesting material in cages.

The committee has required a number of projects that plan to administer new compounds or cells to complete and submit toxicology screens *in vitro* prior to commencement of work *in vivo*.

Use of remote underwater video instead of trapping and releasing fish as a less intrusive research method.

Use of pilot studies to refine techniques before large numbers of animals are used.

The development of "observational only" for wildlife studies. Less invasive sampling methods used where possible.

### 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. (\*Catering for seminar for AEC members not included)

Fees and retainers	3,759.30		
Travel and subsistence	7,189.27		
Stores (including catering*) and printing	1,870.85		
Freight and postage	578.97		
TOTAL	\$13,398.39		

# Appendix J: ARRP policies and guidelines

(Available from http://www.animalethics.org.au)

#### **Policies**

- 2. Payment of External Members of Animal Ethics Committees (revised 15/5/2009)
- 3. Procedures Prohibited under the NSW Prevention of Cruelty to Animals Act (revised 24/4/2009)
- 4. Non-Research Animals at Accredited Animal Research Establishments (revised 4/8/2010)
- 5. Annual Reporting by Animal Ethics Committees to Accredited Animal Research Establishments (revised 17/2/2010)
- 5a. Institutional Support for Animal Ethics Committees
- 6. Differentiation Between Acts of Animal Research and Acts of Veterinary Treatment
- 8. Establishment of Protocols for Grievance Procedures
- 9. Criteria for Assessment of Animal Ethics Committee Membership
- 10. Emergency Procedures
- 11. Formal Agreements between Accredited Research Establishments sharing Animal Ethics Committees
- 12. Frequency of Animal Ethics Committee Meetings
- 13. Inspections by Animal Ethics Committees
- 14. Acts of Veterinary Science and the Use of Restricted Drugs
- 15. Orientation of New Members of Animal Ethics Committees
- 16. Conflict of Interest with Membership of Animal Ethics Committees

### Guidelines

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

# Appendix K: Animal Welfare Unit fact sheets

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

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

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

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

# Accreditation

- 1. That any site inspection is satisfactory.
- 2. Details of changes to Animal Ethics Committee membership (including the qualifications of new members and the categories to which they are appointed) must be provided to the Director-General of the Department of Primary Industries within 30 days of membership changes. The revised composition of the AEC must meet the approval of the Director-General.
- 3. Rabbits should be housed in groups in pens. Rabbits may only be housed in cages with the express permission of the AEC on the basis of compelling evidence for the need to use such housing. Lack of space or facilities for pens should not be considered sufficient justification for the use of cages. Where rabbits are held in cages, these cages should be enriched by methods such as pair housing in double cages. (Australian Code of Practice for the Care and Use of Animals for Scientific Purposes Clause 4.4.19) (See ARRP Guideline 18: Guidelines for the Housing of Rabbits in Scientific Institutions (http://www.animalethics.org.au/reader/animal-care))
  - (For establishments housing rabbits)
- 4. Unless precluded by the requirements of specific projects, chickens should be provided with housing that meets their behavioural needs including straw or other suitable bedding to cover the floors of cages, perches and dust bathing substrate.
  - (For establishments housing chickens)
- 5. Dogs should be housed in accordance with ARRP Guideline 14: Guidelines for the Care and Housing of Dogs in Scientific Institutions (<a href="http://www.animalethics.org.au/policies-and-guidelines/animal-care">http://www.animalethics.org.au/policies-and-guidelines/animal-care</a> ). (For establishments housing dogs)

- 6. Unless otherwise approved by the Animal Ethics Committee, animals should be housed in accordance with the ARRP guidelines on animal housing for specific species found at: <a href="http://www.animalethics.org.au/policies-and-quidelines/animal-care">http://www.animalethics.org.au/policies-and-quidelines/animal-care</a>.
- 7. Unless otherwise approved by the Animal Ethics Committee, wildlife studies should be carried out in accordance with the ARRP guidelines on wildlife research found at: <a href="http://www.animalethics.org.au/policies-and-guidelines/wildlife-research">http://www.animalethics.org.au/policies-and-guidelines/wildlife-research</a>.
- 8. Animals (other than exempt animals) may only be obtained from a licensed animal supplier (see <a href="http://www.animalethics.org.au/policies-and-guidelines/animal-supply">http://www.animalethics.org.au/policies-and-guidelines/animal-supply</a>).
- 9. It is essential that the AEC members are provided with a copy of the inspection report of {date} and that the AEC is involved in the assessment of, and provision of responses to, the conditions, recommendations and observations contained in this report.

(Added after inspection)

10 A response to conditions {xx} of the inspection report of {date} must be provided to the Director-General of the 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*.

