



Animal Research
Review Panel
New South Wales



Annual
Report

2003–04



NSW DEPARTMENT OF
PRIMARY INDUSTRIES



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Animal Research Review Panel

161 Kite StreetS
Locked Bag 21S
ORANGE NSW 2800S

Telephone (02) 6391 3682S
FacsimileS(02) 6391 3570S

The Hon Ian Michael Macdonald, MLCS
Minister for Agriculture and FisheriesS
Level 30 Governor Macquarie TowerS
1 Farrer Place
Sydney NSW 2000S

Dear Mr Macdonald,S

In accordance with Section 11 of the Animal Research Act 1985, the Animal Research Review Panel presents its Annual Report covering the period S
1 July 2001 to 30 June 2002.S

Yours sincerelyS

MARGARET ROSE
Chairman
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 using animals. The Act incorporates a system of enforced self-regulation, with community participation at the institutional and regulatory levels.

The Code of Practice

Ultimate responsibility for animal care and use lies with those who use the animals: the researchers and teachers. This responsibility includes the need to comply with the National Health and Medical Research Council (NHMRC) *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*. This Code is incorporated in the Animal Research Regulation 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 For serious or repeated breaches, accreditation or authority to conduct research may be withdrawn. Conducting animal research without appropriate authorisation is an offence with substantial custodial and financial penalties.

The Animal Research Review Panel

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

NSW Department of Primary Industries Animal Welfare Unit staff provide executive support for the ARRP.

Animal Ethics Committees

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

Administration and planning

In 2003–04 there were 100 accredited research establishments, 69 accredited schools and 27 holders of animal suppliers' licences.

Inspections

In the 2003–04 year the ARRP carried out 47 inspections of accredited research establishments/animal suppliers and independent researchers. The inspections place a major focus on reviewing the operation of the AECs and ensuring that the AECs, investigators and institutions understand their responsibilities under the legislation and Code of Practice.

Support for Animal Ethics Committees

Support for AECs is provided through site inspections, through publications (including policies, guidelines and fact sheets), and through the extension activities of Animal Welfare Unit staff and the ARRP. An extensive review of the ARRP's *Guideline 10: Wildlife Surveys* was undertaken in the 2003–04 year.

Complaints

The Animal Research Act establishes a mechanism for lodging formal complaints against institutions and individuals. The mechanism includes the requirement that these complaints must be referred to the ARRP. No formal complaints were received in 2003–04.

PART ONE: ORGANISATION

1.1 The Animal Research Act 1985

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

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

The Act came fully into force in 1990, when the Animal Research Regulation was gazetted. 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 for Primary Industries. 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 affected the areas of

licensing, fees, lethality testing, AEC procedures, schools, and wildlife studies. A later amendment to the Act also allowed for the appointment by the Minister of a Deputy Chairperson to the ARRP. The Minister appointed Associate Professor Rosemarie Einstein to this position.

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

The *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (the Code of Practice) is a nationally accepted code and is included in 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 ARRP and the Animal Welfare Unit of NSW Department of Primary Industries are represented on the Code Liaison Group.

The ARRP 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

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 be achieved only by restricting competition.



Cats used in feeding trials are provided with the 'comforts of home', such as lounges, soft sleeping beds and climbing and scratching posts, as part of a program of environmental enrichment.



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 released a revised draft in October 2003, which was again circulated widely in NSW for comment.

The ARRП (as well as the Animal Welfare Unit) submitted detailed comments during both rounds of public consultation.

Meetings of the Code Liaison Group were held in early 2004 to revise the draft based on the comments received. A seventh edition of the Code was released in late 2004.

1.3 The Animal Research Review Panel

1.3.1 Mission statement

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

The ARRП was created by the Act to provide a mechanism for representatives of the scientific and broader communities to participate in monitoring the self-regulatory process, which is established within institutions by the Act.

The strength of the ARRП 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.

1.3.2 Functions of the ARRП

Section 9 of the Act defines the functions of the ARRП 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' Conference: three nominees
- Medicines Australia Inc.: one nominee
- New South Wales Minister for Health: one nominee
- New South Wales Minister for Education and Training: one nominee
- New South Wales Minister for Primary Industries: one nominee

Associate Professor Rosemarie Einstein views floor pens for rabbits during an inspection of a research facility.



- New South Wales Minister for the Environment (Department of Environment and Conservation): one nominee
- Animal Societies Federation (New South Wales): two nominees
- Royal Society for the Prevention of Cruelty to Animals (New South Wales): two nominees.

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

During the period 2003–04 Mr Ron Haering joined the ARRP as nominee of the Minister for the Environment (replacing Mr Bob Harden, who had resigned in the 2002–03 period); Ms Katrina Sharman, a nominee of the Animal Societies Federation, resigned and was replaced by Ms Stephanie Abbott; and Mr Steve Buckley resigned from the Department of Education and a new nominee was sought.

Members of the Animal Research Review Panel in 2003–04 were:

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 boards 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 ARRP in 1986 as a nominee of the NSW Vice-Chancellors' Conference and has served as the ARRP's Chair since that time.

***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' Committee. She was appointed to the ARRP in October 1998. She is an Honorary Associate Professor in Pharmacology at the University of Sydney. Her research interests are 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 1993–96. Associate Professor Einstein was appointed Deputy Chair of ARRP in October 2001.

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 is also the Vice Chair of the NSW Young Lawyers Animal Rights Committee, which she joined in 2002. Ms Abbott has a keen interest in animal law as well as in animal rights and welfare issues generally, and seeks to apply her legal skills to improve the lives of animals. Ms Abbott is the Manager of Knowledge, Learning and Development at Gilbert and Tobin.

Mr Steve BUCKLEY

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

Mr Buckley, Assistant Director-General, Department of Education and Training, Special Needs Students and Equity Programs, was the nominee of the Minister of Education and Training and was appointed to the ARRP in 2001. He has had an outstanding career in public education as a teacher, consultant, principal,

director of schools, director of finance and resources, Assistant Director-General for an area of over 100 000 students and 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.

Dr Regina FOGARTY

BVSc, PhD

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

Mr Ron HAERING

BSc, Grad Dip Ed, BApp Sc, PhD, JP

Nominee of the Minister for the Environment and employee of the Department of Environment and Conservation with expertise in wildlife research.

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 ARRP from July 1993 to August 1996. He was nominated by his employer, the RSPCA NSW, and rejoined the ARRP 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 the external parasitology of farm and companion animals and intra-ruminal controlled release of



Guinea pigs in floor pens enriched with straw bedding, enclosed hiding areas and hay.

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 ARRPP 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 worked full time with the World League for Protection of Animals and is a former director of the Australian and New Zealand Federation of Animal Societies (ANZFAS). She is also a member of a number of animal protection agencies, including the RSPCA NSW and the NSW Animal Welfare League.

Ms O'Sullivan is currently writing a PhD within the discipline of Government and International Relations at the University of Sydney, where she is focusing on the structure of animal legislation. Siobhan also teaches animal welfare and animal rights to ethics, law, veterinary and research students.

Ms O'Sullivan was appointed to the ARRPP in 2002. She is a nominee of 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 ARRPP in May 2002. He has extensive experience in biomedical animal research. He is a consultant in gastroenterology at the Prince of Wales Hospital, Randwick. He was formerly the elected staff representative on the Board of the Eastern Area Health Service and 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 ARRPP 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' Committee. She was appointed to the ARRPP in October 1998. She holds a Chair in Neuroscience and Animal Behaviour at the University of New England. 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 and a recipient of the Clarke Medal.

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*; *Birds: Their Habits and Skills*; and *Comparative Vertebrate Cognition*). She has a strong international reputation for her research on brain development and lateralization, funded by the Australian Research Council. Her research includes study of the behaviour of marmosets, chicks, magpies and a number of other species.

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

Ms Katrina SHARMAN

BA LLB (University of New South Wales)

Ms Sharman was a nominee of the NSW Animal Societies Federation. She was appointed to the ARRPP 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 practises as a litigation lawyer at the law firm Minter Ellison Lawyers.

1.4 Animal Ethics Committees

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

AECs are responsible for monitoring research within institutions, including inspections of animals and facilities. They must consider and evaluate applications to conduct research, on the basis of the researchers' responses to a comprehensive set of questions, including 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, 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 the institution on the changes that need to be made to physical facilities to provide for the needs of the animals used.

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

Committee membership must be as follows:

Category A: a veterinarian 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 ARRPP for assessment of AEC membership were clarified in an ARRPP policy document, *Policy 9: Criteria for the Assessment of Animal Ethics Committee*

Membership (www.animaethics.org.au/reader/operation-aecs). In examining an application from an institution for accreditation as an animal research establishment, the membership of the institution's AEC is assessed to ensure that it is of acceptable composition and size. During audit inspections, the ARRPP assesses the operation of the AEC.

1.5 Accreditation and licensing

The legislation requires that all applications for accreditation and animal supply licences are referred to the ARRPP for consideration. The ARRPP 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 ARRPP:

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

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

1.5.1 Evaluation of written applications

The ARRPP has appointed an applications sub-committee to facilitate the assessment of

applications. New applications for accreditation or licences are assessed by ARRPP executive staff, according to criteria developed by the ARRPP. These applications and assessments are then referred to the applications sub-committee, which makes recommendations to the full ARRPP. Recommendations on the applications are then made by the ARRPP to the Director-General of NSW Department of Primary Industries.

A small number of applications are also viewed directly and considered by the full ARRPP. These include applications from individuals or organisations about which the ARRPP 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 ARRPP executive staff, and the ARRPP considers the recommendations arising from these assessments.

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

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

1.5.2 Conduct of site inspections

Following the evaluation of written applications, the second phase of the process of assessing establishments is the site inspection. The aim of site inspections is to determine whether institutions and individuals are complying with the legislation. The Code of Practice provides the criteria against which institutions are assessed. The range of items assessed includes the membership, procedures and activities of the AEC; animal care procedures; animal research procedures; and the physical facilities for housing



Rabbits in floor pens with a hiding box that doubles as an elevated area for sitting on.

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 2003–04 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 the written material provided by the institution or individual. This includes lists of the research applications considered by the AEC and the 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 AEC's 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 ARRPP members who have been nominated to participate in the inspection. This pre-inspection evaluation allows likely problem areas to be identified



Sheep are held in indoor facilities for research purposes such as parasite trials.

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 AEC. 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 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, standards for wildlife transportation and the recognition and relief of pain.

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

As soon as possible after the inspection, a detailed report is prepared. The report covers an

evaluation of the AEC and an assessment of the animals' wellbeing, housing and holding, and their care and monitoring. Once the ARRPP 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 ARRPP 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 ARRPP 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 ARRPP to commend the institution, individual researchers or animal attendants for initiatives that raise the standards of the overall operation of the research facility or for techniques or facilities that enhance the welfare of research animals.

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

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

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.

1.6.1 The Animal Research Act in schools

The use of animals in teaching activities in schools is governed by the Animal Research Act. Any school that uses animals is required to be accredited, and teachers using animals must hold an animal research authority issued by an AEC. Animal use in schools must be conducted in accordance with the requirements of the *Australian 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 teaching activities that use animals and are carried out in schools are

described in a list approved by the ARRPP. Teachers wishing to undertake an activity on the approved list may do so, provided that they follow the comprehensive guidelines developed and published by the SAEC. These guidelines have ARRPP 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 ARRPP and a significantly revised document was released in 2001.

The ARRPP liaises regularly with the SAEC. In general, complaints received by the ARRPP 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 ARRPP. If necessary, as in the case of serious complaints, the ARRPP 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.

A productive meeting was held with the Schools sector in 2003 to discuss amendments to its SAEC application form. The inclusion of teachers as well as SAEC members at this meeting was especially useful in exploring the most effective means of gaining relevant information in applications to the SAEC. As a result of the meeting, teaching application forms better tailored to obtaining the information required by the SAEC were developed.

1.6.2 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 ARRPP, 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 ARRPP met with representatives of TAFE and its ACEB twice in the 2000–01 reporting period and undertook an intensive 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 ARRPP with a revised system of management for implementing the Animal Research Act. This system centred around the disbanding of regional AECs and expansion of the role of the ACEB in approving and monitoring animal use activities. Discussions are still under way to finalise this new system to ensure its compliance with the animal research legislation.

The ARRPP 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.

1.7 Administration

The Animal Welfare Unit was established in October 1993 as an independent program within NSW Agriculture, reporting directly to the Director-General of NSW Agriculture. A permanent subsection of the Unit is maintained in the inspectorial office in Sydney. During 2004 plans were developed by the State Government to amalgamate the Departments of Agriculture, Fisheries, Forests and Mineral Resources into a new Department of Primary Industries, to become operational from July 2004.

The functions of the Animal Welfare Unit cover:

- animal research issues under the *Animal Research Act 1985*, including providing Executive services to the ARRPP
- 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 Primary Industries

- animal display issues under the *Exhibited Animals Protection Act 1986* (EAPA), including the operation of the Exhibited Animals Advisory Committee
 - Departmental animal welfare activities.
- The Animal Welfare Unit can be contacted at:

Animal Welfare Inspectorial Office
NSW Department of Primary Industries
95 Castle Hill Road
WEST PENNANT HILLS 2125

PO Box 100
BEECROFT NSW 2119

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

Animal Welfare Unit
NSW Department of Primary Industries
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

In financial year 2003–04 the following staff were assigned to provide inspectorial and/or executive support to the ARRPP.

Orange:

Ross Burton BVSc, MVSc, Manager
Amanda Paul BVSc, Veterinary Officer (part-time)
Len Cantrill BVMS, Veterinary Officer
Kathleen Mullins, Acting Unit Coordinator
Angela Thompson, Licensing Clerk
Tammy Kirby, Clerical Officer / Acting Licensing Clerk
Rebecca Hutchinson, Clerical Officer

Sydney:

Lynette Chave BVSc, Senior Veterinary Officer
Peter Johnson BVSc, PhD, Veterinary Officer
Ann Sullivan, Clerical Officer

PART 2: REPORT ON WORK AND ACTIVITIES

2.1 Administration and N planningN

Administrative functions have varied from activities such as assessments of licensing and accreditation to formulating the ARRPN's operational plan for 2003–04. The appendixes to this annual report contain details of many of the operational and strategic functions of the ARRPN. These include the dates of, and attendance at, ARRPN meetings (Appendixes A and B); dates and attendance of ARRPN members at inspections of accredited research establishments and premises of animal supply licence holders (Appendixes C and D); the ARRPN Strategic Plan 2002–05 (Appendix E) and Operational Plan for 2003–04 (Appendix F); and ARRPN operating expenses (Appendix I).

2.1.1 Strategic Plan 2002–05

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

2.1.2 Operational Plan for 2003–04

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

2.1.3 Liaison with organisations, accredited institutions and authority holders

The ARRPN 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. (See examples of activities under '1.6.1 The Animal Research Act in schools' and '2.6 Support for Animal Ethics Committees'.)

2.1.4 Meeting with the Minister for Primary Industries

The Chair of the ARRPN, Associate Professor Margaret Rose, met with the Minister for Primary

Industries, the Hon. Ian Macdonald MLC, to discuss animal welfare-related issues, including the activities of the ARRPN. The Minister hoped to attend a meeting of the ARRPN at a later date.

2.2 Assessment of N applicationsN

Applications for accreditation and/or licensing were reviewed by an applications sub-committee of Ms Katrina Sharman / Ms Stephanie Abbott, Dr Barry Lowe and Mr Mark Lawrie. The sub-committee discussed applications via teleconference and made recommendations to the ARRPN.

During 2003–04 the ARRPN considered:

- 37 applications for accreditation
- 23 applications for school accreditation
- 6 applications for animal suppliers' licences.

2.2.1 LD50 testing

LD50 is a toxicity test used to determine the dose or concentration of a test substance—that is, the lethal dose—that is expected to kill 50 per cent 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 Primary Industries. Applications for permission to conduct LD50 tests are evaluated by an ARRPN sub-committee. Members of the sub-committee in 2003–04 were Associate Professor Einstein, Dr Lowe and Dr Fogarty. The sub-committee makes recommendations to the ARRPN, which in turn advises the Minister.

In 2003–04 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 ARRPN recommended to the Minister that he approve the applications on the conditions that the organisation report to the ARRPN progress with

the development of replacement in vitro tests, and provide annual statistics for the numbers of animals used in each test. (Two ARRPP members did not approve the recommendation because of fundamental objections to the use of animals for research.)

The ARRPP has also been briefed on the ongoing activities of the Animal Welfare Working Group in identifying 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. A position paper outlining the key issues was presented by Department of Primary Industries staff and included in the proceedings of the Australian Veterinarians for Animal Welfare and Ethics special interest group of the Australian Veterinary Association (AVA) at the May 2004 Annual Conference of the AVA. A meeting was held with representatives of the Australian Pesticides and Veterinary Medicines Authority in November 2004 to discuss some of issues affecting the development and adoption of alternative tests. The ARRPP continues to support an intergovernmental, inter-agency approach in cooperation with industry to develop a practical policy that will bring significant animal welfare benefits, together with efficiencies for industry, through the phase-out of large-scale animal-based tests.

2.3 Subcommittees

The ARRPP 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 ARRPP for consideration. There are standing sub-committees that make recommendations on licensing, accreditation, and LD50 testing. Membership of sub-committees is drawn largely from the ARRPP. 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
- applications for accreditation and licences
- applications for LD50 testing
- dealing with concerns raised related to the use of animals in a teaching protocol

- meeting with an accredited establishment concerning the management of a dog colony.

2.4 Legislation

2.4.1 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 wide 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 ARRPP's representative on the Review Group. Mr Fraser Bowen and Mr Charles Wright, who at the time were members of the ARRPP, 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 ARRPP provided a submission focusing on issues relating to the ARRPP, 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.

2.4.2 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 was 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 ARRП 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.

In response to the comments received, the NHMRC released a revised draft in October 2003, which was again circulated widely in NSW for comment. The ARRП again held a special meeting to formulate a submission to the Code review.

Meetings of the Code Liaison Group (which includes members of the ARRП and Animal Welfare Unit) were held in early 2004 to revise the draft on the basis of the comments received. A Seventh Edition of the Code was released in late 2004.

2.4.3 Action on non-compliance

The ARRП was advised by an accredited establishment that its AEC had been non-functional for a considerable period. Although, to its credit, the establishment had brought this to the attention of the ARRП, the ARRП was very concerned about the situation, especially in light

of a previous site inspection that had identified problems with the functioning of the AEC and institutional support for the AEC. In view of this, the ARRП recommended that the accreditation of the institution not be renewed until the problems identified had been rectified (necessitating the halting of all research). An inspection by Animal Research Act inspectors was organised. In addition, the then Director-General of NSW Agriculture wrote to the establishment, requiring specific measures to be put in place to rectify the situation before accreditation was renewed. The establishment complied with the requirements and accreditation was renewed. An ongoing schedule of monitoring of the establishment by the ARRП was implemented, and compliance with the legislation was found to be satisfactory at subsequent inspection.

2.5 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

Elliot traps are used for environmental surveys. Animals such as this brown antechinus that are caught in the traps are identified and immediately released.



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. The system for the collection of statistics was revised in 2001. Advantages of this new system over the previous one include:

1. the recording of an animal in all projects in which it 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, 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 2003.

2.5.1 Lethality testing

Accredited research establishments must keep figures on lethality testing and submit these to the ARRPP. Lethality testing is defined in the *Animal Research Act 1985* 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 31 March 2004 deadline for submission of completed forms to the ARRPP.

2.6 Support for Animal Ethics Committees

The ARRPP and the Animal Welfare Unit 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; the holding of meetings for AEC members; and the supply of advice over the telephone or by correspondence.

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

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

Cattle kept under extensive conditions are used for a variety of scientific purposes in NSW.



The following are examples of ARRP activities related to support for AECs:

- The ARRP liaised with an establishment holding primates regarding the best management in terms of temperature control in its indoor/outdoor facilities and the types of resting areas. The ARRP sought and passed on advice from interstate (non-research) facilities holding the same primate species and sought information from the scientific literature.
- Concerns were brought to the attention of the ARRP about a project being carried out at a teaching facility. The concerns related to the level of impact of the procedures on the animals used in the project and whether this was appropriate in the teaching context. The ARRP agreed with the concerns and, after seeking background information from the AEC, decided to set up a subcommittee to meet with the AEC to discuss the project. The AEC requested that the subcommittee also meet with the teacher concerned, which the subcommittee did, separate to its meeting with the AEC.

The spirit of the meeting with the AEC was one of co-operation and a mutual desire to ensure that the best standards were applied in the assessment of teaching applications. It was noted that the AEC was considering and managing more conventional teaching projects well. Reasons leading to the AEC's approval of the teaching project were identified. From this, mechanisms to ensure critical evaluation (both by the AEC and applicants) of teaching applications, especially in terms of learning objectives and impacts on animals, were examined. The teacher was receptive to the concerns raised and the teaching project was not renewed.

- Advice was sought from the ARRP by an AEC regarding a project using rabbits. The facilities available and the project design did not allow the holding of rabbits in adequately sized floor pens (as outlined in ARRP Guideline 18: *Guidelines for the Housing of Rabbits in Scientific Institutions*). The AEC sought advice on whether such a project should be approved. In view of the project design, the short period over which rabbits would be held (2 weeks), and the plans in place for upgrading rabbit housing facilities,

the ARRP advised that, in its opinion, approval would be reasonable.

- An ongoing issue related to the management of a dog colony was addressed. The AEC concerned had experienced difficulties in obtaining adequate plans of management for the care and use of the dogs concerned. After a condition had been imposed on the establishment requiring the development of a plan of management for the dogs, the ARRP took the matter up with the establishment's Executive, organising a meeting attended by Associate Professor Rose and Mr Lawrie (accompanied by an Inspector). A response, as a result of this meeting, is awaited.

2.6.1 Register of candidates for AEC membership

Finding interested and suitable members has been a problem experienced by a number of AECs. Categories A, C and D have presented the most difficulty. To help AECs to maintain the required membership, the ARRP suggested the establishment of a register of AEC members interested in joining other AECs. The Animal Welfare 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.

2.6.2 Meeting for members and executive officers of AECs

In the past the ARRP 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 ARRP, 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 members of the ARRP subcommittee that worked on this project were Associate Professor Margaret Rose, Professor Lesley Rogers and Ms Katrina Sharman. The meeting was held in July 2003 and was well attended. Topics presented included:

- an update on the revision of the Code of



Fish are used in inland aquaculture research.

Practice (Mrs Elizabeth Grant, Chairman, Code Liaison Group)

- communication between AECs and practitioners (Dr Roger Garsia, AEC Chair; Professor John Roger, Practitioner; Ms Susanna Davis, AEC Executive Officer)
- effective meetings: a view from the corporate world (Ms Mary Brell, Senior Partner, Keys to Success).
- meeting the paperwork challenge (Dr Mary Bate, Animal Welfare Officer, University of Newcastle; Dr Paul Gilchrist, AEC member).

An open discussion session on the review of the Code of Practice resulted in ideas on requirements for reporting to AECs being forwarded to the Code Liaison Group for consideration in the review of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*.

The feedback from the meeting was, in the main, enthusiastic, and it is intended to attempt to hold further meetings on an annual basis. These meetings will be open to all categories of AEC members and AEC Executive Officers. An ARRPP subcommittee made up of Associate Professor Margaret Rose, Associate Professor Rosemarie Einstein and Ms Siobhan O'Sullivan met on a regular basis in 2003–04 to plan for the next meeting, to be held in July 2004.

2.7 Website: Animal Ethics Infolink

Development of a website by the ARRPP was identified as a need in the ARRPP's Strategic Plan 2002-05. 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. The publication of the website was announced at the July 2003 meeting of members of AECs. The site is designed to provide an opportunity for interchange with animal research entities world wide, and to give the general community access to information about animal use for research and teaching in NSW. It is intended to enhance channels of communication and make information more accessible. The website has been developed and is maintained in conjunction with the Animal Welfare Unit. The site is called Animal Ethics Infolink and is accessible at www.animaethics.org.au.

2.8 Site inspections

A list of site inspections undertaken in 2003–04 is provided in Appendix C, and a list of ARRPP members attending is given in Appendix D. There were 47 inspections conducted over a period of 44 working days. The length of these inspections ranged from half a day to 6 days for larger institutions. The inspections included AECs and the facilities of 32 accredited institutions/licensed animal suppliers.

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

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

2.9 Policies, guidelines and fact sheets

The ARRPP and Animal Welfare Unit produce policies, guidelines and fact sheets to aid

researchers, AECs, research establishments, animal suppliers and members of the broader community to understand and comply with the requirements of the animal research legislation. These documents are available from the Animal Welfare Unit and can also be found by following the links from the ARRPs website www.animaletics.org.au (see Appendix K for a list of guidelines and policies).

New policies, guidelines and fact sheets are produced to fill needs identified by the ARRPs. In the 2003–04 reporting year no new policies or guidelines were developed, although editing of a draft guideline on rat housing neared completion.

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 ARRPs also has a policy of actively reviewing older guidelines and policies to ensure they are up to date. The following guideline was reviewed in 2003–04:

- ARRPs Guideline 10: *Wildlife Surveys* (revised draft distributed for comment).

2.10 Initiatives in replacement, reduction and refinement in animal use strategies

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

2.11 Complaints

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

ARRPs 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 ARRPs 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; ARRPs 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 ARRPs, or the Animal Welfare Unit.

The ARRPs did not deal with any complaints in the 2003–04 reporting period.

APPENDIXES

Appendix A: Dates of ARRP meetings 2003–04

Meeting number	Date of meeting
145	9 July 2003
146	27 August 2003
147	15 October 2003
148 (special meeting to discuss review of the Code of Practice)	14 November 2003
149	3 December 2003
150	11 February 2004
151	31 March 2004
152	19 May 2004

Appendix B: Members' attendance at ARRP meetings N 2003–04N

	Meeting number							
Member	145	146	147	148 (special)	149	150	151	152
Assoc. Prof. M Rose (Chair)	*	*	*	*	*	*	*	*
Ms S Abbott	—	—	—	—	—	—	*	*
Mr S Buckley	A	A	—	—	—	—	—	—
Assoc. Prof. R Einstein	*	*	*	*	*	*	*	*
Dr R Fogarty	*	*	*	A	*	A	*	*
Mr R Haering	O	*	*	A	A	*	*	A
Mr M Lawrie	*	*	*	A	*	*	*	*
Dr B Lowe	*	*	*	*	A	A	*	*
Ms S O'Sullivan	*	*	*	*	*	*	*	*
Assoc. Prof. R Pirola	A	A	A	A	*	*	*	*
Mr D Robinson	*	A	*	A	*	*	*	*
Prof. L Rogers	Tel.	*	*	A	*	*	A	A
Ms K Sharman	*	A	*	*	*	—	—	—

* = Present

A = Absent

— = Not applicable

Tel. = Telephone hook-up

O = Observer

Appendix C: Inspections July 2003 – June 2004C

Establishment	Date
ICP Firefly	1/7/2003
Charles Sturt University—Wagga Wagga	6/8/2003
NSW Agriculture—Wagga Wagga	7/8/2003
NSW Agriculture—Yanco	7/8/2003
NSW Fisheries—Narrandera	7/8/2003
Western Sydney Area Health Service	14/8/2003
	15/8/2003
New Children's Hospital	14/8/2003
	15/8/2003
	18/8/2003
Children's Medical Research Institute	18/8/2003
Australian Catholic University	21/8/2003
Director-General's Animal Ethics Committee	25/8/2003
Agrisearch	26/8/2003
Southern Cross University	28/8/2003
Warne and Webster Serum	28/8/2003
Access Pharmaceuticals	11/9/2003
Biotechnology Frontiers	16/9/2003
Friskies Pet Care (Nestlé Purina)	26/9/2003
Bioquiv	24/10/2003
NPWS	27/10/2003
Charles Sturt University—Albury	7/11/2003
Harper Somers	11/11/2003
NSW Agriculture—Tocal	20/11/2003
NSW Fisheries Salamander Bay (Port Stephens)	20/11/2003
NSW Fisheries—Cronulla (with AEC)	9/12/2003
Zoological Parks and Gardens Board—Dubbo	9/12/2003
Australian Museum (met with AEC Chair)	10/12/2003
Macquarie University	11/12/2003
University of Wollongong (met with AEC)	11/12/2003
Zoological Parks and Gardens Board—Mosman	16/12/2003
Clinical Analytics	4/3/2004
Bovine Research Australasia	4/3/2004
Avondale College	30/3/2004
Sydney University (Camperdown / Camden / Orange)	29/3/2004
	1/4/2004
	6/4/2004
	20/4/2004
	22/4/2004
	29/4/2004
Centenary Institute (Animal Supply Licence)	29/4/2004
Australian Museum	28/4/2004
NSW Agriculture—Grafton	29/4/2004
NSW Fisheries—Grafton	29/4/2004
TAFE—North Coast (Wollongbar)	30/4/2004
Fort Dodge	12/5/2004
Australian Nuclear Science and Technology Organisation	20/5/2004
New England Artificial Breeders	2/6/2004
Veterinary Health Research	3/6/2004

Appendix D: Attendance of ARRP members at site inspections 2003–04

Member	Number of days spent on site inspection
Assoc. Prof. M Rose	8
Ms S Abbott	0
Mr S Buckley	0
Assoc. Prof. R Einstein	5
Dr R Fogarty	3
Mr R Haering	1
Mr M Lawrie	1
Dr B Lowe	0
Ms S O’Sullivan	11.5
Assoc. Prof. R Pirola	0
Mr D Robinson	4
Prof. L Rogers	0
Ms K Sharman	0.5

Appendix E: NSW Animal Research Review Panel N

Strategic Plan July 2002 – June 2005N

Priority items are numbers 1.3, 3.2 and 4.2.

Goal or strategy no.	Details
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.
1.2	Maintain a program of site visits to effectively monitor compliance with the legislation.
1.3	Review the methods of conducting site visits and the documentation of these methods on a regular basis to help ensure high standards of efficiency, effectiveness and consistency. (Priority item)
1.4	Identify and implement adjuncts to inspections to better ensure compliance with the legislation.
1.5	Monitor compliance with the Act, Regulations and the Code with respect to the conduct of animal research and teaching and the supply of animals for research and teaching.
1.6	Active participation in national reviews of the Code to ensure that it is effective in regulating the conduct of animal research and teaching and the supply of animals for research and teaching.
1.7	Prepare an annual report to Parliament on the operations and achievements of the Animal Research Review Panel.
1.8	Maintain and review the system for collection and analysis of statistics on animal use for research and teaching; to ensure that it provides useful information that 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	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.
1.12	Maintain a system to consider and make recommendations on applications for permission to carry out LD50 tests.
2	The principles, processes and responsibilities in the Code are actively embraced wherever animals are used, principally through Animal Ethics Committees
2.1	Ensure there is effective participation by researchers and teachers, veterinarians, animal welfare representatives and independent representatives in a formal review of the justification and merit for all proposals for the use of animals for scientific purposes.
2.2	Promote support for AECs within institutions.
2.3	Promote and foster interaction between AECs and researchers/teachers.
2.4	Promote an appreciation of the ethos underpinning the Code through visits and all communications from the Animal Research Review Panel to institutions, AECs, researchers/teachers and animal care staff.
2.5	Promote an understanding of the roles and responsibilities of AECs through encouraging participation in AEC training programs.

Goal or strategy no.	Details
2.6	By identifying problems and suggesting remedies, provide help to institutions, AECs and researchers/teachers to ensure that the principles, processes and responsibilities in the Code are actively embraced.
2.7	Promote discussion and understanding of key technical and ethical issues and foster interaction between AECs by maintaining a program of meetings of Chairs of AECs and participating in AEC meetings during site inspections.
2.8	Review the membership and operation of individual AECs during site visits to ensure that all categories of membership are able to contribute effectively to discussions, decisions and activities of the AEC.
2.9	Develop and promulgate guidelines to help AECs to evaluate protocols effectively.
2.10	Conduct ongoing monitoring of TAFE, schools and Director-General's AECs to identify any special needs.
2.11	Promote a critical review of the operation of AECs with a view to maximising their effectiveness.
3)	Researchers and teachers using animals actively support the principles set out in the Act, Regulation and Australian Code of Practice for the Care and Use of Animals for Scientific Purposes.
3.1	Promote an understanding of the roles and responsibilities of researchers/teachers through encouraging participation in training programs.
3.2	Publish a newsletter to raise key issues and suggest resources. (Priority item)
4	Methods that complement or replace animal use are used wherever possible
4.1	Encourage AECs critically to assess the adequacy of researchers'/teachers' attempts to identify alternatives to animal use.
4.2	Encourage greater awareness of the use of alternatives to animals in research and teaching. (Priority item)
4.3	Collate and disseminate information on alternatives to animal use.
5)	Procedures involving animals are regularly reviewed and refined to minimise the number of animals required and to reduce the impact on individual animals
5.1	Encourage a critical review of the design of experiments before protocols are submitted to AECs.
5.2	Ensure close scrutiny by AECs of breeding programs to minimise overproduction of animals.
5.3	Ensure close scrutiny by AECs of the competence of researchers to carry out specific procedures.
5.4	Promote the critical evaluation of the monitoring of animals being used in procedures.
5.5	Promote the critical evaluation by AECs and researchers of the impact of the type of housing/holding on experimental animals and awareness of its implications for experimental results.
6)	Pain or distress is anticipated, promptly recognised and relieved.
6.1	Promote the use of appropriate analgesia and anaesthesia by facilitating access by researchers/teachers to information resources.
6.2	Ensure that AECs and researchers/teachers focus on the possible impact of procedures at the planning stage and implement appropriate strategies for monitoring and alleviation.
6.3	Promote awareness by researchers/teachers and animal care staff of signs of pain or distress in animals.
6.4	Promote awareness of the effects of handling and other interactions with humans on levels of pain and distress and the use of strategies to minimise adverse impacts.

Goal or strategy no.	Details
6.5)	Monitor and identify deficiencies in anticipation, recognition and relief of pain and distress during site visits and ensure deficiencies are rectified, including by provision of pre-operative analgesia where appropriate.
7)	High standards of housing and routine care are established and met.
7.1	Evaluate housing and routine care through the ongoing site visit program.
7.2	Develop and disseminate policies and/or guidelines for housing and routine care.
7.3	Actively participate in the development and review of appropriate national standards for housing and routine care.
8)	Animals used are supplied in accord with the legislation.
8.1)	Identify areas of non-compliance through scrutiny of records during site visits and investigation of complaints.
8.2)	Develop and disseminate appropriate educational material.
9)	The community (research, teaching, veterinary, animal welfare and lay) has access to information about animal use for research and teaching in NSW.
9.1)	Provide information on ARRPs activities and achievements, areas of concern to the Animal Research Review Panel and statistics on animal use in the annual report.
9.2)	Identify options for disseminating information about specific issues of interest and concern both broadly and to specific groups (researchers, teachers, veterinarians, animal welfare, lay).
9.3)	Develop and maintain a web site for the dissemination of information (including the publication of a newsletter).
9.4)	Provide opportunities for, and encourage the community (researchers, teachers, veterinarians, animal welfare, lay) to have an input into, legislative review, development of standards for housing and care and policy development.
9.5)	Ensure that information about animal use provided by the Animal Research Review Panel is in lay terms where appropriate.
9.6)	Encourage institutions to provide information about their animal use direct to the general community.
10)	The approach to administration of animal research is harmonised between State and Territory regulatory and funding bodies.
10.1)	Promote interaction between State and Territory regulatory and funding bodies as issues are identified.

Appendix F: Animal Research Operational Plan July 2003 – June 2004

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	Two informal complaints investigated by the Animal Welfare Unit and resolved
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 2002–03	Report submitted to Minister	December 2003	Report submitted
1.5 Prepare statistics on animal use for 2002	Statistics presented to Minister	December 2003	Statistics submitted
2 Inspections			
2.1 Conduct site visits of all accredited establishments every 3 years	Number of establishments inspected Number of days for inspections Total number of establishments not inspected within the last 3 years	Ongoing	32 establishments inspected (47 inspections conducted) 44 days of inspections Three establishments (active over the last 3 years and with own AEC) not inspected
2.2 Inspect new establishments applying for accreditation before, or within, 2 months of accreditation	Number of new establishments inspected Number of new establishments not inspected	Ongoing	1 1 (in NSW with own AEC) 3 (out of State with own AEC)
2.3 Conduct site visits of selected independent researchers with animal-holding facilities	Number visited	Ongoing	0
2.4 Review and send inspection reports	Reports sent	Within 3 months of inspection	Reports sent
2.5 Follow up 'problems' identified at inspection or on review of applications for accreditation or licence	Problems rectified	Within 12 months	Problems being followed up as per 'Accreditation/site inspection responses' section of ARRP agendas
2.6 Review inspection procedures	Review commenced	December 2003	Review not commenced
3 Education			
3.1 Develop ARRP website	Trial site developed	July 2003	Website launched July 2003
3.2 Publish 6-monthly newsletter via website	First edition published	Dec 2003	Newsletter published
3.3 Develop learning guide to accompany AEC learning package	Learning guide developed	June 2004	Funding for writing of reference document being investigated

Activity	Measure of performance	Time frame	Status
3.4 Meeting for members of AECs	Meeting held	July 2003	Meeting held July 2003
4 Policies and guidelines			
4.1 Standards linked to performance criteria for rats, mice, guinea pigs and farm animals (sheep, cattle, pigs)	Draft of rat document circulated for comment	December 2003	Rat document due for release late 2004
	Draft of mouse document circulated for comment	March 2004	Draft developed for editing
	First draft of guinea pig document completed	June 2004	Draft not developed
	First draft of sheep document completed	June 2004	Draft being developed
4.2 Develop policies/guidelines where strong need identified (maximum of 2)	Developed as need identified	June 2004	No new policies/guidelines
4.3 Review and revise wildlife guidelines	Revised drafts considered by ARRP	December 2003	Guidelines revised and published
4.5 Develop policy/statement on veterinary procedures related to the Animal Research Act	Policy/statement developed	June 2004	Statement not developed
4.8 Revise current policies and guidelines	Policies and guidelines revised	June 2004	Specific guidelines revised Full review to be conducted
5 Legislation			
5.1 Assess results of revised statistics package	Results assessed	June 2004	Statistics published
5.2 Assess lethality statistics for publication	Statistics assessed	December 2003	Statistics not assessed
6 Subcommittees			
6.1 Activate wildlife advisory group (WAG) if special wildlife issues arise	WAG activated where issues identified	Low priority	No need for activation
6.2 Activate Toxicology Technical Advisory Group (TTAG) for special toxicology issues	TTAG activated where issues identified	Low priority	No need for activation
7 Additional			
7.1 Continue liaison with NHMRC	Meeting held	June 2003	Attended Code Liaison Group meetings
7.2 Continue liaison with APVMA (± include Queensland and Victoria)	Contact with APVMA maintained	Ongoing	Agenda item developed for Animal Welfare Working Group
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 Comments provided
7.4 Participate in review of Animal Research Act	Comment on review documents	Timing at Minister's discretion	No action required

Appendix G: Animal use statistics 2003

In 2001, a new method for gathering statistics on animal use in research and teaching was used by the ARRP. 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; see below). The categorisation of procedures aims to give some indication of the ‘invasiveness’ or ‘impact’ of the work on the animals involved. **Species** are grouped as indicated below.

Some animals are used in a number of projects, for example those used to teach animal handling techniques. 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 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 the numbers of animals recorded in procedure 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

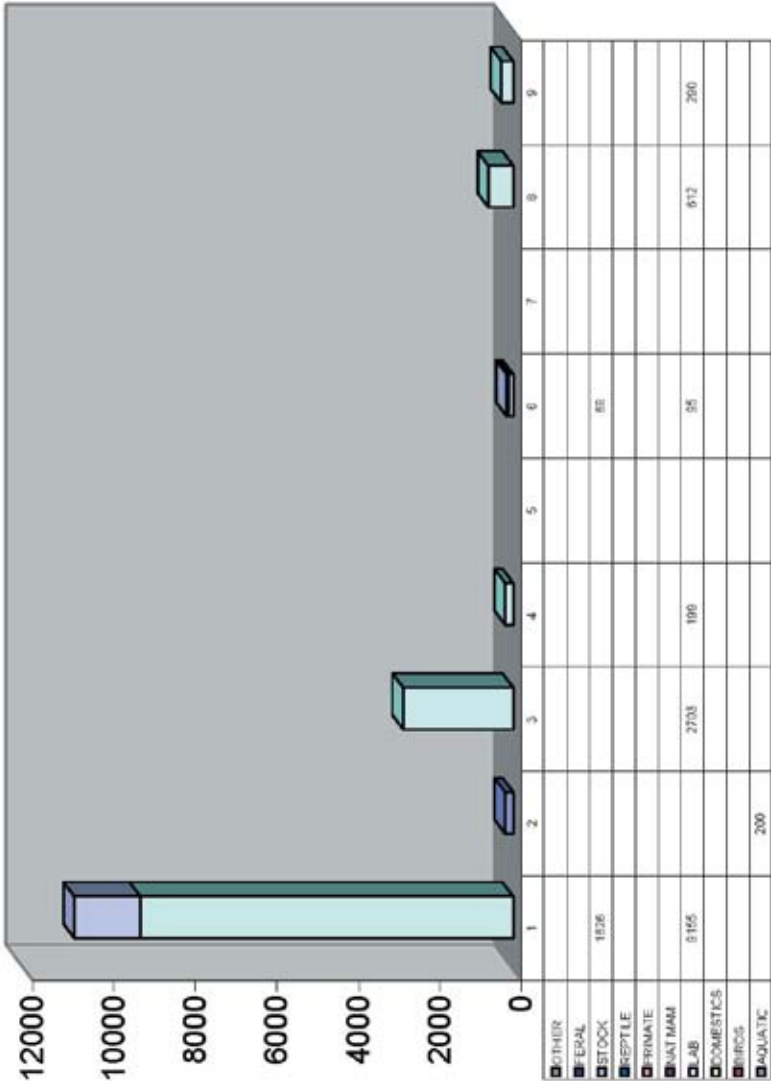
This category applies only in those rare cases where the death of the animal is a planned part of the procedures. Where predictive signs of death have been determined and euthanasia is carried out before significant suffering occurs, the procedure may be placed in category 6 or 7.

9: Production of genetically modified animals

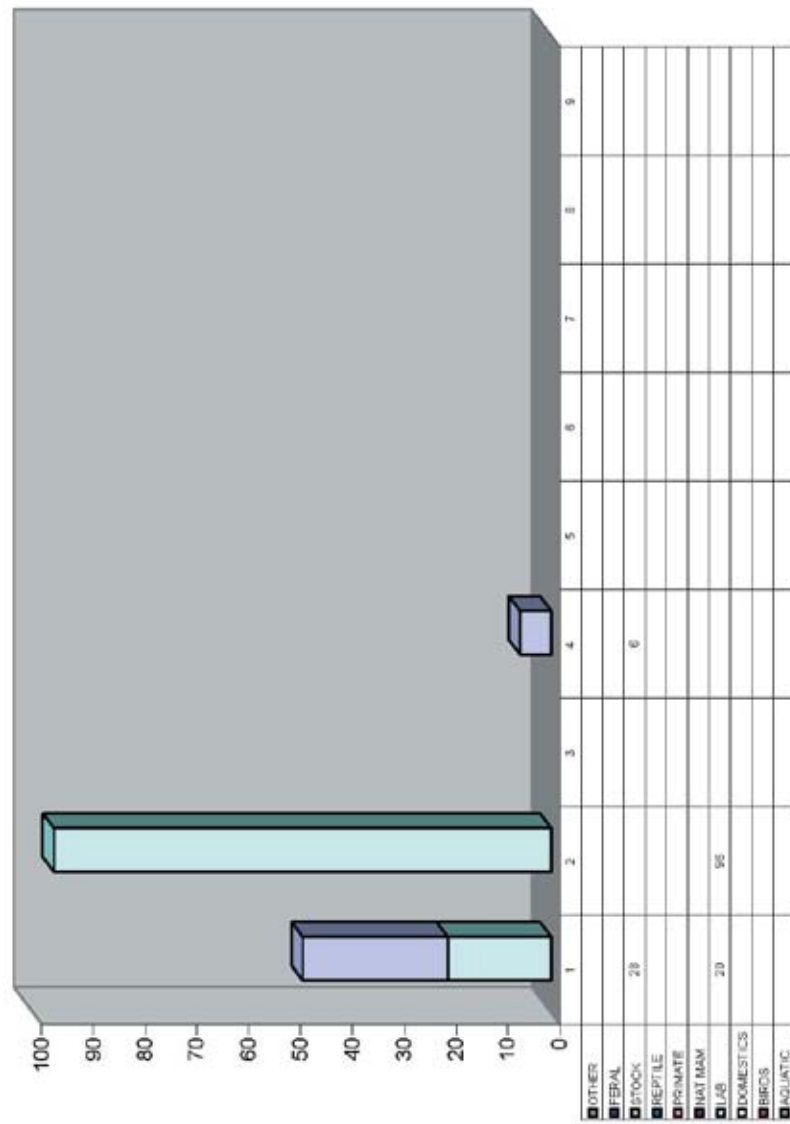
This category is intended to allow for the variety of procedures that occur during the production of genetically modified animals. As animals in this category may be subjected to both minor and major physiological challenges and surgical procedures, this category reflects the varied nature of the procedures 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 (one for each purpose) show the numbers of animals used against the category of procedure (categories 1–9 on page 29).

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

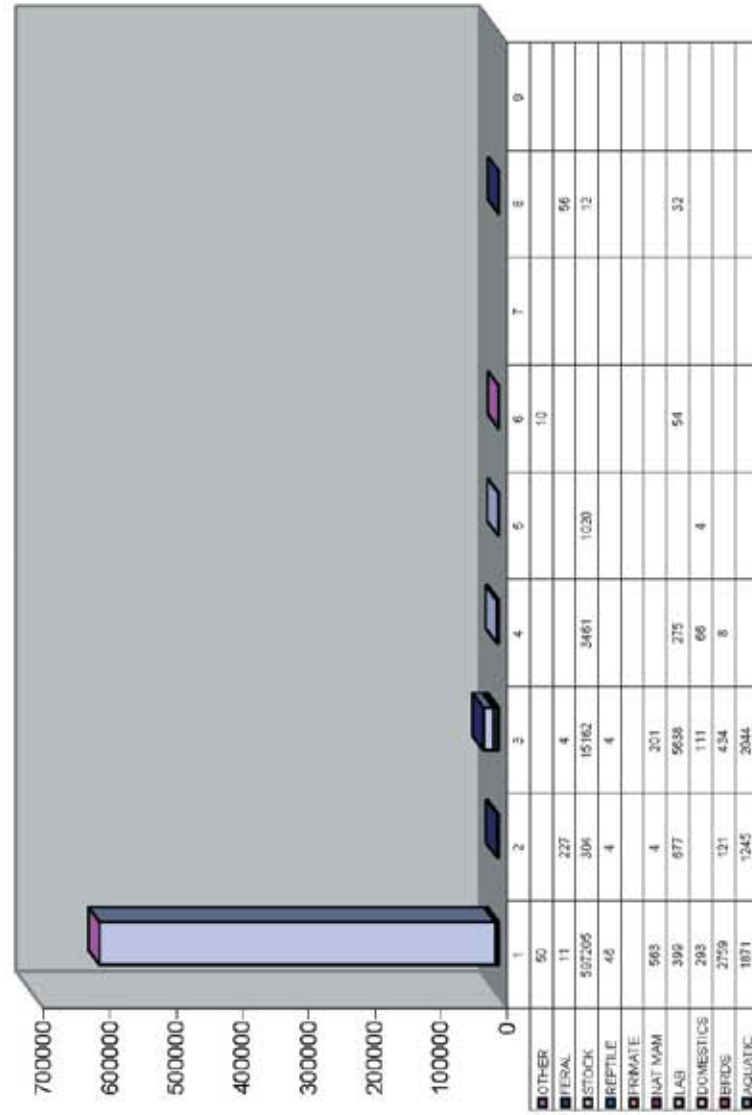


PURPOSE: STOCK MAINTENANCE:
Holding protocols for animals maintained for use in other protocols.



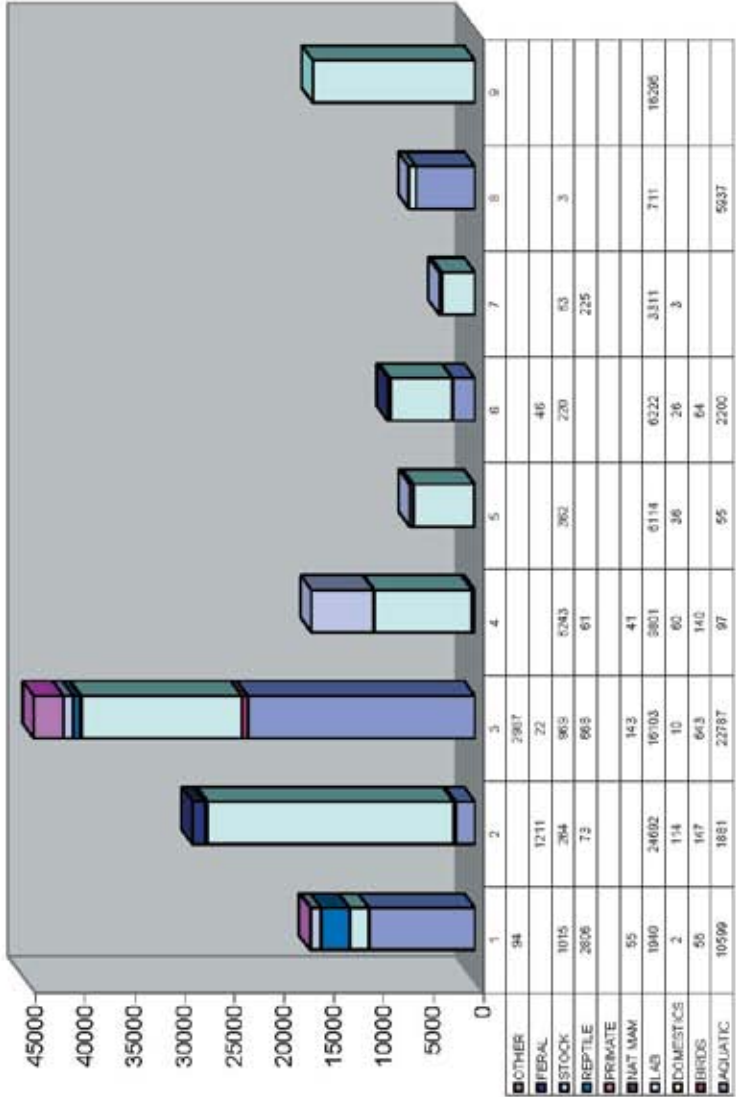
PURPOSE: EDUCATION:

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

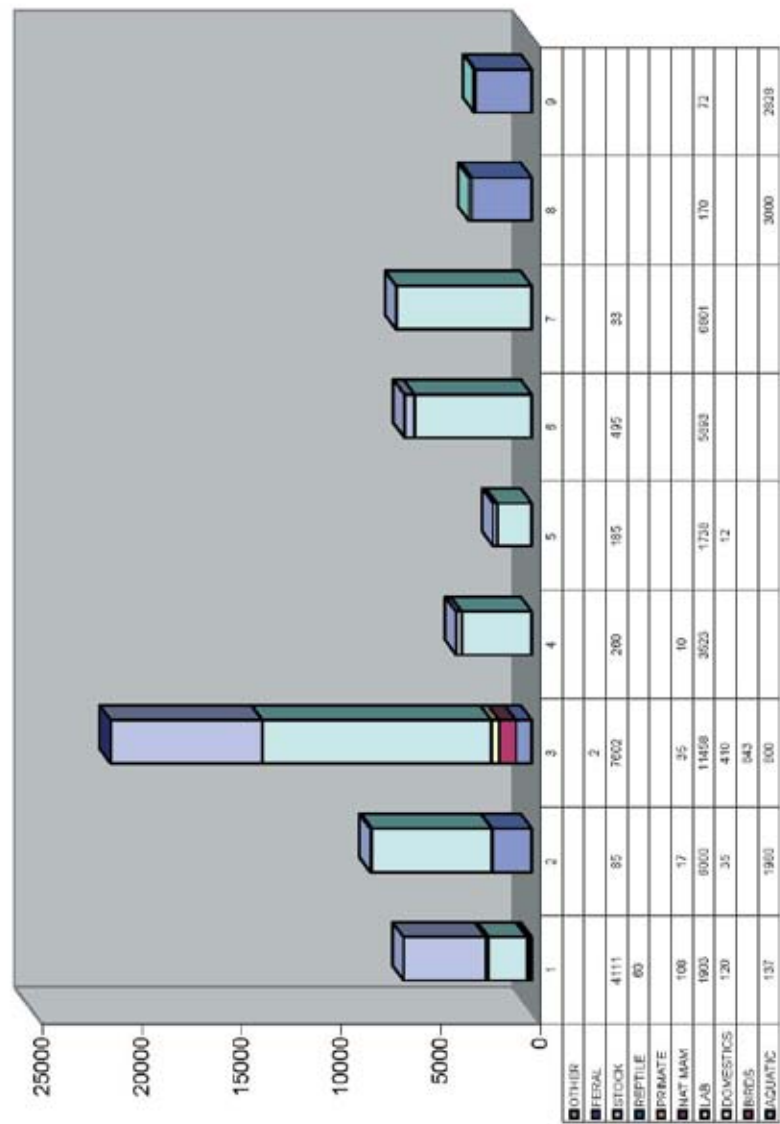


PURPOSE: RESEARCH-HUMAN OR ANIMAL BIOLOGY:

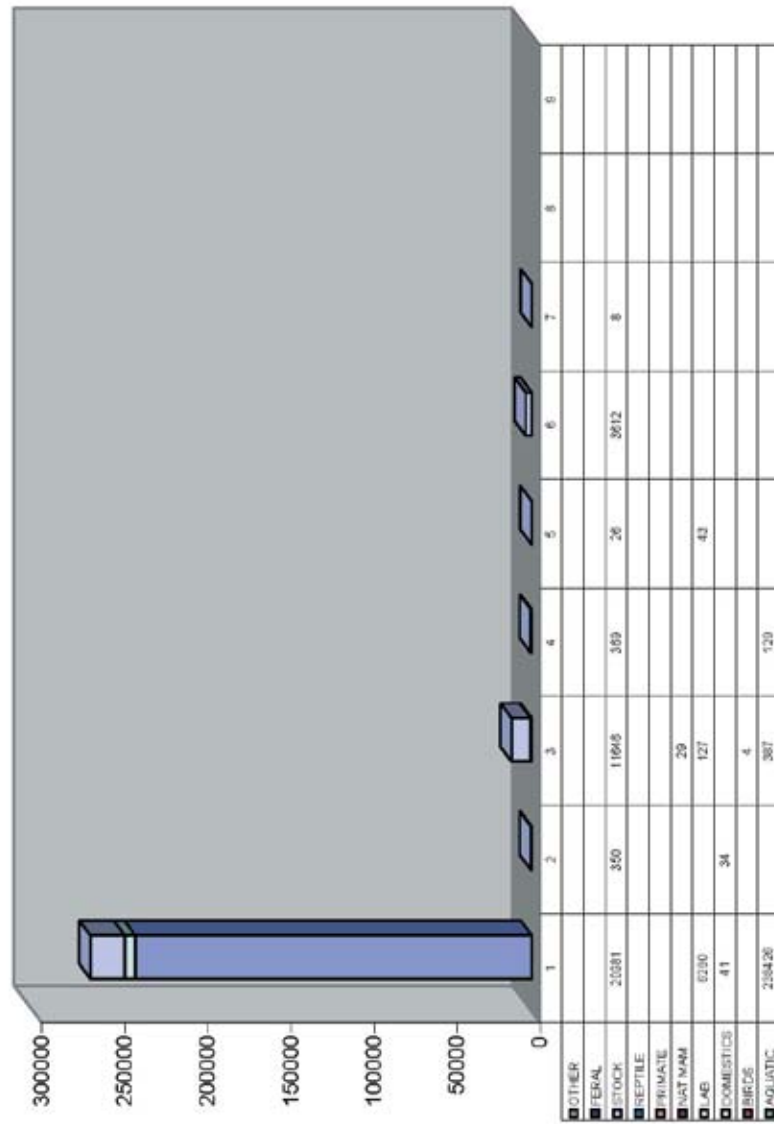
Research protocols that aim to increase the basic understanding of the structure, function and behaviour of animals including humans, and processes involved in physiology, biochemistry and pathology.



PURPOSE: RESEARCH-HUMAN OR ANIMAL HEALTH & WELFARE:
 Research protocols that aim to produce improvements in the health and welfare of animals, including humans.

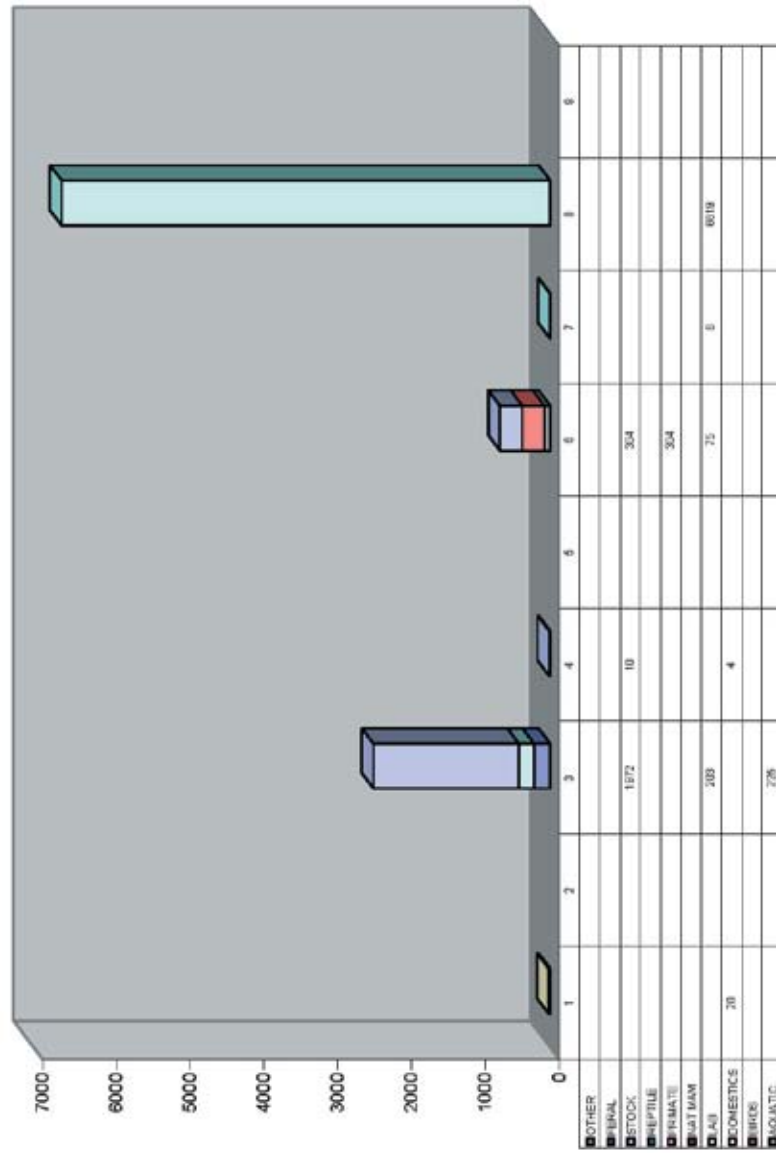


PURPOSE: RESEARCH-ANIMAL MANAGEMENT OR PRODUCTION
 Research protocols that aim to produce improvements in domestic or captive animal management or production.

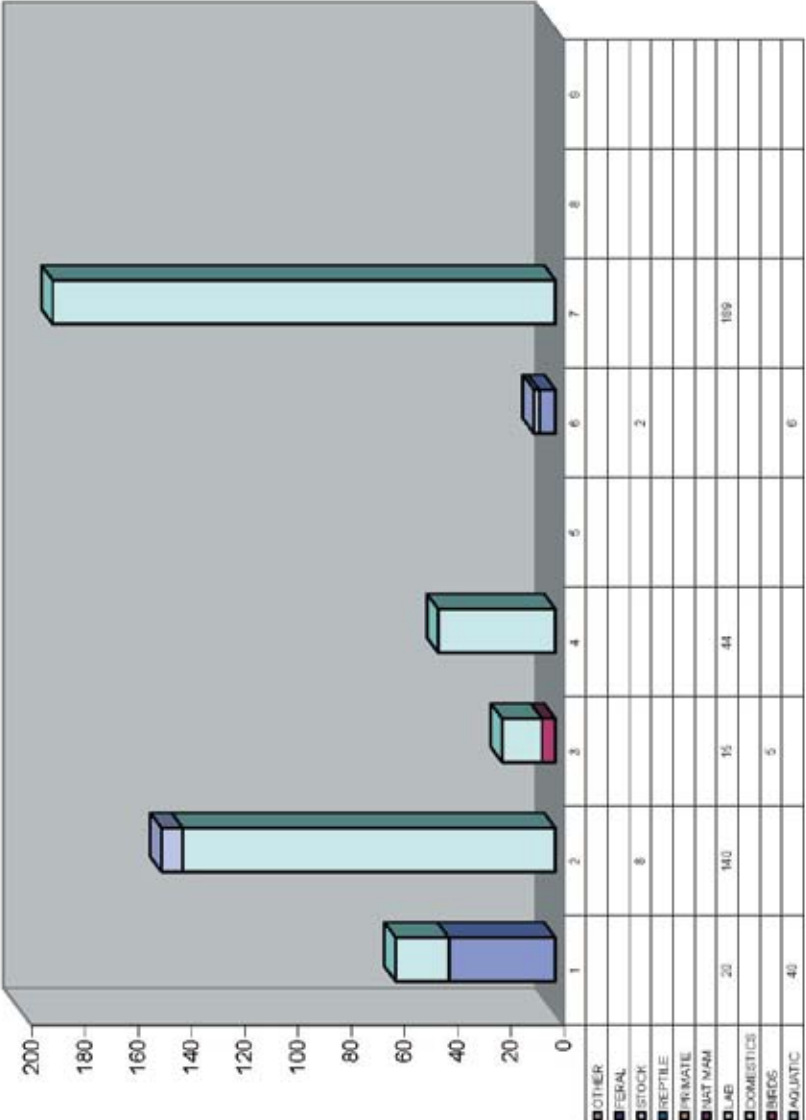


PURPOSE: PRODUCTION OF BIOLOGICAL PRODUCTS

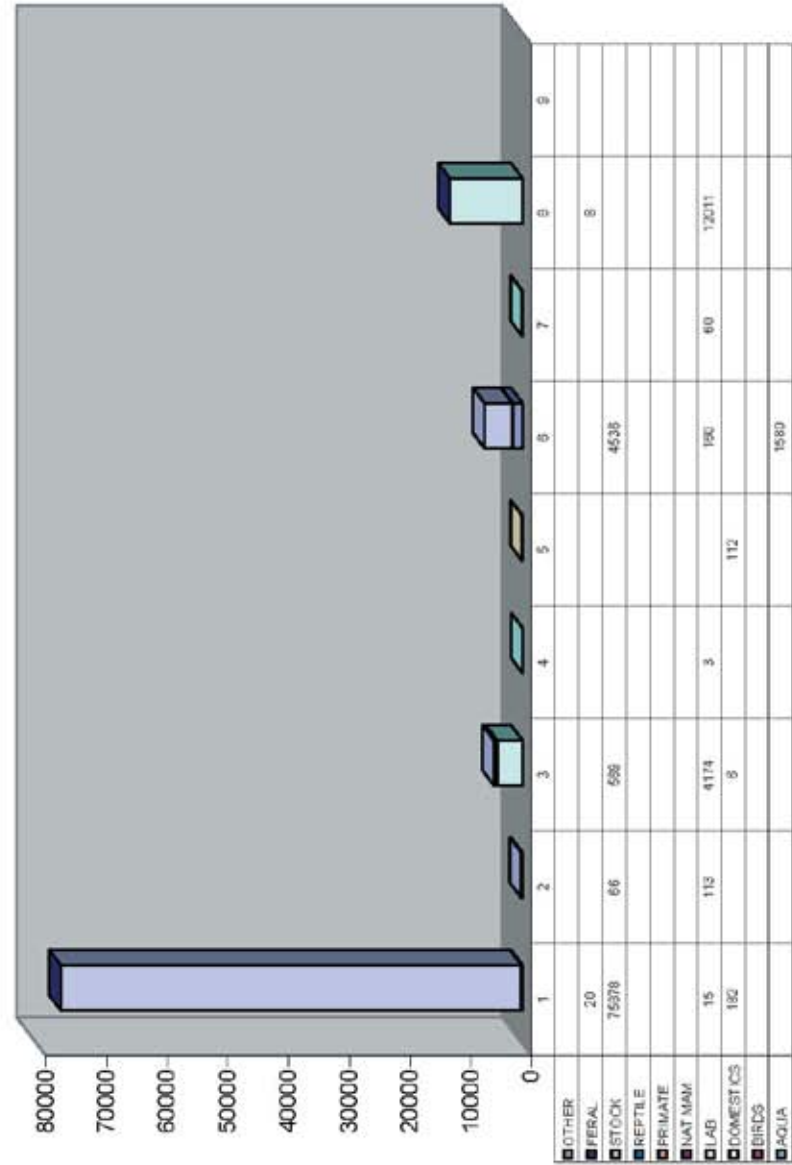
Use of animals to produce products (other than normal milk/meat/eggs, etc.)



PURPOSE: DIAGNOSTIC PROCEDURES
Using animals directly as part of a diagnostic process.



PURPOSE: REGULATORY PRODUCT TESTING
 Protocols for the testing of products 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	Examples of strategies
Replacement	<ul style="list-style-type: none"> • Development of in vitro methods for providing models of sheep worm population dynamics. • Education of AEC members about available alternatives. • Use of audiovisual material such as videos, slides and interactive computer programs. • Use of plant tissue instead of animal tissue for certain enzymatic assays.
Reduction in numbers	<ul style="list-style-type: none"> • Requirement for researchers to supply details of a power analysis calculation to ensure that excessive numbers of animals are not used. Additionally have a statistician as a member of the AEC. • Biometrician’s comments obtained before AEC approval. • Use of organs from terminal animals rather than acquiring from untreated animals. • Purchase of an in vivo animal imaging single photon emission computer tomography system, meaning less animals required for biodistribution studies. • New techniques for embryo freezing rather than continuous breeding to maintain lines. • Use of a tissue availability database and seeking agreement from investigators to make surplus tissue available. • Use of in vitro culture of rabbit and mouse ovaries. • Improvements in experimental approach to deal with: statistical power analysis calculation; randomisation of tumour-bearing mice by both size of tumour and bodyweight; and blinding of animal handling staff from treatment identity. Although these modifications do not directly affect the animals used, they have the potential to further increase the scientific validity of the experiments and reduce the numbers of animals required. • Wise collection and processing of samples allow use of these for validation studies, therefore no new animals are needed. • Fine-tuning of the design of studies and increasing the level of stringency in in vitro studies before they are carried through in vivo has resulted in reduced numbers of animals used. • Reduction in animal use because of increased use of cell lines for initial studies. • Use of the same control group for more than one study. • Use of blood samples already collected as part of routine drug testing programs. • Use of dendritic cell lines rather than bone marrow from cull animals to grow dendritic cells. • Use of nerve tissue cell lines in culture, rather than fresh brain tissue, for studies that require the isolation of synaptosomes (isolated nerve endings). • Refinement of the surgical approach to ovaries in mice, resulting in fewer post-operative problems (e.g. chewing and removing of stitches). • Improved analgesic regimes. • Use of abattoir specimens and cadavers. • Obtaining more data from the use of fewer animals by combining objectives.

Category	Examples of strategies
Refinement of techniques	<ul style="list-style-type: none"> • Development of a new laparoscopic technique for delivery of products into specific parts of the intestines to avoid interactions in other parts of the gut. • Refinement of several anaesthetic and analgesic protocols for animals undergoing surgery. • Adaptation of sheep faecal collection bags to allow sheep to be in deep litter instead of metabolism cages. • Replacement of mesh flooring in lambing shed with timber slats to improve comfort for ewes and lambs. • Provision of hay racks for sheep kept indoors. • Reduced animal handling time for animals used in flea research, by developing a ‘comb-out’ technique. • Use of adjuvants known not to cause adverse reactions. • Earlier endpoints in xenograft studies. • Use of jugular cannulation before clamp studies, where arterial cannulation not required. This resulted in improved recovery times from surgery and a lower incidence of post-operative complications compared with after arterial cannulation. • Continuing education of animal care staff to raise overall standards of animal care. • Improved methods and increased frequency of monitoring so that adverse impacts are more accurately detected and acted on. • Untreated companions provided for rats used in individual studies. • Revision of best practice guidelines. • Use of the saphenous vein for standard blood collection in rodents. • Use of analgesia in all recovery surgical procedures. • Replacement of invasive intratracheal surgery for the delivery of infectious material into the lung with a technique involving the delivery of material via a catheter inserted into the trachea with the aid of an endoscope. • Individual identification of some sharks using photography and drawing of markings around the head and of scars and injuries to fins, rather than via the use of tags. • Refinement of anaesthetic regimes from injectable to gaseous, resulting in less stress to animals, fewer mortalities, and improved recovery of animals. • Use of TitreMax Gold® (Sigma Chemical Co.) adjuvant eliminated the development of granulomas in NZ white rabbits, while still achieving a reasonable titre (1/1000) with peptides that were generally poorly immunogenic. • Development of a method to assess reproductive status in whales and key hormone levels by using the ‘blow’ from the whale, thus negating the need to take skin samples.

Appendix I: ARRP expenses

Note: The following figures do not include the time spent 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' meetings, and input into the development of guidelines.

Fees and retainers	\$21,229.09
Travel and subsistence	\$6,920.33
Stores and printing	\$4,840.36
Freight and postage	\$2,398.36
TOTAL	\$35,388.14

Appendix J: Abbreviations

ACEB	Animal Care and Ethics Board
AEC	Animal Ethics Committee
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARRP	Animal Research Review Panel
ATLA	Alternatives to Laboratory Animals
AWAC	Animal Welfare Advisory Council
CSIRO	Commonwealth Scientific and Industrial Research Organisation
EAPA	<i>Exhibited Animals Protection Act 1986</i>
NHMRC	National Health and Medical Research Council
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
'3Rs'	Replacement, Reduction and Refinement in animal use strategies

Appendix K: ARRP policies and guidelines

(Available from www.animaletics.org.au)

Policies

2. Payment of External Members of Animal Ethics Committees
3. Procedures Prohibited under the POCTAA
4. Non Research Animals on Designated Land
5. Accredited Establishment Policy on the Operations of Animal Ethics Committees and Annual Reporting
6. Differentiation Between Acts of Animal Research and Acts of Veterinary Treatment
7. Relationships Between Accredited Research Establishments and Licence Holders
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 S4 and S8 Drugs
15. Orientation of New Members of Animal Ethics Committees

Guidelines

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

Appendix L: Animal Welfare Unit fact sheets

(Available from www.agric.nsw.gov.au/Aw/index.html)

- 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 12: *Staff of the Animal Welfare Unit*
- Fact Sheet 13: *Publications available from the Animal Welfare Unit*
- Fact Sheet 14: *Animal Research Review Panel policy statements and guidelines*
- Fact Sheet 15: *Example of fauna emergency procedures for wildlife researchers*
- Fact Sheet 16: *Guidelines for minimum standards for keeping horses in urban areas*
- Fact sheet 17: *Summary of amendments to the Animal Research Act made in 1997*
- Fact Sheet 19: *Summary of amendments to the Animal Research Act and Regulations made in 1999*
- Fact Sheet 20: *Protecting the welfare of horses competing in bush races in NSW*
- Fact Sheet 21: *Supply of dogs and cats for use in research*

Appendix M: Standard conditions for accreditation and animal supply licences

The following are standard conditions that are placed on establishments seeking accreditation as animal research establishments or 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 NSW Department of Primary Industries within 30 days of membership changes. The revised composition of the AEC must meet the approval of the Director-General.
3.) Rabbits should be housed in groups in pens. Rabbits may be housed in cages only 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)
(For establishments housing rabbits)
4.) 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)
5.) A response to conditions {xx} of the inspection report {date} of must be provided to the Director-General of NSW Department of Primary Industries by {date—within 2 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 *Code of Practice for the Care and Use of Animals for Scientific Purposes*.

