



Animal Research
 Review Panel
 New South Wales



Annual
 Report

2002-03



NSW Agriculture



Animal Research Review Panel

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The Hon Ian Michael Macdonald, MLC
Minister for Agriculture and Fisheries
Level 30 Governor Macquarie Tower
1 Farrer Place
Sydney NSW 2000

Dear Mr Macdonald,

In accordance with Section 11 of the Animal Research Act 1985, the Animal Research Review Panel presents its annual report covering the period 1 July 2002 to 30 June 2003.

Yours sincerely,

A handwritten signature in black ink that reads 'Margaret Rose'.

MARGARET ROSE
Chair
Animal Research Review Panel



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SUMMARY AND HIGHLIGHTS

The Animal Research Act 1985

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

The Code of Practice

Ultimate responsibility for animal use and care lies with those who use the animals: the researchers and teachers. This responsibility includes the need to be familiar with the National Health and Medical Research Council (NHMRC) *Code of Practice for the Care and Use of Animals for Scientific Purposes*. This Code is scheduled in the Animal Research Regulation 1995. Adherence to the Code is achieved through a system of enforced self-regulation. Institutions must be accredited and individuals must be authorised to use animals. Failure to comply with the Act, Regulation or Code of Practice results in conditions being imposed on the accreditation or authority. For serious or repeated breaches, the accreditation or authority to conduct research may be withdrawn. Conducting animal research without appropriate authorisation is an offence with substantial custodial and financial penalties.

The Animal Research Review Panel

The Animal Research Review Panel (the Panel) 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 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 Panel 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. NSW Agriculture Animal Welfare

Unit staff provide executive support for the Panel. In 1998–99 the Minister conferred an additional function on the Panel: a formal role in the consideration of amendments to the Regulation.

Animal Ethics Committees

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

Administration and planning

In 2002–2003 there were 107 accredited research establishments, 66 accredited schools and 29 holders of animal suppliers' licences.

Inspections

In the 2002–2003 year the Panel has carried out 30 inspections of accredited research establishments/animal suppliers and independent researchers. The inspections place a major focus on reviewing the operation of the AECs and ensuring that the AECs, investigators and institutions understand their responsibilities under the legislation and Code of Practice.

Support for Animal Ethics Committees

Support for AECs is provided through site inspections, through publications including policies, guidelines, fact sheets and through extension activities of Animal Welfare Unit staff and the Panel. A new guideline on teaching cervical or vaginal artificial insemination of sheep was published. In addition, four of the Panel's existing policies/guidelines were revised.

Complaints

The Animal Research Act establishes a mechanism for lodging formal complaints against institutions and individuals. No formal complaints were dealt with in 2002–2003.

PART ONE: ORGANISATION

The Animal Research Act 1985 -

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

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

The Act came fully into force in 1990 (when the Animal Research Regulation was gazetted). This Regulation was repealed under the requirements of the Subordinate Legislation

Act, and a new Regulation was gazetted on 1 September 1995. The *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* was adopted by the Animal Research Regulation 1995. The Code provides guidance on day-to-day operations within research institutions.

The Act has been amended twice, first in 1989 and again in 1997. It was amended in 1989 to prohibit the use of certain toxicity tests, except with the permission of the Minister. The 1997 amendments were designed to maintain the licensing scheme for animal research but to reduce adverse impacts on competition policy¹ to a minimum level commensurate with achieving the welfare objectives of the Act.

The majority of the 1997 amendments could not commence until amendments were made to the Animal Research Regulation. These amendments to the Regulation came into effect in July 1999. The amendments affect the areas of licensing, fees, lethality testing, AEC procedures, schools, and wildlife studies. An emendation to the Act also allowed for the appointment by the Minister of a Deputy Chairperson to the Panel. The Minister appointed Associate Professor Rosemarie Einstein to this position.

¹ The Competition Principles Agreement requires that legislation should not restrict competition unless it can be demonstrated that the benefits to the community as a whole outweigh the costs and that the objectives of the legislation can only be achieved by restricting competition.

Ms Siobhan O’Sullivan (right of centre, facing camera) participates in an inspection of a fish research facility. The water plants provide natural cover for the fish.



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

The *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (the Code of Practice) is a nationally accepted code and is included in the NSW animal research legislation (in the Animal Research Regulation 1995). The code is reviewed regularly by the Code Liaison Group, which includes representatives from the National Health and Medical Research Council (NHMRC), the Commonwealth Scientific and Industrial Research Organisation, The Australian Research Council, the Australian Vice-Chancellors' Committee, the State Government Ministries with responsibility for animal welfare, the RSPCA and Animals Australia. Members of the Panel and the Animal Welfare Unit of NSW Agriculture are represented on the Code Liaison Group.

The current edition of the Code of Practice is the sixth and was published in September 1997. The Panel has had significant input into successive revisions of the Code. A review of the sixth edition of the Code was initiated by the NHMRC in August 2001. In the course of this review, a number of meetings of the Code

Liaison Group and of its working groups have been held. A draft seventh edition of the Code was developed by the Code Liaison Group and released for comment in March 2003. In NSW, information was circulated widely to Animal Ethics Committees, Animal Welfare Groups, Scientific Groups and independent researchers to alert them to the fact that the Code was being reviewed and thus enable them to comment.

In response to the comments received, the NHMRC intends that a revised draft of the seventh edition of the Code will be produced and sent out for public comment.

The Animal Research Review Panel

Mission statement

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

The Animal Research Review Panel was created by the Act to provide a mechanism for representatives of the scientific and broader

Rabbits use ledges to climb on and to hide under.



communities to participate in monitoring the self-regulatory process, which is established within institutions by the Act.

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

Functions of the Panel

Section 9 of the Act defines the functions of the Panel as:

- the investigation of matters relating to the conduct of animal research and the supply of animals for use in connection with animal research
- the investigation and evaluation of the efficacy of the Code 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 Minister, the Hon. Richard Amery MP, conferred the following additional function on to the Panel, 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 Panel under section 9(d) of the Act since it commenced.

Membership

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

- New South Wales Vice-Chancellors' Conference: three nominees
- Medicines Australia Inc.: one nominee
- New South Wales Minister for Health: one nominee
- New South Wales Minister for Education: one nominee
- New South Wales Minister for Agriculture: 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 Panel are part-time and are normally appointed for a term of 3 years. During the period 2002–2003 Dr Regina Fogarty was welcomed to the Panel, replacing Dr Richard Sheldrake as a nominee of the Minister for Agriculture. Also during this period, Mr Bob Harden, a nominee of the Minister for the Environment, resigned from the Panel.

Members of the Animal Research Review Panel in 2002–2003 were:

Mr Steve BUCKLEY

Bachelor of Theatre Arts (St. Edwards University, Austin, Texas); Certificate of Teaching (Bathurst Teachers' College, NSW)

Mr Buckley, Assistant Director-General, Special Needs Students and Equity Programs, is the nominee of the Minister of Education and Training and was appointed to the Panel in 2001. He has had an outstanding career in public education as a teacher, consultant, principal, director of schools, director of finance and resources and assistant director-general for an area of over 100 000 students. He is also currently a Director of TAFE Global NSW.

Mr Buckley served as a teacher, school principal and regional director in country NSW for over two decades and is well acquainted with agricultural programs and practices in the Department of Education and Training. Mr Buckley has a strong commitment to promoting the interests and achievements of students, teachers and schools in the NSW public education system.

**Associate Professor Rosemarie EINSTEIN
(Deputy Chair)**

BSc(Hons), PhD (University of Sydney)

Associate Professor Einstein is a nominee of the New South Wales Vice Chancellors' Conference. She was appointed to the Panel in October 1998. She is an Honorary Associate Professor in Pharmacology at the University of Sydney. Her research interests are in cardiovascular and autonomic pharmacology, especially the effects of stress in laboratory animals. She was Chairman of the University of Sydney Animal Ethics Committee from 1991 to 1996 and is also a member of the Westmead Hospital Animal Ethics Committee (appointed 1991). She was a member of the NHMRC Animal Welfare Committee from 1993–1996. Associate Professor Einstein was appointed Deputy Chair in October 2001.

Dr Regina FOGARTY

Dr Fogarty is the General Manager, Strategic Review, at NSW Agriculture. Dr Fogarty has been actively involved in animal welfare issues in previous positions with the Department as Manager of NSW Agriculture's Animal Welfare Unit, as Program Leader, Intensive Livestock Products, and as Veterinary Officer (Pig Health). Before joining the Department in 1991, Dr Fogarty worked at the University of Queensland's Faculty of Veterinary Science in research, teaching and clinical veterinary practice. Dr Fogarty joined the Panel in 2003 as the nominee of the Minister for Agriculture.

Mr Don Robinson (at right), a member of the ARRP, participating in a site inspection at an equine research facility.



Mr Bob HARDEN

BRurSc (University of New England)

Mr Harden is a Senior Project Officer in the Biodiversity Research and Management Division of the National Parks and Wildlife Service (NPWS). He has been an active wildlife researcher for many years on a variety of species, including native and introduced small mammals, macropods, dingoes, feral goats and the Lord Howe Island woodhen. He was also a member of the Director-General's Animal Ethics Committee. He was appointed to the Panel in 1998 as the nominee of the Minister for the Environment. Mr Harden resigned from the Panel in April 2003.

Mr Mark LAWRIE

BVSc (University of Sydney); Grad. Cert. Man. (University of Western Sydney); Chief Veterinarian, RSPCA

Mr Mark Lawrie was a member of the Panel from July 1993 to August 1996. He was nominated by his employer, the RSPCA NSW, and rejoined the Panel in August 2000.

Mr Lawrie has been a member of two major institutional AECs – each for 3 years – and currently sits on the University of NSW Animal Ethics Committee. He has been a practising veterinarian in Australia and the United Kingdom and has worked as a volunteer in India, Nepal and Rarotonga. In July 2002 he assisted the RSPCA Papua New Guinea in restarting its veterinary clinic in Port Moresby.

He has particular interests in:

- the link between cruelty to animals and humans
- international animal welfare, especially in relation to urban animal management
- the behaviour and training of dogs.

Dr Barry LOWE

BSc (University of Melbourne), BEd (University of Melbourne), PhD (University of Sydney)

Dr Lowe currently holds an international position as Director of Research and Development with Elanco Animal Health, the animal health division of Eli Lilly and Company. His field of research is in external parasitology of farm and companion animals and intra-ruminal controlled release of drugs in sheep and cattle. He has been involved in research into the health and nutrition of farm animals for 25 years with the same company and has been Chairman of the Elanco Animal Ethics Committee for 8 years.

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

Ms Siobhan O'SULLIVAN

BA (Hons)

Ms O'Sullivan began working for animals as a volunteer with Animal Liberation NSW. She has since gone on to work full time for the animal welfare/ rights movement as Office Manager with the World League for Protection of Animals and is currently a director of the Australian and New Zealand Federation of Animal Societies (ANZFAS).

Ms O'Sullivan is vegan and has campaigned against the use of animals in research for the last 7 years. She is currently undertaking a PhD in Government and International Relations at the University of Sydney, where she is focusing on the structure of animal legislation.

Ms O'Sullivan was appointed to the Panel in 2002 after being nominated by the NSW Animal Societies Federation.

Associate Professor Romano (Ron) PIROLA
OAM; MB BS (University of Sydney); MD (University of New South Wales); FRACP

Associate Professor Pirola is the nominee of the Minister for Health and was appointed to the

Panel in May 2002. He has extensive experience in biomedical animal research. He is Consultant in Gastroenterology at the Prince of Wales Hospital, Randwick. He was formerly the elected staff representative on the Board of the Eastern Area Health Service and the Chairman of the Research Ethics Committee of the South-Eastern Area Health Service – Eastern Division.

Mr Don ROBINSON

Justice of the Peace

Mr Robinson is a nominee of the RSPCA (NSW). He served in rural areas with the NSW Police for 23 years before becoming the Chief Inspector for the RSPCA from 1994 to 1997. During that period he was a member of the Animal Research Review Panel. After a period in the hotel industry, he was re-employed by the RSPCA as Chief Inspector in December 2001. He rejoined the Panel in February 2002.

Professor Lesley ROGERS

BSc (Hons) (Adelaide University); DPhil, DSc (University of Sussex), FAA

Professor Rogers is a nominee of the New South Wales Vice Chancellors' Conference. She was appointed to the Panel in October 1998. She holds a Chair in Neuroscience and Animal Behaviour. For many years she served as a member and then Chair of her university's Animal Ethics Committee and in a number of other senior positions at her university. She has been President of the Australian Society for the Study of Animal Behaviour and the International Society of Comparative Psychology. She is a Fellow of the Australian Academy of Science.

Professor Rogers is author and co-author of several books related to animal welfare (including *Minds of Their Own: Thinking and Awareness in Animals*, *Songs, Roars and Rituals: Communication in Birds, Mammals and Other Animals*, and *Birds: Their Habits and Skills*). She has a strong international reputation for her research on brain development and lateralization, funded by an Australian Research Council Special Investigator Award. Her research interests also include the behaviour of orang-utans and marmosets.

Her research publications include over 200 papers in leading international journals and 14 books.



Associate Professor Margaret Rose, ARRPs Chair, during a site inspection of an animal research establishment.

**Associate 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, which developed the proposal for the Animal Research Act, and since 1990 she has been closely involved in the revisions of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*. She was responsible for the development of the proposal to establish ANZCCART (Australian and New Zealand Council for the Care of Animals in Research and Teaching) and, as a member of the Board until 1994, was actively involved in its establishment. She is a member of the editorial board of three international journals devoted to the welfare of laboratory animals: *ATLA (Alternatives to Laboratory Animals)*, *Laboratory Animals* and the *Journal of Applied Animal Welfare Science*.

She has been involved in the development, delivery and assessment of courses on animal care and ethics in both the university and TAFE systems. Professor Rose holds the position of Area Director of Animal Care in South Eastern Sydney Area Health Service and is a conjoint Associate Professor at the University of New

South Wales. She has been a member of the NSW Government's Animal Welfare Advisory Council since 1981 and in 2002 was appointed to that government's Bioethics Advisory Committee.

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

Ms Katrina SHARMAN

BA LLB (University of New South Wales)

Ms Sharman is a nominee of the NSW Animal Societies Federation. She was appointed to the Panel in November 2001.

Ms Sharman has been Chair of the NSW Young Lawyers Animal Rights Committee since November 1999. The Committee is part of a voluntary organisation of young lawyers devoted to progressive change, and is a division of the Law Society of New South Wales. Ms Sharman is seeking to raise the profile of animal law in Australia and to establish a network of animal law lawyers.

Ms Sharman practices as a litigation lawyer at the law firm Minter Ellison Lawyers.

Animal Ethics Committees

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

AECs are responsible for monitoring research within institutions, including inspections of animals and facilities. They must consider and evaluate requests to conduct research, on the basis of the researchers' responses to a comprehensive set of questions, including the justification for the research, its likely impact on the animals, and procedures for preventing or alleviating pain or distress. On behalf of the institution, they 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. They also provide guidance and support to researchers on matters relevant to animal welfare, through preparation of guidelines and dissemination of relevant scientific literature. They are responsible for advising the institution on the changes to physical facilities that are needed to meet required standards.

The membership and duties of AECs are laid down in the NSW legislation and in the Code of Practice, which also provides the benchmark

against which the committees operate.
Committee membership must be as follows:

Category A: a veterinarian or person with equivalent expertise

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 is not a researcher and (in most cases) is not employed by the institution.

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

The criteria used by the Panel for assessment of AEC membership were clarified in a Panel policy document, *Policy 9: Criteria for the Assessment of Animal Ethics Committee Membership*. 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 Panel assesses the operation of the AEC.

Accreditation and licensing

The legislation requires that all applications for accreditation and animal supply licences

are referred to the Panel for consideration. The Panel has established procedures to deal with the considerable workload this entails and has regularly reviewed and updated these procedures to take account of changes in needs and resources.

The application forms for accreditation and licence were extensively revised in 2000–01 to take into account changes to the legislation and to meet evolving needs for particular information.

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

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

The recommendations of the Panel are referred to the Director-General of NSW Agriculture, 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 Agriculture. Other conditions may also be stipulated, as relevant to the operation of each institution.

This large animal research facility has provided sheds to enable sheep to shelter from sun, wind and rain.



Evaluation of written applications

The Panel has appointed an applications sub-committee to facilitate the assessment of applications. New applications for accreditation or licence are assessed by Panel executive staff, according to criteria developed by the Panel. These applications and assessments are then referred to the applications sub-committee, which makes recommendations to the full Panel. Recommendations on the applications are then made by the Panel to the Director-General of Agriculture.

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

Routine applications for renewal of accreditation or supply licences are assessed by Panel executive staff, and the Panel considers the recommendations arising from these assessments.

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

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

Conduct of site inspections

Following the evaluation of written applications, the second phase of the process of assessing establishments is the site inspection. The aim of site inspections is to determine whether institutions and individuals are complying with the legislation. The Code of Practice provides the criteria against which institutions are assessed. The range of items assessed includes: the

membership, procedures and activities of the AEC; animal care procedures; animal research procedures; and the physical facilities for housing and using animals. An evaluation is also made of the wellbeing of the research or breeding animals.

Audit visits are arranged in advance and usually take from 1 to 4 days per site. Large establishments with multiple sites can take up to 2 weeks to inspect. Information about inspections conducted in the 2002–2003 year is provided in Appendix C and Appendix D. The dates provided represent days on site and do not include preparation and follow-up time, which is often considerable.

Assessment commences before site inspection with an examination of written material provided by the institution or individual. This includes lists of the research protocols 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 Panel members who have been nominated to participate in the inspection. This pre-inspection evaluation allows likely problem areas to be identified and a general idea to be gained of how the establishment is operating.

On the day(s) of the inspection the inspection team looks at the animals and the facilities and talks with researchers before meeting with the committee. The 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 issues arising from the inspection with the AEC 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 or for the recognition and relief of pain.

A meeting is usually held with the head of the institution at the beginning or end of the inspection. Any serious concerns are immediately referred to the institution at the appropriate level. A letter is usually sent to the institution within a week of the visit, providing the general

impressions of the site visit team and reinforcing the need to deal with any serious problems that may have been identified during the visit.

As soon as possible after the inspection, a detailed report is prepared. The report covers an evaluation of the AEC and an assessment of the animals' wellbeing, housing and holding, and their care and monitoring. Once the Panel has considered the report, recommendations may arise that will alter the terms of accreditation or licence. Conditions of an earlier accreditation may have been met, or the Panel may feel that additional conditions should be imposed. For example, a condition may be that appropriate post-operative procedures must be implemented.

In addition to conditions for accreditation or licence (which are mandatory and must be implemented), the Panel report usually contains a number of recommendations – for example, for more effective operation of the AEC, for improvement of the management of research within the 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 Panel to commend the institution, individual researchers or animal attendants for initiatives that raise the standards of the overall operation of the research facility or for techniques or facilities that enhance the welfare of research animals.

Horses at an accredited establishment have been trained to urinate in response to a signal (whistling). This removes the need to fit them with invasive or movement-inhibiting collection devices and is an excellent example of refinement.



The Panel 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 Panel aims to carry out full audit visits for all institutions every 3 years, as well as unannounced visits by inspectors to follow up problems. Re-inspections 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.

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.

The Animal Research Act in schools

The use of animals in teaching activities in schools is governed by the Animal Research Act. Schools that use animals are required to be accredited, and teachers using animals must hold animal research authorities. Animal use in schools must be conducted in accordance with the requirements of the *Code of Practice for the Care and Use of Animals for Scientific Purposes*, which devotes a section to such use. The Schools Animal Ethics Committee (SAEC) oversees the use of animals in schools. Each school overseen by the SAEC appoints an Animal Welfare Liaison Officer to communicate with the committee.

Most of the activities carried out in SAEC-approved schools are described in a list approved by the Panel. Teachers wishing to undertake an activity on the approved list may do so, provided they follow the comprehensive guidelines developed and published by the SAEC. These guidelines have Panel approval and set the

parameters for the conduct of approved activities. Approved activities include observation; measurement of weight and growth rates; collection of samples such as urine and faeces; and the teaching of normal husbandry procedures. Teachers wishing to carry out activities that are not on the approved list, or activities that are in higher categories on the approved list, must submit a detailed proposal to the SAEC for approval. A major review of the guidelines was undertaken with detailed input from the Panel and a significantly revised document was released in 2001.

The Panel liaises regularly with the SAEC. In general, complaints received by the Panel about the use of animals in schools are referred to the SAEC and the relevant school system. In this way, prompt and effective action can be taken without unnecessary interference by the Panel. If necessary, as in the case of serious complaints, the Panel may initiate its own investigation into the matter.

A meeting with the SAEC, as part of an inspection to assess its activities, was undertaken in 2002. Continuing improvements were noted, especially in the areas of monitoring by the SAEC of animal use activities and communication by the SAEC with teachers.

The Animal Research Act in TAFE

The wide variety of animal use within the extensive TAFE system prompted the development of a special administrative structure. Over 50 per cent of TAFE institutes within NSW use animals, in some 20 different courses. These range from courses teaching normal stock husbandry procedures (such as shearing sheep and drenching cattle), to more specialised areas such as training laboratory animal attendants, research technicians, veterinary nurses and zoo keepers.

With approval from the Panel, NSW TAFE established a two-tiered structure to approve and monitor the different types of activities carried out in each institute. Regional AECs were put in place in TAFE institutes. These AECs approved and monitored those teaching activities that were conducted at the institutes and used animals. The AECs were overseen by the TAFE Animal Care and Ethics Board (ACEB).

To monitor the implementation of this system first-hand, the Panel met with representatives of TAFE and its ACEB twice in the 2000–2001 period and undertook an intense program of

inspections of TAFE AECs and facilities. Early results of these activities included revision of the memberships and procedures of some regional AECs.

Early in 2003, TAFE presented the Panel with a revised system of management for implementing the Animal Research Act. This system centred around the disbanding of regional AECs and expanding the role of the ACEB in approving and monitoring animal use activities. Discussions are still under way to finalise this new system.

The Panel will continue to monitor the activities of, and liaise with, TAFE to help it to maintain high standards of animal care and management under the Animal Research Act.



Where rabbits cannot be housed in groups in floor pens, enriched cages add to their quality of life. This cage provides a ledge for climbing on and a hiding area and is large enough to accommodate three rabbits.



This doe has been provided with an L-shaped hutch in her floor pen. The top of the hutch has been removed to view the nest she has made with bedding/nesting material.

Administration

The Animal Welfare Unit was established in October 1993 as an independent program within NSW Agriculture, reporting directly to the Director-General of Agriculture. A permanent subsection of the Unit is maintained in the inspectorial office in Sydney.

The functions of the Animal Welfare Unit cover:

- animal research issues under the *Animal Research Act 1985*, including providing Executive Services to the Panel
- general animal care and cruelty issues under the *Prevention of Cruelty to Animals Act 1979* (POCTAA), including the operation of the Animal Welfare Advisory Council (AWAC) under the Minister for Agriculture
- animal display issues under the *Exhibited Animals Protection Act 1986* (EAPA), including the operation of the Exhibited Animals Advisory Committee and Departmental animal welfare activities.

The Animal Welfare Unit may be contacted at:

NSW Agriculture
Animal Welfare Inspectorial Office
Suite 3, Level 12
309 Pitt Street
PO Box A 970
SYDNEY SOUTH NSW 1232
Phone (02) 9264 9533
Fax (02) 9264 9632

or at NSW Agriculture's Head Office:

Animal Welfare Unit
NSW Agriculture
161 Kite Street
Locked Bag 21
ORANGE NSW 2800
Phone (02) 6391 3715
Fax (02) 6391 3570
E-mail: animal.welfare@agric.nsw.gov.au



The use of a dog kennel in this rabbit pen provides a stable hiding area that can't be tipped over by the rabbits and allows two rabbits to rest in the kennel together. A ledge, which can be seen in the background, provides the rabbits with a structure to climb on as well as hide under.

In financial year 2002–2003 the following staff were assigned to provide inspectorial and/or executive support to the Panel.

Orange:

Ross Burton, Manager, BVSc (University of Sydney), MVSc (University of Melbourne)

Amanda Paul, Veterinary Officer (part-time), BVSc (University of Sydney)

Len Cantrill, Veterinary Officer, BVM&S (University of Edinburgh)

Libby Neal, Unit Coordinator

Angela Thompson, Licensing Clerk, BLM

Liz Etherton, Licensing Clerk

Tammy Kirby, Clerical Officer

Sydney:

Lynette Chave, Senior Veterinary Officer, BVSc (University of Sydney)

Peter Johnson, Veterinary Officer, BVSc, PhD (University of Sydney)

Ann Sullivan, Clerical Officer

PART 2: REPORT ON WORK AND ACTIVITIES

Administration and planning -

Administrative functions have varied from assessments of licensing and accreditation to formulating the Panel's operational plan for 2002–2003. The appendixes to this annual report contain details on many of the operational and strategic functions of the Panel. These include: dates of, and attendance at, Panel meetings, dates and attendance of Panel members at inspections of accredited research establishments and animal supply licence holders, the Panel Strategic Plan 2002–2005 and Operational Plan for 2002–2003, representation by Panel members on important committees, and Panel operating expenses.

Strategic Plan 2002–2005

In 2002, the Panel developed a new 3-year strategic plan. The plan identifies the primary goals of the Panel and strategies for achieving these goals. Details of the plan are given in Appendix E.

Operational Plan for 2002–2003

The Panel Operational Plan, including a performance review of each activity, is provided in Appendix F.

Liaison with organisations, accredited institutions and authority holders

The Panel met with several organisations, accredited institutions and research authority holders to offer advice and to facilitate the implementation of legislative requirements and adherence to replacement, reduction and refinement principles. Such activities (in addition to liaison during routine inspections) included the attendance of a representative of NSW TAFE at a Panel meeting to present plans for a revised system for implementation of the Animal Research Act. As a result of the meeting, further changes are being made to the system before final implementation.

Assessment of applications

Applications for accreditation and/or licensing were reviewed by an applications sub-committee of Ms Katrina Sharman, Mr Bob Harden and Mr Mark Lawrie. The sub-committee discussed applications via teleconference and made recommendations to the Panel.

During 2002–2003 the Panel considered:

- 19 applications for accreditation
- 9 applications for school accreditation
- 25 applications for animal suppliers' licences.

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 agreement of the Minister for Agriculture. Applications for permission to conduct LD50 tests are evaluated by an ARRP sub-committee comprising Associate Professor Einstein, Dr Lowe, Dr Fogarty and Ms Sharman. The sub-committee makes recommendations to the Panel, which in turn advises the Minister.

In 2002–2003 the sub-committee considered one application from an Accredited Research Establishment. The testing was required as part of the registration process for biological agents. The Panel recommended to the Minister that he approve the applications on the conditions that the organisation report to the Panel progress with the development of replacement in vitro tests, and provide annual statistics for the numbers of animals used in each test. The



The deer paddock at this research establishment has timber shelters for fawns. These shelters are supplemented with natural brush in the fawning season.

Panel also considered and endorsed a briefing paper for the Animal Health Committee, which includes representatives from Australia and New Zealand. The paper explained the need to identify opportunities and strategies for reducing the numbers of animals used in product tests to meet requirements for the regulatory testing of veterinary and other biologicals and registration requirements for veterinary chemicals. The Panel considers that development of an appropriate strategic commitment and practical policy will bring significant animal welfare benefits, together with efficiencies for industry, through the phase-out of large-scale animal-based tests, which can be achieved by an intergovernmental, inter-agency approach in cooperation with industry.

Sub-committees

The Panel appoints sub-committees to deal with particular issues. They explore issues in depth, including discussions with relevant members of the scientific and broader communities. Sub-committees provide reports and recommendations to the full Panel for consideration. There are standing sub-committees that make recommendations on licensing, accreditation, and LD50 testing. Membership of sub-committees is largely drawn from the Panel. External members of sub-committees are occasionally co-opted on a voluntary basis. Issues considered by sub-committees in the past year include:

- the hosting of a meeting for members and executive officers of AECs
- the ARRP Strategic Plan 2002–2005

- applications for accreditation and licences
- applications for LD50 testing.

Legislation

Review of the Animal Research Act

A review of the *Animal Research Act 1985* began in November 1998 and was brought about to meet the Government's obligations under the Competition Principles Agreement. In addition, the then Minister for Agriculture directed that it was also to have broad terms of reference, canvassing the views of the research and broader communities on issues of concern in relation to the regulation of animal research.

The Terms of Reference of the review included considering the appropriateness of 'the constitution, functions and powers of the Animal Research Review Panel'.

Associate Professor Margaret Rose was the Panel's representative on the Review Group. Mr Fraser Bowen and Mr Charles Wright, who were, at the time, members of the Panel, were also nominated to the Review Group by the Australian Pharmaceutical Manufacturers' Association and the RSPCA, respectively.

The Review Group first met in January 1999. Consultation with the public included the production of an Issues Paper in April 1999, calling for submissions; the holding of public meetings in Sydney, Newcastle, Armidale and Wagga Wagga; and the consideration of representations of peak industry and stakeholder bodies to the Review Group.

The Panel provided a submission focusing on issues relating to the Panel, accreditation and licensing systems, AECs, complaints, public accountability and restrictions on information disclosure.

The Review Group was chaired by Mr Don Hayman, Executive Director Policy and Corporate Planning, NSW Agriculture. The report of the Review Group was forwarded to the Minister for Agriculture in 2002.

Review of 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* is incorporated into the NSW animal research legislation. A review of the Code is being undertaken, and a revised draft Seventh Edition was released for comment in March 2003. In recognition of the importance of the Code as central to the conduct of animal research in NSW, the Panel held a special meeting to discuss this revised draft and to formulate comments to be sent to the Code Liaison Group. As a result of the meeting a detailed submission was developed. It is expected that a revised draft of the Seventh Edition will be produced in response to the comments received and circulated by the NHMRC in late 2003.

Statistics on animal use

The Animal Research Regulation 1995 requires accredited research establishments (other than schools) and animal research authority holders to record and submit information on the number of animals used in research each year.

The requirements for reporting on animal use provide data on the numbers of animals used in all research protocols in NSW, reported against the purpose of the research and the type 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. Advantages of this new system over the previous one include:

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

3. the recording of the types of procedures used, combined with the recording of the purpose of the research
4. the ability to collate and submit statistics electronically.

The categories used are based on those planned to be used in a future national database. Figures will relate to the calendar, rather than to the financial, year. Appendix G of this report provides a summary of animal usage in 2002.

Lethality testing

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

Approved forms for the recording of these figures were sent to all accredited research establishments, with a deadline for submission of completed forms to the Panel of 31 March 2003.

Support for Animal Ethics Committees

The Panel and Executive continue to use various means to support Animal Ethics Committees in performing their duties. These means include thorough site inspections; the writing of policies, guidelines and fact sheets where a need is identified; and the supply of advice over the telephone or by correspondence.

The Panel is used as a reference source by the State's AECs, for example as a source of information on successful policies developed at other institutions. It provides advice to institutions on the suitability of an individual to serve in particular categories as a member of an AEC (see below). All establishments are required to advise the Director-General of Agriculture of changes to AEC membership. The Panel advises the Director-General on the suitability of the qualifications of the new members for the categories of membership to which they are nominated.

Register of candidates for AEC membership

Finding interested and suitable members has been a problem experienced by a number of AECs. Categories A, C and D have presented the most difficulty. To assist AECs in maintaining the

required membership the Panel has 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.

Meeting for members and executive officers of AECs

In the past the Panel has hosted meetings for Chairs and Executive Officers of AECs. However, in recent years such meetings have not been held. The need to reinstate these meetings to help AECs was identified by the Panel, and plans were put in place to hold a meeting in 2003.

It was decided that attendance at the meeting should be broadened to include all interested AEC members rather than limiting this to the Chairs of AECs. In an effort to ensure that the program for the meeting met the needs of AECs, comment was sought from all NSW AECs on topics they wished to discuss and the format for conducting the meeting. Valuable feedback was provided,

and a program was structured accordingly. The meeting was scheduled to be held on 11 July 2003.

Website: Animal Ethics Infolink

Development of a website by the Panel was identified as a need in the Panel's Strategic Plan. The development of such a website is an important project aimed at providing educational material for those involved in the care and use of animals for research and teaching in NSW. It will provide an opportunity for interchange with animal research entities world-wide, and will also give the general community access to information about animal use for research and teaching in NSW. It will enhance channels of communication and make information more accessible. The Panel is developing the website in conjunction with the Animal Welfare Unit. The site will be called Animal Ethics Infolink and will be accessible at www.animaethics.org.au or through the NSW Agriculture site. It is intended to launch the site during the meeting for members and Executive Officers of AECs to be held on 11 July 2003.

The screenshot shows the homepage of the Animal Ethics Infolink website. The browser address bar displays <http://www.animaethics.org.au/index.asp>. The page has a dark header with the title "ANIMAL ETHICS INFOLINK". Below the header, there is a "Welcome" section with a "print friendly" link. The main text explains that the website was developed by the Animal Research Review Panel and NSW Agriculture's Animal Welfare Unit. It states the aim is to assist researchers, teachers, and members of Animal Ethics Committees by providing access to information about the Animal Research Act 1993, the Animal Research Regulation 1993, and the Code of Practice in New South Wales. The text also mentions that the site provides general information about legislation in other states and countries and links to many other useful general information promoting the humane care and use of animals for scientific purposes. A search bar is located on the left side of the page, and there is a "What's New" section at the bottom left.

The Animal Ethics Infolink is being developed by the Panel in conjunction with the Animal Welfare Unit.



Calves used at a teaching institute receive supplementary feeding as well as access to pasture

Site inspections

The list of site inspections undertaken in 2002–2003 is provided in Appendix C, and the list of Panel members attending is given in Appendix D. There were 30 inspections conducted over a period of 35 working days. The length of these inspections ranged from half a day to 4 days for larger institutions. The inspections included AECs and the facilities of 28 accredited institutions/licensed animal suppliers and three independent researchers.

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

The Panel 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.

Policies, guidelines and fact sheets

The Panel 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 are available from the Animal Welfare Unit and have been published on the Department's internet website. The documents

can be found by following the links from the Animal Welfare Unit's home page at www.agric.nsw.gov.au/Aw/index.html. Once the Panel's new website is completed, a number of the documents will be available at www.animaethics.org.au.

New policies, guidelines and fact sheets are produced to fill needs identified by the Panel. In the 2002–2003 year a new Panel guideline (Guideline 19) was published on *Teaching Cervical or Vaginal Artificial Insemination of Sheep*.

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 Panel also has a policy of actively reviewing older guidelines and policies to ensure they are up to date. Guidelines and policies that were reviewed in 2002–2003 included:

- Policy 16: *Conflicts of Interest with Membership of Animal Ethics Committees*
- Guideline 11: *Guidelines for Tick Serum Producers*
- Guideline 17: *Training Personnel*
- Guideline 18: *Guidelines for the Housing of Rabbits in Scientific Institutions*.

Initiatives in replacement, reduction and refinement in animal use

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 Panel. A list of some of the initiatives can be found in Appendix H.

Complaints

A formal process for making specific complaints about animal research is set out in sections 22, 28 and 42 of the *Animal Research Act 1985*. The process allows any person to make such a formal complaint. The complaint must be made in writing to the Director-General of NSW Agriculture, who refers the complaint to the Panel for investigation. The Panel 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.

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



This horse holding yard at a teaching institute is constructed to avoid the chance of injury to horses. This is especially important where young horses, which may take fright easily, are held.

The Panel did not deal with any complaints in the 2002–2003 period.

These young horses demonstrate the benefits of good handling by readily approaching their carer.



APPENDIXES

Appendix A: Dates of Panel meetings 2002–2003 -

Meeting number	Date of meeting
138	17 July 2002
139	4 September 2002
140	30 October 2002
141	18 December 2002
142	12 February 2003
143	2 April 2003
Special meeting	14 May 2003
144	21 May 2003

Appendix B: Members' attendance at Panel meetings 2002–2003 -

Member	Meeting number							
	138	139	140	141	142	143	14 May	144
Assoc. Prof. M Rose	1	1	1	1	1	1	1	1
Mr S Buckley	A	A	1	A	1	1	A	A
Assoc. Prof. R Einstein	1	1	1	A	1	1	1	1
Dr R Fogarty	–	–	–	–	–	1	A	A
Mr B Harden	1	A	A	1	A	A	A	–
Mr M Lawrie	A	1	1	1	1	1	1	1
Dr B Lowe	1	1	1	1	1	1	1	1
Ms S O'Sullivan	1	1	1	1	1	1	1	1
Assoc. Prof. R Pirola	1	A	A	1	1	A	1	1
Mr D Robinson	1	A	1	A	A	1	A	1
Prof. L Rogers	1	A	1	A	1	1	A	1
Ms K Sharman	1	1	A	1	1	1	1	1
Dr R Sheldrake	A	A	A	–	–	–	–	–

1 = Present

A = Absent

– = Not Applicable

Appendix C: Inspections of accredited research establishments and independent researchers, July 2002 – June 2003

Entity	Date
Bunge Meats	15/07/2002
	16/07/2002
TAFE – Hunter Institute	24/07/2002
TAFE – Northern and Southern Institutes	25/07/2002
Engenic	12/08/2002
Novartis	16/08/2002
Biosis Research	21/08/2002
Carwood	22/08/2002
N Sherwood / E Clayton	23/08/2002
Centenary Institute (ASL)	26/08/2002
TAFE – Western Sydney/South Western Sydney Institutes	27/08/2002
CSAHS – Baboon Colony	25/09/2002
Fort Dodge	19/10/2002
Yvette Cameron-Cook (Paul Hamilton)	23/10/2002
Department of Education and Training	29/10/2002
Catholic Education Commission	29/10/2002
University of NSW	22/10/2002
	23/10/2002
	24/10/2002
	01/11/2002
South Eastern Sydney Area Health Service	24/10/2002
South Western Sydney Area Health Service	28/10/2002
	01/11/2002
NSW Agriculture – Elizabeth Macarthur Agricultural Institute	12/11/2002
Bioquiv	20/11/2002
TAFE – Illawarra	12/12/2002
Macquarie University	12/12/2002
	13/12/2002
CSIRO – Molecular Science	06/02/2003
Bioquest	06/02/2003
Northern Serums	09/04/2003
Keith Curtin	09/04/2003
University of Western Sydney	09/04/2003
	10/04/2003
Garvan Institute	12/05/2003
St Vincent's Hospital	12/05/2003
Victor Chang Cardiac Research Institute	12/05/2003
Johnson and Johnson	12/05/2003
Virbac	20/05/2003
Engenic	04/06/2003
NSW Thoroughbred Racing Board	11/06/2003
University of NSW – Fowler's Gap	25/06/2003

Appendix D: Attendance of Panel members at site inspections 2002–2003

Member	Number of days spent on site inspection
Assoc. Prof. M Rose	2
Mr S Buckley	0
Assoc. Prof. R Einstein	3
Dr R Fogarty	0
Mr B Harden	0
Mr M Lawrie	4
Dr B Lowe	3
Ms S O’Sullivan	4
Assoc. Prof. R Pirola	1
Mr D Robinson	5
Prof. L Rogers	0
Ms K Sharman	1

Appendix E: NSW Animal Research Review Panel Strategic Plan, July 2002 – June 2005

Mission Statement

To protect and enhance the welfare of animals used in scientific research, testing and teaching in NSW.
To promote the participation of the NSW community in consideration of the ethical and technical issues involved in the use of animals for scientific research, testing and teaching.

Goals and strategies. Note: Numbers on the right refer to items from the 2002–2003 operational plan (Appendix F) that address the strategies. Priority items are numbers 1.3, 3.2 and 4.2.

Goal or strategy no.	Details	operational plan no.
1.	Effective and efficient implementation of the statutory requirements of the <i>Animal Research Act 1985</i> , the <i>Animal Research Regulation 1995</i> and the <i>Australian Code of Practice for the Care and Use of Animals for Scientific Purposes</i> .	
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 program of site visits to effectively monitor compliance with the legislation.	2
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. (Priority item)	2.6
1.4	Identify and implement adjuncts to inspections to better ensure compliance with the legislation.	2.5, 3
1.5	Monitor compliance with the Act, Regulations and the Code with respect to the conduct of animal research and teaching and the supply of animals for research and teaching.	2
1.6	Active participation in national reviews of the Code to ensure that it is effective in regulating the conduct of animal research and teaching and the supply of animals for research and teaching.	7.3
1.7	Prepare an annual report to Parliament on the operations and achievements of the Animal Research Review Panel.	1.4
1.8	Maintain and review the system for collection and analysis of statistics on animal use for research and teaching; to ensure that it provides useful information that accurately reflects the use of animals, without imposing an undue administrative burden on institutions or government.	1.5, 5.1, 5.2
1.9	Maintain a system for receiving and investigating complaints relating to the requirements of the legislation.	1.2
1.10	Review the system for receiving and investigating complaints with a view to raising standards of efficiency and effectiveness.	
1.11	Provide opportunities to the research, teaching, veterinary, animal welfare and lay communities to provide feedback on the activities of the Animal Research Review Panel and respond appropriately.	2, 7.4
1.12	Maintain a system to consider and make recommendations on applications for permission to carry out LD50 tests.	1.3

Goal or strategy no.	Details	operational plan no.
2.1	Ensure there is effective participation by researchers and teachers, veterinarians, animal welfare representatives and independent representatives in a formal review of the justification and merit for all proposals for the use of animals for scientific purposes.	2,3
2.2	Promote support for AECs within institutions.	2
2.3	Promote and foster interaction between AECs and researchers/teachers.	2, 3
2.4	Promote an appreciation of the ethos underpinning the Code through visits and all communications from the Animal Research Review Panel to institutions, AECs, researchers/teachers and animal care staff.	2, 3, 4
2.5	Promote an understanding of the roles and responsibilities of AECs through encouraging participation in AEC training programmes.	2, 3, 4
2.6	By identifying problems and suggesting remedies, provide assistance to institutions, AECs and researchers/teachers to ensure that the principles, processes and responsibilities in the Code are actively embraced.	2
2.7	Promote discussion and understanding of key technical and ethical issues and foster interaction between AECs by maintaining a program of meetings of Chairs of AECs and participating in AEC meetings during site inspections.	2, 3.3, 3.4
2.8	Review the membership and operation of individual AECs during site visits to ensure that all categories of membership are able to contribute effectively to discussions, decisions and activities of the AEC.	2
2.9	Develop and promulgate guidelines to help AECs to evaluate protocols effectively	4
2.10	Conduct ongoing monitoring of TAFE, Schools and Director-General's AECs to identify any special needs.	2
2.11	Promote a critical review of the operation of AECs with a view to maximising their effectiveness.	2
3.1	Promote an understanding of the roles and responsibilities of researchers/teachers through encouraging participation in training program.	3
3.2	Publish a newsletter to raise key issues and suggest resources. (Priority item)	3.2
4.1	Encourage AECs critically to assess the adequacy of researchers'/teachers' attempts to identify alternatives to animal use.	2
4.2	Encourage greater awareness of the use of alternatives to animals in research and teaching. (Priority item)	2
4.3	Collate and disseminate information on alternatives to animal use.	
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 program to minimise overproduction of animals.	2
5.3	Ensure close scrutiny by AECs of the competence of researchers to carry out specific procedures	2, 3
5.4	Promote critical evaluation of the monitoring of animals being used in procedures.	2, 3
5.5	Promote critical evaluation by AECs and researchers of the impact of the type of housing / holding on experimental animals and awareness of its implications for experimental results.	2, 3, 4.1
6.1	Promote the use of appropriate analgesia and anaesthesia by facilitating access by researchers/teachers to information resources.	2, 3.1
6.2	Ensure that AECs and researchers/teachers focus on the possible impact of procedures at the planning stage and implement appropriate strategies for monitoring and alleviation.	2, 3

Goal or strategy no.	Details	Operational plan no.
6.3	Promote awareness by researchers/teachers and animal care staff of signs of pain or distress in animals.	2, 3
6.4	Promote awareness of the effects of handling and other interactions with humans on levels of pain and distress and the use of strategies to minimise adverse impacts.	2, 3
6.5	Monitor and identify deficiencies in anticipation, recognition and relief of pain and distress during site visits and ensure deficiencies are rectified, including by provision of pre-operative analgesia where appropriate.	2
7.1	Evaluate housing and routine care through the ongoing site visit program.	2
7.2	Develop and disseminate policies and/or guidelines for housing and routine care.	4.1
7.3	Actively participate in the development and review of appropriate national standards for housing and routine care.	7.3
8.1	Identify areas of non-compliance through scrutiny of records during site visits and investigation of complaints.	1.2, 2
8.2	Develop and disseminate appropriate educational material.	3
9.1	Provide information on ARRPs activities and achievements, areas of concern to the Animal Research Review Panel and statistics on animal use in the annual report.	1.4, 1.5
9.2	Identify options for disseminating information about specific issues of interest and concern both broadly and to specific groups (researchers, teachers, veterinarians, animal welfare, lay people).	3
9.3	Develop and maintain a website for the dissemination of information (including the publication of a newsletter).	3.1, 3.2
9.4	Provide opportunities for, and encourage the community (researchers, teachers, veterinarians, animal welfare, lay) to have an input into, legislative review, development of standards for housing and care, and policy development.	4, 7.3, 7.4
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.	
10.1	Promote interaction between State and Territory regulatory and funding bodies as issues are identified.	7.1, 7.2

Appendix F: Animal Research Operational Plan, July 2002 – June 2003

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)	All applications processed and recommendations made to the Director-General
1.2 Investigate formal and informal complaints	Recommendation to Director-General	Interim or final recommendations within 3 months	No new complaints. Investigation of 1 complaint from 2001–02 year 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 2001–02	Report submitted to Minister	December 2002	Report prepared and submitted for publication before submission to the Minister
1.5 Prepare statistics on animal use for 2001	Statistics presented to Minister	December 2002	Statistics for 2001 to be presented to the Minister with annual report
2. Inspections			
2.1 Conduct site visits of all accredited establishments every 3 years	Number of establishments inspected	Ongoing	30 establishments inspected (including independents)
	Number of days for inspections		29 days of inspections
	Total number of establishments not inspected within the last 3 years		13 non-active establishments with their own AECs not inspected since July 2000.
2.2 Inspect new establishments applying for accreditation before, or within 2 months of, accreditation	Number of new establishments inspected	Ongoing	3
	Number of new establishments not inspected		2 (with own AECs)

Activity	Measure of performance	Time frame	Status
2.3 Conduct site visits of selected independent researchers with animal holding facilities	Number visited	Ongoing	3
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 being followed up, as per 'Accreditation/Site Inspection Responses' section of ARRPA agendas
2.6 Review inspection procedures	Review commenced	June 2003	Review not commenced
3. Education			
3.1 Develop ARRPA website	Trial site developed	March 2003	Website due for release July 2003
3.2 Publish 6-monthly newsletter via website	1st edition published	June 2003	Newsletter to be published once website finalised
3.3 Develop learning guide to accompany AEC learning package	Learning guide developed	June 2003	Development in progress
3.4 Meeting for members of AECs	Meeting held	July 2003	Meeting scheduled for 11 July 2003
4. Policies and guidelines			
4.1 Standards linked to performance criteria for rats, mice, guinea pigs and farm animals (sheep, cattle, pigs)	Rabbit document revised in the light of comments received	December 2002	Document revised and to be published
	Draft of mouse document circulated for comment	February 2003	Draft developed
	Draft of rat document circulated for comment	February 2003	Draft developed and being edited
	First draft of guinea pig document completed	June 2004	Draft not developed
	First draft of sheep document completed		Draft not developed
4.2 Develop policies/guidelines (maximum of 2) where strong need identified	Developed as need identified	June 2003	Sheep Artificial Insemination Guideline finalised

Activity	Measure of performance	Time frame	Status
4.3 Review and revise wildlife guidelines	Revised drafts considered by ARRPP	March 2003	Revision not completed
4.5 Develop policy/statement on veterinary procedures related to the Animal Research Act	Policy/statement developed	June 2003	Statement not developed
4.8 Revise current policies and guidelines	Policies and guidelines revised	June 2003	Specific guideline revised Full review to be conducted
5. Legislation			
5.1 Assess results of revised statistics package	Results assessed	June 2003	Statistics to be published
5.2 Assess lethality statistics for publication	Statistics assessed	December 2002	Statistics not assessed
6. Sub-committees			
6.1 Activate wildlife advisory group (WAG) if special wildlife issues arise	WAG activated where issues identified	Low priority	Not activated
6.2 Activate Toxicology Technical Advisory Group (TTAG) for special toxicology issues	TTAG activated where issues identified	Low priority	Not activated
7. Additional			
7.1 Continue liaison with NHMRC	Meeting held	June 2003	Attended Code Liaison Group meetings Chair of AWC attended ARRP inspection
7.2 Continue liaison with APVMA (+/- include Qld and Victoria)	Contact with APVMA maintained	Ongoing	Raised issues with Animal Welfare Committee
7.3 Participate in review of Code of Practice	Attend review meetings Comment on further draft(s)	Timing at discretion of NHMRC	Representatives attended Code Liaison Group meetings
7.4 Participate in review of Animal Research Act	Comment on review documents	Timing at discretion of NSW Agriculture	Review Code not released
7.5 Continue liaison with NSW Health re animal use in hospitals.	Follow up on previous contact	December 2002	No progress
7.6 Establish a sub-committee to identify wildlife issues and ways to deal with them	Sub-committee met	June 2003	Meeting not held

Appendix G: Animal use statistics 2002

In 2001, a new method for gathering statistics on animal use in research and teaching was used. The advantages of the new method include the counting of animals in each project where they are used, an attempt to give some idea of the level of 'invasiveness' or 'impact' of the study on the animals involved, and the ability to collect and submit data electronically.

The following graphs (one for each **purpose**) show the numbers of animals used against category of **procedure** (1–9). 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, where procedure categories are also explained.

Some animals are used in a number of protocols, for example those used to teach animal handling techniques. Animals that are re-used are counted in each protocol for which they are used. In welfare terms, this gives a more meaningful indication of the number of animals involved in research and teaching.

The new system also includes observation of free-living animals that were previously excluded from the statistics. This has brought about a huge increase in numbers of animals recorded in purpose category 1. For example, an aerial survey of birds can include many hundreds of thousands of individual animals.

Animal species categories used for collection of data

Group	Comprises
Aquatic vertebrates	Fish, amphibians and other aquatic vertebrates
Birds	All birds except poultry
Domestic animals	Dogs and cats
Laboratory mammals	Mice, rats, guinea pigs, rabbits
Native mammals	Macropods, possums/gliders, native rodents, dasyurids, wombats, koalas
Primates	All non-human primates
Reptiles	All reptiles
Stock animals	Sheep, horses, goats, pigs, cattle, poultry
Other	Any not categorised above

Data collection: procedure categories and guidelines used for classification

1: Observation involving minor interference

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.

2: Animal unconscious without recovery

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.

3: Minor conscious intervention

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.

4: Minor surgery with recovery

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 post-operative analgesia may be appropriate. Field capture using chemical restraint methods is also included here.

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. Post-operative pain is usually considerable and at a level requiring analgesia.

6: Minor physiological challenge

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.

7: Major physiological challenge

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.

8: Death as an endpoint

This category only applies 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.

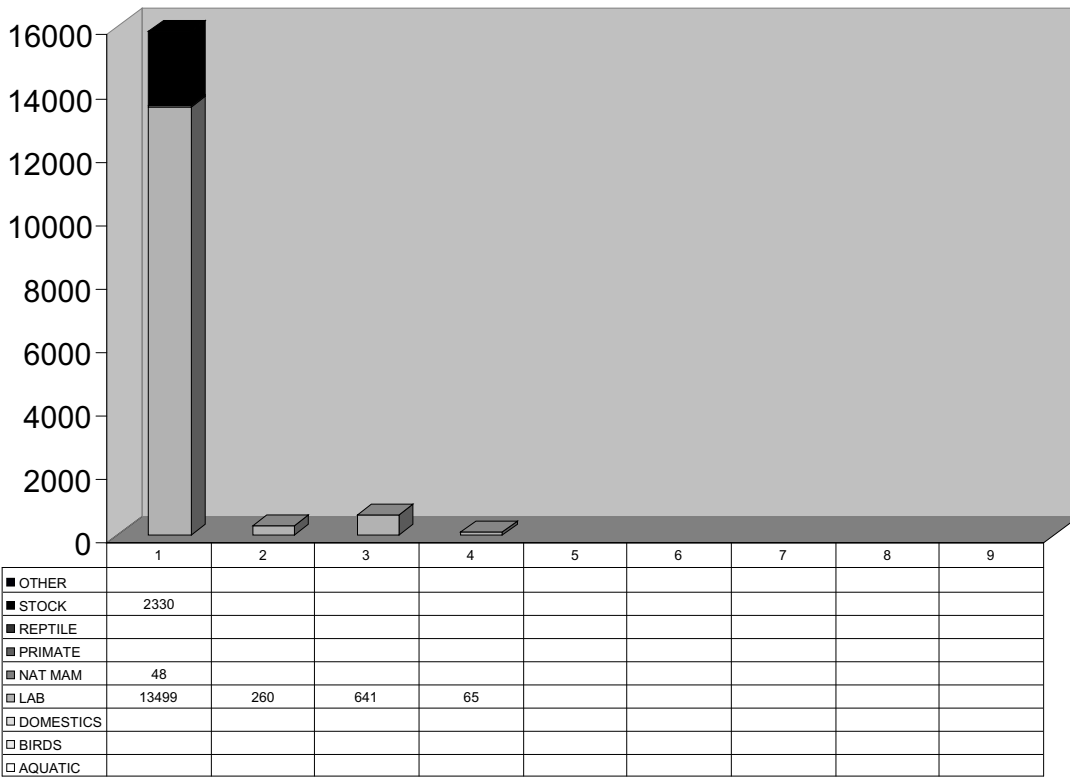
9: Production of genetically modified animals

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.

The following graphs show the numbers of animals in each category used for each type of procedure (1–9; see Table on page 28).

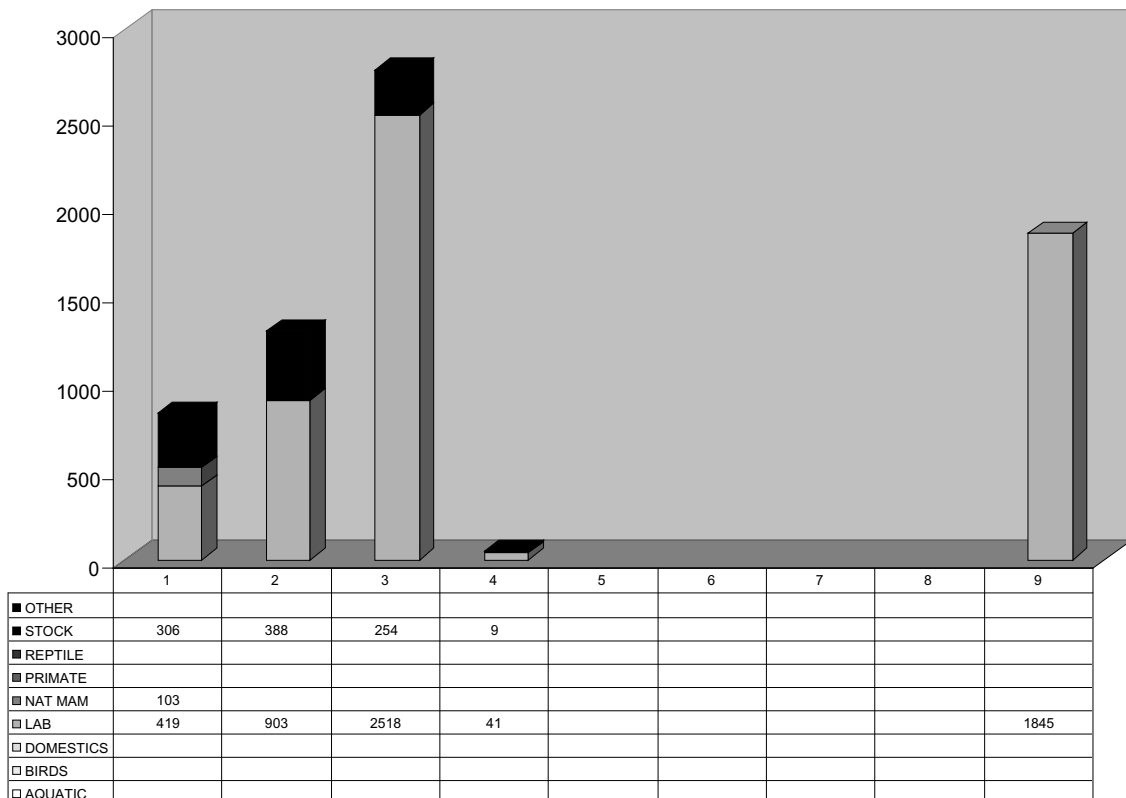
PURPOSE: STOCK BREEDING

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



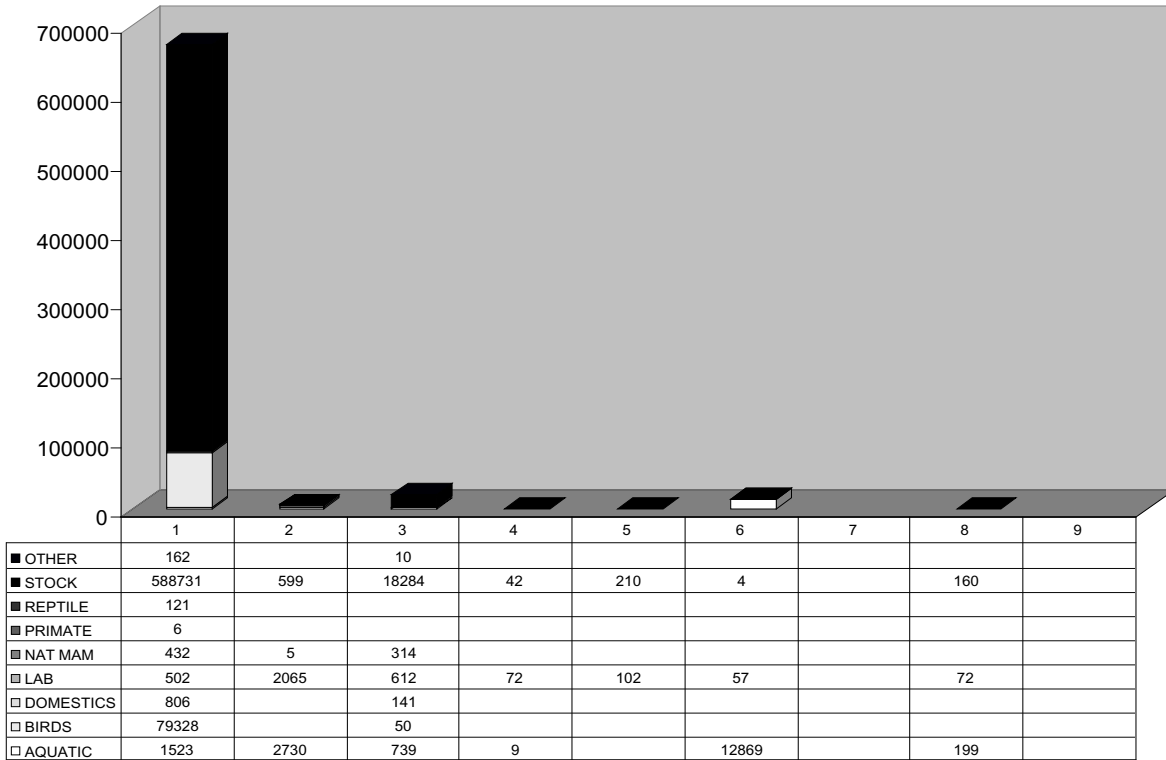
PURPOSE: STOCK MAINTENANCE

Holding protocols for animals maintained for use in other protocols



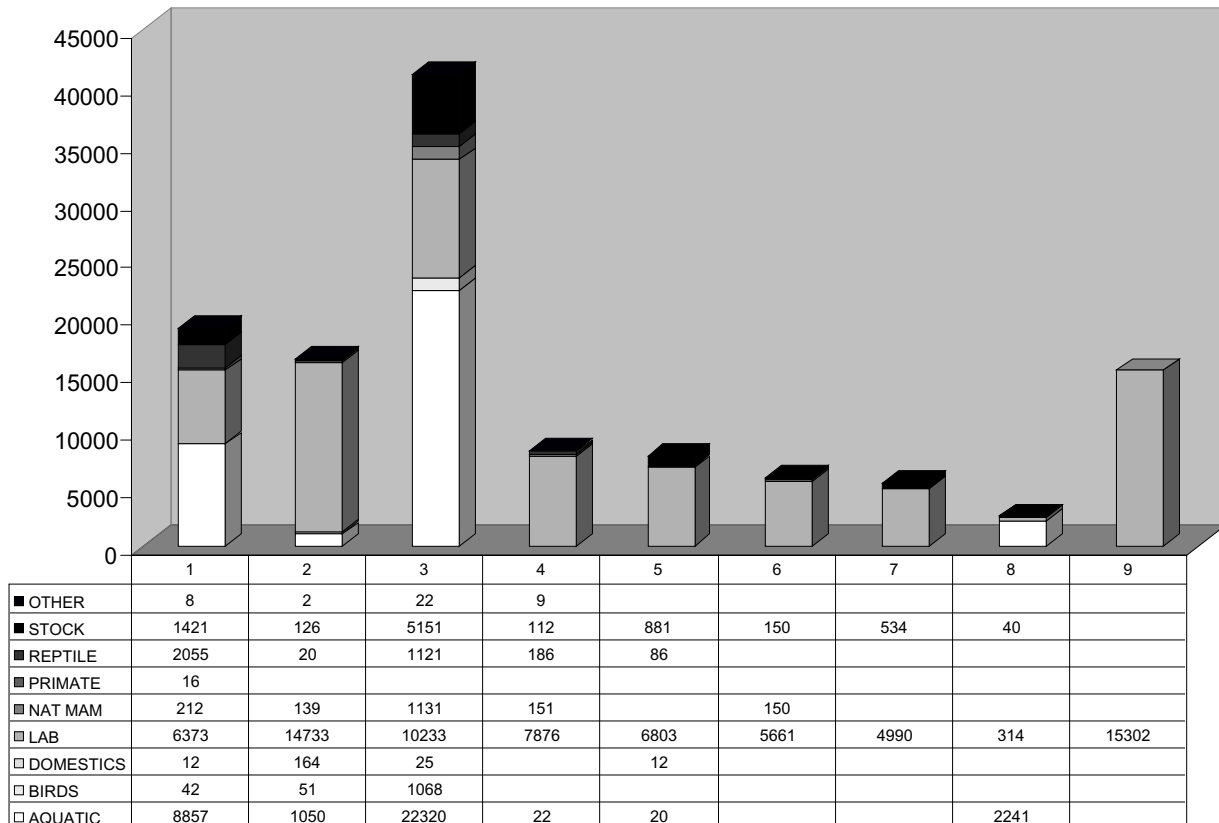
PURPOSE: EDUCATION

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



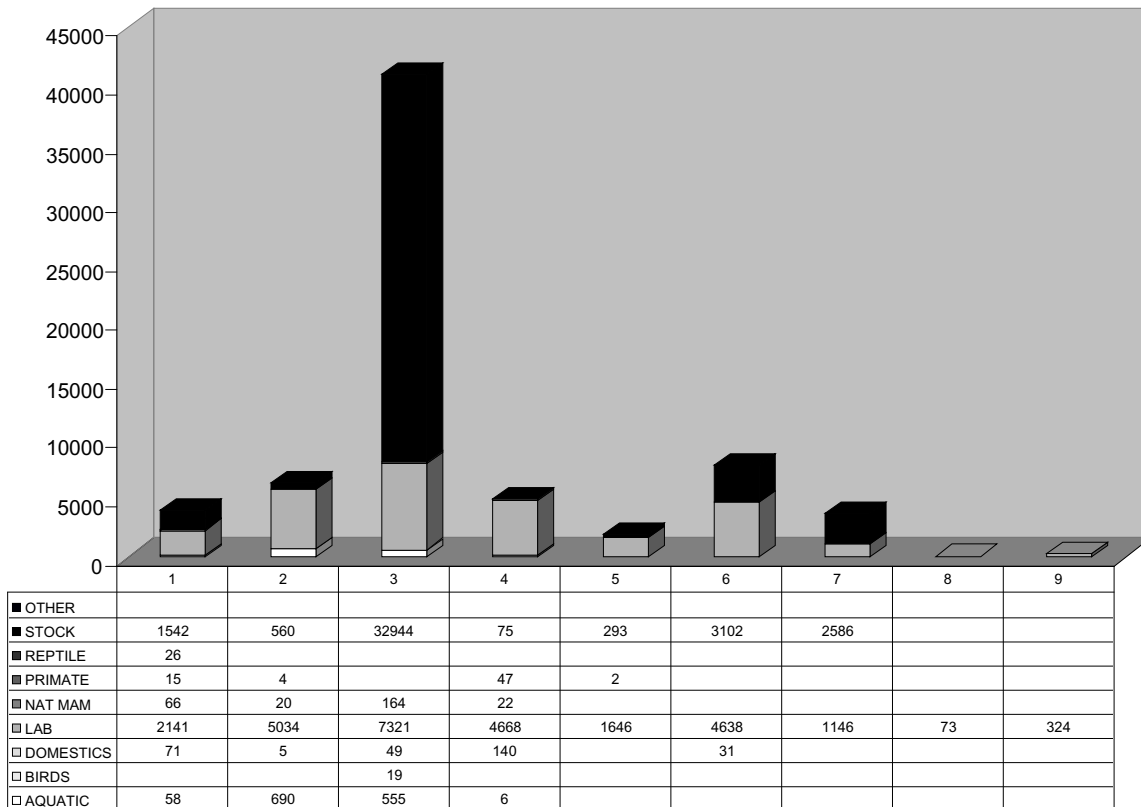
PURPOSE: RESEARCH-HUMAN OR ANIMAL BIOLOGY

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



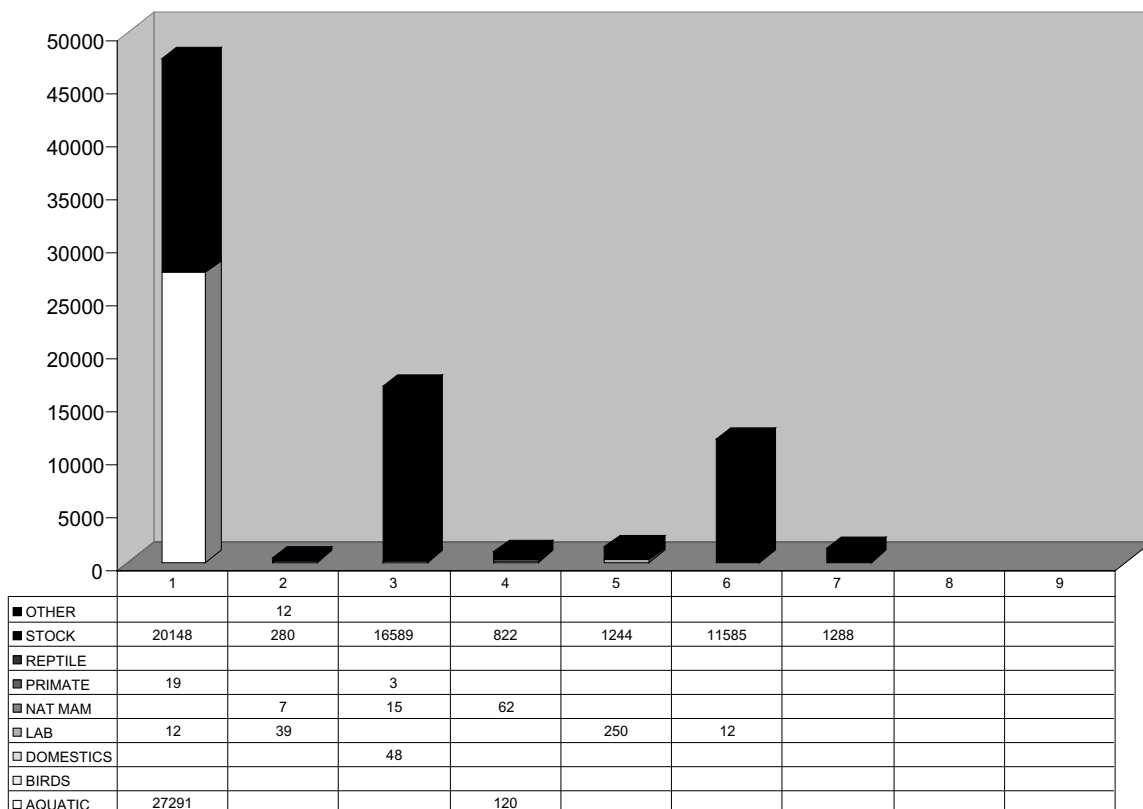
PURPOSE: RESEARCH - HUMAN OR ANIMAL HEALTH AND WELFARE

Research Protocols that aim to produce improvements in the health and welfare of animals, including humans



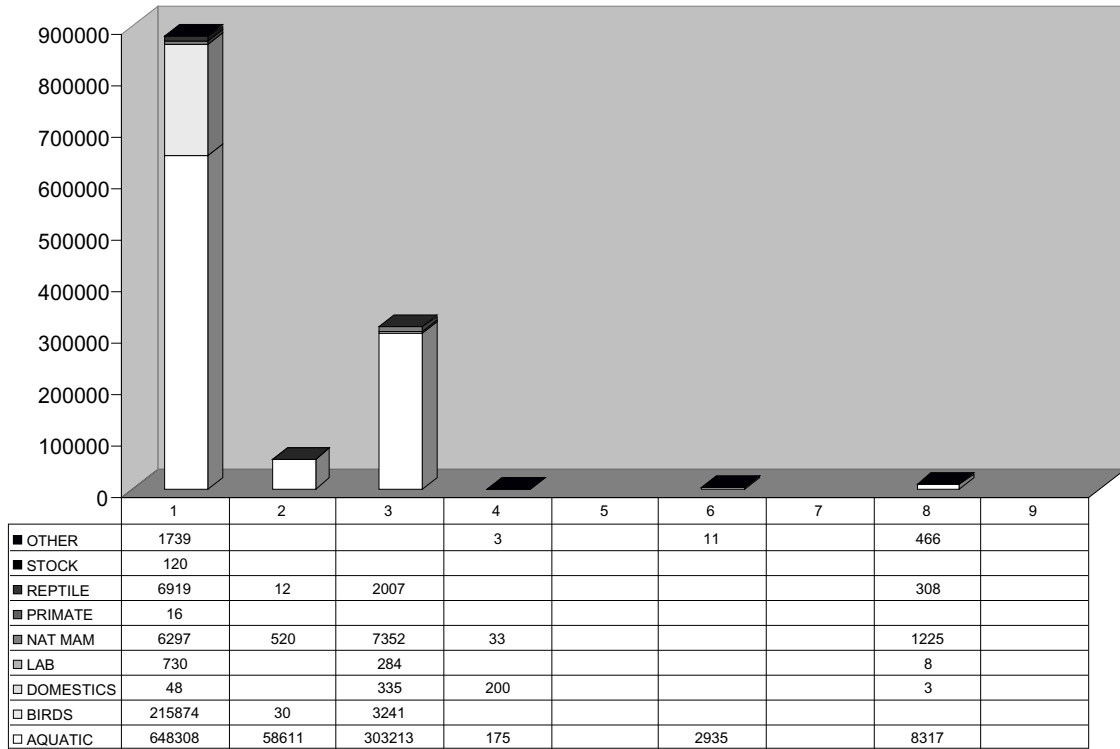
PURPOSE: RESEARCH - ANIMAL MANAGEMENT OR PRODUCTION

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



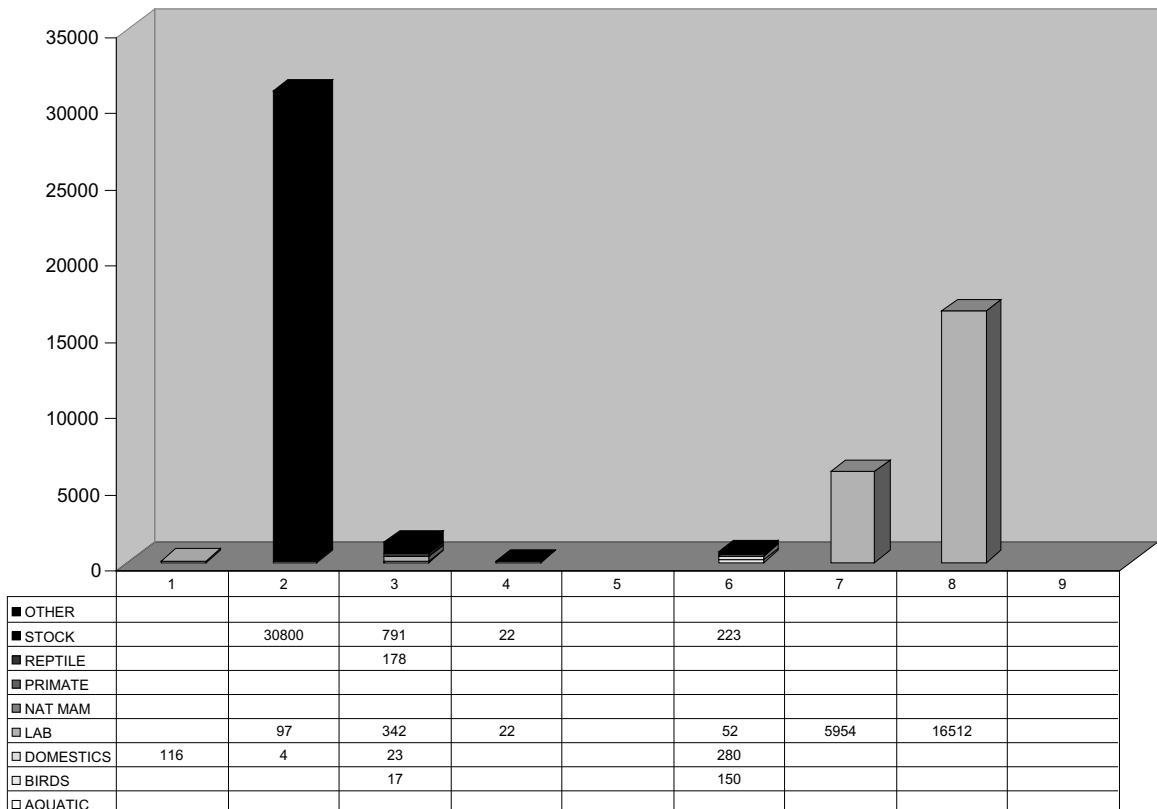
PURPOSE: RESEARCH - ENVIRONMENTAL STUDIES

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



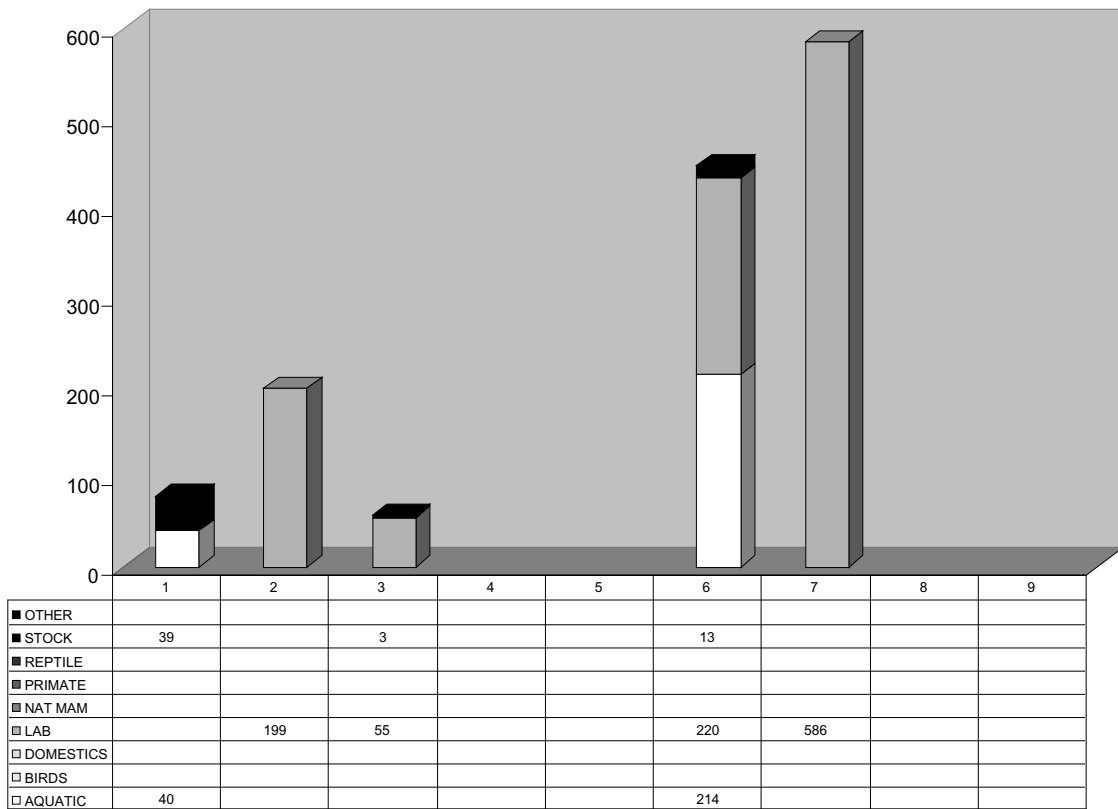
PURPOSE: PRODUCTION OF BIOLOGICAL PRODUCTS

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



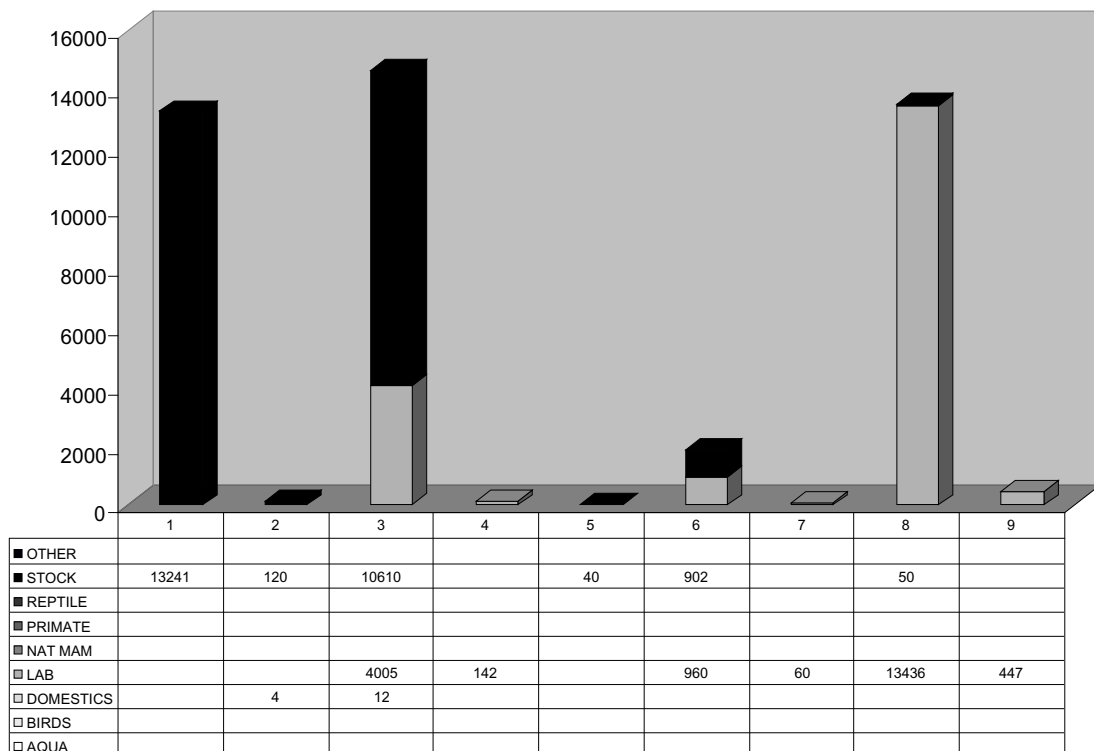
PURPOSE: DIAGNOSTIC PROCEDURES

Using animals directly as part of a diagnostic process



PURPOSE: REGULATORY PRODUCT TESTING

Protocols for the testing of products, as required by regulatory authorities



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 strategies). These examples have all been reported by accredited establishments. They are under the headings of ‘Replacement’ (of animals with other methods), ‘Reduction’ (in the number of animals used in specific protocols) and ‘Refinement’ (of techniques used to reduce the impact on animals).

Category: Replacement

Examples of strategies

- Initiative to establish an in vitro screening assay to permit evaluation of efficacy of chemical compounds against liver fluke. This will significantly reduce the number of animals used for such efficacy tests.
- Use of several models to replace the use of animals for the study of ligand-gated ion channels.
- Use of plant tissue as a replacement for animal tissue in certain enzymatic assays.
- Use of commercially available tissue cultures or antibodies.
- Use of alternatives in preliminary training of students in animal husbandry techniques.
- Syllabus required coordination of activities to be performed on animals with cooperating managers’ actual husbandry routines for those animals.
- Promotion of alternatives to animals in teaching (e.g. ‘Muscle Physiology’ CD Rom).
- Artificial animals used for teaching wherever possible, to reduce the numbers of live animals used. They are also used for any techniques that would be stressful for the live animal.
- Use of stuffed toys for demonstration of handling techniques.
- Use of fruit for demonstration of injection techniques.
- Use of audiovisual material such as videos, slides and interactive computer programs.
- Education of Animal Ethics Committee members about available alternatives to the use of animals.

Category: Reduction in numbers

Examples of strategies

- Close scrutiny of the number of animals requested in applications to the committee.
- Use of a biometrician’s comments before approval by AEC.
- Reduction in animal numbers through review of experimental design.
- Refinement of experimental procedures so that a single animal may serve as its own control.
- Number of animals always determined by statistical analysis or by minimum required for regulatory purposes. The Animal Ethics Committee continually strives to ensure that investigators fully understand the need to design protocols that will provide maximum beneficial scientific data but, at the same time, minimise the number of animals required to acquire data.
- The Animal Ethics Committee has a policy of re-evaluating treatment group outcomes after the first three experiments. Only if the initial results are positive are all the planned experiments completed. This has resulted in the number of experiments performed in two study groups being restricted to three.

- Sharing of tissue among researchers. Use of abattoir specimens and cadavers.
- Improvement in the methodology for the handling of brain slices, resulting in a reduction in the number of animals needed over the course of a set of experiments.
- Combining of class groups.
- Reduction in the number of animals used for training in animal husbandry techniques.
- Obtaining more data from the use of fewer animals by combining objectives.
- The Animal Ethics Committee has encouraged researchers to develop embryo freezing as a technique for minimising the holding of breeding stock or the culling of unused animals.

Category: Refinement of techniques

Examples of strategies

- Development of monitoring checklists to identify, and allow action to be taken on, adverse impacts of procedures.
- Close monitoring of animals.
- Identification of early intervention points and early endpoints.
- Introduction of companion animals to reduce single housing in rats.
- Group housing of animals wherever possible, with separation of animals only when required and for the minimum period of time.
- Improvements to animal housing and management.
- Increased awareness and use of environmental enrichment.
- Procedures used routinely so that animals become accustomed to them.
- Restraint time kept to a minimum.
- Use of several new anaesthetic and analgesic techniques.
- Requirement for the use of analgesia in all recovery surgical procedures.
- Development of new surgical techniques using modern technologies to minimise impacts on animals. Replacement of invasive surgical procedures with non-invasive methods (e.g. bile duct ligation replaced by autologous serum administered via the intraperitoneal route; dosing via the intratracheal route replaced with dosing via the oral route; use of a needle-free transcutaneous immunisation protocol which is less traumatic than parenteral or oral immunisation).
- Promotion of adequate training of researchers in research methods and procedures.
- Minimisation of handling times associated with weighing birds.
- To avoid leg problems and handling stress, limitation of the final average live weight that male boilers are allowed to reach.
- Spontaneous voiding of urine samples by horses on demand.
- Avoids long-term catheterisation or the use of urine collection harnesses.
- Reduction in the dose of anti-cancer drugs by about 20% so that the effect on the observed weight loss in mice (during treatment) is minimised.
- Also, the use of small pilot studies, before proceeding with major studies, to predetermine the optimal (minimal) dose of anti-cancer drug required.
- Use of adjuvants known not to produce adverse reactions.
- Use of the saphenous vein for standard blood collection in rodents.

Appendix I: ARRP expenses -

Fees and retainers	\$15,081.09
Travel and subsistence	\$ 5646.33
Stores and printing	\$ 2254.43
Freight and postage	\$ 1926.12
Total	\$24,907.97

Appendix J: Abbreviations

ACEB	Animal Care and Ethics Board
AEC	Animal Ethics Committee
ANZCCART	Australian and New Zealand Council for the Care of Animals in Research and Teaching
ANZSLAS	Australian and New Zealand Society for Laboratory Animals in Science
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARMCANZ	Agriculture and Resource Management Council of Australia and New Zealand
ARRP	Animal Research Review Panel
ATLA	Alternatives to Laboratory Animals
AWAC	Animal Welfare Advisory Council
CSIRO	Commonwealth Scientific and Industrial Research Organisation
EAPA	<i>Exhibited Animals Protection Act 1986</i>
NHMRC	National Health and Medical Research Council
NPWS	National Parks and Wildlife Service
POCTAA	Prevention of Cruelty to Animals Act
RSPCA	Royal Society for the Prevention of Cruelty to Animals
SAEC	Schools Animal Ethics Committee
TAFE	Technical and Further Education