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ANIMAL EXPERIMENTATION

Report by the
Senate Select Committee on Animal Welfare

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ABBREVIATIONS USED IN REPORT

AAC	Australian Agricultural Council
AAHR	Australian Association for Humane Research
AATA	Australian Animal Technicians Association
ABAH	Australian Bureau of Animal Health
ACCART	Australian Council for the Care of Animals in Research and Teaching
AEEC	Animal Experimentation Ethics Committee
AFWA	Australian Federation for the Welfare of Animals
ANAHL	Australian National Animal Health Laboratory
ANU	Australian National University
ANZFAS	Australian and New Zealand Federation of Animal Societies
APS	Australian Psychological Society
ARC	Animal Resources Centre
ARRP	Animal Research Review Panel
ASAC	Antarctic Scientific Advisory Committee
ASLAS	Australian Society for Laboratory Animal Science
ASMR	Australian Society for Medical Research
AVA	Australian Veterinary Association
AVCA	Australian Veterinary Chemicals Association
AVCC	Australian Vice-Chancellors' Committee
AWAC	Animal Welfare Advisory Council
CSIRO	Commonwealth Scientific and Industrial Research Organisation
CTFAA	Cosmetic, Toiletries and Fragrance Association of Australia
DARA	Department of Agricultural and Rural Affairs (Victoria)

DASETT	Department of Arts, Sport, Environment, Tourism and Territories
DCSH	Department of Community Services and Health
DITAC	Department of Industry, Technology and Commerce
JAWC	Joint Animal Welfare Council
NBSL	National Biological Standards Laboratory
NHMRC	National Health and Medical Research Council
NIH	National Institute of Health (U.S.A.)
OTA	Office of Technology Assessment (U.S. Congress)
RSPCA	Royal Society for the Prevention of Cruelty to Animals
UFAW	Universities Federation for Animal Welfare
UNSW	University of New South Wales
USDA	United States Department of Agriculture

2.30 The Committee RECOMMENDS that the Commonwealth, State and Territory Governments publish annually accurate and comprehensive information on the extent and forms of animal experimentation conducted within their respective jurisdictions. In addition, government authorities should provide some analysis of the statistics to make them meaningful to the public, and to reduce the potential for misinterpretation.

5.49 The Committee RECOMMENDS that the Commonwealth Government establish a separate fund for research into the use of alternatives to animal experimentation and that grants be disbursed from this fund by a board composed of representatives of the scientific community, animal welfare organisations, ACCART and government authorities.

7.80 The Committee ... RECOMMENDS that the Draize test be banned in Australia.

7.81 The Committee RECOMMENDS a ban on the classical LD50 test in Australia but that acute toxicity tests be allowed with ministerial approval.

8.41 The Committee RECOMMENDS that ACCART in co-operation with the relevant bodies with specialist knowledge draw up appropriate guidelines and standard operating procedures for the capture of wildlife and their housing, nutrition and management in captivity.

8.48 The Committee RECOMMENDS that Antarctic research protocols be assessed and approved under the Code of Practice and that additional detailed guidelines be drawn up on the techniques, procedures and practices to be used by experimenters on animals in the Antarctic.

9.34 The Committee RECOMMENDS that all institutions which conduct animal experimentation have periodic analyses done on animal feed to ensure that it is of a high and consistent quality, not only to maintain standards of animal welfare but also to guarantee the validity of experimental data.

9.69 The Committee RECOMMENDS that animal house supply and breeding units develop appropriate pricing policies to enable recovery of all recurrent costs including caging and minor equipment and that surpluses generated be used to develop animal house facilities.

9.80 The Committee RECOMMENDS that a study be undertaken by ACCART to determine the most effective means for production planning of laboratory animals in terms of minimising excess production.

10.29 The Committee RECOMMENDS that State Governments legislate so that pounds hold dogs for at least seven days before disposing of them to an institution except where a dog is surrended by its owner.

10.30 The Committee RECOMMENDS that State Governments legislate so that all owners who surrender dogs to pounds be informed in writing of the possible transfer of the animals to a research institution and that pounds obtain the written authorisation of owners to transfer the dogs to an institution.

10.46 The Committee RECOMMENDS that institutions either breed or purchase cats from an institution in which they are bred for experimental purposes and not acquire them from pounds or other non-institutional sources.

11.29 The Committee RECOMMENDS that all institutions with animal houses require unqualified staff to undertake technical training courses in animal care at colleges of technical and further education.

12.18 The Committee ... RECOMMENDS that extra funds be made available by the Commonwealth Government to enable the University of Sydney to establish a course in laboratory animal science.

12.20 The Committee RECOMMENDS that funds be made available to the University of Queensland to establish a chair in animal welfare and behaviour.

13.46 The Committee RECOMMENDS that all States and Territories upgrade animal welfare legislation, and establish animal welfare advisory councils and departmental animal welfare units as has been done in New South Wales, Victoria and South Australia.

15.57 The Committee RECOMMENDS that the system of controlling animal experimentation in New South Wales, Victoria and South Australia be extended to the other States and Territories. This system is based on upgraded legislation; incorporation of a code of practice in regulations; the accreditation and licensing of institutions in which animal experimentation is conducted; and the appointment of inspectors to monitor the work of ethics committees, animal house facilities and practices, and the conduct of animal experimentation.

15.69 The Committee RECOMMENDS that the Commonwealth Government enacts legislation to remove any doubt that the conduct of animal experimentation by Commonwealth employees comes under the control of Commonwealth authorities.

16.15 The Committee RECOMMENDS that future revisions of the Code of Practice be carried out by a national conference consisting of representatives of governments, institutions which conduct animal experimentation, experimenters, animal house staff, specialist societies, animal welfare organisations, educational organisations and funding bodies and that final approval for those revisions be given by Commonwealth, State and Territory Governments which include the Code of Practice in regulations.

16.62 The Committee RECOMMENDS that the Australian Council for the Care of Animals in Research and Teaching prepare guidelines on procedures and practices in relation to animal experimentation to supplement the Code of Practice.

CHAPTER 1

INTRODUCTION

Appointment of the Committee and its Terms of Reference

1.1 The Senate appointed the Select Committee on Animal Welfare on 16 and 17 November 1983 and reappointed it on 22 February 1985 and again on 22 September 1987, in each new Parliament, to inquire into and report upon:

> the question of animal welfare in Australia with particular reference to:
>
> (a) interstate and overseas commerce in animals;
> (b) wildlife protection and harvesting;
> (c) animal experimentation;
> (d) codes of practice of animal husbandry for all species;
> (e) the use of animals in sport.

1.2 Because of the wide scope of the terms of reference, the Committee decided to divide the inquiry into a number of discrete areas and, as far as possible, to examine two or more simultaneously.

1.3 Although the Committee took a little evidence on animal experimentation in preliminary public hearings in mid-1984, the Committee decided to defer its consideration of this area in order to give priority to investigations into kangaroos, the export of live sheep from Australia and the keeping of dolphins and whales in captivity. The Committee reported on live sheep exports on 13 August 1985, on dolphins and whales in captivity on 29 November 1985 and on kangaroos on 1 June 1988. The Committee has also been examining animal welfare issues in sheep husbandry and has taken evidence in other areas of animal husbandry.

Conduct of the Inquiry

1.4 In this report the Committee examines the use of animals in experiments in research and toxicological testing but not, except in some peripheral areas, in teaching. The Committee has taken very little evidence on the use of animals in primary and secondary schools while its consideration of their use in tertiary courses has not been extensive. This area will therefore be taken up later in the Committee's general inquiry into animal welfare.

1.5 Some preliminary evidence on the use of animals in research and teaching was taken during hearings of the Committee between May and September 1984. The evidence taken then made it clear to the Committee that publicly available information on the extent and nature of the use of animals in experiments in Australia was extremely limited.

1.6 In order to obtain information about animal experimentation in Australia to help prepare for further hearings, the Committee prepared a questionnaire. The questionnaire covered the nature and extent of animal use; the development of alternatives; the constitution, operation and membership of ethics committees; compliance with the Code of Practice; animal supply; animal house facilities; and animal house staff.

1.7 The questionnaire was sent to universities, hospitals and other research institutions that were known to use animals in research and teaching. Fifty completed questionnaires were returned to the Committee. Additional copies of those completed by universities were sent to the Australian Vice-Chancellor's Committee (AVCC) by arrangement between the Committee and the AVCC.

1.8 The Committee held hearings and conducted inspections of animal house facilities at universities and other institutions in all State capitals and Canberra between August 1986 and November 1988. The Committee received submissions and took oral evidence from a wide range of organisations and individuals. A list of witnesses who gave oral evidence is provided in Appendix 1.

Nomenclature

1.9 During the inquiry, the Committee found that people used different terms to describe the same thing. The Committee decided, in order to avoid confusion, to standardise as far as possible on key terms in this report.

1.10 A person who conducts experiments on animals is called a researcher by some people, an investigator, an experimenter or a scientist by others. The Committee has decided to refer to such a person as an experimenter or scientist, depending on context.

1.11 An application to carry out a project in which experiments are conducted on animals is referred to as a protocol. Although the word 'proposal' is used in the Code of Practice, the meaning of the word may be confused with the more general meaning of the word in some contexts. Such ambiguity is not likely to happen with the word 'protocol'.

1.12 The term 'Code of Practice' refers specifically to the 'Code of practice for the care and use of animals for experimental purposes' which was issued in 1985 by the National Health and Medical Research Council (NHMRC), the Commonwealth Scientific and Industrial Research Organisation (CSIRO) and the Australian Agricultural Council (AAC). The Code of Practice has recently been revised but the revised edition has not yet been endorsed by all of its sponsors. The latest draft given to the Committee by the NHMRC was dated 22 February 1989. It is referred to in this report as the 'draft revised Code of Practice.'

1.13 The Committee uses the term 'ethics committee' to denote the term 'animal experimentation ethics committee' used in the Code of Practice or 'animal care and ethics committee' used in New South Wales legislation or the variations of it used in some institutions.

1.14 A list of acronyms and abbreviations used in the report is set out at the front of the report.

Animal Experimentation Debate

1.15 Animal experimentation has been an area of animal use that has been at the forefront of the animal welfare debate for a long time. In the United Kingdom, anti-vivisection organisations have opposed the use of animals in experiments for two hundred years or more. At the birth of the current animal welfare movement in Australia in the mid 1970s, animal experimentation was identified as a key area of animal use for abolition or reform.

1.16 The animal welfare movement in Australia is not a homogeneous body with a single set of policies. Its constituent organisations have differing policies on animal experimentation and other animal welfare issues. Although some of those organisations espouse an uncompromising policy of immediate abolition of the use of animals in experiments, other organisations, while maintaining a long-term goal of abolition, take a more pragmatic position by seeking reforms in the short term to enhance animal welfare.

1.17 A diversity of views on animal experimentation also exists within the scientific community. The Committee acknowledges marked changes in attitude towards animal experimentation even during the course of its inquiry. The questionnaire distributed to some 50 institutions and the long

series of public hearings focussed attention on the subject. It made institutions and experimenters think more about the ethical, welfare and scientific issues involved in animal experimentation. In many institutions, ethics committees are now working better, controls have been tightened, facilities have been upgraded and greater attention has been paid to the care of animals. There is also a growing realisation within the scientific community that reproducible experimental data requires a close definition of the health and genetic status of the animals used in the experiments. Better facilities will be needed to provide the higher quality animals which are now required in many research projects.

1.18 The Committee distributed the questionnaire because of the paucity of information publicly available about the use of animals in experiments in Australia. Experimenters and scientific institutions have traditionally been reluctant to disseminate information about their use of animals and the facilities in which they are housed. This attitude has been adopted largely as a reaction to opposition to animal experimentation from various animal welfare organisations. Some issues focussed on by such organisations have been blown out of perspective by the media. Added to this have been the acts of wanton vandalism against institutions or personal property of experimenters perpetrated by fringe elements of the animal welfare movement. Fortunately, the extent of such criminal activity in Australia has been minimal compared to the level of violent activities in some other countries. Nevertheless, it has been a matter of concern to experimenters and research institutions.

1.19 There is no doubt that the majority of the population supports biomedical research involving the use of animals[1] provided that effective controls are operating to keep the number of the animals and the level of pain and distress to a minimum. Until such time as the majority of Australians are persuaded that

animal experimentation should not be carried out, and that is translated into legislative form, experimenters have a right to use animals within the regulations and guidelines imposed on such use by government and the scientific community.

1.20 The Committee condemns the use of violence to attain objectives which cannot be attained by rational argument or legitimate and lawful activity. Violence causes revulsion and is in most cases counter-productive. It will also adversely affect the work of other organisations and individuals who are striving to improve animal welfare and reduce the number of animals being used in experiments by legitimate means. Those people who pursue their cause by illegal means should be subject to the full force of the law.

1.21 There is a general feeling within the scientific community to withdraw behind barriers when faced with violence or other illegal actions. That attitude is quite understandable. Yet it has been the secretive approach in the past and the reluctance to publish information about their use of animals in experiments which have led to public misapprehension about the nature of animal experimentation in this country. Secrecy breeds suspicion and the media feed on suspicion. What might have been a misunderstanding becomes a crisis.

1.22 The most potent weapon in the armoury of research institutions is public opinion. If the public is satisfied that animals are being used humanely in experiments, there is little threat to such use. It is important, therefore, for institutions to be open and forthcoming about their experimental practices. Responsible animal welfare organisations should also be able to inspect institutional facilities. This would help to allay suspicions that animals are being housed in poor facilities or are not being given proper care.

1.23 Institutions and government have a responsibility to ensure that animal experimentation is conducted humanely in accordance with approved rules and guidelines. By fulfilling that responsibility and by keeping the public informed of the extent and nature of animal experimentation, public disquiet should be kept to a minimum.

Acknowledgements

1.24 The Committee wishes to thank all the people who made submissions, gave evidence or otherwise contributed to the inquiry. In particular, it wishes to thank the staff of the Committee: Mr P. Barsdell, Mr D. Hynd, Ms B. Allan and Mrs D. Pratezina.

CHAPTER 2

ANIMAL EXPERIMENTATION IN AUSTRALIA

Introduction

2.1 Few statistics are kept of the extent and range of animal experimentation conducted in Australia. Consequently, the Committee does not have accurate figures on the number of experiments conducted or the number of animals of each species which have been used in experiments. It also follows that the Committee does not know with any degree of accuracy whether the use of animals in experiments is increasing or decreasing.

2.2 The Victorian and Western Australian Governments collect statistics on animal experimentation and the New South Wales Government will do so under its new legislation. The other States and Territories do not collect such statistics.

2.3 In this chapter the Committee sets out the statistics and other information available to it to form a rough picture of the pattern of animal experimentation in Australia.

Victoria

2.4 Detailed statistics on animal experimentation are currently collected by the Department of Agriculture and Rural Affairs in Victoria. These statistics are based on the biannual returns submitted by individual experimenters to the Department. These figures have been published in an annual report entitled 'Statistics of Animal Experimentation'. The figures are now available for the period July 1982-June 1987. The public

availability of detailed statistics for a five year period enables some conclusions to be drawn as to the broad patterns of use of animals as well as trends in Victoria.

2.5 Table 2.1 provides information on the number of animals used annually by species of vertebrate in Victoria from July 1982 to June 1987. The Victorian figures do not include animal experimentation carried out in Commonwealth establishments in Victoria.

2.6 The Victorian statistics are based on animals used, not on the number of scientific procedures carried out. Dr Crossing of the Department of Agriculture and Rural Affairs explained that:

> The legislation provides for a series of related scientific procedures, or a scientific procedure. In other words, one can have a program made up of a number of similar scientific procedures or it can be classed as one experiment. We do not count experiments. What we are looking at is the usage of animals, because it is possible to describe a series of related scientific procedures as one experiment. It can be difficult to differentiate between those, so we look for the number of animals used, amongst other things.[1]

2.7 Table 2.2 summarises the number of animals used and percentage changes from year to year, by type of use, for the period July 1982 to June 1987.

Table 2.1: Numbers of Animals Used by Type of Vertebrate in Completed Experiments: Victoria, 1982-83 to 1986-87

Type of Vertebrate	Total					% Change			
	82-83	83-84	84-85	85-86	86-87	82-83/83-84	83-84/84-85	84-85/85-86	85-86/86-87
Mouse	121 447	151 734	119 840	168 508	125 399	+24.7%	-21.0%	+40.6%	-25.6%
Rat	37 077	52 819	38 622	51 995	39 429	+42.4%	-26.9%	+34.6%	-24.2%
Guinea Pig	3 983	3 354	2 480	2 276	2 758	-15.8%	-26.0%	-8.2%	+21.2%
Other Rodent	21	34	66	-	21	+62.0%	+94.1%	n.c.	n.c.
Rabbit	2 641	2 482	2 177	3 276	4 179	-6.0%	-22.3%	+50.5%	+27.6%
Cat	379	271	290	303	217	-28.5%	+7.0%	+4.5%	-28.4%
Dog	781	597	551	788	663	-23.6%	-7.7%	+41.2%	-14.8%
Other Carnivore	7	188	4	98	-	+2 685.0%	-97.9%	+2 450.0%	n.c.
Horse, Donkey or Cross	57	24	8	109	9	-57.9%	+66.7%	+1 362.0%	-91.7%
Bovine	1 827	1 007	994	1 165	1 398	-44.9%	-1.39%	+17.2%	+20.0%
Sheep	9 214	5 886	12 355	10 646	7 788	-36.1%	+110.9%	-13.8%	-26.8%
Goat	281	184	1 192	198	570	-34.6%	+5 489.0%	-83.4%	+287.9%
Deer	-	-	-	12	-	n.c.	n.c.	n.c.	n.c.
Pig	1 038	1 205	1 091	4 536	5 178	+16.1%	-9.5%	+415.8%	+114.2%
Other Ungulate	-	30	-	-	-	n.c.	n.c.	n.c.	n.c.
Marsupial	314	200	289	329	360	-36.3%	+144.5%	+13.8%	+9.4%
Primate	9	3	10	21	41	-66.7%	-233.0%	+210.0%	+195.2%
Other Mammal	107	172	26	12	2	+3.0%	-84.9%	-53.8%	-83.3%
Domestic Fowl	23 593	23 804	24 430	28 547	35 622	-7.0%	+2.6%	+16.9%	+24.8%
Other Domestic Poultry	206	89	9	97	-	-56.8%	-89.9%	+1 007.7%	n.c.
Other Bird	63	261	131	61	107	+414.0%	-49.8%	-53.4%	+75.4%
Amphibian	3 460	2 268	2 602	1 838	2 761	-34.5%	+14.7%	-29.4%	+150.0%
TOTAL	206 505	246 612	207 167	274 815	226 502	+19.4%	-15.8%	+32.6%	-17.6%

SOURCE: Victorian Department of Agriculture and Rural Affairs: 'Statistics of Animal Experimentation'.

Table 2.2: Numbers of Animals Used and Percentage Changes by Type of Use - Victoria, 1982-83 to 1986-87

	82-83	83-84	84-85	85-86	86-87
Research Investigation	189,901	218,031 +14.8%	184,880 -15.3%	259,885 +40.6%	203,679 -21.6%
Diagnostic Procedure	1,853	2,885 +55.7%	1,943 - 32.7%	881 -54.7%	801 -9.1%
Education	11,355	10,547 -7.1%	12,541 +11.9%	10,734 -14.4%	12,527 +16.7%
Production of Biological Products	1,655	1,594 -3.7%	2,807 +76.1%	2,251 -19.2%	3,001 +33.9%
Product Quality Testing	325	3,215 +989%	4,805 +49.5%	747 -85.4%	6,408 +857.8%
Other	1,416	10,340 +730%	191 -98%	317 +66%	86 -72.9%
TOTAL	206,505	246,612 +19.4%	207,167 -15.8%	274,815 +32.6%	226,502 -17.6%

SOURCE: Victorian Department of Agriculture and Rural Affairs: 'Statistics of Animal Experimentation'.

2.8 The category of 'Education' in the Victorian statistics refers solely to animals used for educational programmes in tertiary institutions and does not include any animals that may have been used in primary and secondary schools.

2.9 The Victorian statistics for this period of five years do not show any decline in the use of animals in research. Although the annual totals fluctuate, in no year has the total number of animals used annually not dropped below the level of 1982-83, the first year for which statistics were collected.

2.10 An examination of the statistics of rodents issued by the Monash University central animal house (Table 2.3) shows a similar pattern of animal use for experimental purposes. This animal house produces animals not only for use within the University but also for sale to other institutions in Melbourne and interstate. The figures of animals issued (which exclude any animals euthanased as surplus) show a relatively stable output.

Table 2.3: Rodents Issued by Monash University Animal House 1982-1987

Year	Mice	Rats
1982	25,093	60,334
1983	20,545	53,942
1984	23,770	63,337
1985	24,440	60,763
1986	22,186	55,196
1987	28,962	57,246

SOURCE: Compiled by Committee from response to questionnaire

Western Australia

2.11 A summary of the numbers of animals used for research purposes were provided by the Health Department of Western Australia for the years 1981-1986 is contained in Table 2.4. There was no breakdown of the use of animals into categories of experiments.

Table 2.4: Numbers of Animals Used for Research Purposes in Western Australia 1981-1986

Type of Animal	1981	1982	1983	1984	1985	1986
Mice	1 723	2 263	2 495	1 430	2219	1644
Rats	2 753	3 290	2 253	2 176	2403	2236
Dogs	465	447	327	300	401	586
Cats	104	86	105	141	112	68
Sheep	8 979	7 696	12 138	14 034	10331	12788
Cattle	14	52	72	80	21	12
Other	1 966	2 587	3 217	2 907	2284	2177
TOTAL	16 004	16 421	20 607	21 068	17771	19511

SOURCE: Health Department of Western Australia.

2.12 The use of animals in the categories of experiments covered by the Health Department return has increased by about 25 per cent over the period of four years for which figures are available.

2.13 The number of animals recorded in these statistics is substantially less than the combined total of those provided to the Committee by Murdoch University and the University of Western Australia, which are shown in Table 2.5.

Table 2.5: Numbers of Animals Used in Experiments in the University of Western Australia and Murdoch University, 1980-84

1980	1981	1982	1983	1984
39,890	43,976	43,578	96,388	86,738

SOURCE: Compiled by Committee from responses to questionnaire.

2.14 According to the Health Department, the difference is explained by the instructions contained in the 'Notes on Completing the Annual Statistical Vivisection and Experiments Return Form' which include the following:

- Information is only required on operations and other experiments of a similar nature which are performed on living animals. Purely sacrificial procedures are not included, nor are necropsies, dissection or experiments on dead animals.
- Under the Regulations information is not required on any operation of the nature of an inoculation or feeding experiment.

The form of statistical return is directly covered by the provisions of Western Australian Prevention of Cruelty to Animals Act 1920-1976, sections 6 (1) F and 6 (1) G.

2.15 The statistics relate, therefore, only to a limited category of uses of animals for experimental purposes. Because they are not comprehensive, few conclusions as to overall trends in animal experimentation in Western Australia can be based on them.

Universities

2.16 One section of the questionnaire on animal experimentation sent out by the Committee to universities, hospitals and research institutions, dealt with the extent and types of animal experimentation being conducted at those institutions.

2.17 The replies from the universities fall into three groups.

2.18 Four universities were unable to supply details of which animals were used for all facilities and departments for the five year period 1980-84. Included in this group were Griffith University, Macquarie University, the University of Melbourne and the University of Tasmania. To ensure consistency and comparability, any figures supplied by them were not included in the tables which follow.

2.19 Three universities were able to supply details of animals issued for the period 1980-1984 from their respective central animal houses but were unable to supply full details for all other departments and breeding units for this period. They were the University of Sydney, the University of New South Wales and the University of Queensland. The statistics for the central animal houses of these universities are provided in Table 2.6.

2.20 The statistics for animals used for experimental and teaching purposes for the other 12 universities in existence at the time the questionnaire was issued are provided in Table 2.7. Table 2.8 reports the annual percentage change in the number of animals used for each of the four categories in Table 2.7.

2.21 Table 2.8 reports the annual percentage changes for each category of animals.

Table 2.6: Animals Issued from Central Animal Houses at the University of Sydney, University of New South Wales and the University of Queensland, 1980-1984

	1980	1981	1982	1983	1984
Mice	67,771	53,939	61,945	54,205	53,275
Rats	29,180	28,934	29,692	31,690	33,242
Guinea Pigs	3,233	2,639	3,485	3,414	2,812
Other Animals	10,689	9,089	8,214	8,597	7,681
TOTAL	110,873	94,601	103,336	97,906	96,010

SOURCE: Compiled by Committee from responses to questionnaire.

Table 2.7: Animals Used for Experimental and Teaching Purposes by Australian Universities*, 1980-84

	1980	1981	1982	1983	1984
Mice	198,698	182,133	195,494	216,644	205,546
Rats	99,344	94,132	106,262	111,682	118,172
Guinea Pigs	4,097	4,746	4,842	4,759	4,856
Others	43,839	36,751	46,182	56,796	45,245
TOTAL	345,978	317,762	352,780	389,881	373,819

* Universities include: Newcastle, New England, Flinders, La Trobe, James Cook, ANU, Deakin, Wollongong, Monash, Adelaide, Murdoch, Western Australia.

SOURCE: Compiled by Committee from responses to questionnaire.

Table 2.8: Animals Used for Experiments and Teaching in Australian Universities* % Change Year to Year

	1980-81	1981-82	1982-83	1983-84
Mice	-8.39%	+7.3%	+10.8%	-5.1%
Rats	-5.2%	+12.9%	+5.1%	+5.8%
Guinea Pigs	+15.8%	+2.0%	-1.7%	+2.0%
Other Animals	-16.2%	+25.7%	+23.0%	-20.3%
TOTAL	-8.1%	+.11%	+10.5%	-4.1%

* Universities as defined for Table 2.6.

SOURCE: Compiled by Committee from responses to questionnaire.

2.22 Few firm trends in animal use for experiments and teaching in Australian universities are apparent in the statistics presented in Table 5, 6 and 7. There are substantial variations in the numbers used from year to year for most species of animal.

CSIRO

2.23 As Table 2.9 shows, the CSIRO has an extensive involvement in the use of animals for research purposes. The Committee notes that many farm animals used by CSIRO for purposes of research were subjected only to normal husbandry practices. The CSIRO submitted that:

> In laboratory tests it is taken that some intervention to the animals occurs, eg injection, bleeding, or dosage of a drug or infection Agent. In animal husbandry tests,

animals are subjected only to normal farming practices, with the possible exception of occasional weighings, for example in an animal breeding trial.[2]

2.24 Table 2.10 provides a comparison between the number of sheep and cattle used in laboratory tests with those used in animal husbandry research.

Table 2.9: Numbers of Animals Used by CSIRO, 1981-82 to 1983-84

	1981-82	1982-83	1983-84
Cattle	3 797	3 560	3 587
Sheep	24 341	22 890	22 769
Goats	66	4	11
Pigs	202	196	191
Horses/Donkeys	5	5	5
Marmosets	38	18	48
Dogs	19	17	14
Rabbits	461	397	407
Guinea Pigs	1 063	1 092	1 298
Rats	9 991	7 216	7 157
Mice	118 530	130 904	110 863
Chickens	13 302	13 847	14 524
Other	-	152	-
	161 815	180 498	160 854

SOURCE: Table 4, CSIRO, Additional Information supplied to the Committee on 27 November 1985 in response to questions at hearing, 3 July 1984.

Table 2.10: Numbers of Cattle and Sheep Used Involving Interventions or Routine Husbandry, 1981-82 to 1983-84

	Cattle			Sheep		
Year	Inter-vention	Routine Husbandry	Total	Inter-vention	Routine Husbandry	Total
1981-82	527	2,207	2,734	6,675	8,471	15,146
1982-83	353	2,287	2,640	5,906	7,815	13,721
1983-84	397	2,326	2,723	4,969	5,706	11,175

SOURCE: CSIRO - Additional information supplied to the Committee on 27 November 1985 in response to questions at hearing, 3 July 1984, Table 6.

2.25 The CSIRO statistics show a pattern which appears to be common to the statistics supplied by the universities and the Victorian Department of Agriculture and Rural Affairs, of substantial annual variations without any clear long-term trend.

Conclusions

2.26 The Committee believes that there is a need for the Commonwealth, State and Territory Governments to publish annually details of the numbers and particular uses of animals, by species, used in experiments in research and teaching. All experiments, including husbandry and observational, on living and dead animals should be included in the statistics. There is no difference, for statistical purposes, between animals which are killed before experiments are conducted on them and animals which are killed after having undergone experiments.

2.27 Statistics by themselves can be subject to various interpretations unless some analysis is provided by the Government to assist the reader. For example, alternatives to the use of animals might have been introduced in a range of projects but a single project involving a large number of rodents might distort the total figure giving the impression that alternatives were not gaining ground within the scientific community. Similarly, a marked increase in funds available for research in one year could increase the number of projects carried out resulting in an increase in the total number of animals used even though the average number of animals used for each project might have declined.

2.28 The scientific community has been wary about the publication of statistics of animal use in experiments because of the potential misinterpretation of those statistics by the public. The Committee believes that the public has the right to know the extent of use of animals in experiments in Australia and that the statistics should therefore be published. However, it would be preferable for some analysis to accompany those statistics to make them more meaningful to the public and to reduce the possibility of misinterpretation.

2.29 The collection of such statistics need not be onerous or expensive, either for the institutions or for the government departments or authorities responsible for animal welfare. Animal houses need to keep accurate records if they are to be managed efficiently. Ethics committees also need this information for their role in monitoring animal experimentation in their institutions. It should be, therefore, little more than an exercise of collating data for inclusion in statistical returns with some additional analysis of the statistics.

2.30 The Committee RECOMMENDS that the Commonwealth, State and Territory Governments publish annually accurate and comprehensive information on the extent and forms of animal experimentation conducted within their respective jurisdictions. In addition, government authorities should provide some analysis of the statistics to make them meaningful to the public, and to reduce the potential for misinterpretation.

CHAPTER 3

THE MORAL STATUS OF ANIMALS AND THE ETHICS OF ANIMAL EXPERIMENTATION

Introduction

3.1 The scientific community put forward a number of arguments to justify the use of animals in experiments, few of which were philosophical in nature. Instead, the practical benefits of such experiments were heavily emphasised, as was the fact that animals are irreplaceable in some forms of experimentation. These arguments are discussed in later chapters dealing with specific areas of research.

3.2 Opponents of animal experimentation have criticised the actual practice of animal experimentation but have largely based their case against the use of animals in experiments on philosophical arguments about the moral status of animals.

3.3 In surveying the philosophical debate, the Committee noted that leading advocates of the animal welfare movement, such as Professor Tom Regan and Professor Peter Singer, offer different philosophical rationales for their views on the moral status of animals. Although their conclusions are similar, they argue their respective cases along different lines. In fact, there is no unanimity either in philosophical circles or in the animal welfare movement on the exact moral status of animals and the accompanying question of the use of animals in experiments.

3.4 This chapter will therefore be devoted to an outline of the main arguments that have been placed before the Committee concerning the moral status of animals, at the end of which the Committee draws its own conclusions.

Historical Perspective

3.5 Debate over the moral status of animals and the ethics of animal experimentation is not simply a contemporary philosophical fad. The issue was discussed by the earliest Greek physicians, while anatomical researchers during the Renaissance developed arguments to justify vivisection.[1]

3.6 The 17th century French philosopher Descartes developed a position on the nature of animals and their ability to experience pain that was to be very influential. Animals were viewed as automata that could not experience real pain. It was believed they went through external motions which in humans are symptomatic of pain without experiencing its mental sensation. Descartes' arguments were used to justify undertaking physiological experiments on animals.[2]

3.7 The Cartesian position finds very little support in current debates over animal experimentation. There are, however, philosophical positions being put forward currently which deny any significant status to animals. The philosopher, R.G. Frey, for example, argued that animals have desires but not minds. They have no interests and no rights. They can therefore be legitimately used and exploited by humans.[3]

3.8 Others base the right of humans to use animals with minimal restriction on a variety of religious and scientific arguments. There is the evolutionary theory; humans are at the top of the evolutionary ladder and are therefore superior to animals. There are also fundamentalist interpretations of the Biblical story of man being given dominion over the animals.[4]

3.9 Much more common is the 'humane' interpretation of the right of humans to use animals. On this principle humans must not cause animals unnecessary pain and distress. However, animals do not have inherent rights and may be killed painlessly for legitimate purposes. As a test of necessity, the criterion of legitimate purposes, seems weak. Apart from outright cruelty or obviously pointless use, almost any purpose could be argued to be legitimate. No rigorous evidence or argument is required on this basis to justify animal experimentation.

> As it is presently articulated, humane beneficence, fails to provide criteria for determining the legitimacy of those human purposes in whose service animals may be caused pain or distress. In practice, traditional adherents of beneficence tend to find virtually all animal research justifiable.[5]

Utilitarianism and Suffering

3.10 In recent years, the most common philosophical argument in the debate over the use of animals in experiments has been utilitarian in form. It can be used, however, to argue a case either for or against animal experimentation.

3.11 Utilitarianism involves the calculation of the consequences of action in terms of the total costs and benefits or, alternatively, pleasure and pain. The positive outcomes should outweigh the costs of any course of action or project.

3.12 Simply put, permissive utilitarianism justifies particular painful experiments on the grounds that the pain experienced by animals will be more than outweighed by the benefits resulting from the relief of suffering of humans or other animals, or other improvements in the quality of human life. Human pain in this calculation is regarded as intrinsically

worse and is therefore given a greater weighting in the calculation than animal pain. Conversely, human enjoyment, pleasure or benefit will carry a heavier weighting than similar animal experiences because it is assumed to be richer and much wider in its scope.

3.13 The calculation of pain and benefit can be developed to justify a quite different position on animal experimentation. In this view animal research causes more pain than benefit. This is based on the assumption that very little animal research produces significant benefits for humanity although many experimental techniques inflict significant pain and distress on the animals used. Dr Judith Hampson, who gave evidence on behalf of ANZFAS, argued that the vast majority of animal experimentation is not done to conquer life-threatening diseases.[6]

3.14 An essentially utilitarian argument that is critical of the use of animals in experiments need not take, however, the form just outlined.

3.15 An Australian philosopher Professor Peter Singer has made a significant contribution to the development of an alternative line of argument. The core of his argument is that the granting of moral consideration to a subject is grounded in the capacity to suffer pain or to experience pleasure:

> ... the principle of equal consideration of interests is sensitive to differences in the kind of interests different beings may have. But the fundamental common interests between humans and other animals remains the interest in not experiencing pain and suffering. The only acceptable limit to our moral concern is the point at which there is no awareness of pain or pleasure, and no preferences of any kind. That is why the principle of equal consideration of interests has implications for what we may do to rats, but not for what we may do to lettuces. Rats can feel pain, and pleasure. Lettuces can't.[7]

3.16 The key principle for Professor Singer in his calculation is equality of consideration. This does not imply that both humans and animals must be treated in the same way. The principle of equality does not require equal or identical treatment; it requires equal consideration which may lead to different treatment. If the demand for equality for animals was based on the actual equality of animals it could be refuted simply because it is not true. Animals vary greatly in their capacities and attributes. Equality here is a moral idea not an assertion of fact. The principle of equality is a prescription as to how we should treat animals. As this principle is stated in the ANZFAS submission:

> ... it is reasonable to regard the death of a fish as a smaller loss than the death of a normal human - smaller to the fish because the fish does not have hopes and plans for the future which are unable to be fulfilled, and smaller for others because there is not the same kind of grief and mourning that is likely to attend the death of a normal human. But in making such a distinction, we are not saying that the death of a fish matters less because the fish is not a human being. It is not the species of the human and the fish that matters, but their capacities. So, on the same grounds, if there were a human being so severely brain-damaged as to be on a par with the fish, and if there was no-one who cared in the least for this unfortunate human being, then the death of this human being would also be a smaller loss than the death of a normal human being.[8]

3.17 Professor Singer argued that if this principle of equality is violated with respect to animals, then this attitude of violation may be referred to as 'speciesism'. He posed the question: if possessing superior intelligence does not entitle one human to use another for his own ends, how can it entitle humans to exploit non-humans for the same purpose?

3.18 This then leads to the question: what characteristic is it that gives a being the right to equal consideration? Professor Singer's answer was: the ability to suffer. If a being suffers there can be no moral justification for refusing to take that suffering into consideration. The principle of equality requires that suffering to be counted equally with like suffering. If a being is not capable of suffering then there is nothing to be taken into account.[9]

Difficulties with Utilitarianism

3.19 There are problems with utilitarianism based simply on the calculation of benefits and costs as a practical moral theory. Within the context of animal experimentation these take a number of forms.

3.20 Although it is difficult to measure human pain and pleasure it is even more difficult to do so for animals. The issue of animal pain and distress and their measurement is discussed in Chapter 4.

3.21 Conceptually, it may not be possible to quantify animal pain and distress in the way that the utilitarian calculus requires. Although we may be able to make approximate comparative judgements about the level of pain inflicted on animals of the same species, accurate comparisons among different species is virtually impossible, especially as pain perception is influenced by psychological and environmental factors.

3.22 Pleasure, too, is impossible to quantify. What is pleasurable to one person may not be to another. Even if something gives pleasure to many people, the intensity and duration of pleasure varies among individuals. If it is impossible to quantify both pain and pleasure, how does one compare pain and pleasure to give effect to the utilitarian calculus?

3.23 Even assuming for the purposes of the argument that the calculations can be made, there is a further problem. Consider the situation in which a very few animals are each caused great pain to provide a huge number of people with a very small amount of additional pleasure, and that the total pleasure experienced exceeded the total amount of pain inflicted and hence is justifiable. Compare this with a situation in which a large number of animals are caused minimal pain which results in the saving of the life of just one person. The experiments in this case are not justified because the total amount of pain suffered by the animals is greater than the benefits to the human being over the remainder of his life.

3.24 Intuitively, people may take the view that the moral status of the animals in the first case has been undervalued and in the second case overvalued by the utilitarian calculus.

3.25 Utilitarian arguments, as noted earlier, can be used in defence of human interests at the expense of those of animals. Professor T. Regan, whose arguments for animal welfare are not based on utilitarian considerations, has commented that 'the animal industry is big business',[10] that employs hundreds of thousands of people who in total have hundreds and thousands of dependents. Regan argues that a utilitarian must insist on the relevance of these people's interests and also the relevance of the interests of those additional people who might be affected by 'its sudden or gradual cessation'[11] to any calculation which attempts to maximise happiness or minimise suffering. A utilitarian argument must have the hard data to show that a humane alternative is not only possible but, judged on utilitarian grounds, desirable. It is not <u>obviously</u> true that on this basis the consequences for all involved would be better if,

for example, animal experimentation were terminated. The utilitarian approach would require that the interests of those employed who benefited from animal experimentation would in some way be traded off against the interests of the animals used in experiments.

3.26 By way of reply to this line of argument, Professor Singer stated in evidence:

> I think there are significant costs to any desirable reform and we have to consider the importance of the reform and meet those costs ... the costs must also be borne in the field of animal welfare.[12]

3.27 Professor Singer's form of utilitarian argument offers an apparently clear and simple moral principle, which provides the basis for making decisions about a wide range of issues arising out of human - animal interactions. This line of argument, particularly its appeal to a single moral principle, was subjected to criticism by Dr Margaret Stone:

> ... there are no simple answers to be found here and there is no single guiding principle that will answer the questions that are raised about the problems of animal welfare and the use of animals in our society. There have been, I think, laudable attempts, which have had very many beneficial results, to provide such a principle but they have all failed. One reason why they have failed, it seems to me, is that, where ethical principles are concerned, there is no possibility of proving the validity of an ethical principle and that a single principle does not take account of what I would see as the competing interests of humans and animals. There is no doubt that those interests compete, and to try to resolve them with reference to a single principle is to ignore that competition or at least to talk at a level of generality which does not help us resolve individual problems.

> If you take Professor Singer's point, not only is his principle in relation to equality no more logically valid than the exactly opposite principle, that animals and people should be treated unequally, but, even if we accept it as a working rule, it does not enable us without further ethical input to answer specific questions about what we do in any particular case. So it seems to me that we have to move on very quickly from that ill-fated search to find a single principle and get down to the nitty-gritty of trying to resolve problems that arise in particular instances.[13]

Animal Rights

3.28 The other major philosophical theory upon which attention has been focussed in recent years has been that of animal rights. The leading exponent of a theory of animal rights has been the philosopher, Professor Tom Regan.

3.29 Professor Regan has contended that it could be claimed that humans have certain natural rights that animals lack. He posed the question: on what grounds can rights be ascribed to humans but not to animals? His answer was that rights cannot be claimed on the grounds of reason, free choice or concept of identity because these cannot be attributed to some humans, namely infants and the mentally enfeebled. Moreover, even if all human beings possessed rights on these grounds it still would not follow that only human beings possessed them. He posed another question: on what grounds could it be claimed that no animals can reason, make free choices or form a concept of themselves? His answer was that the mere supposition that only humans have these capacities could not bear the moral weight placed upon it.

3.30 Returning to the issue of rights, if something is a right, it belongs equally to all humans because they are humans. Professor Regan argued that it cannot be a right if some humans can acquire it by doing something that other humans are unable to do. A right is something all humans have equally.

3.31 There is one argument according to Professor Regan that meets these requirements. Humans have natural rights because humans have interests, and these can be demonstrated wherever choices or preferences are in evidence.

3.32 Professor Regan developed his argument further by arguing:

(a) that all humans are the kind of beings that have rights;
(b) that to cause any human undeserved pain is to treat him unjustly; and
(c) that any time we treat a human unjustly we violate one of his rights.[14]

3.33 From this it is inferred that to cause a human undeserved pain is to violate one of his natural rights - the right to be spared undeserved pain. This is then a right all humans have just because they are humans.

3.34 But, if the most plausible basis for attributing a natural right to be spared undeserved pain to all humans depends on the idea that it is unjust to cause pain to a human, then, given that it is unjust to do this to an innocent animal, it follows that animals equally have a natural right to be spared undeserved pain. The assumption as to the injustice of causing undeserved pain to animals is central to the argument.

3.35 In summary, autonomy expressed as an interest in being spared undeserved pain, commands respect and provides the grounds for the basic rights such as the right to life and the right not to be harmed. Moral status is therefore grounded in autonomy.

Animal Freedom and Other Moral Claims

3.36 There are other approaches to the concept of 'rights'. It can be argued, for example, that animals have a moral claim to freedom from interference. However, the claim to freedom from interference cannot be absolute. Even humans are constrained from doing something harmful to other humans. Interference with experimental animals, though, goes well beyond that necessary for their own self-protection or the protection of others. The arguments for human liberty need therefore to be examined to determine their applicability to animals.

3.37 Traditional liberal arguments have held that human individuality requires a suitable environment for its development in which a principal constituent is liberty; more particularly, unique human qualities are developed only through exercising choices. Dr Kleinig in evaluating this position stated:

> Animals do not seem to possess a capacity for the kind of "individuality" on which Mill's argument depends. So great is the difference that the case for animals' freedom from interference is a considerably attenuated one. Animals do, of course, have a certain life of their own - which consists in eating, reproduction and certain limited kinds of social behaviour ...
>
> There is often something very fine about animals in their native habitat, something which is all-too-often lost in confinement. But this, while it may warrant some claim to freedom from interference, does not come anywhere near the sort of claim to such freedom which a human being may assert. Most, if not all, of an animal's life-world can be accommodated within a relatively confined situation. The requirements that animals have for freedom are nowhere as demanding as those needed for human flourishing.[15]

3.38 Dr Kleinig argued in his submission that animals have interests 'whose frustration can be harmful to them'.[16] He further argued that these interests do have some claim to moral consideration but not to the extent that they have equal standing with the interests of humans. The standing of human interests after all is determined by their amenability to rational evaluation. The claim of animals to moral consideration means at a minimum that their interests should not be needlessly restricted or overridden.

3.39 An Australian philosopher, Professor McCloskey, has written a critique of animal rights. He argued that a moral right is an entitlement that confers moral liberties on its possessor. It is also an entitlement which imposes moral constraints on others to abstain from interference with the rights' possessor. Professor McCloskey's position was that it is the capacity for moral autonomy, for moral self-direction and self-determination that is basic to the possibility of possessing a right. Other beings, whether angels, martians or mice could be ascribed rights if they possessed a capacity for moral autonomy.

3.40 Professor McCloskey concluded that if an animal has the relevant moral capacities, actual or potential, then it can be a bearer of rights. According to him, while empirical evidence does not provide support for the ascription of rights to animals he does not rule out the possibility in principle. While primate research has indicated that a degree of rationality exists among chimpanzees, in his view there is no evidence that they exercise moral judgement. He further argued that different beings may possess different rights because of possession of different attributes. This would create the problem of developing a hierarchy, or determining the priority, of rights of various species.

> Would there be specifically animal rights, tiger rights, pelican rights, tape-worm rights, if animals were to be capable of possessing rights? I suggest that any specifically animal rights are likely only to arise from special needs of the different animals, where these are needs that ought to be respected. Thus carnivores, needing to kill other animals in order to live, might be claimed to have the right to kill these other animals, whereas their vegetarian victims may lack the right to kill other animals except in self-defence, but have the right to eat grass, leaves, or the like, provided they leave enough for other animals.[17]

3.41 Professor McCloskey in his critique of the concept of animal rights noted that apart from the possession of rights, there are other considerations:

> Typically, the claim that animals possess rights is seen as adding to and strengthening other important considerations. Thus, even if it could be shown that animals do not possess rights and are incapable of possessing rights, many other kinds of considerations would need to be explored to determine what constitutes morally proper treatment of animals.[18]

> Clearly, whether or not animals possess rights, ethically important conclusions concerning how they ought to be treated would follow if claims that life, sentient life, conscious life, self-conscious life, possessed intrinsic value, could be sustained ...

> Thus just as it might be argued that it is intrinsically wrong to take innocent human life (whether or not it possesses intrinsic value), so it may be argued that it is intrinsically wrong to take innocent animal life.[19]

3.42 Even if some form of rights argument were in fact established, that, by itself, would not necessarily be the end of the matter.

3.43 Dr Margaret Stone, in response to a question as to what sort of rights animals should have, explained:

> We already have accepted in this society that animals have interests that need to be protected and they have an interest in not being exposed to pain. That is something that has been in our society for a long time. There have been statutes preventing cruelty to animals for centuries. If you say to someone, 'Is it right to be cruel to animals?', it invites, as it should, the answer, 'No, it is not right'. That is the simple question. The hard question is when we balance the interests of these animals in not being hurt against the interests of humans in getting this information. To make the competition more even, let us suppose we have got a disease that affects only animals, that causes a great deal of pain and suffering to animals in the wild but never affects people. It does not affect animals that are economically useful to us, but it does affect these animals and it causes them a lot of pain and distress. You would then have the question, quite divorced from the question of species, of whether it is right to experiment on these animals in order to protect those animals from pain - the same species, if you like. There you have got competing interests and no amount of saying that animals have interests full stop will resolve that question for you. That is because the animals that are subject to the experiment have interests which conflict with the interests of the animals that are getting sick.[20]

3.44 It is important in this context to clarify the relationship between moral rights and legal rights.

3.45 Originally, talk of rights was confined to the law. What one had a right to at law, one had a legal guarantee to and the force of law could be invoked to secure it. But in recent centuries, rights-talk has been taken over into the sphere of morality, and there has developed the notion of a moral right. The function of this move has been to justify the invocation of legal support for a moral claim. To claim a right is to claim to

be in a position to require the forbearance or contribution of others. Rights justify coercion. That is why they have a special political significance, and why it has become popular to cast the case for animals in terms of rights.

3.46 Given this development the logic behind the concept of ascribing rights to animals is clear. Dr Kleinig stated in his submission:

> Those who wish to improve the lot of animals probably need to have their concern enshrined in law. The reason for this is fairly obvious. Certain kinds of mistreatment are deeply embedded in our social practices, and closely tied up with economic factors. Change is not likely to come about voluntarily, or simply as the result of moralizing. This is a case where morality requires some form of legal backing. But how to secure that backing in a democratic community? If it can be argued that animals have rights, and that these are being violated by current practices, then the battle is half won.[21]

3.47 There has been extensive debate over the derivation of rights; are they discretionary powers, that is, claims against others which may be 'assented or waived, insisted upon or set aside'[22] or are they rights based upon the possession of interests? It was argued by Dr Kleinig that rights possession:

> ... does not require anything so strong as the capacity for rational choice, and therefore that a case can be made out for ascribing rights to animals.[23]

Kleinig thought that his point of view represented a minority position in the debate on this subject.

3.48 Further, if animals qualify as rights holders they have 'very powerful claims'[24] to moral, and as a consequence, legal protection. If animals do not qualify it does not mean that they lie outside our protective concern, but that human beings as

rights-holders will take precedence over non-rights-holders. In addition, acknowledgement of animals as rights-holders does not rule out the possibility that they may have fewer and different rights vis-a-vis humans, such as a very qualified right to life, to freedom from suffering and to quality of habitat. Such rights will inevitably come into conflict with human rights but they can be ordered by examining and weighing the relative importance of the interests underlying them.

3.49 On the relationship between legal and moral rights, Dr Kleinig expressed the view:

> ... that one can argue for moral rights on behalf of animals, though they are perhaps not as extensive or as compelling as the moral rights that attach to human beings. But it does seem to me that animals have claims, by virtue of the kinds of welfare they have, which are strong enough to justify enforcement at law. For me, that constitutes their having a moral right to those particular claims.[25]

3.50 When asked whether moral rights should be enforceable by statute, he responded:

> Moral rights constitute a case for enforcement, in my view. They constitute moral grounds which are strong enough to justify intervention of a coercive nature. It may be by legal statute or by other means. Coercion is not the exclusive province of law, of course, but it is perhaps the main source.[26]

3.51 When asked whether it was appropriate to say that animals themselves have legal rights, Ms M. Stone responded that it was:

> Entirely appropriate, and we have already done that.[27]

3.52 If this view is accepted, the issue is not whether or not animals have rights but which rights will be granted and who will have standing to ensure that such rights are enforced.

Animals and Equality

3.53 The question of relative status necessarily invokes the question of equality of rights. Here the argument from marginal cases has been advanced. This argument holds that the distinctions between human species and other species are not as clear as is commonly assumed. In particular, infants, the severely intellectually handicapped and, possibly, the comatose, have capacities and abilities which are more limited than those of the 'higher' animals, and therefore equality of treatment should be extended to animals. Dr Kleinig commented in evidence that:

> My own worry about the argument from marginal cases is that it tends to overlook on the part of human beings the potentiality for development which humans have and which, I think, most, if not all, the higher animals do not have ... Human infants do have a capacity to develop into morally responsible and sensitive beings and I think that this potentiality, as it were, reaches back into infancy and determines the appropriate ways for treating those who are still in their infancy.
>
> In the case of retarded people, we obviously need to distinguish between different degrees of retardation. Some retarded people obviously have a great deal of potential for development of moral and other sensitivities. In the case of the extremely severely retarded, it may be that there is no absolute distinction which can be drawn between their positions so far as capacities are concerned and the capacities of some of the animals. There are, however, I suspect, strong social policy reasons for drawing a distinction there, which includes those retarded people within the protections

> that we give to other human beings, namely, that if we do not draw the line below them, then the borderline will be an arena for various kinds of abuses of those people. Again, that is not to say ... that means that the distinction between humans and animals is such that we can do what we like to animals, but should not do that at all with human beings. That certain humans are, perhaps, accorded protections beyond those which would be justifiable in terms of their capacities is not a reason for treating as we wish those who do not have that protection.[28]

3.54 A further objection has been advanced by Dr Margaret Stone who commented that equal consideration of interests is simply an assertion of values which can neither be proved nor disproved:

> Singer declares that the duty not to exhibit a preference for a particular species must prevail over the duty to promote human interests; yet this is no more or less valid than the converse assumption, that human interests take precedence.[29]

3.55 By giving primacy to one value, equality of consideration of interest, there is a refusal to recognise a 'tragic choice'. In this case it is the choice between the competing and profound moral values, between the duty to respect the interests of humans and the duty to respect the interests of animals.

3.56 As Professor Les Holborow noted, the history of increasingly stringent regulation and legislation to protect animals suggests that the generally accepted view has been shifting towards an increasing recognition of the claims of animals. The problem remains of attempting to balance the competing claims.

3.57 Professor Holborow supported an approach based on rights. He stressed, however, that rights as he understands them are not absolute but are better understood as side constraints 'because they impose powerful restrictions on what agents may do to others'.[30]

3.58 What has been established by the philosophical debate reviewed here is that at a minimum, the autonomy and capacity to experience distress that animals possess in varying capacities, are enough to ensure that humans as moral agents have real and important obligations and duties to them. According to Dr Arthur Caplan:

> Human beings bear the burden of being responsible moral stewards for respecting and protecting the interests and welfare of those creatures which are alive and do have minimal levels of sentience ...
>
> Both the capacity for a full mental life and the ability to suffer place demands on the responsible moral agent that are sufficient in themselves to demand compliance and discharge. Animals deserve no less respect than that which we accord the most helpless and vulnerable members of our own species.[31]

Conclusions

3.59 The autonomy and clearly demonstrated capacity of animals to experience pain, though varying in degrees, is enough to establish that human beings, as moral agents, have real and substantial obligations and duties toward them. Anyone involved in the use of animals for research purposes is therefore accountable to the wider community for the performance of those duties.

3.60 Through animal cruelty, wildlife protection and other legislation, society has acknowledged that animals, whether as individuals or species, have certain claims or interests which may be expressed as rights, that are afforded protection. Such rights are not inviolable. When rights of animals come into a conflict with those of humans, the rights of one will normally succumb to the other. Although human rights have usually predominated in such conflicts, each case should be examined on its merits and human rights should not automatically prevail.

CHAPTER 4

ANIMAL PAIN AND DISTRESS

Definitions

4.1 Discussion of pain presents difficulties of both definition and communication. Some of the difficulties were outlined by Dr M. Rose, Chairman of the Animal Research Review Panel of New South Wales:

> I think it is important to note that in relation to pain we tend to use four terms ... 'pain', 'suffering', 'anxiety', and 'stress'. The interpretation of those words depends very much on whether you are talking to physiologists, psychologists, behaviourists or philosophers - they all seem to interpret this sort of terminology differently. I think this language problem with pain is one of the most difficult things ...[1]

4.2 The International Association for the Study of Pain defined pain as:

> ... an unpleasant sensory or emotional experience associated with actual or potential damage or described in terms of such damage.[2]

4.3 A similar definition is contained in a report to the European Commission:

> Pain is an unpleasant sensation that is perceived as arising from a specific region of the body and which is commonly associated with actual or potential tissue damage, or communicate in terms of such damage.[3]

Communication in this context includes signals and non-verbal communication.

4.4 The simplicity of this definition may be misleading. It is necessary to emphasise the fact that there are two distinct aspects to be considered in evaluating pain - stimuli and perception. There is not a simple one to one correlation between the two. The same amount of stimulus will not cause identical perceptions of pain by animals of different species, nor will it necessarily do so for different animals of the same species. This is explained in the introduction to an anthology of research reports on animal pain:

> Most authorities agree that pain is a perception, not a physical entity, and that perception of pain depends on a functioning cerebral cortex. Unlike most other sensations, no single area of the cerebral cortex seems specifically necessary for the perception of pain. The term noxious describes stimuli that, if perceived, give rise to the perception of pain ... The receptors specifically responsive to noxious stimuli are termed nociceptors. A stimulus must be a certain strength before a nociceptor will generate nerve impulses in peripheral nerve fiber of which it is a part. This stimulation strength is called the nociceptive threshold. In certain circumstances this amount of neural activity may be too little to result in perception of pain. The strength at which noxious stimulation is perceived by a human being as pain is referred to as the pain detection threshold. The strongest intensity of noxious stimulation that a human being will permit an experimenter to deliver is called the pain tolerance threshold. The strength of noxious stimulation necessary to reach the nociceptor threshold is rather constant and varies little among humans and animals. The strength needed to cross the pain detection threshold is slightly more variable, especially among humans experiencing clinical pain. The pain tolerance threshold is the most variable of the three thresholds.[4]

4.5 To understand the perception of pain as a sensation requires constant reference to both the sensory functions of the nervous system and the anatomic or physiological organisation of an animal. In humans pain is further linked to the emotions through the functioning of the brain which integrates it with information from the outside world and results in behavioural responses.

4.6 Pain can be divided into two categories: quality, which ranges from mild to severe; and temporal, either acute or chronic. The temporal category can be broken down further into causation, impact and treatment.

- Acute Pain results from a traumatic, surgical, or infectious event that is abrupt in onset and relatively short in duration. It is generally alleviated by analgesics.

- Chronic Pain results from a long-standing physical disorder or emotional distress that is usually slow in onset and has a long duration. It is seldom alleviated by analgesics but frequently responds to tranquillizers combined with environmental manipulation and behavioural conditioning.[5]

4.7 The term 'anxiety' is also used in connection with animal behaviour. There is some evidence that vertebrates at least are able to experience a physiological form of anxiety similar to that seen in humans. Brain receptors for benzodiazepine (chemical substances that relieve anxiety) have been found in mammals, reptiles, amphibians and bony fish but not in invertebrates.

4.8 The term 'suffering' is commonly used in relation to animals. It is often paired with the term pain in an attempt to indicate that the well-being of animals is not simply a matter of freedom from pain.

4.9 There are, however, difficulties with the term. Suffering is even more difficult to define than pain. It covers in humans a wide range of mental or emotional states. Fear, hunger, boredom, frustration and grief may all indicate suffering. Suffering then involves a scale or continuum of unpleasant experiences that vary in intensity.

4.10 The Committee does not find the use of the term 'suffering' to be very helpful. There is presently no agreed definition of suffering that would provide guidance to ethics committees and experimenters. The concerns with animal well-being that are not directly related to pain are more appropriately described by the term 'distress'.

4.11 In coming to an understanding of 'distress' we need first to consider the nature of 'stress'. Stress may be simply a normal healthy reaction to changes in an animal's environment or metabolism, for example, injury, disease or exposure to extremes of temperature. If stress were prolonged because the physiological response was not able to adapt to the changed conditions, a stage of exhaustion would be reached, characterised by impairment of those body functions involved in growth, reproduction, resistance to disease and general activity. The problem is deciding when stress becomes distress.

4.12 In the draft revised Code of Practice, 'distress' is defined as:

> Acute or chronic response of an animal caused by stimuli that produce biological or psychological stress to which the animal cannot adjust by normal physiological or behavioural means.

4.13 The EC report defines chronic stress in animals as:

> ... a feeling related with the entire process of emergence of pathologies (anatomically:

ulceration of digestive tract; behaviourally: stereotypes and redirected behaviour).[6]

Scientific Attitudes to Animal Pain

4.14 The willingness of the scientific community to consider whether animals experience pain let alone anxiety seems to have been influenced as much by the philosophical assumptions of their age as by the findings of research on the subject. Pain researchers Kitchell and Erickson presented the following view based on the current state of research into pain:

> When considering pain in animals, analogies must be drawn between human and animal anatomy, physiology, and behaviour. Knowledge about pain in animals remains inferential, however, and neglect of the probabilistic nature of pain perception in animals leads to anthropomorphism. On the other hand, overemphasis on the uncertainty of our knowledge about pain perception in animals, which leads to a denial that pain perception exists in animals, is logically as well as empirically unfounded. That tacit assumption is that stimuli are noxious and strong enough to give rise to the perception of pain in animals if the stimuli are detected as pain by human beings, if they at least approach or exceed tissue-damaging proportions, and if they produce escape behaviour in animals.[7]

4.15 This represents a balanced if cautious view on the issue. Changing views on the reality of animal pain in recent years have resulted from both advances in physiology and changes in philosophy which now allow for the possibility that animals experience some form of consciousness.

4.16 There was substantial agreement among the experimenters appearing before the Committee as to the reality of animal pain. According to Professor Egerton:

> My belief is that we should approach this question from the basic premise that at least vertebrate animals suffer pain. I cannot really argue about the level to which they suffer pain and their appreciation of that level. I know that the mechanisms are available in vertebrate animals sufficient to receive pain messages. They have brains that are sufficiently developed to make them appreciate those pain messages that they get from injured parts of their bodies.[8]

4.17 Although in basic agreement, Professor Titchen sounded a note of caution:

> ... one should remain aware of the fact that we make a number of assumptions, that is, that the receptivity for pain in animals is the same as or similar to that in humans. There is some supporting electrophysiological and neurophysiological evidence for that, but beyond that point, once we leave the issue of reception and we start into the area of perception and sensory appreciation of pain, our evidence is flimsy in the extreme. Indeed, there is some anatomical evidence which does not support the idea that the same pathways for pain exist in all animals as in humans ...[9]

4.18 Dr M. Rose pointed out to the Committee that there is a relationship between pain perception and the environment or context in which the pain is inflicted. A person's perception of pain is heightened when pain is expected compared with pain caused by an accident. She went on to say that there is evidence that this also occurs with animals.[10]

4.19 Mr Richard Ryder of the United Kingdom, who appeared for the Australian Federation of Animal Societies (now ANZFAS), agreed that animals and humans both experience pain in similar ways. He added:

> Dr Kelly and others in Britain and elsewhere have discovered the chemicals that seem to be associated with the transmission of pain in

> the central nervous system and have found that these chemicals are present in all the major classes of animals, including fish.[11]

Difficulties in the Assessment of Animal Pain and Distress

4.20 The assessment of whether animals are experiencing pain or distress is often difficult since it is mostly done on the basis of indirect evidence. Criteria for assessment of animal well-being include:

(a) physical health;
(b) behaviour of animals in the wild;
(c) physiological measurements such as heart rate and hormone levels;
(d) abnormal behaviour patterns;
(e) animal preferences; and
(f) anthropomorphism.

These criteria, in many cases, cannot be used to make definitive statements about the level of pain or distress experienced by an animal. At best, they can give an indication of such suffering.

4.21 Disease and injury are major causes of distress and their absence is necessary to an animal's well-being. Animals may still suffer distress despite an appearance of good health. According to M. Stamp Dawkins:

> The occurrence of physiological and behavioural disturbances in apparently healthy animals suggest that other methods of assessing suffering should be looked for.[12]

4.22 Some people may try to draw inferences about the well-being of confined animals by means of comparisons between animals in restricted environments with those of the same species in wild or semi-wild conditions. However, genetic and

environmental differences between wild and domesticated animals make comparisons difficult. A difference in the behaviour of free and restricted animals in itself does not automatically mean that the restricted ones are distressed. Distress must be established by independent means.

4.23 The problem of physiological measurements such as heart rate and hormone levels is to decide how much of a physiological change an animal can tolerate before it can be said to be distressed. The taking of physiological measurements may also be stressful to an animal and this additional stress may distort the results.

4.24 With abnormal behaviour patterns, the question to be asked is: when does such behaviour constitute distress? Some abnormal behaviour clearly indicates distress because visible physical damage is done to the animal. However, abnormal behaviour often does not reach that level.

4.25 One method of research into stressful environments is by establishing animal preferences. This involves giving animals the opportunity to choose for themselves which environments they prefer. Animals may choose, however, an environment with which they are familiar rather than a 'better' one which they have not experienced. The results may be different if the animals had been raised in different conditions.

4.26 Anthropomorphism in the interpretation of animal behaviour should only be used in association with behavioural or other scientific information on the animals concerned. It is nevertheless very difficult to make judgements which avoid at least some degree of anthropomorphism.

Animal Pain Assessment

4.27 British veterinarians have developed a series of species specific assessments that enable the extent of pain being experienced by an animal to be defined in a general way. The elements involved in this assessment include:

(a) behaviour indicating pain, distress and discomfort: posture, vocalising, temperament, locomotion and other behaviour;
(b) common clinical signs: cardiovascular, respiratory, digestive, nervous and musculoskeletal, miscellaneous.

These elements are in addition to any changes in appearance and food and water intake.

4.28 Not all of the signs may be present simultaneously and no sign by itself is indicative of the degree of pain experienced. The scheme involves measuring or assessing a number of independent variables: bodyweight, appearance, clinical signs, unprovoked behaviour and responses to an appropriate stimulus.

> Scores of 0 to 3 are assigned to each of these variables in an animal ... While more precise quantitative assessments would be preferred this is not possible. Consequently, one has to try to group clinical observations into broad categories and the following have been assigned for this purpose: No obvious deviation from the normal range; possibly abnormal, ie, minor change; a definite change from normal but not marked; and a gross change from normal.
>
> Scores of 0 to 3 are assigned to these four groups with 0 given when no abnormal variation is detected.[13]

4.29 The broad categories of pain assessment and necessary action are set out in Table 4.1.

Table 4.1: Possible Interpretation of Total Scores from an Overall Assessment of an Experimental Animal

Total Score	Overall Assessment
0 to 4	Normal
5 to 9	Monitor carefully, should consider the use of analgesics and sedatives
10 to 14	Ample evidence of suffering, some form of relief must be seriously considered; should be under regular observation; seek expert advice; consider termination
15 to 20	Relief should be given, unless the animal is comatose. Is it a worthwhile experimental animal because physiologically it is likely to be abnormal? There is ample evidence of severe pain. If likely to endure, terminate the experiment.

SOURCE: 'Guidelines on the Recognition of Pain, Distress and Discomfort in Experimental Animals and an Hypothesis for Assessment', by P. H. M. Griffiths, Veterinary Record (April 20 1985, Vol.116, pp.431-436)

4.30 Such a scheme is species specific and requires a detailed knowledge of many dimensions of the normal behaviour, diet and metabolism of each species. It is particularly relevant for post-operative care as well as monitoring during non-invasive experiments. However, David Adams, an Australian expert in pain research, warned:

> Words such as 'measurement' and their like have limited application to pain. They imply the possibility of a system for ranking pain and a single universal formula for reckoning its severity. Pain is a perception in the physiological sense of the word and varies

> both in quality and intensity. Pain is 'pluridimensional'. A scale of severity would be spurious and, more importantly, inconsequential to pain relief or prevention. Pain is better categorised according to the action necessary to alleviate it. Diagnosis as opposed to measurement is implied here.[14]

4.31 The alternative approach to assessing animal pain is to grade the experimental techniques upon the basis of what is known about the techniques, the extent to which they are invasive, their length, degree to which analgesia is necessary etc. Dr A. Rowan provided a model for such a classification in Table 4.2.

Table 4.2: Research Techniques, Pain and Distress

Categories	Examples
1. No pain or only minimal and momentary pain	Injections*, blood samples, tube-feeding*, diet experiments*, breeding studies, behavioural studies without aversive conditioning, routine procedures from small animal vet. practice
2. Animals painlessly killed or anaesthetised animals not allowed to recover	Blood pressure studies, organ and tissue removal, studies on organ survival, perfusion experiments
3. Surgery on anaesthetised animals with recovery but where postoperative pain will be minimal	Biopsies, transfusion or vascular studies, cannulation, castration, pituitary removal in rodents using standard techniques, some CNS lesions
4. As above but with considerable postoperative pain	Major surgical operations, burn studies, graft studies
5. Experiments planned on unanaesthetised animals expected to become seriously ill from the treatment or to suffer considerable pain or distress	Toxicity testing, radiation, transplants of tumours or infections, stress, shock or burn studies, behaviour experiments involving aversive conditioning
6. Experiments on unanaesthetised animals (or only local anaesthesia) where the animal is curarised or paralysed	Some physiological or pharmacological studies on CNS

* These procedures may produce pathological states (e.g., injection of pathogens, feeding of toxic chemicals) and, if so, would have to be graded differently.

SOURCE: Dr A. Rowan, 'Of Mice, Models and Men', State University of New York, 1984, p.82.

Pain Classification System

4.32 There has been some debate in Australia whether the Code of Practice should include a pain classification system that would require researchers to specify in their protocols in which pain category their experiments would fall. It has been argued that a pain classification system would enable ethics committees to give special consideration to experiments which fall into the more severe categories of pain. It would also identify for non-scientist members of ethics committees those experiments which caused more than mild pain or suffering.

4.33 Although a pain classification system has some benefits, it has administrative problems and may bring about some undesirable practices.

4.34 There is the obvious problem of deciding in which category to place an experiment. It is inevitably a subjective decision even with documented criteria to assist experimenters in their decisions. It is also human nature to downgrade the severity of an experiment, particularly in cases where the level of pain is difficult to determine.

4.35 In a series of experiments, different levels of pain and suffering may be experienced by the animals. Should the categorisation be on the basis of the most painful, the least or the average? One painful experiment in a hundred may distort the categorisation if the most painful experiment forms the basis of categorisation. If the average is used, it may hide a few excruciating experiments amongst many mild ones.

4.36 Professor Taylor of the University of Sydney commented:

> I cannot see the advantage of such a scheme. In the first place, I think any sort of scale would be extraordinarily difficult to devise

> and agree on so that it became a matter of common consent all over Australia and, indeed, internationally that a grade 2 experiment meant exactly the same thing. Without that sort of agreement a scale would be meaningless.[15]

4.37 A pain classification system concentrates attention on the severe end of the scale and diverts attention from the other end. An experiment which causes any pain at all should be scrutinised carefully by an ethics committee. Even minimal amounts of pain should not be disregarded. The questions that should be asked of all experiments are whether animals need to be used at all and, if so, whether there needs to be any pain or distress. Experiments which fall in the lower end of the scale should not be disregarded as unimportant because they account for most of the animals used.

4.38 Professor Dorsch, Pro-Vice-Chancellor of the University of Sydney, argued:

> It (a pain classification system) would be positively counterproductive ... If an ethics committee gives you a grade 2 for pain, you think, 'I am not doing anything very painful so I do not really have to take much care of these animals'. It takes out the individual care and the individual responsibility for the experiment. So I think that sort of artificial scale, firstly, is difficult to establish and, secondly, would probably lead to less care than the responsibility being right there for looking at the animal and establishing whether it is suffering pain and discomfort.[16]

4.39 Dr Rose, in her capacity as Chairperson of the New South Wales Animal Research Review Panel, expressed the view that a pain classification scheme engenders a belief among experimenters that minimal pain in animals is acceptable and does not have to be treated or monitored.[17]

4.40 The level of pain or distress caused by an experiment is often determined by the experience and competence of the experimenter. Dr Hampson illustrated this point in her evidence by showing that one experimenter can keep distress to a minimum by proper and caring techniques while another experimenter will cause significant distress to the animal while conducting the same experiment.[18]

4.41 In evidence to the Committee, Dr W. Anderson, representing the NHMRC, said that pain categories might be useful for statistical purposes, referring, by way of example, to the collection by the Victorian Government of statistics on types of experiments.[19] This use of pain categories is subject to the same problems as those inherent in the use of categories by ethics committees. Such categories are only useful if they can be defined in such a way as to make the statistics meaningful. However, because classifying pain is so subjective and defining categories is so difficult, the Committee can see little purpose in including pain categories in statistics on animal experimentation.

4.42 Apart from the severity of pain, there are other factors to be considered, such as the duration of the pain and the types of procedures being used. Then there are other forms of stress or anxiety occurring either during or after an experiment which might not be painful but might be more distressful to the animal than pain itself. An experiment might, for example, result in paralysis of part of the body or in the impairment of some bodily function. This might be more distressful to the animal than being subjected to pain.

4.43 The draft revised Code of Practice states:

> The AEEC (ethics committee) may adopt or develop a system to categorise experiments, to help identify areas of special concern.[20]

4.44 Although this provision in the draft Code of Practice does not specifically require the adoption of a pain classification scheme, it is couched in a way to suggest it is preferable to establish one. The Committee believes that its adoption will not serve the interests of animal welfare.

Pain Relief in Laboratory Animals

4.45 Despite the difficulties outlined in measuring and assessing pain as experienced by animals, the need for pain relief in animals used for experimental purposes is clear. Dr P. Flecknell, a leading expert on analgesia and anaesthesia, has outlined the basis on which experimenters should consider relief of pain.

> Until further progress is made in assessing the nature of pain in animals, it should be assumed that if a procedure is likely to cause pain in man, it will produce a similar degree of pain in animals. Although such anthropomorphic views have been much criticized, no satisfactory alternatives have so far been proposed, therefore the relief of pain, particularly in the postoperative period, must be considered essential.[21]

4.46 According to the same author:

> Anaesthesia is a relatively neglected area of laboratory animal science. Many of the advances in technique which have been introduced into human clinical anaesthesia have been largely ignored by research workers and, at the time of writing, ether and pentobarbitone remain the drugs which are most widely used for anaesthetising laboratory animals. As will be discussed later, both of these drugs have serious disadvantages as anaesthetics, and they are generally better replaced by other agents.

> A second common failing of current laboratory animal anaesthetic practice is the lack of consideration given to the pre- and post-operative care of the animal. Careful attention to the needs and well-being of the animal during these periods should be considered an integral part of the anaesthetist's responsibilities. Not only will such attention do much to prevent the animal from experiencing any unnecessary pain and distress, it will also considerably reduce anaesthetic mortality and hasten post-operative recovery.[22]

4.47 Control of pain extends well beyond the administration of analgesia. Good surgical techniques and provision of appropriate areas for recovery from anaesthesia and for post-operative nursing are also important.

4.48 There is a need for continual in-service training of experimenters to assist them in keeping up to date with developments in anaesthesia and analgesia. Few opportunities for training in this area are currently provided in Australia.

Pain in Codes of Practice

4.49 The draft revised Code of Practice contains the following general principles on the infliction of pain on experimental animals and the use of anaesthesia and analgesia:

> 1.12 Experiments must be designed to avoid pain or distress to animals. If this is not possible, pain or distress must be minimised.
>
> 1.13 Pain and distress cannot be easily evaluated in animals and therefore investigators must assume that animals experience pain in a manner similar to humans. Decisions regarding the animals' welfare must be based on this assumption unless there is evidence to the contrary.

1.14 Experiments which may cause pain of a kind and degree for which anaesthesia would normally be used in medical or veterinary practice must be carried out using appropriate anaesthesia. When it is not possible to use anaesthesia, such as in certain toxicological or animal production experiments or in animal models of diseases, the end-point of the experiments must be as early as possible to avoid or minimise pain or distress to the animals.

1.15 Investigators must avoid using death as an experimental end-point whenever possible.

1.16 Analgesic and tranquillizer usage must be appropriate for the species and should at least parallel usage in medical or veterinary practice.

1.17 Animals which develop signs of pain or distress that are more severe than is acceptable in medical or veterinary practice must have the pain or distress alleviated promptly or be killed humanely without delay. Alleviation of such pain or distress must take precedence over finishing an experiment.

4.50 Sections 3.3.1 to 3.3.15 of the draft revised Code of Practice set out the specific steps necessary for these general principles to be implemented. Emphasis is placed on monitoring animals for signs of pain and distress. The approach taken draws heavily on the work of Morton and Griffiths discussed earlier in this chapter.

4.51 In its discussion of pain and anaesthesia, ANZFAS recommended to the Committee:

> That no procedure be permitted which may cause pain or, suffering (in its broadest sense), of more than trivial extent unless -
>
> i) appropriate analgesia or anaesthesia is administered including during any period of post-operative care, or
>
> ii) other refinements are utilized,
>
> to eliminate the potential for such pain or suffering.[23]

4.52 This is a more restrictive form of the requirement in the current Code of Practice which requires that:

> Procedures which are liable to cause pain of more than trivial extent, or those other than of a routine husbandry nature carried out in accordance with accepted farming practice, must not be carried out without anaesthesia which is adequate and appropriate for that species of animal and is administered for the duration of the procedure.[24]

4.53 The relevant provision in the draft revised Code of Practice is:

> Experiments which may cause pain of a kind and degree for which anaesthesia would normally be used in medical or veterinary practice must be carried out using appropriate anaesthesia.[25]

4.54 ANZFAS made the following observations about the proposed new provision:

> (i) the existing, pain threshold of 'more than trivial extent provides a higher standard of animal welfare than does the proposed threshold of normal 'medical and veterinary practice';
>
> (ii) the normal treatment of a human or an animal in a medical or veterinary practice, where the object of the treatment is for the benefit of the individual concerned, should not apply as the standard in circumstances where the animal is subjected to pain or distress as part of an experiment;
>
> (iii) the experimental animal should not be subjected to levels of pain that would be unacceptable to healthy human volunteers in a similar experiment;
>
> (iv) the existing pain threshold of 'more than trivial extent' provides a clear, unambiguous guideline of the circumstances in which anaesthesia and analgesia are prescribed

> by the Code. By contrast the proposed threshold is loosely worded, and subject to variable interpretation. There is ambiguity as to whether veterinary practice includes procedures of a routine husbandry nature.[26]

4.55 Central to the ANZFAS case is the assertion that the concept of 'pain of more than trivial extent' provides a 'clear unambiguous guideline' for the level of pain which requires anaesthesia. Professor Singer commented:

> I have understood this is to mean the kinds of pain that one would inflict on humans without too much thought. For instance, giving an anaesthetic itself will involve an injection and that may cause some momentary pain. But I would consider that to be pain of a trivial extent and something that could be justified. The same may be true of drawing a blood sample. Again, that is something that would be done in humans without the use of an anaesthetic.[27]

4.56 However, as Dr Hampson pointed out in evidence, the giving of an injection may cause distress if the animal is not handled properly by the experimenter.

4.57 Dr Gleeson, the Executive Officer of the ethics committee at La Trobe University, emphasised the subjective nature of this concept. Asked to define it he replied:

> I cannot really define it for everybody else but in my mind I would, perhaps, know what trivial is to me. In my experience at La Trobe, I find the experiments there to be pretty non-invasive and whilst for some of them you may not use the word trivial, I think that the amount of pain involved is small and the animals were always closely monitored so that if it does get beyond a particular, again subjective, threshold, something can be done about it.[28]

4.58 Given the subjective nature of the 'trivial extent' option there can be no guarantee that it will lead as the first part of the ANZFAS comment suggests to a higher standard of animal welfare than the proposed alternative.

4.59 The variability of the human pain threshold also casts some doubt on the usefulness of the test proposed in part (iii) of what would be acceptable or unacceptable to healthy human volunteers.

4.60 The proposed wording in the draft revised Code of Practice is an attempt to establish a more objective basis for decision-making by ethics committees. However, the reference to medical and veterinary practice needs to be tied more closely to specific species. What is acceptable practice for one species may not be for another species. The spaying of cattle in remote areas of Queensland, for example, is routinely done without anaesthesia. Surgical interventions of a similar nature conducted on companion animals would normally be done under anaesthetics.

4.61 The Committee prefers the following wording instead of that which is contained in the draft revised Code of Practice. It ties veterinary and medical practice closer to specific species and procedures.

> Experiments which may cause pain of a kind and degree for which anaesthesia would normally be used in the area of medical or veterinary practice most closely related to the proposed procedure and species, must be carried out using appropriate anaesthesia.

4.62 What both definitions (that is, Code of Practice and ANZFAS) point to is the shared moral consensus within the community which acknowledges that animals are not to suffer pain above some fairly minimum level. The definitions in the Code of Practice are there to guide experimenters in the planning of projects and assist the ethics committees in their assessment of them.

4.63 Inevitably, a decision by an experimenter or an ethics committee whether to use anaesthesia will be subjective, irrespective of which definition is used in the revised Code of Practice. Whatever wording is adopted, the meaning is clear: minimal pain only will be acceptable to the community and to the authorities which sponsored the revision of the Code of Practice. Where tightly defined terminology is impossible by virtue of the subjective nature of the topic, the spirit of the regulatory provisions overrides any interpretation of the actual words used in the regulation. The intention of the Code of Practice is clear and it is the intention which is paramount in the interpretation of the provisions of the Code of Practice in this subjective area.

CHAPTER 5

THE USE OF ANIMALS IN BIOMEDICAL RESEARCH

Introduction

5.1 In this chapter, the Committee examines the arguments for and against the use of animals in biomedical research. The arguments used also apply generally to the use of animals in experiments. Issues specifically related to other forms of animal experimentation are examined in succeeding chapters.

5.2 During the course of the inquiry, the Committee received a wide spectrum of views on the value of and justification for the use of animals in experiments. Some opponents of biomedical research or animal experimentation in general advocated an immediate ban on experiments; others supported the phasing out of animal experimentation as alternatives to the use of animals become available. There were other people, again, who wanted to reform the conduct of experiments on animals but who did not see the abolition of such experiments as a possible option, at least for a long time.

5.3 It would be true to say that all people would like to abolish experiments on animals, provided that there were suitable alternatives available. No-one likes to kill sentient beings or cause pain or distress to them. However, the scientific community argued that, at the current stage of technological development, it is still dependent on the use of animals in the conduct of biomedical research.

5.4 Besides philosophical arguments, which were discussed in Chapter 3, critics of the use of animals in biomedical research focussed on the following issues:

- scepticism or actual rejection of the value of animal experimentation for human medicine and the questioning of the adequacy of particular animal models of human disease;

- the unnecessary repetition of experiments;

- the distortion of experimental results as a consequence of the unnecessary pain and distress of the animals undergoing experiments.

Value of Biomedical Research

5.5 The Australian Association for Humane Research (AAHR) argued for the immediate cessation of experiments on animals. It questioned the efficacy of animal experimentation and suggested that:

> ... animal experimentation is not only leading modern medicine further and further away from the goal of health, but the data obtained from animals has even proved dangerous on more than one occasion.[1]

5.6 Mrs E. Ahlston, representing the AAHR, told the Committee:

> That there is absolutely no correlation between animal experiments and improvements in health can be illustrated by the fact that America, with an estimated 100 million animals dying in laboratories each year, has been placed 17th on the World Health Organization's list of healthy nations despite the sophisticated technology of its medical services. A knowledge of medical history provides further proof.[2]

She went on to say:

> An animal 'model' mimicking human disease in the artificial environment of a laboratory can never reproduce the complex factors of the human lifestyle and, without these components, the study of the disease process artificially produced in animals is of little, if any, value.[3]

5.7 In an earlier hearing in 1984, Mrs Ahlston denied that many advances in medical science have been made as a result of animal experimentation.[4]

5.8 The views of the AAHR were disputed strenuously by proponents of animal experimentation throughout the inquiry. They argued that biomedical science, largely dependent on animal experimentation, has made many advances over the last century in developing cures for diseases and for the relief of pain and distress. They went on to say that although alternatives were being introduced, the use of animals would still be essential for biomedical research in the forseable future. According to Professor Darian-Smith:

> ... we are not at a stage where we can ease up on biomedical research. We are right at the beginning of all the really difficult testing. Relatively, the simple questions have been resolved. They may not have been simple in terms of the social implications but biologically they have been relatively simple. The real questions, the real problems, will confront us in the next 50 years.[5]

5.9 The role that community expectations play in justifying research was taken up by Dr Campbell:

> The community expects continuing advancement in health benefits to it. A good example of this is perhaps the recent occurrence of AIDS in which there is a strong demand from the

> community at large for a cure for AIDS to be found. It is the best example that comes to mind of where the community demands research to be performed and demands an outcome that is satisfactory to the health of the community. Research into AIDS ... will depend a lot on the use of animals.[6]

5.10 The Committee is convinced of the value of animal experimentation in the area of biomedical research, both as a result of past discoveries and of the potential to find new cures for diseases for which there is currently no or little treatment available. The evidence put before the Committee in submissions and at hearings and the information contained in the scientific literature clearly demonstrates the important role animal experimentation has played in the development of treatments for many diseases which once were the scourges of people and animals throughout the world.

5.11 Having said that, it should not be taken that animal experimentation or, in fact, biomedical research itself, is the panacea for all the ills of humans and animals. As ANZFAS pointed out in its submission, many of the world's fatal diseases are to a large extent caused or exacerbated by environmental conditions and lifestyles. Control of these diseases is often in the hands of humans themselves. Much can be done to reduce the incidence of heart disease, cancer and strokes without resort to biomedical science. In many cases, biomedical science has little to offer by way of cures.

Use of Animals in Basic Research

5.12 Stronger opinions were held in the evidence on the use of animals in basic or fundamental research compared with applied research. In its submission, ANZFAS commented that:

> Fundamental research is not goal-oriented and the application of any knowledge flowing from it cannot be predicted in advance. While it is acknowledged that some fundamental research may lead to important and unforseen breakthroughs and applications, there is a tendency on the part of the scientific community to over generalise from a small number of particular examples. Most fundamental research leads to no benefits whatever. Often it is carried out for postgraduate projects, or because of pressure to publish, or because grants happen to be available. A great deal of research is low grade and is never published at all.[7]

5.13 ANZFAS went on to recommend that legislation be enacted to ban all experiments in basic research which caused pain or suffering.

5.14 Professor Boura of Monash University commented that when scientists are working on the peripherary of existing knowledge, they cannot accurately predict the results of research. He went on to describe how experiments on a non-addictive analgesic accidentally revealed two valuable veterinary drugs. (Evidence, pp.7818-9)

5.15 Dr Janssens of the Australian National University expressed the research imperative in the following terms:

> We believe that basic research, is an appropriate and necessary activity for science. The physiology, biochemistry, structure and function of animals are important areas of study in their own right. We can only maintain the physical and biological world if we understand it; only by knowing the way in which animals function can we understand how changes in the environment will affect them; only by studying animals can we understand our relationships to them. We make no apology for saying that we support the use of animals in basic research.[8] (Evidence, A.N.U., p.103)

5.16 The Committee noted that ANZFAS did not recommend that all experiments related to basic research should be banned; only those which caused pain or suffering. This is in line with ANZFAS' recommendation to ban all experiments which cause pain or suffering. The main argument put by ANZFAS against basic research was the amount of poor quality basic research carried out, particularly in Australia. The Committee does not condone poor quality research, especially where animals are used in experiments. However, the existence of poor quality research, if it can be proven to be of poor quality, is not an argument against the principle of using animals in basic research. It is an argument for tightening controls over the conduct of such research.

5.17 With regard to the argument that much basic research leads to no benefit at all does not invalidate the conduct of such research. Inevitably, the nature of basic research militates against a high success rate in benefits and discoveries, particularly when compared with the results of applied research.

5.18 The Committee has not recommended the banning of experiments which cause pain or distress to animals. Consequently, as the Committee does not draw a distinction between basic and applied research, it does not recommend a ban on one and not the other.

5.19 The important point to address is the need for research to be well thought out. Where endpoints of research are largely indefinable because of the nature of the research, greater care should be taken to ensure that animal experimentation is absolutely necessary. Ethics committees, funding bodies and accreditation panels have a responsibility to ensure that standards of basic research are upheld.

Repetition of Experiments

5.20 The scientific method is based on the replication of experimental data. It is important to be able to verify the results of a project, particularly one which has significant ramifications for scientific research. Replication is also a disincentive for deliberate scientific fraud.

5.21 Dr G. Alexander, representing AFWA, explained:

> Every time a new worker takes up a piece of work or a new laboratory takes up a piece of work they have to establish baselines and until they can make sure that the baseline or the factors reported in the literature get the same result they cannot advance. If you are trying to determine dose rates for any treatment, animal variation is a major problem and you have to repeat things until you have a reasonable mean value ...[9]

5.22 Professor King, who also appeared for AFWA, outlined his understanding of the guidelines for repetition of experiments.

> If you do an experiment you make a statement at the end of it. If statistics were applied to the data, you make a statement such as this could have happened by accident, one out 20 times. You do not know whether you have picked up one out of 20 or whether it is a regular 19 out of 20. So for that reason you have to repeat and the more unreliable your data is, the more you have to repeat it. So there are guidelines for repetition. If you have a difference that has one in a million times chance of happening by accident then, obviously, you feel you are on a pretty strong thing. If you have something that could have happened by accident one in 20 times then there is much more room for scepticism in there.[10]

5.23 The Committee received much criticism of repetition of experiments on animals. Although some repetition is essential, not all of it is necessary. Unnecessary repetition of experiments is where experiments are repeated, usually by different

experimenters, in the knowledge that no useful purpose will be achieved in conducting them or because the experimenters were not aware of the earlier projects. Not all projects have their results published or the results are not readily accessible.

5.24 The difficulty is often deciding whether experiments need to be repeated. This is something that departmental heads in institutions, funding bodies and ethics committees need to scrutinise carefully before approving projects.

5.25 Sometimes, both critics and experimenters fail to make explicit the distinction between a research project and the ensemble of actual experiments that make up the project as a whole. The funding bodies and ethics committees will view the project as a whole. Numbers of the experiments within a project may in fact repeat previous work in order to establish a baseline for those experiments within the project which extend the boundaries of previous work.

5.26 Witnesses for the scientific community repeatedly emphasised that unnecessary repetition of experiments was unlikely because funds within Australia for biomedical research are limited. There is an intense competition to obtain research grants. The success rate for NHMRC grants for example is about 30 per cent.[11]

5.27 Some of the funding for biomedical research has not come from outside funding bodies but from funds available through university departments. This has meant that the peer review system has not been applied rigorously to all projects.

5.28 It also needs to be acknowledged that research science as a whole is a 'social system' in which judgements of value will be made extensively when it comes to funding priorities. It seems unlikely that such decisions will not be influenced by such factors as the general standing of the person or organisation

requesting funds and assumptions as to the significance of the project, such as, whether it fits into current thinking in the field in question or whether it is regarded as being socially desirable. Even the most rigorous assessments cannot provide any guarantee that 'low priority' and relatively repetitious experiments will not be funded. Studies of the peer review system and refereeing of articles for journals in a variety of fields of science within the U.S.A. have suggested that randomness and reviewer bias exist even in the most prestigous funding bodies.[12]

5.29 Repetition of experiments is another area where departmental heads in institutions, ethics committees and funding bodies need to be vigilant to prevent abuse occurring. It is not something that can be controlled by regulation or other government control. Unnecessary repetition of experiments involving animals is both unethical and a waste of scarce resources. It is in no-one's interest to allow unnecessary repetition of experiments to occur. Scrutineers of protocols need to be fully satisfied that repetition is essential for the success of the project and that the experimenter has assiduously searched the scientific literature for similar projects elsewhere before the protocol is approved.

Alternatives

5.30 Alternatives to animal experimentation include those techniques or methods that replace the use of laboratory animals altogether, reduce the number of animals required or refine the existing procedure or technique so as to minimise the amount of pain or distress endured by the animal. Most of the alternatives to the use of animals in experiments fall into one of the categories listed below:

(a) the continued but modified use of animals, including alleviation of pain and distress through analgesics and less intrusive methods, substitution of cold-blooded for warm-blooded vertebrates, co-operation among investigators in the shared use of animals, and the better statistical design of experiments to enable reliable information to be obtained with fewer animals than were used previously;

(b) the greater use of living systems, including micro-organisms, invertebrates and the in vitro culture of organs, tissues and cells;

(c) the greater use of non-living systems, including epidemiologic data bases of human diseases and causes of death and physical systems that mimic biological functions; and

(d) the further development of computer programs that simulate biological functions and inter-actions.

5.31 A recent extensive report by the U.S. Congress Office of Technology Assessment summarised the advantages and disadvantages of alternatives in biomedical research. The advantages of alternative methods in biomedical research include the following:

* reduction in the number of animals used;
* reduction in animal pain, distress, and experimental insult;
* reduction in investigator-induced, artifactual physiological phenomena;
* savings in time, with the benefit of obtaining results more quickly;
* the ability to perform replicative protocols on a routine basis;
* reduction in the cost of research;
* greater flexibility to alter conditions and variables of the experimental protocol;

* reduction of error stemming from interindividual variability; and
* the intrinsic potential of in vitro techniques to study cellular and molecular mechanisms.[13]

Many of these alternative methods are accompanied by inherent disadvantages. The relevance of any of these disadvantages will vary substantially from one experiment to another. The disadvantages are:

* reduced ability to study organismal growth processes;
* reduced ability to study cells, tissues, and organ systems acting in concert;
* reduced ability to study integrated biochemical and metabolic pathways;
* reduced ability to study behaviour;
* reduced ability to study the recovery of damaged tissue;
* reduced ability to study interaction between the organism and its environment;
* reduced ability to study idiosyncratic or species-specific responses;
* reduced ability to distinguish between male- and female-specific phenomena; and
* a handicap to probing the unknown and phenomena not yet identified.'[14]

5.32 Some of the points in the OTA summary above were illustrated by comments made by Professor Shellan at the University of Western Australia. Asked about the developments in in-vitro methods and the reduction in the use of animals in experiments Professor Shellan replied:

> In the area of immunology, which is my area of interest and expertise, in vitro research has been the predominant mode of research since the mid-1960s and I should think that the discipline is perhaps pre-eminent in its use of tissue culture systems. There has been, however, a slight swing back to the use of whole animals in the last five years or so as it has become recognised that the in vitro system does not mirror in any way the complex interactions which one sees in whole animals. One has to regard the operation of the immune

> system as very much like an electronic circuit with feed-back loops and so forth, if you will pardon the jargon. The immune system in the whole animal operates like this. In tissue culture systems one can only study parts of this but not understand the whole. There is now a move in immunology and other related biological sciences, not a predominant move but at least a trend, towards going back into the whole animal now to put the whole system back together, if you like, to see how it works.[15]

Tissue Cultures

5.33 The potential of tissue cultures to replace animals in biomedical research is often mentioned in the debate on alternatives.

5.34 'Tissue culture' is used as a generic term for a number of types of preparation in which living tissue is kept in vitro. It has been divided into three forms:

> (1) Tissue culture proper. This term describes the placing of very small fragments of living tissue into a suitable nutritive fluid, so as to keep it alive. If the culture is successful, living cells rapidly migrate from the fragment, leaving the original tissue disorganised. The method is now rarely used, having been replaced in many applications by cell culture.
>
> (2) Organ culture. This technique also begins with a fragment of tissue, but the fragment is studied only in the early, organised state, where the cellular elements of the culture are intact, functional and in their normal relationships with each other. Organ cultures are short-lived compared with other in vitro models. They are difficult to maintain, except in the case of certain embryonic organs, and their use seems, within the forseeable future, likely to be in specialised, ad hoc investigations, rather than as generally applicable alternatives to animals.

(3) Cell culture. Here the tissue is deliberately disorganised at the outset by disaggregating the cells. The usual method is simple mechanical disruption or enzymic disgestion, which destroys the normal connective structures of tissue leaving a suspension of living cells in nutritive fluid. These cultures are probably the commonest models used in vitro for biomedical experiments.[16]

5.35 These three forms of tissue culture are often referred to interchangeably or are not clearly defined in popular discussion. Each form has a distinctly different potential to replace the use of animals in experiments.

5.36 In recent years, there has been an increasing trend in the use of tissue culture in substitution for the use of animals in experiments. There are, however, inherent limitations in the use of tissue culture in that it cannot replace whole systems with all the interactions among their component parts.

Refinement of Experimental Procedures

5.37 Refinement as part of the 'alternatives strategy' has not received nearly the same amount of attention as replacement of whole animals and reduction in the numbers used. Yet it offers an immediate improvement in laboratory animal welfare. Refinement of techniques includes the following:

- the reduction of environmental stress;
- the reduction of handling stress; and
- the minimisation of the severity of the endpoints of experiments.

5.38 The reduction of environmental stress can be achieved by the provision of appropriate lighting, humidity and temperature control, air circulation, cage cleaning procedures and housing requirements.

5.39 To reduce handling stress, proper training of both experimenters and laboratory and animal house staff is required. Staff training is discussed in Chapter 11 while training of experimenters is discussed in Chapter 12.

5.40 Minimising the severity of the endpoints of the experiment includes such things as keeping the amount of tissue damage or the size of tumours to a minimum and euthanasing an animal instead of allowing death to be the endpoint. The types of studies amenable to this type of refinement include radiation studies, certain animal models of disease and toxicity studies limiting the survival times of animals with induced abnormalities.

5.41 The appropriate use of anaesthesia during surgery and analgesia in post-operative care is another area where refinements in procedures can improve welfare. Dr P. Flecknell, a British expert, commented:

> ... relatively little attention has been given to the problem of minimizing the pain and distress caused to animals by the various procedures to which they are subjected ... The prevention or alleviation of the pain associated with such procedures is a complex problem with no single, simple solution. Consideration must be given to the use of analgesic drugs, the provision of high standards of general care, and the use of special nursing techniques. When dealing with post-operative care, the pre-operative management of the animal, the operative procedures and the anaesthetic regime must all be evaluated and, when necessary, modified to minimize pain or discomfort.[17]

5.42 Experimenters should seek to induce only the minimum pathological change necessary to assess the efficency of therapeutic measures. They should also provide relief for symptoms that do not interfere with the pathology that is being studied.

Funding of Alternatives

5.43 It was argued by some experimenters that specific funding for research into alternatives is not required because experimenters will naturally tend to seek out and develop alternative methods without such encouragement. Professor Setchell commented:

> I believe, as I have already said, that these things will flow naturally as the science progresses.[18]

5.44 However, several experimenters appearing before the Committee endorsed the concept of funding alternatives. Dr Aitkin of Monash University drew attention to the difficulty of finding a source of funds to conduct research into alternatives because often such research does not fall neatly into the scope of existing research grant programmes.[19]

5.45 As mentioned in Chapter 2, animal experimentation is likely to continue until satisfactory alternatives are found. In recent years, experimenters have become more aware of the ethical issues involved in using animals in experiments and of public concern about that use. This has led to a greater use of alternatives, in one form or another. Little research has been done, however, in Australia to expand the range of alternatives available to experimenters. Funding of such research has always been a low priority, particularly in times of contraction of government research funds. Yet, if the use of animals in experiments is to be reduced or abolished, alternatives have to be found. A greater commitment must therefore be made by the scientific community and government to finding alternatives and to reducing the use of animals in experiments.

5.46 There is a case for the establishment of a special fund to encourage the development of alternative methodologies. Requiring funding bodies to assign quotas to their grants as recommended by ANZFAS may not be the most effective way of proceeding.

5.47 The Committee believes that a fund should be established to finance research into the use of alternatives. It should be separate from existing funding bodies and its funds should be disbursed by a board made up of representatives of the scientific community, animal welfare organisations, ACCART and relevant government authorities. It should be funded mainly by the Commonwealth Government but the board should solicit donations from the corporate sector and the community at large. A small secretariat should be funded and located in a Commonwealth Government department.

5.48 By establishing a separate fund for research into alternatives, more emphasis will be given to such research and to the use of alternatives. It is difficult at present to get funding for research into alternatives because it is usually a lower priority than biomedical research itself. In the highly competitive biomedical research arena, few experimenters will try to seek grants for research into alternatives because of the difficulty in receiving funding. With a separate fund set aside for this purpose, experimenters will have a better prospect of having research into alternatives funded.

5.49 The Committee RECOMMENDS that the Commonwealth Government establish a separate fund for research into the use of alternatives to animal experimentation and that grants be disbursed from this fund by a board composed of representatives of the scientific community, animal welfare organisations, ACCART and government authorities.

5.50 Alternatives to toxicological testing are discussed in Chapter 7.

CHAPTER 6

THE USE OF ANIMALS IN THE PSYCHOLOGICAL AND BEHAVIOURAL SCIENCES

Introduction

6.1 The phrase 'psychological and behavioural sciences' is used throughout this chapter as a generic term to cover a number of diverse but partially overlapping fields of research. These include ethology, comparative psychology and physiological psychology.

6.2 Comparative psychology is that branch of psychology which deals with the comparison of behaviours of organisms of different species. Physiological psychology explores the physiological bases of behaviour including the anatomical structures and physiological processes which are related to psychological events and mental functions. The central nervous system and neurological processes are central areas of concern. Ethology is the study of animal behaviour:

> In addition to being a challenging science, worthwhile in itself in the same way in which other explorations of Nature have been, ethology is also increasingly assuming a practical role. In almost every case where man takes decisions concerning other animals - in zoos, wildlife refuges, laboratories - a knowledge of animal behaviour can aid his understanding of the problems. Whether the aim is exploitative (persuading poultry to lay the greatest number of eggs), concerned with welfare (assessing possible adverse effects of intensive indoor husbandry), 'pest' control (limiting the damage caused by the bearers of

> disease or by pests on food crops), or conservation (reserve management and design), the key to success often lies in a proper understanding of animal behaviour. Many ethological experiments are undertaken with the aim of solving a particular practical problem in fields like these ...[1]

Ethology is mainly dealt with in Chapter 8.

6.3 There are, however, difficulties in precisely defining the boundaries of the behavioural sciences in general and the discipline of psychology in particular.

6.4 Much of the research in the field of physiological psychology, for example, is similar to basic biomedical research. The University of Newcastle noted:

> The definitive line between these areas is not necessarily obvious because although psychological research is directed at the Central Nervous System (CNS) and the brain, the techniques are often common with other research areas.
>
> Thus in order to identify those projects involved in 'psychological and behavioural research' we include those studies which address questions concerning the function of the CNS and brain disorders and which incorporate any behavioural techniques including general observation.[2]

6.5 The scope of experimentation and the extent of its overlap with other areas of biomedical research is illustrated by the following six subject areas under which research projects in psychological and behavioural research carried out at the University of Newcastle during 1986-87 were classified:

- Behavioural Manipulation of the Immune System.
- The Pharmacology of the Drug Withdrawal Response.
- Hormonal and Neurochemical Effects of Psychological Stress.

- Biochemical Control of Sleep Patterns.
- Neural Basis of Visual Perception and Memory.
- Cortical Mechanisms Underlying Psychosis.[3]

6.6 Professor Bond from Macquarie University made a similar point:

> ... I think there is considerable evidence that many of the disorders that one sees are, in fact, physiologically-based and then often require animal research to tease out problems associated with them. I am thinking of things such as schizophrenia, manic-depression, the various dementias, Alzheimer's disease and movement disorders such as Parkinson's disease, disorders associated with substance abuse like Korsakoff's disease and so forth. The use of animal research in psychology in examining these sorts of problems has been both to have a look at what happens in normal situations and what happens in abnormal situations. In that respect I do not see them as standing outside, for example, other biomedical sciences.[4]

Extent of Psychological and Behavioural Research in Australia

6.7 The Australian Psychological Society submitted that most psychological and behavioural research conducted in Australia and overseas does not involve the use of animals. It stated:

> The use of infra-human animals in Australian psychology is not extensive. Indeed, research with animals, despite its theoretical impact, probably constitutes considerably less than 10% of published work. At an international level, 7.4% of papers abstracted in Psychological Abstracts in 1979 used animals as subjects.[5]

6.8 Experiments range from observation of animals in their natural state to experimental studies of the behaviour of animals which have been reared and maintained in laboratories. Laboratory studies extend from those which are relatively non-invasive (for example, studies of maternal behaviour in rats) through to those

which place animals in situations of varying levels of stress; studies of patterns of behaviour influenced experimentally by food deprivation or aversive stimuli (for example, by electric shock); and invasive studies which include pharmacological, surgical and other physical interventions.

6.9 As was noted in Chapter 2, comprehensive figures on animal experimentation in Australia are not available. The breakdown of figures collected by the Victorian Bureau of Animal Welfare provides, however, some indication of the extent of animal use in psychological and behavioural experiments within that State. The figures are set out in Tables 6.2 and 6.3 for the five years from July 1982 to June 1987. Table 6.1 covers only animals used for research purposes. The category of animals used for teaching purposes does not include a breakdown of the various subject areas in which animals are used.

Table 6.1: Animals Used in Psychological and Behavioural Research in Victoria by Techniques

Type of Vertebrate	Interference with special senses for behavioural studies					Interference with central nervous system other than special senses for behavioural studies					Use of aversive stimuli					Induction of psychological stress other than by aversive stimuli				
	1982–3	1983–4	1984–5	1985–6	1986–7	1982–3	1983–4	1984–5	1985–6	1986–7	1982–3	1983–4	1984–5	1985–6	1986–7	1982–3	1983–4	1984–5	1985–6	1986–7
Mouse	740	–	–	50	457	160	180	–	–	379	726	188	–	–	–	1	–	–	–	–
Rat	2,188	1,160	386	283	327	905	853	500	548	887	15	–	193	170	–	212	–	198	125	–
Guinea Pig	–	2	1	–	–	–	–	–	–	–	–	–	36	–	–	–	–	–	–	–
Other Rodent	4	–	3	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Rabbit	–	–	7	–	–	–	50	12	15	4	67	–	–	–	–	–	–	–	4	–
Cat	–	–	–	2	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Dog	–	–	–	–	–	–	4	–	1	–	–	–	–	–	–	–	–	–	–	–
Other Carnivore	–	–	–	–	–	–	–	–	–	–	–	5	–	–	–	–	–	–	–	–
Horse, Donkey	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Bovine	40	–	–	–	–	–	–	9	–	–	–	–	–	–	–	–	–	–	–	–
Sheep	–	–	11	–	7	–	14	5	10	23	2	–	297	–	–	–	–	–	4	–
Goat	–	–	–	–	–	–	–	–	–	–	–	–	–	–	8	–	–	–	–	–
Deer	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Pig	–	–	124	–	–	–	–	–	–	–	–	32	–	–	–	–	–	–	–	–
Other Ungulate	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Marsupial	6	6	–	12	–	–	20	–	–	5	–	–	–	–	–	–	–	–	–	–
Primate	–	–	–	–	–	2	–	–	2	–	–	–	–	–	–	–	–	–	1	–
Other Mammal	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Domestic Fowl	–	200	–	–	312	13,732	10,825	10,030	8,780	20,585	–	–	–	–	–	–	–	–	–	–
Other Domestic Poultry	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Other Birds	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	10
Amphibian	–	–	1	–	–	–	–	–	–	–	25	–	–	–	–	–	–	–	–	–
TOTAL	2,978	1,368	533	347	1,103	14,799	11,946	10,556	9,356	21,885	835	225	526	170	8	213	–	198	134	10

SOURCE: Department of Agriculture and Rural Affairs. Statistics of Animal Experimentation, Victoria. June 1984, May 1985, September 1986, October 1987, December 1987. Extract from Table 8, Numbers of Animals Used by Type of Vertebrate and Special Techniques Used.

Table 6.2: Animals Used in Psychological and Behavioural Research in Victoria

	Annual Total
1982-3	18,825
1983-4	12,704
1984-5	13,358
1985-6	10,007
1986-7	23,006

Table 6.3: Experiments to Study Behaviour in Animals

Types of Vertebrate	1982-3	1983-4	1984-5	1985-6	1986-7
Mouse	951	2,513	-	200	150
Rat	1,304	796	314	1,001	922
Guinea Pig	-	-	76	2	25
Other Rodent	-	-	-	-	18
Rabbit	-	-	-	11	4
Cat	-	-	-	7	-
Dog	-	-	-	-	-
Other Carnivore	4	5	4	26	-
Horse, Donkey	-	-	-	-	-
Bovine	-	-	-	-	67
Sheep	-	19	324	119	411
Goat	-	-	-	80	210
Deer	-	-	-	-	-
Pig	12	24	50	33	490
Other Ungulate	-	-	-	-	-
Marsupial	34	50	105	53	71
Primate	-	-	-	-	-
Other Mammal	84	24	12	-	-
Domestic Fowl	1,185	550	-	-	366
Other Domestic Poultry	-	-	-	-	-
Other Bird	-	-	1	7	30
Amphibian	-	-	-	-	-
TOTAL	3,574	3,981	886	1,539	2,764

SOURCE: Department of Agriculture and Rural Affairs. Statistics of Animal Experimentation, Victoria. June 1984, May 1985, September 1986, October 1987, December 1987. Extract from Table 2 Numbers of animals used by type of vertebrate and major purpose of animal use.

6.10 The Committee received information through the AVCC from 15 Australian universities on the extent to which animals were used in research and teaching in the psychological and behavioural sciences. The numbers of animals used in those universities in 1986 and 1987 are tabulated in Table 6.4. Three out of the 15 universities were not involved in animal use for research and teaching in this field. Only four of the 15 universities used animals for teaching purposes in the psychological and behavioural sciences.

6.11 The increase in the number of animals used in 1987 was largely due to the increased use of chickens at La Trobe University. The experiments involving chickens were explained by Dr Coleman of La Trobe University:

> There is a research team in our department which is basically looking at the physiology of memory. What it has been doing is to develop a model of the phases through which the acquisition of information goes from short-term memory when it decays very quickly to permanent memory. Basically what the team is trying to do is to tease out what the physiological mechanisms of these are - which proteins are involved and so on. Each chick is only ever used once. It pecks once at something and that is it. That is why the numbers of units are so large.[6]

Table 6.4: Statistics of Animals Used in Teaching and Research in the Behavioural Sciences in Australian Universities

	1986	1987
Rats	8,940	8,486
Mice	1,816	3,262
Fish	50	192
Chickens	13,626	31,252
Birds	40	88
Australian Native Mammals	503	558
Cats	10	2
Rabbits	100	100
Guinea Pigs	220	171
Primates	10	10
Fish	5	5
Cattle	600	600
Sheep	600	600
Goats	600	600
TOTAL	27,120	45,926

SOURCE: AVCC (Universities for which statistics were not available were: University of Melbourne, University of Queensland, University of Western Australia, Murdoch University).

6.12 The Australian Association for Humane Research submitted to the Committee in May 1984 a survey of psychological and behavioural research conducted within Australia between 1966 and 1983. The survey was based upon a search of the Psycinfo computer data base which provides a coverage of the literature in psychology and the behavioural sciences. The experiments reported in the literature survey are classified by:

(a) species of animals used;
(b) type of experiments; and
(c) institution at which the study was conducted.

The information is reproduced in Tables 6.5, 6.6 and 6.7.

Table 6.5: Australian Behavioural Research Literature Survey 1966-1983 - Species of Animals and Numbers of Experiments

Species of Animals Used	Number of Experiments	Species of Animals Used	Number of Experiments
Rats	92	Mice	2
Pigs	2	Pigeons	1
Parrots	1	Octupii	1
Cattle	1	Spiny Anteater	1
Chickens	15	Fish	1
Dogs	2	Shrimp (fresh water)	1
Cats	4	Un-named	1

Table 6.6: Australian Behavioural Research Literature Survey 1966-1983 - Types of Experiments

Types of Experiments	
Avoidance Conditioning	83
Operant Conditioning	5
Aversive Conditioning	14
Escape Conditioning	5
Other	18
TOTAL	125

Table 6.7: Australian Behavioural Research Literature Survey 1966-1983 - Number of Experiments Performed at Various Institutions

Name	Number
Macquarie University	31
University of N.S.W.	8
Sydney University	5
Newcastle University	15
Queensland University	1
Australian National University	1
La Trobe University	20
Western Australia University	8
University of New England	4
Monash University	5
Melbourne University	1
Adelaide University	6
Flinders University	1
Otago University (N.Z.)	1
Animal Research Institute (Werribee, Vic.)	2
N.S.W. College of Paramedical Studies	2
Royal Childrens Hospital (Parkville, Vic.)	1
Secondary Teachers College (Melbourne, Vic.)	1
Lincoln Institute (Carlton, Vic.)	2
Psychiatric Research Unit (Rozelle, N.S.W.)	2
Austin Hospital (Heidelberg, Vic.)	1
C.S.I.R.O. Division of Food Research (Sydney, N.S.W.)	1
Health Commission of N.S.W.	1
Australian Military Forces Research Report	1
Department of Agriculture (Perth, W.A.)	1
Division of Occupational Health (Lidcombe, N.S.W.)	2
Cumberland College of Health Sciences	1

The Use of Animals in Psychological and Behavioural Research

6.13 Proponents of the use of animals in this area of research presented similar arguments to those advanced in the previous chapter on biomedical research. They emphasised the benefits to both humans and other animals based on results derived from psychological and behavioural experiments.

6.14 The Australian Psychological Association submitted that animal research has provided the basis for the development of therapeutic techniques for the treatment of a wide range of psychopathologies. Teaching practices have also benefited from such experiments.

> In addition to therapeutic practice and models of psychopathology, principles of learning derived from animal research have profoundly influenced teaching practices. The influences include the use of positive reinforcement (reward) instead of punishment as the basis of effective teaching and classroom management and systems of programmed learning. More recently in Australia, animal research on classical conditioning has prompted a re-examination of certain problems that arise in teaching children to read, namely, the interference between pictures and words.[7]

6.15 Such experiments were viewed by the Society as being technically necessary or at least highly desirable if certain types of information were to be obtained. Developmental studies, in which age as a function of behaviour is examined, are an example of this category of experiment. This is because there are difficulties in doing developmental studies on humans. They are expensive; samples of different age groups have to be used; and there are various cultural factors which add to the variables which may distort the results. Because of the short life span of animals, longitudinal studies over the life of animals can be done, reducing the risk of variables, other than age, affecting the results. Experiments on animals can also be done in an environment which removes cultural differences from among individual animals.[8]

6.16 Another argument supporting the use of animals in behavioural research by the Australian Psychological Society was that:

> Many hypotheses about human behaviour are derived from research with animals that could not be performed with humans. For example, animal research has frequently been able to model a variety of psychological problems (e.g., psychopathology, addiction) which occur in humans. Research of this kind provides fundamental knowledge about the processes that are involved in a variety of disorders.[9]

6.17 The Australian Psychological Society also outlined in its submission the benefits for animals derived from experiments on animals, such as the non-lethal control of animals that are harmful to crops, improvements in the care of farm animals and 'the design of optimal captive environments for the protection and breeding of endangered species'.[10]

6.18 The Society submitted that human benefits from psychological experiments on animals ranged from the application of behaviour therapy and behaviour modification to treat various disorders including enuresis, phobias, anxiety, anorexia nervosa amd stuttering. These techniques are also used in connection with sexual dysfunctions, disorders of conduct and self care in psychiatric institutions.[11]

6.19 Many types of psychological and behavioural experiments mentioned above by the APS are not and have not been conducted in Australia. They were put forward as a general case supporting the use of animals in psychological and behavioural research.

6.20 Some pyschologists deny that experiments involving animal behaviour are at all relevant to human psychology.[12] ANZFAS submitted that it:

> ... questions the principle underlying the reasons for using animals in psychology research, that is, that interference and modification of animal behaviour patterns constitute a suitable model for the study and treatment of human behavioural problems.

> Finally, it may be noted that the humanistic school of psychology, which involves counselling of individuals, does not make use of the results of animal experimentation and opposes the theory of the behaviourist school. Techniques of the humanistic school are appropriate to many neuroses, addiction and anxieties, etc.[13]

6.21 The use of animals in psychological and behavioural research has been questioned, not only on the grounds of the humane treatment of the animals, but also in what Andrew Rowan refers to as 'the psychologist's paradox'.

> Since we should, if consistent, confer moral worth according to some property (or properties) of the organism's nervous system, then the more suitable the animal is as a model of the human psyche, the greater should be the attention to the ethical issues relating to the research. The paradox boils down to this - the better the animal is as a model of the human psyche, the more restricted its use should be. As a result of this paradox, psychologists using animal models to gain insight into human psychology must show:
>
> 1) that the animal is being studied in a manner that does not raise moral issues, using human criteria as a guide but not necessarily as absolute standards; or
> 2) that the animal is sufficiently different from human beings in its psychological and mental makeup to create no moral problems and that it is still a relevant model for learning about a particular question in human psychology; or
> 3) that the animal's psyche has relevant similarities to the human psyche, but that this does not create a moral problem.[14]

6.22 This view was not accepted by some scientists. Addressing this 'paradox', Dr Bond told the Committee that he assumed that the ethical standards remained the same for all animals and that standards did not vary according to the similarities between various animals and humans. He also did not believe that experiments on particular animals were conducted

just because of similarities between those species and humans. Sometimes a species is chosen because of the differences between it and humans in order to get a broader view of the subject. He added, however, that if a species were 'a totally unreasonable model, then of course it should not be employed'.[15]

6.23 The manner in which animals are used in psychological research has been strongly criticised. The issue of pain and stress was raised in the ANZFAS submission and a number of examples of experiments conducted within Australian institutions in recent years were cited. These included use of electric shocks to study aversive behaviour[16]; administration of substances subjected to abuse by humans[17]; and aggression research.[18]

6.24 The actual extent of pain caused in the procedures involving the use of electric shocks was queried by experimenters representing the Australian Psychological Society.[19] They pointed out that the effect on the animal depended not just on the intensity but also on duration and other factors. They argued that in aversive experiments in Australia, low intensity shocks have been used.

6.25 As mentioned earlier, there are various forms of psychological and behavioural experiments, ranging from observational to invasive or aversive conditioning experiments. Some of these experiments overlap with biomedical, agricultural or veterinary research. The levels of pain or distress caused to animals by these experiments range from insignificant to severe. It is not possible, therefore, to categorise psychological or behavioural experiments as an homogeneous whole. Similarly, the recommendation by ANZFAS that psychological experiments be banned by legislation is inappropriate.

6.26 From the evidence available, it appears that there is a greater awareness by scientists that some types of experiments are either unacceptable to the public or are no longer regarded as necessary from a scientific point of view. It also seems that greater use is also being made of alternatives in the teaching of psychology.

6.27 The Committee concludes that although it does not believe that a ban on psychological or behavioural experiments is justified, each protocol involving such experiments should be considered carefully by the relevant ethics committee and funding body to determine whether the project is necessary and whether it conforms to the Code of Practice. Although it is inappropriate to use humans in some psychological and behavioural experiments, consideration should always be given to their use. Liaison between animal and human ethics committees in such cases would be desirable.

CHAPTER 7

ANIMALS IN TOXICOLOGICAL TESTING

Introduction

7.1 An assessment of the use of animals in testing drugs and cosmetics requires some understanding of the nature of toxicological research and the regulatory framework within which it currently operates. A brief account of the scientific basis of toxicological testing is given before regulatory issues are considered.

7.2 There are two basic approaches to the science of toxicology - the mechanistic and the descriptive. Mechanistic toxicology is the study of the chemical processes by which a toxic effect occurs. It relies on techniques developed by physiologists, biochemists and analytical chemists to monitor these processes. Mechanistic toxicology is research oriented. It provides the basis for the design and interpretation of descriptive tests and is essential to the development of testing methods that could replace whole-animal testing.

7.3 Descriptive toxicology relies on the information provided by pathology, statistical analysis, physiology and pharmacology. It involves, for example, evaluation of changes in the appearance of an organ or its cells, the appearance of tumours or signs of irritation. An understanding of the exact nature of the processes by which the toxic effects occur is not necessarily required. Regulation of chemicals requiring testing for toxicity relies largely on descriptive toxicology.[1]

7.4 Many toxicological tests currently require the use of whole animals. The most appropriate animals are those which predict the human response to a specific substance most accurately. The choice of animal is influenced not only by the similarity of the animal's organism or biochemical mechanism of concern to the testing authority to that of humans, but also of such factors as the convenience of breeding, the extent of pre-existing knowledge of the species, species lifespan, ease of handling of species under experimental conditions, cost of purchase and maintenance, litter size and gestation period.

Testing Strategies

7.5 In most toxicity tests the substance being tested is administered by the same route as occurs in the course of accidental exposure or use by humans. On occasions the palatability, solubility, stability, and volatility of a substance determines the routes that are feasible.

7.6 The dose levels employed in a testing programme need careful consideration. If the dose is so large that many animals die before the end of the test, it will not be possible to detect long-term effects. If the dose is representative of human exposure levels it may not produce detectable effects without the use of an excessively large number of animals over a long period of time.

7.7 The test design must be statistically sound if valid results are to be obtained. Factors influencing the number of animals needed for a given test include:

(1) the need to allow for unexpected death and illness in the test group;
(2) variability in the sensitivity of individual animals to the substance being tested; and

(3) the need for an untreated control group to provide information on the background incidence of disease against which the incidence in the groups discussion in being tested can be assessed.[2]

Drug and Chemical Testing in Australia - Regulatory Requirements

7.8 The Commonwealth has no direct constitutional power to regulate drugs and chemicals. It does have, however, some indirect means of control by virtue of its constitutional power over imports. This power is exercised through the Customs (Prohibited Imports) Regulations. Under these Regulations, the Commonwealth can ban the importation of particular drugs or ingredients. However, the Commonwealth cannot prohibit drugs which are manufactured from ingredients sourced within a State and sold within the same State. State legislation covers the extent and nature of testing required before marketing of therapeutic goods and agricultural or industrial chemicals.

7.9 Through the co-operation of Commonwealth and State Governments, there is national co-ordination of the safety assessment and control of chemicals. A plethora of expert committees comprising Commonwealth and State officers and experts from the industry and universities carry out the assessments and provide advice to government on the control and regulation of chemicals.

7.10 Drugs for human therapeutic use are evaluated by the Australian Drug Evaluation Committee supported by the Drug Evaluation Branch of the Department of Community Services and Health.

7.11 The NHMRC is responsible for the toxicological assessment of most chemicals not designed for therapeutic use, including agricultural chemicals. With regard to agricultural and veterinary chemicals, national co-ordination has been in the

hands of the Co-ordinating Committee on Agricultural Chemicals which has been responsible to the Australian Agricultural Council. The enactment of the Agricultural and Veterinary Chemicals Act 1988 represents an attempt to provide a more co-ordinated approach to the regulation of agricultural and veterinary chemicals. Under the Act an Australian Agricultural and Veterinary Chemicals Council will be established to co-ordinate the evaluation of chemicals proposed for registration in Australia, including assessments of toxicology, human safety, environmental hazard and overall efficacy.

7.12 Plans to regulate industrial chemicals are intended to complement current national arrangements for the evaluation of agricultural chemicals, pharmaceuticals and food additives that are already in place.

7.13 The scheme will be established under Commonwealth legislation although State Governments may decide to enact complementary legislation. In essence, importers will have to notify NOHSC of imports of industrial chemicals and to provide it with enough information for NOHSC to assess the potential health and environmental hazard of the chemicals. The NOHSC will generally rely on data used to satisfy regulatory requirements overseas but will if necessary seek additional information. It is expected that most additional tests will be done overseas.

Cosmetics

7.14 The responsibility for national standards for cosmetics ingredients was transferred in 1987 from the NHMRC Consumer Products Safety Committee (of the then Department of Health) to the new Bureau of Consumer Affairs within the Attorney-General's Department. In 1986 the Consumer Products Safety Committee of NHMRC had set up a Working Party to prepare appropriate standards for cosmetics ingredients. According to the Department of Community Services and Health:

> The Working Party used the general structure of the EEC cosmetics Directive as a working document, but amended the lists of acceptable colours, sunscreens and so on to suit Australian circumstances. Like the European standard, it was proposed that the NH & MRC Standard would not list all possible cosmetic ingredients. Ingredients were to be included in the various Annexes to the Standard on the basis of either a history of safe use or as a result of a toxicological assessment.[3]

7.15 The Committee was told by the Department that in preliminary work prior to the transfer of responsibility to the Bureau, it was established that many chemicals were being used without toxicological work having been done on them. The Department said that the industry had pointed out that these chemicals had been used without ill effects to consumers. Although the Department did not intend to seek toxicological information on chemicals currently in use, it would have insisted on the submission of toxicological data on new chemicals.[4]

General Issues in Testing

7.16 In discussing its approach to testing requirements, the Department of Community Services and Health made the following points:

> 1. Animal studies are not required unless they will contribute worthwhile information on the new medicine;
>
> 2. Large numbers of animals in any one test are not required providing that the number used will be capable of discerning the problem to be investigated;
>
> 3. The LD50 test as such is not required, being replaced with acute studies to include relevant observations;
>
> 4. Non-human primates were required in some studies but this requirement, as such, has now been deleted;

5. The use of in vitro screening tests is recognized and accepted;

6. The Australian guidelines are very similar to and consistent with many overseas requirements so that any additional animal testing for some medicines is kept to a minimum;

7. Some overseas countries have required a certain amount of animal testing to be repeated in their own country. The Australian Department of Health accepts data generated overseas without any requirement for animal studies to be repeated in Australia.[5]

7.17 Although Australian guidelines are similar to overseas guidelines, there are differences between them. The Australian guidelines are being rewritten to achieve a greater harmonisation of requirements with overseas countries and international organisations such as the European Community, the Organization for Economic Co-operation and Development and the World Health Organization.

7.18 It should be noted that the demand for further testing caused by a lack of uniformity in requirements does not mean that such tests would be carried out in Australia. A lack of uniformity would be most likely to result in an increased use of animals for toxicological testing overseas.

Toxicological Testing in Australia

7.19 Toxicological tests using live animals are not done on a large scale in Australia. Most tests are conducted overseas where the products are developed. Data from these tests are submitted to Australian authorities in support of applications for registration of products. The former Australian Bureau of Animal Health outlined the main purposes for which testing was conducted in Australia:

> Some chemical evaluation studies are performed in Australia using animals. The purpose of additional testing is to generate data on the performance of the chemical under Australian conditions, e.g. efficacy against local pest species of weeds, insects or internal and external parasites. Local testing is also performed on veterinary drugs to show that the product is safe for the target animal. These tests usually take the form of a medium scale field [trial] where animals are treated with the drug at an elevated dose rate to assess the safety in situations of accidental overdose. Rarely, however, do such tests involve the estimation of the LD50 in the target animal.[6]

7.20 In its submission the Cosmetic Toiletry and Fragrance Association of Australia stated:

> In this country, the cosmetic industry consists largely of subsidiaries of overseas companies and as a consequence, most research resulting in toxicological validation is carried out abroad, with an insignificant level of safety testing locally, carried out by independent toxicological laboratories.
>
> Australian manufacturers of cosmetics have access to all relevant hard copy and computerised data banks through the CTFAA or from their principals abroad, thus enabling them to eliminate almost all animal testing for cosmetics in this country.[7]

7.21 There was, however, a distinct reluctance or possible inability of the relevant industry associations to supply the Committee with statistics from their members on the actual extent of use of animals for toxicological testing within Australia.

7.22 The Department of Community Services and Health provided indirect evidence on the extent of animal use for toxicological testing within Australia. Dr Imray of the Department stated:

> There has been no data submitted that I have seen in the time that I have been with the Department that has ever been generated anywhere other than in the major toxicology

> contract laboratories overseas or through company laboratories overseas. In all of the submissions that I have seen, I have never seen data generated in Australia.[8]

7.23 Although the Committee accepts that commercial toxicity testing using animals for regulatory purposes conducted within Australia is minimal in extent, it is of the view that a willingness by commercial enterprises to be more open with the public would do much to assuage public concern.

National Biological Standards Laboratory

7.24 The numbers of animals used in the National Biological Standards Laboratory (NBSL) is contained in Table 7.1. Its use of animals was explained as follows:

> 3.1 NBSL testing of products is intended to assess their quality, safety and efficacy. Quality is a wide ranging concept covering aspects of conformity with specifications, fitness for intended use and consistency of production ...
>
> 3.2 NBSL testing of products for quality is, wherever possible, performed using chemical or physical methods. These methods generally offer advantages of speed, precision and economy over biological methods. However they are usually only generally applicable to products whose chemical or physical characteristics are known. Many biological products such as vaccines, hormones, enzymes and blood products are heterogeneous mixtures of complex compounds whose chemical and physical characteristics have not been established. It is usually necessary to perform at least some biological tests on these types of products when assessing their quality.
>
> 3.3 Biological methods can range from in vitro methods such as biochemical techniques, immunological techniques, cell culture techniques and isolated cell or organ culture

techniques through to in vivo techniques involving embryonated eggs or whole animals. Where in vitro methods cannot adequately assess a characteristic of a product a whole animal technique must be used.

3.4 Safety tests in particular often require the use of whole animals. Safety from the NBSL viewpoint usually refers to lack of adventitious contamination with toxic substances rather than to the inherent toxicity of the product.[9]

Table 7.1: The Numbers of Small Animals Issued to Users from NBSL 1975-1989

Period	Mice	Rats	Guinea Pigs	Rabbits	Chickens
1975	77,610	1600	1490	*	*
1976	62,230	900	1370	*	*
1977	49,200	980	2030	*	*
1978	87,760	1030	3520	*	*
1979	75,640	890	2960	*	850
1980	96,470	830	4510	*	1254
1981	63,060	230	3440	410	1032
1982	52,950	520	3260	405	1573
1983	51,650	290	2300	400	1269
1983-84	44,420	600	2630	370	1138
1984-85	35,900	1450	2130	280	1026
1985-86	32,000	530	2190	225	614
1986-87	27,400	370	1590	300	1020
1987-88	18,000	1560	1410	370	925
1988-89 Prorata	24,000	2280	1704	370	656

* No records available
SOURCE: Evidence, p.S8045

7.25 Detailed statistics on the use of animals in toxicological tests, including those conducted in course of research as well as those done to satisfy regulatory requirements, are currently only available for Victoria.

7.26 Because Commonwealth departments or statutory authorities involved in animal experimentation are not registered or licensed under the relevant Victorian legislation such statistics would not include, for example, those animals used by the Commonwealth Serum Laboratories or the CSIRO Division of Animal Health. The Victorian Government publishes annually the number of animals used in the State for toxicological and related pharmacological research and testing. Figures from that statistical report for the five years 1982-83 to 1986-87 are shown in Table 7.2.

7.27 Table 13 in of the Victorian report contains a breakdown of the figures reproduced in Table 7.2 by types of tests including a category for tests performed to meet the NHMRC Toxicological Data Requirement. Because of difficulty in reconciling the figures in these two tables for most categories in most years it was not possible to use the disaggregated figures with any high degree of confidence. Hence they have not been used in this report.

Table 7.2: Number of Animals Used in Toxicological and Pharmacological Testing in Victoria 1982-1987

	Toxicity Tests	Teratological Tests	Distribution Metabolism excretion and residue tests of substances	Total
1982-83	2,927	100	22,704	25,731
1983-84	6,097	643	11,983	18,723
1984-85	832	124	3,676	4,632
1985-86	3,885	3	5,692	9,580
1986-87	7,787	312	3,985	12,084

SOURCE: Department of Agriculture and Rural Affairs, Bureau of Animal Welfare. Statistics of Animal Experimentation in Table 4; 1982-83, 1983-84, 1984-85, 1985-86 and 1986-87 reports.

The Role of Animals in Toxicological Testing - Rationale and Alternatives

7.28 Consideration of animal use in toxicological testing brings into focus a major conflict in public expectations. On the one hand the public wants to minimise the risks to humans, animals and the environment arising from the development and widespread use of chemicals. On the other hand there are undoubtedly public reservations about or opposition to the use of animals for toxicological testing.

7.29 The rationale for the use of animals in toxicological testing arises from the responsibility of the appropriate authorities at least to ascertain the risks associated with the

use of chemicals by the public. This prima facie responsibility is regarded by government as overriding, but not negating moral responsibility for the welfare of animals.

7.30 It appears that whole animal tests are unlikely to be completely replaced by non-animal or in vitro methods[10] because in vitro tests cannot reproduce the functional and structural complexity of the intact animal. In vitro tests cannot preserve the diversity of mechanisms for toxicity and detoxification that exist in living organisms. At each successive level of biological organisation properties appear which are not evident or even present at less complicated levels of organisms or systems.

7.31 Three issues about testing whole animals were raised by ANZFAS in its submission.

7.32 The first is the difficulty of extrapolating results from non-human species to humans.[11]

7.33 ANZFAS drew attention to the following cautionary note in the OECD Guidelines for Testing of Chemicals:

> There is no experimental laboratory species which is identical to man in terms of structure or metabolism. There are obvious resemblances and similarities in function between man and other animal species, but even in the case of man's fellow primates, these are not such that straightforward extrapolations from animal tests to man are possible. The interpretation of animal test results in the assessment of possible human health hazard remains a matter of skilled judgement.[12]

ANZFAS went on to say:

> While authorities require the use of at least two mammalian species for the testing of one substance, the problem of extrapolation is

> increased two-fold. Not only are there differences between two species, but also between animals of the same species within one laboratory.[13]

It then referred to the work of Zbinden and Flury-Roversi:

> It (the LD50) can vary markedly from one animal species to the other, and within one species of laboratory animals the numerical value of the LD50 determined experimentally is influenced by a large number of factors.[14]

7.34 Mr Van Rijswijk of the Australian Veterinary Chemicals Association (AVCA) responded to the criticism:

> Whenever we use a test animal to work out the effect of a chemical or a drug we rely on that test animal to parallel somehow what happens in our bodies. Because the biology is different - we are not rabbits or rats - that model is only a model, it is not a perfect duplication of the human system ... we can test thousands of animals and we can test many different species of animals but we are never going to duplicate what that chemical does inside our body. That is recognised by toxicologists. If that is the case, adding more and more animals to that list of testing is not going to give us much more information that really duplicates what is happening inside us.[15]

7.35 The scientific literature suggests that while the extrapolation of the fact of toxicity to humans on the basis of animal studies is a reasonable working assumption, caution is needed in extrapolating the form of toxic action based on those studies.

7.36 In a symposium held in November 1982, Ralph Heywood commented:

> Surprisingly, there has been little effort to examine the qualitative predictability of human side-effects from animal studies.

> Occasionally, general papers have suggested that predictions are unreliable ...
>
> In the absence of better data, it must be concluded from these limited studies attempting to extrapolate data between laboratory animal species, and between laboratory animals and man, that there is no reliable method of predicting what type of toxicity will develop in different species in response to the same compound.[16]

7.37 ANZFAS emphasised the extent to which the logistics of testing influence the choice of species to be used in the tests. It drew attention to the OECD Guidelines for Testing of Chemicals which pointed out that such factors 'as ease of breeding or purchasing, animal husbandry, speed of growth/development and handling under the experimental conditions' are considerations in choosing the species. ANZFAS went on to state:

> For acute oral, dermal inhalation studies the rat is the most frequently used species. The extensive use of rodents in toxicological studies would appear to be perhaps nearly as much a function of the logistic requirements referred to above as any particular superiority in predicting the likely human response.[17]

7.38 ANZFAS also raised concerns about the extent to which data from different testing laboratories were comparable.[18] As an example of the deficiencies in this area it cited the example of the difficulties encountered by the FRAME Cytotoxicology Research Project which was completed in 1985. The Project was involved in the development of non-animal alternatives for cytotoxicology tests. In order to carry out validation studies of the non-animal tests, toxicity data on 100 chemicals was sought, against which the in vitro methods could be measured.

> The toxicology data are often not strictly comparable, being developed in different laboratories using different species or different protocols. The reports describing the toxicology data are often inadequate and

> the data itself may present inherent problems of interpretation, which would result in legitimate differences in assessments of their toxic effects by different toxicologists.[19]

Alternatives

7.39 In Chapter 5 the discussion on alternatives to the use of animals in experiments included those techniques or methods that replace the use of laboratory animals, reduce the number of animals required or refine the existing procedure or technique so as to minimise the amount of pain or distress endured by the animal.

7.40 The major developments in alternatives in toxicity testing to date have come from the reduction of the number of animals required for each test and the refinement of the test procedures to reduce animal suffering.

7.41 Most of the alternatives to the use of animals in testing fall into one of the following four categories:

(a) the continued but modified use of animals;
(b) the greater use of living systems;
(c) the greater use of non-living systems; and
(d) the further development of computer simulation.

7.42 The continued but modified use of animals includes alleviation of pain and distress through analgesics and less intrusive methods, substitution of cold-blooded for warm-blooded vertebrates, co-operation among experimenters in the shared use of animals, and a statistical design of experiments which enables reliable information to be obtained with fewer animals than were used previously. This can be achieved by reducing the number of animals used as controls, by using the same group as controls for several simultaneous experiments, avoiding duplication of testing by storing data, reducing pain and distress by changing procedures, refining the end point of a study.

7.43 The greater use of living systems includes micro-organisms, invertebrates and the in vitro culture of organs, tissues and cells. The advantages and disadvantages of this approach have been summarised by the OTA:

> Although animals are still required as a source for these in vitro systems, the animal would experience distress for a much shorter time, and perhaps less distress overall, than occurs with whole-animal testing because it would be killed before any experimental manipulations were carried out. Occasionally, different cells, tissues, or organs from the same animals can be used for different investigations. In addition, many fewer animals would be required for a given test, in part because variability in the toxic response is smaller than it is with whole-animal tests and in part because one animal can be used for multiple data points, further reducing variability. The fact that human tissues sometimes can be used confers an additional advantage because the need for extrapolation from animal data is obviated.
>
> These isolated components also have disadvantages. They are usually unable to produce the complete physiologic responses of a whole organism. The components often become undifferentiated and lose their ability to perform their special functions when isolated from the organism, particularly when the sample is broken up into its constituent cells, and even more so when the cells replicate. Another disadvantage is that the effect of the route of exposure, a variable that can have profound effects on test results, is often impossible to determine.[20]

7.44 Micro organisms such as bacteria and fungi are principally used to measure genotoxic effects. They can be cultivated more easily and quickly than most animal or human cells. Their genetic makeup is simple and changes in it are relatively easy to detect.

7.45 Invertebrates such as insects offer the greatest variety of models. The fruitfly Drosophila Melanogaster is best understood and has been used for detecting teratogenicity, mutagenicity and reproductive toxicity. The sea urchin has also been widely used for screening for mutagenicity, teratogenicity and reproductive toxicity.

7.46 The greater use of non-living systems includes epidemiologic data bases of human diseases and causes of death and physical systems that mimic biological functions. However, these cannot be relied on for prospective toxicity testing of drugs or chemicals.

7.47 Whole animals have been replaced with analytical chemistry for tests involving detection of a substance or measurement of potency or concentration, such as vaccines, anti-cancer drugs and vitamins.

7.48 There is the further development of computer programs that simulate biological functions and inter actions. Sophisticated mathematical models have been developed which predict biological responses to the drug and hence toxicity on the basis of physical and chemical properties, structure and available toxicological data. The major limitation of these models is the lack of understanding of the mechanisms by which toxic effects occur.

7.49 In considering the impact of alternative tests the Department of Community Services and Health commented:

> ... the general consensus of scientific opinion at present appears to be that, on the basis of current knowledge, no single in vitro (or for that matter, alternative) test will directly replace any one in vivo test. A combination or battery of in vitro tests will probably be required for most if not all toxicological parameters. As a result of

> putting a chemical through such a battery of tests, it may still be necessary in some cases, depending on the results, to test it on whole live animals to obtain final confirmation of the nature of potential toxicity. One example of particular concern because of its importance is carcinogenesis, which is a complex process, unlikely to be shown up in a single in vitro assay. Thus it is likely that a selected battery of short-term assays, including both in vivo tests, and in vitro tests in bacterial and mammalian cells, will be needed to screen chemicals for their potential to cause genetic effects and carcinogenicity.[21]

Development of Alternatives in Australia

7.50 Probably because of the small amount of toxicity testing actually undertaken in Australia little work has been done to develop non-animal toxicological tests by Australian scientists. Most of the developments have been within NBSL and are listed in its submission to the Committee.[22]

Specific Toxicological Tests

The Draize Test

7.51 The Draize test is designed to test the irritation to eyes of chemical compounds. It has been criticised on the following grounds:

(a) it can only provide a pass/fail answer and lacks fine discrimination, i.e. it does not provide useful data on degrees of irritancy;

(b) because of differences between human and rabbit eyes its applicability must be in doubt (i.e. it is an unsatisfactory model for human eye irritation comparability); and

(c) there are questions about the comparability of results in routine testing from different laboratories.[23]

7.52 As far as the Committee can determine, the Draize test has been little used in Australia. Among the institutions surveyed by the Committee only the Department of Pharmacology within the University of Melbourne had conducted Draize tests in the period since January 1980. Over the period 1980-1984, 216 Draize tests had been conducted within the Department. Each involved three rabbits and according to the University, were done using the most recent modifications to the test.[24]

7.53 Following a strong campaign by animal welfare organisations in the United States, funding was provided by firms in the cosmetic industry to develop in vitro alternatives to the test. Rowan noted that the response to the availability of funding demonstrated:

> ... that the availability of funding is a potent stimulus to thought. When scientists learned of a possibility of research support to develop an alternative to the Draize test a number of speculative and creative proposals were produced and circulated.[25]

7.54 According to the OTA Report, the current scientific view is that no single alternative is likely to be adequate but that a battery of in vitro tests may be a useful replacement.[26]

7.55 In vitro methods to test for irritation are under development. One promising bioassay for tissue irritation makes use of the chorioallantoic membrane of the chick embryo. Another alternative involves testing whole eyes in vitro. This method has particular appeal when cow eyes are used because of their ready availability from abattoirs.

7.56 The OTA Report, in summarizing the current state of research into alternatives to this test, said:

> Several types of cell cultures have been used in developing an in vitro test for eye irritation. The cells used are rabbit and human corneal cells, mouse and hamster fibroblasts, human hepatoma cells, and mouse macrophages.
>
> ... Rapid progress is being made in the development of techniques, but none can be considered validated at this time.
>
> To date, little work has been done on in vitro replacements for skin irritancy testing. However, the growth of skin in tissue culture is of interest for treating burn victims, and it is expected that culture techniques currently being developed for that purpose can be used in testing methods. In addition, it has also been suggested that suitable specimens can be obtained from cadavers and surgery and from judicious use of human volunteers.[27]

7.57 Draize tests using small dose volume and direct corneal application are being validated currently by Proctor and Gamble. They are of the view that this modified form of test is more accurate in predicting human experience and less stressful to animals.[28]

7.58 Although the Draize test remains in use, a reduction in animal suffering and the numbers of animals used could be achieved by:

(a) not testing substances with physical properties known to produce severe irritation.
(b) screening out irritants using in vitro or less stressful tests.
(c) using smaller volumes of the test substance to reduce trauma and enable dose response studies to determine safety margins; and

(d) the use of local anaesthetics where it is necessary to test substances that cause pain and irritation in the rabbit.

7.59 Some scientists have rejected the use of anaesthetics because they deprive the animal of its natural defence mechanisms, such as blinking.

7.60 The Committee regards the efforts to develop alternatives to the Draize test as an encouraging example of what can be achieved by co-operation among animal welfare organisations, scientists and industry when appropriately targeted funding is provided.

LD50 Test

7.61 The LD50 test is a general measure of toxicity which determines the dose which will kill 50 per cent of the target group of animals.

7.62 The LD50 test has been the subject of widespread criticism by animal welfare organisations. Its usefulness has also been called into question by toxicologists.[29] The figure derived from the test procedure is variable and can be affected by the species, as well as the strain of species used, diet, microbiological status of the animals, the ambient temperature, time of the year and social factors such as the number of animals per cage.

7.63 Fourteen institutions out of those surveyed by the Committee reported that such tests had been undertaken over the five year period 1980-84. In most cases the number of tests conducted by any specific institution was not large. It was not clear from the answers whether the tests were conducted under contract to manufacturers or were University initiated research.

7.64 The CSIRO during 1986 called for a review of the test. It does not currently use the test but has done so in the past to establish the toxicity of naturally occurring plant or microbial substances suspected of being the cause of domestic animal diseases and to obtain the toxicity of pest control agents for both target and non-target species.

7.65 The design and conduct of LD50 studies by CSIRO staff to establish the effect of 1080 baits on non-target species preceded the establishment of ethics committees within CSIRO. The project was specifically designed to reduce the number of animals used to an absolute minimum. CSIRO argued that although the studies undoubtedly caused pain and suffering, the knowledge gained should enable the use of 1080 in controlling feral animals in a manner which minimises losses among non-target species.

Current Status of the LD50 Test

7.66 A number of professional societies and inter-governmental bodies have taken positions recently on the LD50 Test, including the National Society for Medical Research, the Society of Toxicology, Canada and the British Toxicology Society.

7.67 There is substantial agreement that only in very rare circumstances is the precise determination of the LD50 scientifically justifiable. Procedures that allow the classification of toxicity without the determination of the LD50 (e.g. the limit test) could replace it.

7.68 According to the British Toxicological Society:

> ... acute toxicity tests should be carried out with the objective of examining a few animals in detail rather than many animals for statistical purposes. Thus for example the determination of accurate LD50s would not

> appear to be necessary in the drug industry. Acute toxicity tests with minimal numbers of animals and a full description of toxic signs should be adequate for drug development and registration purposes.[30]

Alternatives

7.69 Tests providing the same information have recently been developed using as few as ten animals: that is, a three-fold to ten-fold reduction.

> The development of an in vitro test system for general acute toxicity will be very difficult. Combining in vitro data with computer modelling would probably be the most promising approach ... it will take much money and many years to develop and validate an alternative which will replace animals in LD50 testing.[31]

7.70 Testing for mutagens, carcinogens and possibly teratogens seems to represent a more promising area for the development of non-animal alternatives.

7.71 According to a presentation to the New York Academy of Sciences:

> In establishing non-animal alternatives, two important criteria must be met:
>
> (1) The alternative test, if implemented on a routine basis, will not result in a health risk to humans greater than that presently permitted by use of the animal model.
>
> (2) The introduction of the alternative test will lead to greater efficiency in the assessment of the particular toxic endpoint(s) than currently available animal models.
>
> In the case of genetic testing, these two criteria appear to be attainable.[32]

7.72 Consider, for example, a comparison of the test performance of short-term tests for genotoxicity with the standard rodent bioassay for identifying human carcinogens. The results show that there is approximate equality between the two tests in making an accurate designation.[33] Neither test is a perfect model but there appears to be no loss in the ability to protect humans from carcinogens when non-animal techniques are used.

7.73 The OECD Ad Hoc Meeting of Experts on Acute Toxicity Testing (Paris 7-11 April, 1986) made the following recommendations that would reduce the number of animals required in LD50 tests and refine the techniques used so as to limit animal suffering:

(a) Acute toxicity test guidelines (i.e. OECD) 401 and 402 should be amended so that:

i) oral and dermal tests are carried out on one sex only (with a subsequent check on toxic response of the second sex).

This should almost halve the numbers of animals used.

ii) the limit test dose by the oral method is reduced from 5000 to 2000 mg/kg which is a more realistic dose.

A limit test which results in mortality needs to be followed by a full acute toxicity test. The proposed reduction in the limit dose will result in fewer limit tests being followed by full tests and thus will achieve an appreciable reduction in the number of animals used.

iii) animals which show severe pain and distress are humanely killed in order to reduce suffering.

> Additionally, three new approaches which reduce numbers of animals required, and/or possible suffering, should be distributed to Member countries for evaluation and to gain experience in their use.

Regulatory Action in Australia

7.74 The Department of Community Services and Health explained the development of its policy on the requirement for the LD50 test:

> At the time of writing of the 1984 Departmental submission, the oral LD50 was required. At that time, although it was seen that the LD50 test was probably approaching obsolescence, on balance it was thought that there were good reasons for continuing with the test for the immediate future.
>
> However, shortly after that submission was forwarded to the Committee, data requirements were reviewed and it was decided that the LD50 should no longer be required. This requirement was therefore removed. In its place was substituted the requirements specified by Dr Imray at the hearing before the Committee.
>
> With regard to therapeutic substances, the submission states: '3.6 The general Australian guidelines do not include the LD50 test ...'
>
> The Department's policy, therefore, is that the LD50 test is not required. As stated at the hearing before the Committee, this would not prevent companies submitting data from including previously-generated LD50 data. If such data were to be included it would be of value in defining the toxicological profile of the chemical concerned. However, the Department's position is that it does not need LD50 data.[34]

7.75 Recently, regulations have been made in Victoria under the Prevention of Cruelty to Animals Act 1986. Regulation 24 deals with the Draize Test and Lethal Dose Testing and reads as follows:

(1) A person must not carry out any scientific procedure or series of related scientific procedures known as the Draize test to determine the relative irritancy of a chemical or a cosmetic, toilet, household or industrial preparation, using the conjunctival sac of rabbits.

(2) A person must not carry out any scientific procedure or series of related scientific procedures involving lethal dose testing unless:

(a) the scientific procedure is related to potentially lifesaving treatment or research in connection with cancer in human beings; and
(b) the objective of the scientific procedure cannot be achieved by any other scientific means; and
(c) the scientific procedure is recommended for approval by a Peer Review Committee established under section 34 of the Act; and
(d) the scientific procedure is approved by the Minister; and
(e) the scientific procedure is carried out in accordance with any conditions determined by the Minister.

(3) For the purpose of this Regulation, 'lethal dose testing' is any test for determining the relative toxicity of a chemical or a cosmetic, toilet, household or industrial preparation in which the object of the test is to assess the toxicity of the preparation against a predetermined level of mortality.

7.76 This regulation has however been subject to criticism. AFWA submitted:

> The banning of the LD50 test in Victoria has already slowed research in that State and will make it more difficult for the proposed Centre for Toxicology to operate effectively in Victoria. Experience in the Department of Pharmacology at Monash University indicates that it will lead to increased usage of animals rather than to a decrease.[35]

7.77 The Minister for Local Government and Planning in New South Wales announced in November 1988 his intention to propose amendments to the Chemical Research Act to restrict the conduct of certain tests in particular the Draize and LD50 tests. Applications to conduct such tests would be referred to the Animal Research Review Panel for review and would be subject to ministerial decision.

7.78 CSIRO has also called for a review of the need for this test.[36]

7.79 On 11 October 1988 the United States FDA stated of its current policy on the LD50 test:

> The statement provides a short history of FDA's policy on the "classical" LD50, including the fact that the agency revoked all regulatory requirements for the "classical" test in 1985. However, FDA "may not refuse to accept or review data, including acute toxicity data from the 'classical' LD50 test, if they are relevant to a decision FDA must make on the safety of a regulated article ... Thus, FDA cannot revise guideline test protocols or regulations to state that it will never use or consider any 'classical' LD50 data in making safety determinations."
>
> The policy further states, "The scientific community agrees that the 'classical' LD50 test is not necessary for determining acute toxicity. In agreement, FDA has adopted the policy that the 'classical' LD50 test is not a required toxicity study. The agency supports efforts to eliminate continued conduct of the 'classical' LD50 test and to reduce the number of animals used in acute toxicity testing without sacrificing information necessary in the interest of human safety."
> (NABR Update, Vol.9, No.22, 18 October 1988, p.1)

7.80 The Draize test is banned in Victoria and is subject to ministerial approval in New South Wales. It has been criticised on its effectiveness and on animal welfare grounds. It is also a

test which has been little used in Australia. The Committee believes that the Draize test is undesirable and RECOMMENDS that the Draize test be banned in Australia.

7.81 The Committee RECOMMENDS a ban on the classical LD50 test in Australia but that acute toxicity tests be allowed with ministerial approval. The classical LD50 is no longer required for registration purposes and is subject to ministerial approval.

7.82 For registration purposes, data derived from Draize tests or LD50 tests done overseas should still be accepted, provided that the relevant authorities and their advisers are satisfied that the data are valid.

CHAPTER 8

THE USE OF ANIMALS IN AGRICULTURAL AND WILDLIFE RESEARCH

Agricultural Research

8.1 Animal experiments for agricultural purposes are conducted by a number of universities as well as departments of agriculture in each State and the Northern Territory. No comprehensive statistics of the number of animals used in agricultural research are available.

8.2 The CSIRO supplied details of the use of animals for agricultural research during the period 1981-82 to 1983-84. In this three year period, 40,042 animals were used. Of this number, only 15.8 per cent of cattle and 43.8 per cent of sheep were involved in laboratory tests, while the balance underwent husbandry tests. According to the explanatory note provided by the CSIRO the distinction between laboratory and animal husbandry tests is that:

> In laboratory tests it is taken that some intervention to the animals occurs, eg injection, bleeding, or dosage of a drug or infectious Agent. In animal husbandry tests, animals are subjected only to normal farming practices, with the possible exception of occasional weighings, for example in an animal breeding trial.[1]

8.3 Although the main aim of agricultural research involving animals at the CSIRO is to improve productivity and reduce costs in the livestock industries, many of the projects have resulted in improvements in the welfare of animals. For example, research at the Division of Animal Health has produced benefits for both humans and various species of farm animals:

> The Division directs its main research effort towards alleviating the major bacterial and parasitic disease problems of the grazing sheep and cattle industries, with some research into pig and poultry diseases. Emphasis is placed on the production of new and improved vaccines and vaccination procedures and the genetic basis of disease resistance in animals.[2]

8.4 In the departments of agriculture and universities, animals are used in agricultural research to improve both the welfare of the animals and the economics of the livestock industries.

Types of Experiment

8.5 Many of the farm animals used in experiments at the CSIRO are not subject to pain or distress. At most they are likely to experience minor discomfort. As the CSIRO pointed out in its submission:

> ... the techniques applied are the same as, or very similar to, those used by farmers and the standard of general management is usually better. These include experiments to evaluate improved pasture species, grassland management techniques or the results of selective mating of animals which show superior performance for some productive character.
>
> In such cases the research techniques are mainly ways of measuring production, e.g. weighing animals; dyebanding wool; weighing fleeces at shearing; measuring milk production from cows or ewes milked by machine or manually; and measuring meat production through carcass measurements following slaughter. Additional methods may involve collection of samples of blood, urine, faeces or tissue (with appropriate local anaesthesia), the injection of radioisotopically labelled substances in concentrations not hazardous to the animal or the operator, and oral dosing with an inert marker substance for measurement of faecal output.[3]

8.6 Some animals are restrained in metabolism crates in the course of nutrition experiments. Normally the animal is able to move and lie down but cannot turn completely around. The reason for such restraint lies in the nature of the research.

8.7 In a number of institutions, sheep have fistulae created which are fitted with cannulae or tubes into parts of the alimentary tract to enable samples of the contents to be collected regularly from living animals.

8.8 The purposes of these interventions include the sampling of rumen contents for nutritional research, the study of micro-organisms within the rumen, or the introduction of substances directly into the rumen. According to the evidence before the Committee such animals tend to live out a lifespan which is normal for the species and remain in good health and body condition.[4]

8.9 The types of experiment which have caused the most pain and distress to the animals involved were mainly designed, paradoxically, to find better ways to relieve or prevent pain and distress in farm animals. These experiments involve research into animal diseases including the establishment of their cause, the efficacy of new methods of treatment or prevention; and the investigation of poisoning in grazing animals caused by plant associated toxins. An example of the first category is research into foot rot in sheep and of the second is the research into annual ryegrass toxicity.

8.10 The second category relates to toxins which cause extensive mortalities in grazing animals. When a new poisoning problem arises the only way to determine whether a given feed or sample of feed is toxic is to actually feed it to the species concerned. Identification of the specific toxic compound will require still further feeding of extracts of the original feed to animals until it can be concentrated and separated out from the range of compounds present in the original feed. Once the toxin is chemically defined, chemical assessment methods may then replace the use of animals.

8.11 CSIRO identified the following principles which it saw as essential in designing such experiments:

> The minimum number of animals is used; with toxins that appear to cause pain, every effort is made to use end-points other than pain and unpleasant death to the animal; and analgesics and anaesthetics are used if undue pain is apparent at any stage.[5]

8.12 The fact that animals will be the direct beneficiaries of such research does not remove the need for rigour and thoughtfulness in the application of such principles at the stage in the planning of such experiments and in their assessment by ethics committees.

8.13 An example of the need for rigour and in experimental design is provided by an experiment drawn to the attention of the Committee in the ANZFAS submission:

> Example Ellis, T., et al, **Protection of recently shorn sheep against adverse weather using plastic coats,** Aust Vet J 62 [no.7, 1985] 213-217.
>
> Recently shorn sheep were cold stressed by continual wetting in a cool room, with fans to simulate wind, in order to test the protective effect of plastic coats ('polyethylene rubbish bin bags'). There were four groups of ten sheep. One group were kept dry and exposed only to room cooling. Another were give coats after 10.5 hours, by which time they were hypothermic. One did not improve and had to be killed after 2.5 hours. One group had coats from the start of the wetting. One group were wetted but not given coats. The stress was continued for 90 hours. Several sheep became severely hypothermic and depressed and were killed.[6]

8.14 Commenting on this experiment, Dr Alexander, who appeared for AFWA, said:

> I think we could say that there are probably better end points than death, or more humane end points than death. I think that experiment could have been refined, from an ethical point of view...

> The point I am trying to make is that the same result could have been got with perhaps a more humane end point, rather than going to the death of the animal. The body temperature could have dropped a couple of degrees and they could have obtained the same result.[7]

8.15 It is evident that in the years since those experiments were done, a greater awareness of animal welfare has changed attitudes to pain and distress in experiments. Some experiments once condoned will no longer be acceptable to experimenters or to ethics committees. CSIRO, as a co-sponsor of the Code of Practice, has taken a number of steps in recent years to improve animal welfare in research projects under its control.

8.16 The effectiveness of the vetting by ethics committees of State Government experimental projects involving farm animals is not so clear. The Committee looks forward to the enactment of legislation in the States which have not yet upgraded prevention of cruelty to animals legislation to ensure that such experimental projects are approved by ethics committees established and operating in accordance with the guidelines set out in the Code of Practice.

8.17 Although the Committee has primarily used CSIRO evidence in this chapter, it did notice during its inspections of animal houses a number of similar experiments taking place. The comments in this chapter apply not just to the CSIRO but also to other institutions or government authorities which use animals in agricultural research.

Experiments Involving Native and Feral Animals

8.18 There is relatively little research done in Australia which involves native animals. Scientists gave a number of reasons for the use of any native animals in experiments. First, there are the benefits to humans arising from improved understanding of biological processes of native animals. This relates to the use of native animals in biomedical research. According to the NHMRC:

> By studying native fauna, basic knowledge of biological systems that have general relevance to mammalian biology, agriculture and to human medicine will be gained. Some examples include:
>
> - the genetic control of sex determination and the hormonal control of sexual differentiation and descent of the testes;...
>
> - the influence of lactation on mammalian reproduction;
>
> - the mode of action of hormones in inducing gene expression for milk protein synthesis, using the peculiar properties of the marsupial mammary gland;
>
> - investigation of differentiation and development of the nervous system, with the potential for understanding and subsequently alleviating nervous disorders in man and other animals;...
>
> - use of parasites and diseases of native mammals as laboratory models in studies aimed at alleviating human morbidity and controlling human diseases.[8]

8.19 Proponents of the use of native animals in experiments acknowledged that the quest for improved biological knowledge is restricted by ethical considerations. The NHMRC admitted that public sensitivity about the use of native animals in biomedical research suggests that the limits of public acceptance in this area may be narrower than in research using other species.

8.20 Experiments are also conducted on wildlife to obtain more effective and humane methods of controlling them with less detrimental effects on non-target species. Within this area of research specific projects may present difficult decisions for an ethics committee, such as research using traps to check on the contents of dingos' stomachs and LD50 tests to examine the effect of 1080 baiting on non-target species.

8.21 Finally, information from experiments can lead to improvements in the management of habitats and the ability of authorities to conserve endangered species with consequential

benefits to native animals. The conservation of native species is of concern to scientists and animal welfare organisations. ANZFAS expressed the view that it:

> ... endorses such scientific research which results in direct benefits to indigenous species, whether those benefits arise from research into disease control or other such applicable knowledge, thus enhancing the well-being and conservation of native species, but only where no pain or suffering is inflicted in the pursuit of such knowledge. This type of research should be merely observing native animals in their own environment or involve animals which are themselves already diseased and which therefore would benefit in their immediate treatment from the experiment.[9]

8.22 When representatives of ANZFAS were questioned on the Federation's policy, Dr Hampson replied:

> I think the ethical point there, which needs to be taken into consideration, is that as far as I am aware most species that are endangered at the current time are endangered because of what we have done. They are endangered because we have interfered with their habitats, for example, or because we have interfered with other species that have upset the balance in such a way that species have become endangered. I do not see that there is a more pressing ethical point for protecting an endangered species than for saving life in general ... The ethical point here is the degree of invasiveness of the experiment that you are going to do in order to save the endangered species. I would find it hard to imagine experiments where you would be killing endangered animals in order to save endangered animals, for example. You would be far more likely to be doing something that is done out in the field and is less likely to be invasive, and so on.[10]

Supply, Handling and Husbandry

8.23 Most native animals are protected by State and Territory laws which make specific provision for the issue of licences for scientific research. All proposals to capture fauna in the wild

are subject to the approval of the responsible fauna authority. Before capturing native animals, an experimenter must obtain a permit giving details of animal species, numbers of individuals and the location of the proposed capture.

8.24 It is now standard practice for State and Territory fauna authorities to require the experimenter to obtain approval from the ethics committee of the institution at which the researcher is based before a permit is issued.

8.25 Although there is no formal co-ordination between the fauna authority and the ethics committee, no evidence was received by the Committee indicating dissatisfaction with this system. Nevertheless, ethics committees might consider co-opting officers of the fauna authority to assist in the assessment of particular wildlife research projects. This practice has been followed successfully by the CSIRO Division of Rangelands and Wildlife Research Animal Ethics Committee at Gungahlin in the Australian Capital Territory.

8.26 There are, however, problems specific to the handling, care and supply of native fauna which are dealt with in this chapter because of their bearing on the argument as to whether native fauna should be the subject of research outside their natural environment.

8.27 The problems encountered in the capture, handling and care of native fauna, are often different to those for purpose-bred or domesticated animals used for experimental purposes. A working party of the NHMRC warned that:

> Investigators should bear in mind, however, that interactions between the stresses of capture, restraint and housing, artificial nutrition, anaesthesia and pre-existing illness may affect experimental parameters.[11]

Observational Studies of Wild Animals

8.28 Even apparently unobtrusive observations of wild animals may have an undesirable impact on breeding behaviour. Mrs Large appearing for the New South Wales Government's Animal Welfare Bureau commented:

> There may be no actual suffering inflicted on the animals by that observation, but there is the potential for that observation to disrupt, say, the reproductive cycles of those animals, with catastrophic consequences, perhaps, for endangered species.[12]

8.29 This point is emphasised by a British scientist Dr C.M. Perrin who in consideration of ethical issues raised by field experiments offered the following example:

> ... an observer who can be seen by a nesting bird may cause the bird to reduce its visits to the nest or to desert the nest altogether. Even walking along a beach at low tide in mid-winter may seriously interrupt the very limited time available for feeding by wading birds. At such critical periods of the year if enough people do this the birds' survival may be jeopardised. From the scientific viewpoint it is essential that the observer tries to understand the effect of his own behaviour on his study animals and to minimise it or make allowances for it: without this insight the whole study may be invalidated.[13]

Marking of Fish, Birds and Animals

8.30 Techniques used for marking animals include tagging, freeze branding or toe clipping. These all involve catching the animal, marking it and releasing it within its original territory. The techniques of trapping, are of course species and location specific. The stress involved will vary with the specific techniques of trapping and marking and the species involved.

8.31 Whatever the technique involved, frequent recapture of marked animals is required in order to allow for repeated observations of the individual animals.

8.32 The alternative to the repeated trapping and handling of individual wild animals with its associated stress is the use of individual marks that can be seen and identified at a distance. The limitations are that it can only be carried out in a restricted number of individuals because of the difficulties of making individual marks easily recognisable. Examples of markings include the use of colour rings, wing tags, ear tags, collars and the dyeing of hair or feathers.

> These techniques considerably reduce the stress of repeated catching but, by their nature, the rather more striking markings may have other deleterious effects. As many as eight colour-rings have been put on individual birds, back-tags on grouse have been thought to destroy their camouflage and make them more at risk to predators. It has been suggested (actually without good evidence) that the neck collars used on swans may reduce the nesting success by making it more difficult for such individuals to obtain a mate.[14]

Radio Telemetry

8.33 This technique is used for tracking of wild animals. It enables a large number of observations to be made of the movements and behaviour of an individual animal without the need to recapture it.

8.34 Miniaturisation of the transmitter and its power source have largely dealt with one aspect of intrusiveness by substantially reducing the size of the equipment..

Capture

8.35 Some species of native fauna are bred in captivity for research purposes. Even if breeding were more widely undertaken this would not be suitable for projects oriented toward research into the behaviour and functioning of animals and birds in their natural environment.

8.36 Trapping presents its own set of difficulties, irrespective of whether the intention is to obtain a live animal or a dead specimen, particularly guaranteeing minimum pain where death is intended and minimum stress when capture is desired. Trap surveillance needs careful thought to prevent unnecessary pain or distress. There is also the problem of minimising the capture, death or maiming of non-target species.

Conclusions

8.37 The Committee believes that endangered species should only be subject to experiments which are designed to conserve that species. Such projects should be subjected to careful scrutiny to ensure that the research projects are well founded and are likely to have positive outcomes for the endangered species.

8.38 Experiments on other wildlife, particularly native fauna, should also be examined carefully by ethics committees to ensure that the scientific merit and value justify the use of such animals. Wherever possible, purpose-bred animals must be used. The use of native animals in experiments can evoke emotive responses within the community and protocols involving native animals need to be dealt with sensitively. The added stress of capture and confinement of wild animals is an extra dimension which must be taken into account in the consideration of protocols.

8.39 The Committee does not support a complete ban on experiments that might cause some pain or distress to wildlife. However, experimenters must have a very good case to justify experiments which do cause pain or distress. In no event must such experiments cause more than minimal pain as required under the Code of Practice.

8.40 Special attention must be paid to the planning and assessment of projects involving the holding of captured native fauna for any period of time. The Committee endorses the following guidelines laid down by the NHMRC.

4. Animals should only be taken from the wild if animals bred in captivity are not available or are unsuitable for the specific research purposes.
5. If it is necessary to capture animals from the wild, steps must be taken to minimise the distress caused to the animals.
6. Research institutions and funding bodies should work towards the establishment of new breeding colonies and to the development of improved husbandry techniques within those colonies.
7. Endangered animals should only be used when the research will be of direct benefit to the conservation of the species and will not further endanger the species.
8. Investigators must seek expert advice prior to applying to the AEEC. They must thoroughly acquaint themselves with details of the appropriate care, housing and diet for the species to be studied. Handling techniques and experimental methods may differ from those used with other laboratory animals and extrapolation of existing techniques for those animals may not be appropriate.[15]

8.41 The Committee RECOMMENDS that ACCART in co-operation with the relevant bodies with specialist knowledge draw up appropriate guidelines and standard operating procedures for the capture of wildlife and their housing, nutrition and management in captivity.

Wildlife Research in Australian External Territories

8.42 Questions were raised in the Senate on 18 February 1988 and 22 February 1988 concerning the conduct of wildlife research in Australian Antarctic Territories and Macquarie Island. Subsequently, the Minister for the Arts, Sport, the Environment, Tourism and Territories, commissioned the Antarctic Science Advisory Committee (ASAC) to prepare a report on Research Involving Animals in Antarctica.

8.43 The matters dealt with in the ASAC report to the Minister, which was made public in May 1989, fall within the scope of the Committee's inquiry into animal experimentation. The relevant conclusions and recommendations were :

Conclusions

* The techniques used in current Australian research projects involving live animals are justified on conservation grounds and are being administered humanely. There are no better humane ways of collecting this information which is needed for the development of conservation strategies. There is every reason, on conservation and animal welfare grounds, why the projects currently suspended should be allowed to continue. Valuable scientific information will be lost if they do not proceed. The activities of Australia's Antarctic researchers have been commented on favourable by an observer from the Australian Conservation Foundation.

...

* Australian Antarctic scientists are amongst the leaders in the use of humane methods for collecting scientific data on Antarctic animals. To consolidate and continue Australia's progress in achieving high standards in wildlife research, there is a need to develop a code of practice specifically to cover research on Antarctic animals. There is no international code and the existing NH & MRC code on animal research is inappropriate. The new code should include provision for an independent animal care and ethics committee which should review all proposals involving Antarctic animal research.

* Current legislative provisions governing research activities in the Antarctic are unnecessarily complex and require rationalisation and simplification. In the short term there is scope for improved communication of current requirements to researchers. In the longer term, there should be a review of current Commonwealth legislative provisions governing Antarctic activities undertaken with a view to rationalising them and simplifying their administration. The Antarctic Division should also implement measures so that there is an immediate focus of responsibility for oversight of Antarctic environmental management. Such a focus should include scientists, policy experts, logistics co-ordinators and independent specialists.[16]

Recommendations

* a code of practice be developed to cover research involving Antarctic animals ... and that this include provision for an animal care and ethics committee to assess future proposals for Antarctic research projects;

* encouragement be given to research involving the development or refinement of techniques (such as use of anaesthesia and radioactive isotopes) which will enable biological information to be collected from Antarctic animals with minimum effects to them;

* improvements to techniques for anaesthesia on seals ... be evaluated as a matter of urgency in relation to future applications of anaesthetics to these animals;[17]

8.44 The difficulties experienced in the projects mentioned in the Senate point to the need for assessment of all projects involving animal research by a properly constituted ethics committee. Given the endorsement of the Government of the Ross Committee recommendation G26 that 'Commonwealth bodies which breed, hold or use animals in experiments adopt and immediately implement the NHMRC/CSIRO Code of Practice and Guidelines for the Care and Use of Animals in Research in Australia', it is a matter of some concern that the Code's requirements with respect to the composition and operation of animal ethics committees had not been implemented within the Antarctic Division. The evidence[18] was clear that while researchers outside the Division were having projects scrutinised by the ethics committee of the institution of which they were members, those by researchers from within the Antarctic Division itself were not.

8.45 The Committee does not believe that evidence was presented in the report to enable the conclusion to be drawn that application of the Code of Practice to wildlife experiments is inappropriate. The Code of Practice is currently used by scientists conducting wildlife research in Australia in various environments, including Antarctic research conducted by CSIRO officers.

8.46 In view of the working party's recommendation in Appendix G of the Report on the development of a code of practice for wildlife research in Antarctica, there was obviously some confusion as to the nature of a code of practice and its role in the assessment of experiments on animals.

8.47 The working party confused a code of practice with detailed guidelines. A code of practice sets out the administrative arrangements for approval of protocols; the responsibilities of experimenters, ethics committees and institutions; and the principles under which experiments on animals should be carried out. It does not prescribe the actual techniques, procedures and practices which experimenters should carry out on animals in the field. These should be set out in a separate document.

8.48 The Committee RECOMMENDS that Antarctic research protocols be assessed and approved under the Code of Practice and that additional detailed guidelines be drawn up on the techniques, procedures and practices to be used by experimenters on animals in the Antarctic.

CHAPTER 9

ANIMAL HOUSE FACILITIES AND THEIR MANAGEMENT

Introduction

9.1 The standard of care given to animals used in experiments and the standard of facilities in which they are housed have an important bearing not only on the welfare of those animals but also on the scientific data derived from experiments in which the animals are used.

9.2 In the course of this inquiry the Committee paid particular attention to the standard of facilities, training of staff and the quality of animal care. To this end it conducted inspections of a range of animal houses in institutions in which animal experimentation was being conducted.

Animal House Facilities

9.3 The answers to the questionnaire gave the Committee a general picture of the standard of animal house facilities.

9.4 In specialist research institutes, there was reasonable satisfaction by respondents with the standard of facilities. None of the respondents reported any need for more than minor upgrading. Difficulties with maintenance did not feature prominently.

9.5 In research units in hospitals, the standard of facilities varied sharply from institution to institution. Several hospitals reported that major upgrading was necessary. These included the Royal North Shore Hospital, Westmead Hospital and Prince Henry Hospital (Melbourne). The main problems noted by the animal house units attached to the other hospitals were the difficulties in obtaining finance for minor upgrading and routine maintenance.

9.6 A number of universities reported the need for major programmes of building replacement, upgrading of current facilities or substantial expansion of animal house facilities. The need for some of these programmes had initially been identified in reports prepared within the universities up to a decade previously.

9.7 Since 1985 a number of universities have undertaken or announced plans for renovations or, in a few cases, for new facilities. These include: a new sheep house at the University of Tasmania; refurbishment of the Medical School Animal House and the partial barrier unit at the University of Adelaide; a new animal house at the University of Sydney; refurbishment of facilities at the University of Melbourne; new facilities for dogs and other animals and the completion of a specific pathogen free (SPF) rodent production unit at the University of New South Wales.

9.8 Other universities which identified the need for major programmes of renovations were James Cook University, Griffith University, the University of Wollongong and the Australian National University.

9.9 Even in universities where the central facilities were of a high standard, there were often small holding facilities within departments which were far from satisfactory. In one case the animals were housed among the foundations of a building in

conditions that raised concern not only for the welfare of the animals' but also for the staff.[1] At the time of the Committee's inspection of this facility, a new animal house was being built.

9.10 The difficulties experienced in maintaining satisfactory standards of accommodation were common to almost all of the universities. The source of these difficulties lies in a complicated web of institutional and attitudinal factors and is not simply the result of recent financial stringency.

9.11 In a paper delivered to an ANZAAS Conference in 1982 Dr M. Rose stated:

> Far too often animal facilities and personnel are placed at the bottom of a research budget. Even when properly conducted the cost of good animal production is no more than approximately 5-6% of all fiscal expenditure on animal based research programmes. There is a real need particularly in Australia for significant upgrading of animal facilities and for the provision of appropriate training programmes for staff. Part and parcel of this programme is the need to re-educate the scientific community that the animal house is a laboratory and that animal care personnel are a vital part of the scientific research team. Far too often the animal facility and the staff are relegated to positions of least significance in the structural hierarchy of institutions.[2]

9.12 These points were illustrated in a study of animal house facilities at the University of Adelaide during 1985. In the preface to the consultants' report, the Dean of the Faculty of Medicine commented:

> The two factors to emerge from the review of animal services have been the University's failure to recognize the importance of laboratory research animals for the biomedical sciences and the failure to respond to the need to upgrade facilities and staffing to ensure an adequate supply of suitable

> disease-free animals. By comparison if computer facilities within the University were permitted to run down to the same extent as the animal houses with the resultant risk of compromising data, there would be an outcry from the academic community and provision of additional funding would no doubt be approved. The failure to recognize the importance of research animals has meant that requests for additional funding for animal services have been unable to compete with other areas for funding.[3]

The University responded to the report and implemented many of its recommendations.

9.13 The difficulties mentioned in the University of Adelaide report were by no means confined to that institution. Dr Campbell, who gave evidence on behalf of the Australian Society for Medical Research, commented:

> I think this is a problem with medical research funding in Australia. Funds are not specifically allocated for improvement in animal housing facilities or in the employment of well qualified people to look after those animals. I think that with the general downgrading in the level of funding for capital equipment in universities perhaps the university animal houses have suffered even more. I think that a better outcome for animals in medical research will come when it is recognised that special allocation of funding has to be made for that purpose. Research grants or project grants given by the National Health and Medical Research Council are not given on the basis that animals are going to be housed any better.[4]

9.14 There has been some evidence of changes in attitude by institutional managements towards the need for high standards of facilities and care for experimental animals. This is also reflected in the higher priority being accorded to the upgrading of animal houses in a number of institutions.

Standards for Accommodation

9.15 The Code of Practice does not lay down detailed standards for animal care facilities. The guidelines most commonly used by Australian institutions appear to be the Canadian Council on Animal Care Guide to the Care and Use of Experimental Animals the U.S. Department of Health and Human Services, National Institute of Health Guide for the Care and Use of Laboratory Animals and the UFAW Handbook on the Care and Management of Laboratory Animals.

9.16 In its submission ANZFAS recommended that, by statute, provision should be made for legally enforceable national standards of laboratory animal welfare such as:

- housing appropriate to the physiological and ethological needs of the species and strains. This would include, for example, temperature, humidity and lighting specifications, bedding, exercise, social contact, features for the fulfilment of behavioural needs and for designated species unlimited access to outdoor areas. For example, animals suitable for confinement in cages should not be housed in cages which are substandard or too small. Animals' exercise requirements should be met. For example, dogs should at least be provided with an adequate outdoor run and not be kept in cages; and native fauna and primates should be provided with adequate outdoor facilities

- general observation individually of all animals not under experiment at least once every 12 hours

- frequent observation (including nights and weekends) of all animals under experiment or post-operative care by persons competent to alleviate any pain or suffering. The frequency of observation should be stipulated according to the species, the experiment and the severity of the procedure in each case

- pain or suffering relief techniques by species
- methods of euthanasia by species
- the definition of adequate food and water
- the procurement of animals.[5]

9.17 This recommendation raises an important philosophical issue concerning the role of law in encouraging good practice and the development of appropriate attitudes. Put briefly the argument is that detailed prescription is not the most effective way of developing responsible attitudes and facilitating improvement in husbandry practices. Over-emphasis on prescription often leads to an attitude of compliance with the letter of the law rather than its spirit. The development of such an attitude would hardly be beneficial to animal welfare.

9.18 It is often impractical to incorporate detailed standards of care into regulations. In many cases, the care needed is dependent on the nature of the experiments to which the animals are being subjected. However, it is important that general principles of care are included in regulations to provide a recourse by government if institutions do not adhere to standards of practice which have been accepted as a minimum level within the scientific community. These general principles are mainly documented in the Code of Practice but some State Governments may decide to include additional requirements in regulations.

9.19 There is not always unanimity of opinion on the preferred practices in some areas of animal care and handling. Current knowledge in other areas of animal care is deficient. For example, rodents are probably the laboratory animals whose needs have been most studied.[6] Yet it has been pointed out that even for rodents the standards for ventilation and lighting needed to be more specific and relate to cage as well as room conditions:

> ... although for factors such as sound level there is ample evidence that the animal's comfort and well-being can be adversely affected, the information available is inadequate to permit any but the most general recommendations to be made.[7]

9.20 A more recent study, which was conducted for UFAW to determine the size of cage, stocking density and the social group that would make for the well-being and comfort of growing young adult laboratory rats, raised serious doubts about the adequacy of previous guidelines to meet these welfare needs.[8] There is a danger of imposing standards through a legal or quasi-legal mechanism which may subsequently be found to be inadequate or detrimental to animal welfare.

9.21 Because the Committee does not support the recommendation of ANZFAS to incorporate national standards of laboratory animal welfare into legislation, the conclusion should not be drawn that the Committee in any way condones lower standards than those inherent in ANZFAS's recommendation. The Committee believes that a less prescriptive approach will ultimately be more successful in achieving high standards of animal welfare. Under existing laws in some States and in recommendations in this report, there are administrative mechanisms for monitoring standards to ensure that standards are maintained or improved. This approach should meet the desired outcomes better than the prescriptive approach.

Quality Control

9.22 There has been an increasing awareness of the importance of precise biological definition of animals in animal experimentation. In a paper delivered to a seminar at the University of Melbourne in 1987, Dr M. Rose stated:

> The biological definition of animals is arguably the single most important consideration in reducing the numbers of animals used. Animals are complex entities whose biological responses reflect the interaction of their genetic make-up with a multiplicity of environmental variables. It has long been recognised that control, and/or definition of their genetic and health status, and of environmental variables, is an important consideration in the use of animals in research.[9]

In that paper Dr Rose drew together the findings of a large number of scientific studies which reported the effects of environmental variables on animals and the ramifications for research. Some of the variables included light, noise, temperature, humidity, diet, noxious gases (e.g. ammonia) contamination of feeds, type of bedding, chemicals used in cleaning agents and pest control, social interactions with other animals and humans, size of groups, design of pens and so on. Each variable might produce a biological response which could affect experimental data.

9.23 Apart from environmental influences, there are also the effects of infections which, too, can distort experimental data.

According to Lussier and Descoteaux:

> The importance of viral infections as complicating factors of biomedical research is recognized widely.[10]

In their six year study on the prevalence of viruses in 32 Canadian institutions, they concluded:

> ... virus infections of mice and rats are extensive and widespread in Canadian research institutions. Experience has shown that the above mentioned viral infections are good indicators of the standard of husbandry and

> management. The results presented here indicate then that standards have to be revised and that efforts have to be made to improve the quality of the rodents used in biomedical research.[11]

9.24 Apart from the prevalence of viral infections in laboratory animal colonies, genetic contamination of laboratory animals has become a problem in biomedical research and toxicological testing. In some areas of research, specific strains of animals are required because of unique characteristics. In other cases, the inclusion of the name of the strain in the published results of a research project is essential to enable the data to be reproducible. Concern has been expressed that animals obtained from some animal breeding establishments overseas have not been of the right strain. This has resulted in significant losses of money, animals and time.[12]

9.25 Monitoring of health microbiological and genetic status as well as of diet and other environmental factors is essential for both the welfare of the animal and the validity of the experimental results.

9.26 The importance of three basic elements - records, evaluation and surveillance - were emphasised by Dr J. Adams, Director of the Monash University Central Animal House. He stated:

> Quality control occurs at three levels. The first level is indeed at the level of actual records. I will refer the Committee to a publication which is cited and still cited indeed in the NHMRC guidelines entitled Notes for Breeders of Common Laboratory Animals. It was published in 1962 by George Porter and Professor Lane-Petter. In that they talk basically about procedures and what should be occurring. The first topic relates to record keeping and on page 201 they say that proper records shall be kept for the production

> colony management in order, firstly, to determine the efficiency of the operation; secondly, to trace the origin and spread of diseases; and thirdly, to determine biological performance.[13]

9.27 Record keeping is important in providing the health and breeding statistics necessary for both microbiological and genetic monitoring. The ongoing monitoring required to maintain high standard animals is substantial. Dr Adams told the Committee:

> ... if you wish to produce high quality animals and you have a defined status clearly in mind, then you would want to monitor and see whether you have in fact achieved that goal. That involves routinely bleeding animals for viruses - there are 17 or 18 viruses in mice and rats. You would also routinely check them for the common bacterial and parasite-type pathogens that exist in these animals. You would also carry out routine quality control checks using sophisticated scientific procedures for genetic quality control.[14]

9.28 ASLAS has taken an important role in supporting the upgrading of monitoring facilities available in Australia. There is now a National Murine Virus Serology Scheme based in Adelaide which enables production facilities to monitor the health states of SPF stock with screens available for 15 viruses plus mycoplasma.

9.29 ASLAS has drawn attention in recent years to the need for the monitoring of animal feed. Much of the feed comes from feed mills which are mainly concerned with supplying feed to the livestock industries. Feed for laboratory animals is only a sideline and therefore not a high priority for quality control. Representatives of ASLAS gave examples to the Committee of the effects of either toxic or inappropriate materials in the feed supplied to animal houses.[15]

9.30 Apart from the obvious animal welfare problems arising from the use of toxic or poor quality feed, there are more serious ramifications for the results of experiments in which animals are used that have been fed on such feed. Data derived from experiments on these animals may be rendered useless because sensitivity by the animals to the feed may cause a reaction which distorts the data produced.

9.31 Because of the seriousness of the effects of poor quality feed for both the animals and experiments, ASLAS has taken steps to have more monitoring of feed. Dr Kuchel of ASLAS told the Committee:

> So ASLAS took it on board to work with an independent analytical lab to look at diets being fed to laboratory animals throughout Australia, because we recognised that there was a large disparity in reproductive performance. From overseas work we just knew that some of the diets were likely to be substandard.
>
> With the 1987 update, recognising that these are expensive assays, it costs about $750 to assay one diet for 24 analytes. That comes out of the animal house budget. It means that the vet in charge of the facility has to recognise that if you get your diet analysed you do not do something else. However, it is being done and there are 12 institutions in Australia now where money is put aside to analyse the diets. So the researchers can then be given the printout, or given some written verification, that the diet has not changed in the last 12 months. We want to extend this to six-monthly testing because the variation in the quality of constituents within diets may well change with season. So we want to get milling companies to have a fixed formula and to make them realise that their product is being independently checked. By the time we have the system running, by the end of the fourth year I suspect that the enormous variability across Australia, which has been dramatically reduced after the first year anyway, will perhaps be eliminated.[16]

9.32 On animal welfare grounds the Committee regards the development of this monitoring scheme as a significant development. ASLAS is to be congratulated for its initiative in this area.

9.33 The Committee would like to see participation in this monitoring scheme of all institutions involved in laboratory animal experimentation.

9.34 The Committee RECOMMENDS that all institutions which conduct animal experimentation have periodic analyses done on animal feed to ensure that it is of a high and consistent quality, not only to maintain standards of animal welfare but also to guarantee the validity of experimental data.

SPF Animals - Facilities, Breeding and Use in Experimentation

9.35 Increasing sophistication in biomedical research over the past two decades has made experimenters more aware of the range of factors that actually influence the results obtained in research based on animal experimentation. This has led to a increasing demand for animals whose health and genetic status are closely specified.

9.36 Specific Pathogen Free laboratory animals are bred under controlled and closely monitored conditions. Mr Deeny, then Director of the Animal Resources Centre (ARC) in Perth, explained that there are advantages for animal welfare and the validity of data in using such animals:

> The influence of bacteria, viruses and parasites - whether pathogenic or not - may have profound effects on the outcome of experimental results. Therefore, the use of specific pathogen free (SPF) animals is of prime importance in terms of reducing variables and ultimately in minimising the

> numbers of animals used. Organisms such as mycoplasma pulmonis, which continue to be a problem in conventional rat colonies, can cause many misleading results in studies and can also reduce breeding efficiency by 50 per cent, are eliminated in SPF colonies.[17]

9.37 The value of SPF animals was reiterated in evidence given by witnesses appearing on behalf of ASLAS. Questioned about the impact of animal quality on research results Dr Kuchel cited an example from the Institute of Medical and Veterinary Science in Adelaide in which 12 months work was wasted because of a viral infection that got into breeding stock.[18]

9.38 ASLAS provided further detailed evidence to the Committee on the need for the use of SPF animals for experimental purposes. In its view there are very few circumstances in which conventional rather than SPF animals can reliably be used for research purposes.[19]

9.39 Prior to the recent opening of the SPF facility at Little Bay in Sydney the major SPF breeding unit in Australia was the Animal Resources Centre in Perth. It was set up as a statutory authority and financed jointly by the Western Australian Government, the University of Western Australia, Murdoch University and Curtin University (formerly the Western Australian Institute of Technology).

9.40 There is an SPF unit at the Walter and Eliza Hall Research Institute in Melbourne but its output of animals is mostly, if not solely, for use within the Institute.

9.41 Animals produced in an SPF facility are more expensive than conventionally bred animals. However, even with substantial freight costs added to the basic purchase price, 47 per cent of the ARC's income from sales was derived from sales to the eastern States in 1985.

9.42 The scientific and welfare value of SPF breeding operations are not a matter of dispute. Assessment by ethics committees must deal with the adequacy of the proposed animal model in experimental proposals in the light of the type of issues raised by ASLAS. Such assessment should also be an integral part of the evaluation of proposed projects by funding bodies.

9.43 SPF units are capital intensive to construct and are more expensive to run compared with animal houses. The establishment of additional SPF units would require a rationalisation of breeding of experimental animals, particularly rodents, among institutions within the region in which new SPF units were established to ensure the economic viability of those units.

9.44 Mr A. Deeny, then Director of the ARC in Perth, doubted whether Australia has the capacity to support another SPF unit like the ARC, particularly in view of his sales to the eastern States.[20]

9.45 The University of New South Wales has recently commissioned an SPF unit devoted to rodent production at Little Bay in Sydney. In discussing the potential market for SPF animals Professor Ronayne commented:

> I did take the decision to go ahead based upon a new survey of user needs, the closing down of the facility at the Australian Nuclear Science and Technology Organisation and the possible closing down of the facilities at Sydney University in Castle Hill. The market for SPF rodents therefore seemed much rosier. I took the decision to go ahead with the SPF unit and I think the capacity of the unit at this time, which is 60,000 SPF rodents, will be fully committed within a year of its beginning operations ...[21]

9.46 Responses to the questionnaire concerning the advantages of breeding within an institution as opposed to obtaining animals from an outside supplier evoked such a wide diversity of opinions that it was not possible to derive a consensus view.

9.47 There were also marked differences in figures provided to the Committee on the relative costs of internal breeding compared with purchase from a specialist supplier. The differences in costs per animal for internal production of a common species quoted by various institutions may be explained by differences in cost allocation by institutions, in particular, whether caging was included as a recurrent cost; differences in the scale of production; differences in design of facilities and in the age and design of equipment; and differences in the efficiency of the management and staff of the facilities.

9.48 Many institutions at the time of completing the questionnaire were not able to supply the Committee with accurate figures on the relative costs of in-house breeding compared with outside purchase.

9.49 Only seven of the universities had policies that required researchers to pay for animals and in five of these cases the policy did not apply to all breeding units within the university. In the course of hearings the University of Adelaide indicated its intention to require payment for animals.

9.50 The Central Animal Breeding House at the University of Queensland, which does charge for animals issued, reported in its Annual Report for 1986 that its subsidy per animal issued for that year was $5.67. University policy is that the subsidy on laboratory animal breeding should be eliminated or substantially reduced over the next five years.[22]

9.51 Monash University has a two-tiered pricing policy. The price of animals for experimenters within the University includes all recurrent costs but excludes any element attributable to staffing costs. External purchases are charged at a rate which covers the full cost of staff and administration as allocated to the specific species.

9.52 The case for charging experimenters for animals supplied for experimental purposes rests on three grounds. First, payment by the researcher for animals encourages careful planning of experiments and seems likely to minimise the number of animals used. Secondly, if the animal house does not recover costs there is little encouragement to identify costs and enable assessment of the cost effectiveness of production. Staff cannot be held accountable for their performance. Thirdly, once charging is accepted, proper pricing can enable animal houses to accumulate financial surpluses which can be used for capital investment in animal house facilities. Such investment has the potential to increase the efficiency of animal production. Conversely, low pricing of animals will make the animal house dependent on university funding which in the past has not been enough to maintain many animal houses at a high standard.

Rationalisation of Breeding Units

9.53 Except in Perth where the ARC provides institutions with most of their animals for use in experiments, animal breeding and supply is decentralised in Australia. Most institutions carry out some animal breeding programmes for their own use. A few central animal houses in the larger institutions also supply animals to other institutions.

9.54 The question was raised in the inquiry whether the current decentralised breeding system should be continued or whether there should be a rationalisation of breeding

establishments on a regional basis. In essence, it is a question of whether to have a limited number of large animal houses or to have, as there is now, mainly relatively small ones.

9.55 Larger animal houses can achieve economies of scale for many species which will reduce the cost of animals for experimenters. There should also be less wastage from large orders for animals of the same sex because the discarded animals of the other sex may be used in other projects where a particular sex may not be an important factor. The large and more constant throughput of animals gives managers of animal houses more flexibility to operate in an efficient way. Dr J. Adams, Director of the Central Animal House at Monash University, explained:

> ... the operation of small units always has the problem of economy of scale, particularly where there is fluctuation in demand. The university finds in this industry that research workers vary their orders. There are very legitimate reasons why they do that. The logical thing is that, if you want to minimise wastage or the problem of famine and feast in terms of supply, it is better to centralise and go for better economy of scale.[23]

9.56 Dr Adams also told the Committee:

> ... the more sophisticated your product quality control, the greater input you will make to the preparation of your materials or the maintenance of your general environment. So more sophisticated places may have greater staff input. On the other hand, more sophisticated places, particularly bigger ones with better economy of scale, are better suited to the uses of automated pieces of equipment. Particularly if they have been purpose-designed buildings, you will have a better flow of materials and better dynamics of operation, which tend to make the carrying out of those basic tasks more efficient. So sophistication of quality control increases work and the sophistication of man management, building design and the dynamics of operations can reduce the staff input per animal produced.[24]

9.57 By centralising breeding establishments, scarce capital funds can be concentrated on providing high quality facilities with sophisticated equipment rather than being dispersed among many animal houses with a lesser standard of facilities and equipment. This not only improves the quality of animals bred in these establishments but also it improves the environment for the animals and thus enhances animal welfare. It is essential to have high quality animals in many projects to obtain accurate and reproducible data.

9.58 A large animal house has a hierarchical staff structure which affords staff better career prospects and opportunities for training. The greater diversity of species and procedures in a large animal house gives a broader and more interesting range of duties for staff to perform. Technicians will also have more opportunities to develop more specialised skills. The larger animal houses can employ one or two professional staff who can raise standards of care and develop specialised practices and procedures. With professional direction and advanced technology, the animal house will begin to achieve its rightful status for the important and integral role it plays in the research activities of the institution.

9.59 It was argued in the course of the inquiry that by centralising breeding within a region, the extra handling and transportation of animals from the breeding establishment to the institution would cause additional stress to the animals. However, many SPF and other animals are currently transported both within a city and interstate without undue problems. The Western Australian institutions also had no criticism of the centralised system operating in that State. Provided that the animals are given time to recover from transportation and to familiarise themselves with their new environment, the Committee does not believe that the need for transportation negates the advantages of centralisation of breeding.

9.60 At present scarce funds are thinly distributed over many animal houses, although in the last few years there has been an injection of more substantial amounts into a number of animal houses, including at least $3.8 million being spent on the new SPF unit at the University of New South Wales.[25] There still remains a number of animal houses with poor facilities or equipment. From a national perspective, this is not a desirable situation.

9.61 The Committee has already outlined reasons for contracting the number of breeding units to make the scarce funds more cost effective and to enhance animal quality and animal welfare. This contraction is probably inevitable but the Committee believes a planned contraction would serve the scientific community better. It is also essential that the large animal breeding units which emerge are managed by highly professional and experienced veterinarians with training in laboratory animal science.

9.62 There is probably room for no more than four or five large breeding units, with ARC in Perth used as a model. As each unit would serve many institutions, it would be preferable for each to be run independently of the institution in which it is located. The Committee does not have a strong view on whether the large breeding units should be run as commercial or non-profit operations. Non-profit in these terms means that surplus funds are not distributed to shareholders and not that the accumulation of surplus funds should be avoided. In fact, surplus funds would be necessary to develop and maintain the units. Whether run as a commercial enterprise or not, the key element is efficient management and operation.

9.63 Mr Deeny drew attention to the production of little used strains:

> ... we would probably advise the institution that it would be in their best interests to supply it themselves because the costs would be inordinately high if we bred them. What we are trying to do, however - we have started on this process now - is to institute a cryo preservation system within our own facility so that we can freeze mouse embryos, and also in the future rat embryos, of little used strains so that we can actually keep the animals in Western Australia without the expense of having to breed them and to maintain them.[26]

9.64 The other exception is where the breeding is an integral part of the experiment itself. The Department of Genetics at Adelaide University has been engaged in the establishment and breeding of a species of small marsupial mouse. The close attention by staff who are engaged in the experiment enabled results to be achieved which would not be possible in a large-scale operation.[27]

Cost Recovery

9.65 The Committee took evidence from a number of institutions on the question of whether to charge experimenters with the cost of animals or whether to subsidise either fully or partially the supply of animals for experiments. Most institutions have subsidised animals to some extent but there is a trend now towards greater cost recovery. A number of institutions now require experimenters to pay for the animals either bred or purchased on their behalf from the grant received for the project.

9.66 Cost recovery makes experimenters more conscious of the cost of animals and encourages them to consider more carefully the number of animals needed to complete the project. If animals are free, experimenters tend to order more animals than they

need. There is no incentive for the prudent use of animals. Hence, there has been considerable wastage of animals over and above normal and inevitable surpluses occurring to meet special requirements, especially in response to orders for a large number of animals of the one sex.

9.67 Cost recovery programmes recover operational costs, some of which include staff costs, but not the cost of depreciation of buildings and major equipment. Some institutions have a two-tier programme where external orders are charged a premium. This additional revenue is then used to upgrade equipment and other facilities within the animal house.

9.68 Cost recovery insulates animal houses from the vicissitudes of institutional funding, particularly in many institutions which have given animal houses a low priority in the allocation of funds. With increasing contraction of funds in the tertiary sector, an assured income through cost recovery will enable animal houses at least to maintain, if not increase, standards.

9.69 The Committee RECOMMENDS that animal house supply and breeding units develop appropriate pricing policies to enable recovery of all recurrent costs including caging and minor equipment and that surpluses generated should be used to develop animal house facilities.

Surplus Animals

9.70 From answers to the questionnaire and from evidence received by the Committee, it was revealed that many institutions produce large numbers of surplus animals. This practice has developed mainly because some experimenters over-order animals or order large numbers of animals narrowly defined for sex, weight and age, resulting in considerable wastage of animals that did not meet their requirements.

9.71 Much of the over-ordering by experimenters has occurred because the animals have been supplied free of charge. There has been, therefore, no incentive in those institutions for experimenters to calculate the minimum number of animals needed for an experiment or series of experiments.

9.72 It was pointed out to the Committee that it is often difficult for an experimenter to predict accurately the number of animals needed for a project. Sometimes, the design of each experiment in a project is dependent on analysis of data derived from the previous one. The number of animals needed for subsequent experiments in these circumstances can often be only an estimate. Experimenters will almost inevitably tend to order more rather than fewer animals to ensure that enough animals are available at the required time. The Committee accepts that it is not always possible to calculate accurately the number of animals needed for a research project. There have to be tolerances within the system to cater for the unknown and the unexpected, particularly when research is often going beyond the bounds of current knowledge. However, some experimenters have not been as assiduous as they should have been in estimating animal requirements.

9.73 Another factor causing uncertainty in animal requirements is the dependence of many experimenters on annual grants. As Monash University pointed out:

> 1. Research staff don't know whether grant applications have been successful or not.
>
> 2. Biological facts require breeding to commence six weeks to eighteen months in advance of planned use of animals.
>
> 3. Most research work is dependent on post-graduate students, many of whom have some difficulty in establishing techniques.[28]

9.74 The narrow definition of animals, as mentioned above, is a major cause of over-production. Usually animals of the same sex are required and if there are no orders for the opposite sex, or for either sex, of the same species, surplus animals will be produced. According to the ARC:

> Australian animal users purchase predominantly female mice. This creates a surplus of male mice that are culled. In order to attract additional sales of male mice, incentives, such as discounted prices, have been introduced. While females are still the sex predominantly used, these measures have had a small influence on the numbers of males used.[29]

9.75 The Committee noted that this predominance was not universal within Australia as some institutions reported a bias for male mice.[30]

9.76 Mr Deeny, the then Director of the ARC, told the Committee that his experience in the United Kingdom was the opposite to that of Australia as experimenters there tended to use male mice.

9.77 It appears from the evidence that some experimenters both in Australia and overseas are unaware that for some types of experiments, either sex is suitable. In order to avoid wastage of animals, animal houses need to be given as much flexibility as possible in the supply of animals of a sex which will be produced anyway to meet specific requirements. There is obviously a need to educate experimenters about the suitability of the use of animals of either sex in particular types of experiments. In the first instance, this should be done by professional staff employed in animal houses. However, given the cost of breeding, maintaining and disposing of surplus animals, a more concerted effort should be made within the scientific community to keep

surplus animals to a minimum. The Committee believes that ACCART should arrange for studies to be done to determine whether one or either sex is appropriate to use for particular types of experiments.

9.78 The ARC told the Committee in its submission that it provides incentives, such as discounts, in order to secure orders for animals which have to be produced to meet specific requirements.[31] The Committee understands that the Central Animal House at Monash University employs a person to handle external sales and is only involved in the marketing side of the Animal House's operations. If there were fewer animal houses, it would facilitate closer co-operation among them to avoid over-production.

9.79 A statement issued by the New York Academy of Sciences on the Animal Model Selection was critical of an imbalance between sexes in the planning of experiments.

> In planning animal procedures, consideration should be given to equal use of females and males. At present, much research is conducted on male animals; their female littermates, not used for breeding, frequently are disposed of. Results of studies using only males have often been assumed to apply to females as well, sometimes without justification. The appropriate use of both male and female animals may increase the validity of data and decrease animal wastage.[32]

9.80 The Committee RECOMMENDS that a study be undertaken by ACCART to determine the most effective means for production planning of laboratory animals in terms of minimising excess production.

Standard Operating Procedures

9.81 Few institutions were able to supply the Committee with a copy of the standard operating procedures governing animal care within the breeding and holding units. In most cases procedures did exist but were not written down. Staff were either expected to know what needed to be done or to respond to oral instructions.

9.82 Without written standard operating procedures, there is a greater likelihood of mistakes being made, particularly with new staff. Mistakes can have ramifications beyond animal welfare. A project can be put at risk because the wrong husbandry procedure was performed. With greater emphasis being placed on the definition of the animal in results of projects published in scientific journals, accuracy is essential.

9.83 Each animal house or holding area should have written standard operating procedures, which are revised when new information becomes available to update procedures and practices performed there. Writing of a procedural manual is time consuming. The institution should ensure, however, that a shortage of staff does not prevent the task being done.

9.84 Institutions licensed in New South Wales will be required by law to document standard operating procedures for accreditation.

CHAPTER 10

THE USE OF POUND ANIMALS FOR TRAINING AND EXPERIMENTAL PURPOSES

Introduction

10.1 The use in experiments of animals, mainly dogs, taken from pounds is an emotive issue in Australia. Public concern has been heightened from time to time by the lack of sensitivity shown by some institutions towards the use and disposal of pound animals.

10.2 In this chapter, the Committee examines the extent of use of pound animals, the arguments for and against such use in teaching and research, and the controls over that use.

Extent of Use

10.3 The number of pound animals used in experiments is unknown. Not all institutions use such animals and in South Australia, for example, their use is banned by statute, although the pounds in that State had prohibited the transfer or sale of animals to institutions before legislation was enacted.

10.4 The scale of pound animal use in Sydney is substantially larger than in other cities. Sydney University informed the Committee that in 1987 it used 2,000 pound dogs.[1] Of these approximately 75 per cent were used for teaching in the Veterinary faculty and 25 per cent were used for research.[2]

10.5 The University of Queensland reported that it obtained 11 dogs a week for the 26 teaching weeks in each academic year for the Veterinary School.[3] A number of departments also used dogs for experimental purposes. Between 1980 and 1984 the Department of Physiology and Pharmacology, the largest user of dogs for research purposes on campus, used between two and 21 dogs annually.

10.6 Murdoch University, the only other university with a veterinary school which provided figures, reported that it used 574 dogs in 1986.[4] It did not supply a breakdown between teaching and research but the figures for previous years were:

	Teaching	Research
1980	124	24
1981	182	20
1982	167	85
1983	217	214
1984	113	214

SOURCE: Evidence, pp. S5990, S5992, S5994, S5996, S5998

Use of Pound Dogs for Teaching

10.7 A representative of the AVA explained the background to the use of dogs in the training of veterinarians and the changes in practice over the years. Students used to be required to perform surgery on anaesthetised animals and then were responsible for post-operative recovery of those animals. However, today, once the surgical procedure has been done on the anaesthetised animal, most of the animals are euthanased. Some animals are still allowed to recover to enable students to deal with animals coming out of anaesthesia.[5]

10.8 Although it would be possible to restructure veterinary science courses to avoid conducting experiments on pound animals[6], some witnesses argued that this would lead to a lower standard of training with veterinary students less prepared on graduation to cope with the demands of a veterinary practice.[7]

10.9 Professor Rex of the University of Queensland compared training in the United Kingdom and Australia and pointed out that students in the United Kingdom practised surgery only on cadavers. He went on to say that:

> I had no doubt at all that new veterinary graduates in Australia were far more competent than I was when I qualified because they had had the opportunity to do surgical exercise as students on live, anaesthetised dogs which did not recover from anaesthesia and were put to sleep at the end of the day.[8]

10.10 Dr Smith of the AVA conceded that it would be possible to have an internship system for veterinarians but that the extra costs would have to be borne by the community.[9] Witnesses from veterinary faculties generally supported Dr Smith's position and emphasised that the additional costs would have to be met by tertiary funding bodies.

10.11 Another argument put to the Committee against the use of pound animals was that it inculcated in students wrong attitudes about animals; that in effect they are disposable. However, the Committee only received anecdotal evidence on this point. The Committee does not believe that undesirable attitudes would necessarily develop simply because of the source of the animals. The answer to this difficulty would seem to lie at least in part in the hands of the lecturers and the attitudes modelled on and taught by them.

10.12 In essence, the arguments put to the Committee provide support for the use of live animals in the training of veterinarians and do not directly address the issue of the use of pound dogs. It would be possible for institutions to breed dogs for the training of veterinarians. This would, however, be more expensive to do.

The Use of Pound Animals for Experimental Purposes

10.13 Apart from philosophical opposition to the use of animals in experiments discussed in earlier chapters of this report, animal welfare organisations have raised specific criticisms of the use of pound animals in experiments.

10.14 It was submitted to the Committee that institutions using such animals benefit from the current lack of control over breeding of companion animals and the resulting population of stray animals.[10] There is a serious problem with the large number of companion animals which are disposed of each year because they are no longer wanted by their owners. That is a separate problem and should not be confused with the question in hand. The prohibition on the use of pound animals for experimentation would have no impact on the companion animal problem.

10.15 A more serious argument advanced against the use of pound animals was that such random source animals may be unsuitable for research purposes on the grounds that they are poor research models because of their unknown genetic and micro-biological backgrounds and the confounding effects of many extraneous variables. Mr J. Adams, Director of Animal Services at Monash University, commented:

> I think there is another aspect that should be looked at in respect of pound dogs and the question of quality control in animal experimentation: Scientists have a moral

> obligation to ensure that the animals which they put into an experiment are in fact able to yield useful data. In some cases pound dogs are not suitable in that respect.[11]

10.16 Professor J. Egerton of the University of Sydney told the Committee:

> In some research projects there may be a question about the use of this heterogeneous group of animals but in some other projects they would be quite suitable. Whether or not they should be used in experimental studies, in controlled research projects, depends very much on the project itself. There would be some research workers who would prefer to have a standardised animal that they could use over and over again if repetition were required. But other people who are looking at other questions might find the heterogeneous group of animals was quite satisfactory.[12]

According to Professor Egerton, the main issue was the variability of response that one would get to any experimental procedure. He stated:

> If you had a group of animals, say 10 animals of mixed ages, the response in that group might not really be representative of what would be achieved if the target group for the research had been an older group of animals. It comes down to the question of the variability of response that you would get from this mixed group of animals that might be used in an experimental procedure.[13]

10.17 The wider the variability of response, the larger the number of animals that would be required to assure statistically valid results. In other words, random source dogs should only be used for research purposes where it can be demonstrated that their use would not lead to a greater number of animals being used than would be the case if purpose bred dogs were used.

10.18 ANZFAS expressed concern that pound animals by virtue of their background as companion animals would suffer undue stress and suffering if maintained in a laboratory environment. Undue stress, in the opinion of ANZFAS, not only raises the question of humane treatment but also of the validity of data obtained from experiments conducted on those animals.

> These stress related changes alter the data that an experiment will yield and render its validity unreliable.[14]

10.19 This argument might apply to some dogs but not to all, as many dogs which find their way into pounds have been abandoned by their owners. Obviously, experiments which might be affected by abnormal stress caused by the new environment should not be performed on those animals.

10.20 ANZFAS argued that the availability of cheap animals encourages the conduct of experiments which are not properly thought out and the ignoring of possible non-animal alternatives.[15] However, proper evaluation of protocols by ethics committees should ensure the use of non-animal alternatives where it is appropriate. In addition, the costs involved in keeping animals, whether purpose bred or obtained from pounds, is a disincentive to use animals unnecessarily, particularly if the experimenters have to provide for such costs out of their grants.

10.21 The Committee concludes that dogs from pounds may be used in experiments provided that where registered dogs are surrended to pounds, their owners given written consent to their use by institutions. The Committee accepts the argument that if a dog is used in an experiment from which it will not recover consciousness, there is no difference between euthanasia in a pound and destruction at an institution. If by the use of pound animals, which will be destroyed anyway, there is a reduction in

the destruction of purpose-bred animals, then animal welfare is enhanced overall. This argument is based on the premise that facilities for treatment of the dogs in institutions are of an appropriate standard. This is discussed below.

Policies of the Pounds

10.22 State legislation provides minimum holding periods for animals in pounds before action can be taken to dispose of them. In Western Australia the holding period for dogs is 72 hours. In Queensland it is 3 days for unregistered dogs and 6 days for registered dogs. In Victoria the holding period is 8 days but a recently gazetted Code of Practice dealing with the supply of dogs for experimentation requires that if they are supplied for experimental purposes they be held by the institutions to which they are supplied for 21 days before being used. New South Wales requirements call for dogs to be held for 7 days if they are unregistered or carry no identification and 14 days if they do. Dogs which are voluntarily surrendered do not have to be held for a fixed period.

10.23 The Victorian Prevention of Cruelty to Animals Act 1986 (No.46, 1986) Section 26 (2)(h) prohibited the use of a dog or cat from a municipal pound in a 'scientific procedure'. This however was amended by Section 28 of the Agricultural Acts (Further Amendment) Act (No.68, 1987) which enables such use if in accordance with a code of practice.

10.24 It would be possible under the New South Wales Animal Research Act to regulate the provision of pound animals through the requirement to licence animal suppliers under that Act. The Committee understands that a code of practice dealing with the supply of pound dogs for experimentation and teaching is currently being drafted by the Animal Research Review Panel in New South Wales.

10.25 Some pets which are still wanted by their owners may end up being supplied to experimenters. This may be caused by human error or by events beyond the control of the owner. The likelihood of this occurring depends to a large extend on the length of the holding period at the pound.

10.26 The Committee believes that three days is too short a period for a registered dog to be held before disposal unless that dog is surrended by its owner to the pound. For a registered dog, the pound should hold it for at least a week. This should give owners enough time to contact the pound to retrieve their dogs.

10.27 It is not always clear to owners who take their dogs to municipal pounds that those animals might be sent to institutions to be used in experiments. Some owners may not want their animals to be used for such a purpose. Those wishes should be respected. Pounds that supply animals to institutions must ensure that all people who deposit animals with them realise that those animals might be used in experiments. There should be signs at the pounds to that effect and owners should also be given a written notice informing them of any such arrangement with an institution.

10.28 Many owners take animals to pounds because they just do not want them any more. However, some owners dispose of animals for other reasons. They may be moving overseas or into a home unit where animals are not allowed to be kept. Although animals may suffer no more in an institution than they do in a pound, there is sometimes a perception on the part of the owners that additional distress will be caused to the animal if it is given to an institution for experimental purposes. Whether such a perception is correct is immaterial. Owners should have the right to choose wha happens to their pets.

10.29 The Committee RECOMMENDS that State Governments legislate so that pounds hold dogs for at least seven days before disposing of them to an institution except where a dog is surrended by its owner.

10.30 The Committee RECOMMENDS that State Governments legislate so that all owners who surrender dogs to pounds be informed in writing of the possible transfer of the animals to a research institution and that pounds obtain the written authorisation of owners to transfer the dogs to an institution.

Code of Practice

10.31 The Victorian Government has drawn up a draft code of practice to cover the use of dogs from pounds in institutions. Similar codes should be drawn up in other States where experiments on pound animals are permitted. Alternatively, State and Territory Governments should issue regulations to control the use of pound animals in institutions.

10.32 The draft code of practice provides for a written agreement between the pound and the institutions which is to be signed by either the Mayor or Shire President of the Council administering the pound.

Transport of Pound Animals

10.33 The vehicles in which animals are transferred from a pound to an institution must be suitable to carry animals without causing injury or undue stress from extremes of temperature.

Receipt of Dogs at Institutions

10.34 The procedures and practices for the receipt of dogs from pounds as well as facilities for their housing vary significantly among institutions. Some institutions provide good facilities and the dogs receive appropriate care. Other facilities, such as those at the University of New South Wales, are quite inadequate.

10.35 The Committee believes that clear guidelines must be issued in each State and that they be enforced by government inspectors making random visits to institutions.

10.36 All animals received by an institution from a pound must be given a veterinary inspection within 24 hours of receipt. All animals which are diseased, injured or do not meet experimental specifications must be destroyed by a veterinarian immediately and the bodies disposed of responsibly.

10.37 Dogs must be kept in facilities of an appropriate standard and be given proper care, nutrition and exercise. Any animals showing signs of undue stress must be destroyed immediately.

Records

10.38 Both the pound and the institution must keep detailed records of the animals transferred to institutions and allow inspectors to examine those records on request.

The Supply of Cats from Pounds

10.39 Councils in New South Wales and Victoria, at least, have no clear legal basis on which they can take action to impound cats, supply impounded cats to anyone or receive cats surrendered by owners.

10.40 Any action taken with respect to a cat by a council pound could well be the subject of a legal challenge. The Dog Act covers only dogs. While councils have undoubted power under local government legislation to deal with stock it is doubtful if this includes stray cats.

10.41 There are substantial difficulties in establishing ownership of domestic cats. There are no formal schemes for registration of cat ownership. Tagging and identification of cats is at present purely voluntary.

10.42 It is difficult to guarantee that only genuine strays are going to be supplied by pounds to research institutions. This is due to the fact that cats by nature are much more difficult to keep under control.

10.43 There are also no standard holding periods that can be enforced for impounded cats. Cats could be supplied or rehoused before an owner would necessarily begin searching for a missing cat.

10.44 Not all pounds are currently willing to handle cats. Those which do so see it as a community service. The number of cats being supplied by pounds to animal houses from the limited information available to the Committee is therefore relatively small.

10.45 Cat breeding colonies are already in existence in various universities. It would not be difficult to establish a stable source of supply to meet experimental needs.

10.46 The Committee RECOMMENDS that institutions either breed or purchase cats from an institution in which they are bred for experimental purposes and not acquire them from pounds or other non-institutional sources.

CHAPTER 11

ANIMAL HOUSE STAFF

Introduction

11.1 In earlier chapters of this report, the Committee drew attention to the increasing demand for higher quality animals for close definition of their genetic and health status in order to obtain reproducible data. This necessitates both good facilities and equipment and well trained staff. In this chapter the Committee discusses staff of animal houses and their training.

11.2 There are three basic levels of staff in animal houses: professional staff, technicians and attendants. The professional staff are veterinarians who, in most cases, are the directors of the animal houses. From the responses to the Committee's questionnaire, which covered the period 1980-84, in only nine animal houses of the 75 in non-Commonwealth institutions for which information was supplied, were veterinarians employed in this capacity. Few institutions had appointed a second veterinarian. The Committee is aware, however, that the number of veterinarians employed in institutions has increased in recent years.

11.3 The animal technicians form the key element of animal houses. In many institutions, a senior technician supervises the operations of the animal house. The technicians perform the more skilled jobs within the animal house and in many institutions carry out a range of routine experimental procedures.

11.4 The routine jobs within animal houses are carried out by animal attendants who may or may not have had training in animal care at colleges of technical and further education.

11.5 In the larger institutions, there are usually several animal breeding or holding units that function with some degree of administrative autonomy. Of the 98 separate units that had a staffing policy, 55 required formal qualifications or enrolment in appropriate courses as a condition of employment. Even in this group not all the institutions required qualifications or course enrolment for all positions. Animal attendants were the group usually excluded from any formal requirement that they possess relevant qualifications or be enrolled in such a course.

11.6 The other 43 units did not have any formal course requirement for animal house staff. However, most of these animal houses regarded such qualifications as desirable or encouraged staff to enrol in appropriate courses.

11.7 According to the responses to the questionnaire, about 15 per cent of technical staff and about 30 per cent of animal attendants had no relevant qualifications and were not enrolled in courses to gain them in the period 1980-84. These figures are indicative rather than definitive because some institutions did not provide relevant information.

11.8 A survey conducted in Sydney during 1979-80 found that about half the attendants employed in animal houses in research and teaching institutions had no qualifications and were not enrolled in any relevant courses.[1]

11.9 The Committee understands that this situation is improving and there may be now a higher proportion of trained staff in animal houses.

11.10 The lack of a whole-hearted commitment to the employment of qualified animal house staff is a matter for concern. It is acknowledged, however, that some of the unqualified staff employed in animal houses are experienced and capable of a high standard of animal care. For many long-term employees, only on the job training was available during the early years of their employment. There were no TAFE courses in which to enrol.

11.11 With on the job training, much depends on the ability and knowledge of the supervisor. Do all supervisors have the ability to train staff? Are they kept up-to-date with the latest techniques? Do they have time available to give attendants the breadth of knowledge they need or just to meet the requirements of particular duties? Some supervisors may give their staff full training but others may not. This will inevitably result in some inadequately trained staff or, worse, the supply of animals not meeting the specifications of experimenters. Staff need the theoretical as well as the practical knowledge to do their jobs properly. To ensure that all staff have a broad theoretical base from which to develop their expertise and to give them the opportunity to make animal care a satisfying career, institutions must adopt staffing policies which allow unqualified staff to enrol in animal care or animal technician courses. Anything less is both short-sighted and a disservice to the staff.

Status of Animal House Staff

11.12 In the past, animal houses were accorded low priority for funding and were relegated to a low position within the status hierarchy in institutions. Little attention was paid to working conditions, rates of pay, training of staff or even the standard of husbandry in animal houses. The smaller the institution, the worse was the record.

11.13 Concomitant with management's treatment of the staff of animal houses, many experimenters also accorded little respect to animal house staff or had no understanding of the importance of their work.

11.14 A representative of the Australian Animal Technicians Association (AATA) described the attitudes prevailing at the time he began to work in this area:

> I have been working with small animals for 25 years, and when I first started the person working in the animal house was not considered at all. He was just there with a broom or shovel. He just fed the animals and cleaned the animal house. The researcher would come into the animal house and carry out the experiment, possibly not even speaking to the person there.[2]

11.15 Another witness described the attitude to staff in an animal house attached to a hospital in the following terms:

> I am employed as a laboratory attendant. The authorities prefer people to do the course. You are not paid any more and the two wardsmen who look after our animal house do not want to go any further. Of course after years of being there, they are paid on the equivalent scale to me. They say: 'Why should we go to college or whatever because we are not going to get paid any more.[3]

11.16 While attitudes revealed in the institution discussed above are not necessarily typical they point to difficulties in staffing and training of animal house staff particularly in smaller institutions.

11.17 Mr I. Harris, Director of the University of Queensland Central Animal House, expressed the following view:

> The problem now, I think, is nowhere near as acute as it might have been in the past ... Most large institutions around Australia are now employing trained people and actively encouraging people to be trained. The problem, where it exists, tends to be in smaller places.[4]

11.18 During inspections at two universities, the Committee encountered a disregard for animal house rules by some experimenters. Other anecdotal information from a range of sources drew attention to either the unthinking or even the cavalier attitude being taken by a minority of experimenters towards animal houses and their staff. The AATA submitted:

> Animal technicians who remain in the field for any length of time develop a real concern for the welfare of the animals in their charge. Conflict with the animal experimentation practices of some scientists sometimes occurs in experimental animal houses. Given the lowly status of the animal technicians, their views are likely to be ignored in such a situation. In institutions where technicians do not have access to an animal house veterinarian or animal welfare officer, the resolution of such conflicts can be very difficult.
>
> The A.A.T.A. believes that all institutions working with experimental animals should have an animal house veterinarian or animal welfare officer to whom technicians can take their problems in this regard.[5]

11.19 With the trend towards appointing more veterinarians to oversee the operations of animal houses, particularly in the larger institutions, there should be a diminution of this problem. In addition, if the number of animal houses contracts, many of the smaller animal houses will disappear. All the evidence points to the worst problems occurring in those areas. However, even professional staff sometimes have difficulties with some experimenters. It is essential, therefore, that written procedures be adopted to enable difficulties between experimenters and animal house staff to be resolved. Such

difficulties should be brought to the attention of the chairman of the ethics committee and it is his or her responsibility to either rectify the problem or raise it with senior management. Animal house staff must be able to draw attention to improper, inhumane or even illegal practices without any fear of retribution of any kind against them for having raised the matter.

11.20 A number of other difficulties concerning the career options available to animal technicians were raised by the AATA:

> The career structure and promotion opportunities for animal technicians vary widely from institution to institution. In many cases, they lag well behind the opportunities and level of financial reward for laboratory technicians with comparable levels of training. In many institutions it is not recognised as a skilled occupation at all. The fact that it is a small area of employment within some institutions worsens the problem.
>
> The result is that there tends to be a fast turnover in animal technician staff, and the more capable people do not tend to remain in the field very long as they are attracted to better opportunities in other areas.
>
> The A.A.T.A. believes this has a detrimental effect on the quality of experimental animal care, which could be improved if the career structure and promotional opportunities available to animal technicians were comparable to that in other fields with similar training requirements, e.g. laboratory technicians.
>
> Also, in some States, the relevant T.A.F.E. course is not recognized by major employers as providing eligibility for promotion to technical officer grades. This creates a major obstacle to promotion opportunities. This would be overcome if a suitable national core training curriculum was adopted in all States.[6]

11.21 The accreditation of research institutions which is an integral part of the New South Wales Animal Research Act is likely to influence institutional policy on these issues within that State as assessment of the quality and qualifications of the staff is part of the process of accreditation.

Training in Animal Care

11.22 Courses in animal care are currently offered at TAFE institutions in the Australian Capital Territory and every State except Tasmania.

11.23 The publication of a national core curriculum by the Curriculum Projects Steering Group of the Australian Conference of TAFE Directors marks a significant step forward. Core curricula have been agreed upon for both the one year Animal Attendants Course and the four year Animal Technicians Course.

11.24 Work is proceeding in several States to bring animal care courses into line with the core curriculum recommendations. The AATA and ASLAS agreed that adoption by all States and Territories of a common core curriculum would enable greater mobility of staff between States and open up greater options with respect to career paths for qualified staff.[7]

11.25 The Committee encourages the close involvement of employer and industry groups in the development and implementation of new animal care courses. Given the relative shortage of expertise in the laboratory animal area such involvement will be absolutely necessary if standards of teaching and the relevance of courses to students is to be maximised. Priority should be given to the development of ongoing external review and assessment of animal care courses where this does not already exist.

11.26 Providing the resources to implement the curricula effectively is likely to be difficult not only because of direct constraints on finance and equipment but also because of the relatively small size of the industry and hence the lack of appropriately experienced and qualified teachers. Constraints have led to unqualified people being called upon to teach courses in this field.[8]

11.27 One particular development that was drawn to the attention of the Committee has the potential to undermine the effectiveness of even current institutional commitments to upgrading staff qualifications. Dr J. Smith appearing on behalf of the Australian National University pointed out:

> ... while a lot of the TAFE courses are run after normal working hours, there are some that cannot be run after normal working hours for various reasons and people have to be given time off from work to attend tech. With the gradual tightening of the economic situation over the last few years, most animal houses, I think, have been told to increase their efficiency and most have. Part of this is reducing staff because staff is the greatest expense in any animal establishment. A lot of them are reaching the stage where it will be very difficult to give any staff any time off from normal working hours and still maintain their standards of animal care.[9]

11.28 Should this situation occur more widely, the impact on animal welfare both in the long and short term is likely to be substantial and undo much of the progress achieved by the upgrading of facilities that has already occurred. As the Committee argued in Chapter 10, on both welfare and scientific grounds, if animals are to be used in experimentation, facilities and staffing must be of a consistently high standard. This cannot be achieved if research institutions do not have the resources to enable appropriate staff training to be undertaken.

11.29 The Committee RECOMMENDS that all institutions with animal houses require unqualified staff to undertake technical training courses in animal care at colleges of technical and further education.

Professional Staff

11.30 Only the institutions which have a large breeding unit as part of their animal house operations are generally in a position to employ a professional director or manager. Discussing the management of their animal house Professor Cooper explained the difficulties of small to medium sized units in employing full time veterinarians:

> It is again a question of our small size. Ideally, we would like to have somebody with a veterinary qualification in that sort of position, but it is quite clear that the job is not big enough for that. I have alluded in this paper to the fact that we are negotiating with another institution to pay it a retainer and have it act as our veterinary consultant. I may say that we have done very well up until now in getting it free from a number of institutions. So since we cannot appoint at that kind of level, we have appointed at Mr Smallshaw's level, which is at a senior technical level ... It does mean that he has to establish liaison with people off campus to obtain the kind of expertise which we do not have.[10]

11.31 A similar issue was raised by Dr Kuchel. Asked whether it was necessary to employ qualified veterinarians he replied:

> ... with the increased complexity of running research facilities and breeding facilities you need someone with day-to-day administrative and physical control to have veterinary qualifications, so that all of the implications of what is happening at that facility, as far as the researcher is concerned and as far as the breeding program

> is concerned, are picked up as soon as possible and dealt with appropriately. The field of laboratory animal science now is becoming, rather than just an amalgam of general clinical principles, a discipline in its own right that requires, for it to be done properly, the sort of basic sciences background that the degree in veterinary science gives you.[11]

11.32 The Committee acknowledges the difficulty of employing veterinarians in institutions with relatively small animal houses. The best arrangement is to have a veterinarian within the institution or one located nearby to be on call in case of problems. The long-term solution is, however, for the contraction in the number of breeding units and a move towards the centralisation of breeding within a region. In this way, most animals will be bred in purpose-built facilities with professional staff.

CHAPTER 12

INFORMATION AND TRAINING

Introduction

12.1 With State Governments and the Committee opting for enforced self-regulation as the system of administration to control animal experimentation, much responsibility falls on experimenters to fulfil the expectations of the community to maintain a high level of care and welfare in their use of animals. High standards of care and welfare depend on the attitudes and training of and information available to experimenters and animal technicians and attendants. The Committee has already discussed attitudes to the use of animals in experiments in this report. It now examines the role of information and training of experimenters. The training of animal technicians and attendants was covered in chapter 11.

Experimentation Standards

12.2 Representatives of institutions and experimenters generally adopted the attitude during the inquiry of the Committee that experimenters in Australia maintained high standards in the conduct of experiments on animals. Few witnesses questioned the effectiveness of the training and the level of skills of experimenters. An example of this attitude is contained in a special submission made by the Deputy Vice-Chancellor of the University of New South Wales concerning a report which the University had commissioned on animal facilities within the University. The view was expressed in the submission:

Central to this philosophical approach was the creation of an Animal Resources Unit as an academic unit

- to provide professional services to the activities of animal production, and experimentation and public accountability;
- to co-ordinate animal production to support teaching and research activities;
- to provide resources required in animal-based research within the institution in the most cost-effective manner practicable.

According to the report this Unit must be identified as an academic centre and demands on the levels of responsibility and time must be commensurate with other academic appointments.

What this means is that the staff employed in the Unit would spend about one-third of their time on research and would have access to study leave provisions and other benefits accruing to academic staff. In the words of an academic adviser to me on the report

> 'I believe that the creation of the ARU as an academic unit is the dream of many veterinarians involved in animal house management. I suspect such recommendations reveal more about the (academic) aspirations and ambitions of the writers than the needs of the researchers.'

I endorse this view. The rationale for the creation of an academic unit, stated or implied, is that researchers are hopelessly ill-equipped to conduct research on animals. This is patently not true. Researchers at the University of New South Wales will have trained with research groups either in Australia or overseas in which a core of procedures, techniques and animal models are well developed and at the forefront of international practice. The best expertise in the world is available in the University and in Australia and it is simple-minded to assume that our researchers who use animals approach their experimental tasks in a state of ignorance of, and experience in, the latest techniques of animal experimentation.[1]

12.3 The Committee found it ironic when an advertisement appeared in 'The Sydney Morning Herald' of 24 June 1989 for applications for the position of Director of Animal Care at the University of New South Wales. Not only had the University now accepted the need for academic standing for the position, which was stated in the advertisement, but it also had upgraded it to professorial level.

12.4 Further on, the University, commenting on the proposal to establish an Animal Resources Unit as an academic unit, stated:

> The ABHU (the central breeding unit) is in the business of ensuring that animal researchers are provided with experimental animals of the highest quality at least cost and it is expected that those who are in charge of production be doing just that and not carrying out personal research into animal experimentation techniques that may or may not be useful. Nor does the University with its advanced information retrieval systems and well-stocked library in the biomedical sciences see a need in present financial circustances, to provide an information service to researchers who, if the are of the standard we expect in the University, will already be quite aware of, and use, the latest humane and efficient techniques.[2]

12.5 Despite these claims, there are serious criticisms overseas of experimenters' skills and there is enough evidence in Australia to question seriously the claims of many witnesses.

12.6 The Canadian Council of Animal Care prepared a syllabus in 1983 for training of students in laboratory animal science. In its introduction, it is stated:

> A deficiency frequently observed by numerous Canadian Council on Animal Care (CCAC) assessment panels visiting the many institutions in Canada conducting animal based research, teaching and testing, is the number

> of investigators who appear to lack an understanding of the basic principles of laboratory animal science. This is exhibited in many ways ranging from inappropriate animal models and poor experimental design, to inadequate handling methods, poor surgery techniques, which indicate an apparent lack of appreciation of basic surgical concepts, and a failure to recognize and make use of resources available to them.
>
> This deficiency is probably at least partly due to inadequacies in the undergraduate and graduate programs in science and, in addition, to inadequate tutoring or preceptorship, particularly at the graduate level. All too often panels witnessed the propagation by investigators and teachers of poor or antiquated techniques of animal care and use.[3]

12.7 Dr M. Rose drew upon a Handbook published by the Foundation for Biomedical Research in America in her evidence to the Committee. She quoted from the Handbook as followed:

> Environmental and biological factors may profoundly influence data from animal experiments by exerting a subtle influence on animal research and testing. Scientists have begun to appreciate that influence only recently.[4]

Dr Rose went on to refer to a report by the Council for International Organisations in Medical Sciences which is affiliated with the World Health Organization. She told the Commitee:

> In the covering letter to this report, the committee asked CRIMS to convey to WHO its view that for the benefit of health programs everywhere, this activity, the use of animals in research and teaching and testing, should be enhanced and that particular attention should be given to some matters. Its first statement related to education and training. It said that in addition to the development of specific guidelines there was a need for more education and training, both of investigators using animals and of personnel responsible for their handling and care.[5]

12.8 At Monash University in 1981, a review of services of the Central Animal House was done. Two-thirds of the respondents stated that further knowledge about one or more topics contained in a list of 13 topics concerning the use of laboratory animals would be advantageous to their work. In answer to another question, 'In respect of the topics stated above, do you believe that there should be an ongoing programme to keep post-graduates abreast of new developments', 47 of 67 respondents replied 'yes'.[6] There are obviously Australian experimenters who believe that additional information on laboratory animal science would be advantageous to their work.

12.9 At present, most experimenters in Australia learn experimental techniques and practices on the job from the senior experimenters who are their supervisors. Not all senior experimenters have correct techniques or have kept abreast with developments in laboratory animal science. In these cases, bad habits and techniques are passed on to the junior experimenters, who may or may not have such techniques or practices corrected in subsequent appointments. Bad habits are therefore perpetuated. Many experimenters do not know that their experimental techniques are deficient or are out-of-date and resent suggestions that they are.

12.10 The Committee has already referred to the findings of the Canadian Council on Animal Care on this method of training. In the United Kingdom, a Working Party reported in 1983 on courses for experimenters. It stated:

> The system of individual coaching has worked well over a long period and will continue to serve in many circumstances. However, it can be very time-consuming for the senior licensee carrying out the individual coaching, and the tutor is likely to concentrate on the task in hand to the detriment of background information and perspective. It also seems probable that any new legislation concerning animal experiments may require a wider

> understanding of the principles of laboratory animal husbandry and related matters. From such considerations it became apparent that the principle of formal training courses would be generally welcomed.[7]

12.11 Technology can change quickly. New techniques, drugs or changes in experimental design are being developed all the time. Although it is desirable to embrace these changes, it is difficult to get information about them. There is also an inherent resistance to change. If something has worked well for a long time, why change to something new, even if the new product or technique has been proven to be better? There is a reluctance to try an alternative for fear that it will not work as well.

12.12 It must be emphasised that new products and techniques may not only improve animal welfare but may also result in more reliable data. They may also result in lower costs. For example, a new technique may result in fewer animals being used and hence less money spent on the purchase of animals. Animals are often expensive to breed and care for and savings forgone because of resistance to change will lead to fewer funds available for research and teaching.

12.13 Some institutions have held short courses on laboratory animal science for experimenters. The Committee was given information about 'training courses for the research worker' at the University of Melbourne:

> At the commencement of each academic year the University of Melbourne runs a short training course for post graduate students and laboratory assistants embarking on Bio-medical research ... Emphasis in the training program is placed on the law, the relevant Code of Practice and investigator responsibility. Demonstrations cover the proper way to pick up, hold, restrain, administer substances, collect samples and generally care for each of the common laboratory animal species. Investigators are advised where they can go for help and are provided with useful reference material.[7]

12.14 At hearings in March 1987, the Committee was told by representatives of the Department of Physiology and Pharmacology of the University of Queensland that animal care workshops lasting one day were being held for honours year students. An outline of a longer course of one or two weeks duration for undergraduate students had been prepared but had not yet been approved. The Head of the Department, Dr A. Blackshaw, commented that he would like the course extended to post-graduate students.[8]

12.15 Little can be taught in a one day course. It is doubtful that a week is long enough to cover in enough depth the variety of ethical issues, legal and procedural requirements, scientific techniques and animal care and husbandry information that an experimenter needs to know to begin a career involving experiments on animals. Any course or workshop is, however, a step in the right direction and the conduct of such courses is evidence of an awareness within an institution of the need to equip young experimenters with a positive ethical attitude towards experiments on animals and information on scientific techniques and animal care.

12.16 There is no course available in Australia in laboratory animal science. However, the University of Sydney in its submission told the Committee that it was planning to introduce a course in laboratory animal science in the Faculty of Veterinary Science. In referring to this proposal in a public hearing, Professor Titchen of the University of Sydney said:

> These developments would include the development of specialist pathological facilities for monitoring the standards and the care of the common laboratory animals, the development of specialist capacities in the control of pain and the dissemination of knowledge on the techniques of anaesthesia and analgesia in animals. They would include specialist instruction in animal handling. They would also include some level of

> instruction and, perhaps, the performance of experimental surgical procedures. This is an ambitious and expensive undertaking to complete. We see no other way than entering into such an educational program for our undergraduates in science, veterinary science, and the biological sciences, and for postgraduate instruction and to contribute to improvements in animal welfare.[9]

12.17 The University's proposal for a course in laboratory animal science and the preparedness of the University to outlay considerable funds to establish the course is an acknowledgement of the need for such a course in Australia. The University has also sought additional funding from the Commonwealth Government under its key centre scheme.

12.18 The Committee considered the proposal and RECOMMENDS that extra funds be made available by the Commonwealth Government to enable the University of Sydney to establish a course in laboratory animal science.

12.19 Earlier in the inquiry the University of Queensland proposed the establishment of a course on animal welfare and behaviour. In a written proposal, the University said:

> Current public interest in animal welfare issues is high. Livestock industries are in the process of preparing codes of practice for domestic animals. These efforts ... have highlighted many aspects which need proper scientific investigation (e.g. mulesing, tooth and nail clipping, branding, transport, intensive housing, reproductive behaviour, etc.). In addition, topics such as the role and use of companion animals, the use of animals for entertainment and research, and the behaviour and management of wild animals are all due for consideration. Scientific investigations into most of these topics are few, fragmented and they lack focus ...

> A Chair in Animal Behaviour and Welfare would act as a focal point for research and expertise in the above areas. Whilst requiring Governmental support for establishment, there is every indication that it would attract support from groups and industries interested in, or concerned about, animal welfare. The Senate Select Committee on Animal Welfare could envisage such a Chair as a positive contribution towards the welfare of all animals with which humans are associated. In addition, this Chair would be an invaluable aid ... to the public in providing factual and impartial evidence on many contentious issues.[10]

12.20 There are many areas of animal welfare that need further research in order to refine current procedures and practices or to find alternative ways of solving husbandry and other problems. Animal behaviour is a component of animal studies, albeit an important component. However, the focus of the course should be on animal welfare generally rather than on animal behaviour. With that qualification, the Committee supports the proposal. The Committee RECOMMENDS that funds be made available to the University of Queensland to establish a chair in animal welfare and behaviour.

Australian Council for the Care of Animals in Research and Teaching

12.21 For some years there has been a move to establish an Australian Council for the Care of Animals in Research and Teaching (ACCART) based on the model of the Canadian Council on Animal Care. This has been in response to the perceived need to improve the flow of information to experimenters and to provide a resource centre for experimenters who need particular information which may not be readily available from institutional libraries and other normal sources.

12.22 In a submission to the Committee, ACCART stated that it was established as an independent body:

> ... to provide a national forum for effective communication between persons with concerns for the care and use of animals in research and tertiary teaching, and to provide information and advice on optimal standards for their care and use.[11]

12.23 Although ACCART was modelled to some extent on the Canadian Council on Animal Care, after lengthy deliberations among the proponents (AVCC, CSIRO and NHMRC) and other interested organisations, it was decided to exclude accreditation, a major function of the Canadian Council, from the role of ACCART. It was decided that accreditation should remain the responsibility of State Governments.

12.24 As at August 1988, 16 organisations had joined ACCART and another had been granted observer status at its own request. Although both ANZFAS and RSPCA Australia had been invited to join, neither has yet accepted the invitation. ACCART so far lacks input from animal welfare organisations. The Committee believes that animal welfare organisations have a contribution to make to ACCART as ACCART will be preparing and publishing information on a wide range of technical and other matters relating to the use of animals in experiments. The Committee has often espoused the need for discussion among the parties to the animal welfare debate. ACCART will provide an ongoing forum for discussion on issues relating to animal experimentation and it is an opportunity for animal welfare organisations to participate in the work of the Council bringing a different perspective from the other members. The exchange of ideas in a neutral forum will help to find a middle ground on issues where there is a difference of opinion and so enable enduring improvements to animal welfare to be made.

12.25 It was suggested at one stage that ACCART be made an advisory committee to a Commonwealth Minister. The strength of ACCART is its independence from government. It can draw on a wide range of expertise in Australia to provide information and other resources. It can and should give technical advice to government and government authorities, as well as to institutions and individual scientists. The fact that it is not beholden to any government means that it will be accepted more readily by the scientific community.

12.26 ACCART will also provide a forum for Australian and overseas experts to focus attention on a range of animal experimentation matters. Through seminars and conferences, run either by ACCART itself or in association with specialist bodies, such as ASLAS, complicated or controversial issues can be discussed to enable experimenters to keep abreast of developments in these fields.

12.27 Although ACCART's commencement was delayed, despite the efforts of the AVCC and the CSIRO, which were two of the three sponsors of the organisation, it has quickly made its mark with the publication of a newsletter, which has received wide acclamation overseas. Several monographs are also in production. ACCART is beginning to fulfil its important role of disseminating information to the scientific community, filling the void which has existed for a long time.

CHAPTER 13

ANIMAL WELFARE ADMINISTRATION IN AUSTRALIA

Introduction

13.1 The Committee believes it is timely to consider the administration of animal welfare in Australia in this report. Administration of animal experimentation is intertwined with the administration of general animal welfare matters in some States so that consideration of one and not the other would be impractical.

13.2 The administration of animal welfare falls into two areas - the legislative, regulatory and administrative framework on the one hand and operational matters on the other. In this report the Committee will address the former but not the latter. Operational matters, such as the day-to-day administration of prevention of cruelty to animals legislation and the funding of animal welfare organisations with statutory responsibilities, will be examined and reported on later in the Committee's inquiry.

Commonwealth/State Responsibilities

13.3 Under the Commonwealth Constitution, animal welfare is mainly a State responsibility. The Commonwealth Government has direct responsibility for quarantine, customs, exports and imports. It also has other responsibilities which arise indirectly from its activities in the field of foreign affairs. Under the latter, for example, the Commonwealth has to deal with

animal welfare issues on a government to government basis and act as a focal point for other overseas interests in animal welfare in Australia. In recent years, overseas concern about the killing of kangaroos and the helicopter shooting of horses and buffalo, among other issues, has generated considerable work for the Commonwealth Government. It has had to respond to numerous letters from overseas and to defend Australian policies and practices in a number of overseas forums, particularly in Europe and the U.S.A.

13.4 Nevertheless, most animal welfare issues remain State responsibilities. In each State and Territory there is legislation for the prevention of cruelty to animals.

13.5 The legislation in New South Wales, Victoria and South Australia was significantly revised between 1985 and 1986 to take account of changing community attitudes to the use and care of animals. In New South Wales the Government enacted separate legislation (the Animal Research Act 1985) to control the use of animals in research and teaching.

13.6 In Queensland, the Government recently advertised a review of the Animals Protection Act. A wide review of the Prevention of Cruelty to Animals Ordinance 1959 has been done in the A.C.T. The period for public comment on the report of the review has closed and new legislation may be prepared later in the year. A little work has been done on revising the Western Australian Prevention of Cruelty to Animals Act 1920-1976. As far as the Committee can find out, no work has been done to update the Tasmanian Cruelty to Animals Prevention Act 1925 or the Prevention of Cruelty to Animals Act in the Northern Territory.

13.7 Under the revised legislation, animal welfare advisory councils (AWAC) have been appointed in New South Wales, Victoria and South Australia. In New South Wales, in addition to the AWAC, an Animal Research Review Panel has been appointed under the Animal Research Act 1985.

13.8 These three States have adopted a new participative approach to animal welfare administration by including on the advisory councils representatives of a range of animal welfare, community, user and government interests.

13.9 There are two main Commonwealth/State organisations which have been involved in animal welfare issues - the Sub-Committee on Animal Welfare of the Australian Agricultural Council (SCAW) and the Joint Animal Welfare Council (JAWC). SCAW's main function has been to prepare codes of practice for farm animal husbandry and transportation. It was also involved in the preparation of the 1985 edition of the Code of Practice for the Care and Use of Animals for Experimental Purposes and in the current revision of the Code of Practice.

13.10 JAWC comprises the Chairmen of State AWACs and the officers responsible for the administration of animal welfare in the States, Territories and the Commonwealth. At present, membership has been limited to those States which have appointed AWACs, but observers from Western Australia, the A.C.T., the Northern Territory and the Commonwealth have attended meetings.

13.11 The main purpose of JAWC is to provide a forum for State, Territory and Commonwealth animal welfare administrators and representatives of AWACS to discuss issues of mutual concern with a view to the States and Territories adopting, where possible, a common approach to them.

13.12 Because only three States have appointed AWACs, JAWC is still in its formative stage. Nevertheless, it has successfully brought together representatives from States and Territories to consider various animal welfare problems.

13.13 A number of organisations in their original submissions proposed a national structure for animal welfare administration in Australia. These proposals centred on the Commonwealth Government playing a key role in developing and co-ordinating animal welfare policy. These proposals are outlined below.

13.14 In its original submission, ANZFAS proposed that the Commonwealth Government assume responsibility for animal welfare in Australia and establish a statutory authority to administer it nationally. ANZFAS acknowledged that there was no constitutional head of power under which the Commonwealth could make laws concerning animals, but stated that:

> ... reliance upon a combination of existing heads of power capable of application to animals and their welfare would suffice to create a statutory authority equipped to play a significant role in animal welfare in Australia. Perhaps, such existing heads of power could be amplified by co-operation amongst the States.[1]

13.15 ANZFAS recommended the assumption of responsiblity by the Commonwealth Government for animal welfare in order to achieve a greater uniformity in the regulation of animal welfare among the States and Territories. As mentioned above, there are significant differences of approach among the States, although the establishment of JAWC is an acknowledgement of this problem and a realisation that a more uniform approach is desirable.

13.16 In its submission to the Committee in 1984, RSPCA Australia stated its belief that:

> ... to achieve a satisfactorily co-ordinated overview of animal welfare in this country, the Government, through the Minister of Primary Industry should be the controlling influence.[2]

13.17 RSPCA went on to recommend that it become a consultative body to the Minister, situated between the Minister and a proposed national animal welfare advisory committee in the flow chart in the submission.[3] The State Governments would be represented through the Australian Agricultural Council. Both the Council and the advisory committee would be served by the then Australian Bureau of Animal Health (ABAH) within the Department of Primary Industry.

13.18 At the time of the RSPCA's submission, there was a strong body within ABAH supportive of animal welfare. Since then, ABAH has undergone several metamorphoses and the animal welfare function of ABAH has disappeared. Such matters have been dealt with by one division or another as necessary, but no division has displayed any interest in handling animal welfare on a long-term basis.

13.19 The Australian Veterinary Association (AVA) also proposed the establishment of a national animal welfare advisory council in its submission to the Committee in 1984. In this proposal, the role of the advisory council would include the provision of a forum for discussing animal welfare issues; the identification and promotion of research into animal welfare matters and the supervision of the allocation of funds for that research and advice to governments on animal welfare and the need for legislation.

13.20 It should be remembered that these recommendations for the establishment of a national animal welfare advisory committee were made four or five years ago before three of the State Governments had revised animal welfare legislation and established or expanded animal welfare units within their administrations.

13.21 Until 1985, the States had kept a low profile in animal welfare matters. On the other hand, ABAH was playing a leading role in promoting animal welfare. It was natural, therefore, for organisations that sought change in animal welfare policies and practices to focus attention on ABAH and to formulate a structure for the administration of animal welfare with ABAH playing a central role.

13.22 With the demise of ABAH and the moves by State and Territory Governments to take control of animal welfare, the situation is now very different to that which prevailed in 1984.

13.23 In October 1988, following representations from RSPCA Australia, the Minister for Primary Industries and Energy proposed the appointment of a national animal welfare consultative council. The proposal was along the lines of the RSPCA's recommendations although it did not encompass the wider framework as contained in RSPCA's submission to the Committee. It also did not address the potential overlap of functions between the consultative council and SCAW.

13.24 There are major problems with the establishment of a national AWAC, given that constitutional responsibility for animal welfare rests largely with the States.

13.25 The problems can be most clearly identified by considering the lines of authority for implementing advice given by an advisory body. If the person to whom the advice is given has no authority to take action on that advice, it is questionable whether there is justification for that person having a body to advise him.

13.26 A national AWAC would obviously advise a Commonwealth minister on matters for which that minister had responsibility and authority. These are, as mentioned earlier, few in number.

13.27 It is incongruous for State Government representatives on a national AWAC to advise a Commonwealth minister on any matter for which responsibility and authority is vested in State and Territory ministers. For that advice to be implemented, the Commonwealth minister would have to approach the State and Territory ministers asking them to take action. If the State representatives on a national AWAC had assented to particular advice being given to the Commonwealth minister, they would, presumably, in most cases have already taken up the matter with their State AWACs and cleared it with their ministers beforehand. It would therefore be unnecessary for a Commonwealth minister to ask the State ministers to take action on a particular proposal because the State ministers would already have agreed to it.

13.28 With the States and Territories progressively moving to take up animal welfare responsibilities in an active way, there is no prospect of the State Governments voluntarily handing over their responsibilities to the Commonwealth Government. The Commonwealth Government has also shown no inclination to use indirect constitutional mechanisms, if in fact they exist, to usurp those responsiblities. Without a political willingness to transfer responsibility for animal welfare from the States and Territories to the Commonwealth, there is no point in pursuing an approach which is fraught with political and administrative difficulties.

13.29 Even if the Commonwealth were to take on responsibility for animal welfare, it would either depend on the States for much of the administration or it would have to assemble a large bureaucracy to oversee the administration of animal welfare. In the current economic climate of restraint on government spending, the latter is neither desirable nor practicable. If the Commonwealth were to devolve the administration of some of its animal welfare programmes to the States, the question might be asked as to why the States gave up the responsibility in the first place.

13.30 However, even if devolution occurred, there is no assurance that uniformity in approach by the participating States would continue. During its examination of the live sheep export industry, the Committee found significantly different approaches being taken among the State authorities acting on behalf of the Commonwealth Government. There was also a lack of will on the part of the Commonwealth authority to maintain a common approach or uphold uniform standards.

13.31 Without national responsibility for animal welfare in the hands of the Commonwealth Government, there is little point in having a national AWAC responsible to a Commonwealth minister. The minister would have no responsibility to take action on the advice of the AWAC, except in those matters where the Commonwealth has a constitutional responsibility, because responsibility is vested in the States.

13.32 Although the Committee does not see the point in the establishment of a national AWAC, it does acknowledge the need for the Commonwealth to have a source of advice on its own areas of responsibility and on those matters which arise in Commonwealth-State forums or are raised in international forums.

13.33 In a supplementary submission dated November 1988, the CSIRO recommended to the Committee that it support the establishment of a Commonwealth AWAC, the main function of which would be to provide advice to the Commonwealth Government. The AWAC would comprise representatives of several Commonwealth Government departments and authorities as well as a number of national organisations, such as ANZFAS, RSPCA Australia, the AVA, the NFF and so on. It also argued that it would be preferable for the AWAC to be responsible to a neutral minister who would not be placed in a position of a potential conflict of interest.

13.34 For a Commonwealth AWAC to be effective, the Minister to which it provides advice has to have responsibility and authority for animal welfare matters across the spectrum of Commonwealth interests. At present, responsibility is spread over a number of ministers. Therefore Cabinet would need to devolve responsibility for animal welfare to one minister.

Federal System

13.35 Having come to the conclusion that a system of animal welfare administration based on Commonwealth primacy is not practicable either politically or operationally, the Committee turned to a federal system.

13.36 An important principle has already been included in animal welfare arrangements in New South Wales, Victoria and South Australia - the participation of animal welfare, community and user representatives in the administrative and policy process. This is necessary if there is to be future co-operation and development of effective animal welfare policies which have broad community support. It cannot be emphasised enough the role which these representatives play. Without this community representation, polarisation of the interests in the debate will lead to more bitter confrontations which can only disrupt the progressive development of policies and programmes to enhance animal welfare in Australia.

13.37 Another essential element in an effective administrative system is extensive consultation and co-operation with other interested organisations which are not represented on the AWAC. By developing policies and practices in conjunction with interested bodies, there will be a greater likelihood of support and co-operation by the organisations and their members.

13.38 Over the period that they have been operational, the three State AWACs have already shown their value.

13.39 The Committee believes that each State and Territory should establish an AWAC along the lines of the three already in existence. Each should be responsible to a neutral minister and served by an animal welfare secretariat in the minister's department. For example, in New South Wales, the Minister for Local Government has responsibility for animal welfare matters while in South Australia, that responsibility is vested in the Minister for Lands.

13.40 Legislation in States and Territories other than New South Wales, Victoria and South Australia needs to be updated to cover the revised administrative arrangements and to provide for regulations which might also include codes of practice.

13.41 Although each State and Territory has responsibility for most animal welfare matters within its borders, there is a need for the States and Territories to achieve as much uniformity as possible in legislative and regulatory requirements and in animal practices. A similar approach should be taken even if identical requirements cannot be achieved because of different environmental and other factors prevailing among the States and Territories.

13.42 As responsibility for animal welfare is vested ultimately in ministers responsible for animal welfare in the States and Territories, questions of uniformity of approach should be considered by them. In many areas of Commonwealth/State relations, there are ministerial councils comprising Commonwealth, State and Territory ministers. It would be appropriate for a council of animal welfare ministers to be established when most States and Territories have appointed AWACs and have updated animal protection legislation.

13.43 If a ministerial council for animal welfare were formed, JAWC would become the standing committee to function along similar lines of standing committees associated with other ministerial councils.

13.44 Until such time as a ministerial council for animal welfare is formed, JAWC should continue to meet to discuss animal welfare matters at AWAC and officer level. Rather than meet annually as it has done, it should meet quarterly to enable more timely discussion of issues as they arise. Throughout the inquiry, the need for uniformity has continually been advocated. At least discussions within JAWC will increase the opportunity of similar or uniform approaches being taken among the States and Territories. Each State and Territory Government will still retain the right to implement policies and enact legislation which it thinks will best enhance animal welfare within its jurisdiction. However, any Government will at least have the benefit of broad advice, not only from its own advisory council but from experience obtained in other States and Territories, before it makes its decisions.

13.45 It is also hoped that JAWC will provide a continuing service distributing information about animal welfare matters among the States.

13.46 The Committee RECOMMENDS that all States and Territories upgrade animal welfare legislation, and establish animal welfare advisory councils and departmental animal welfare units as has been done in New South Wales, Victoria and South Australia.

CHAPTER 14

CURRENT REGULATORY SYSTEM

Introduction

14.1 Significant changes in the regulation of animal experimentation in Australia have occurred within the last ten years. These changes have been made both by the scientific and educational community and by government. The former has developed a code of practice, set up ethics committees and has generally taken steps to promote a more ethical approach to animal experimentation and animal welfare. The latter has begun to update legislation and improve the regulation of animal experimentation.

14.2 In this chapter, the evolution and the current state of the regulatory system are described.

Evolution of the Code of Practice

14.3 Until recently, government had taken a mainly non-interventionist role in the control of animal experimentation. It was left to the scientific and educational community to regulate itself. In 1965 the NHMRC began work on a code of practice which was issued in 1969. Its stated aim was to define a code of conduct which would encourage humane treatment of experimental animals. The code was designed to promote awareness of animal ethics and welfare but not to provide mechanisms for accountability.

14.4 In 1979, the NHMRC and CSIRO jointly revised the Code of Practice. An important inclusion in this edition was the requirement for institutions to establish ethics committees.

14.5 In the 1982 revision of the Code of Practice, provisions were included to make ethics committees more accountable to the wider community. The ethics committee had to include a person not employed by the institution to represent community interests and the committee had to maintain a register of all approved research.

14.6 The next edition of the Code of Practice was issued in April 1985. This edition was endorsed by the Australian Agricultural Council as well as by the NHMRC and CSIRO.

14.7 The fifth edition of the Code of Practice is in draft form. It has been endorsed by the NHMRC but is awaiting the endorsement of its other sponsor bodies and State Governments. It both tightens up and clarifies some of the provisions of the previous edition. It also sets out more clearly the responsibilities of institutions, ethics committees and experimenters in relation to animal experimentation.

14.8 The NHMRC, as now do many other funding bodies, requires applicants for funds and their institutions to comply with the provisions of the Code of Practice. Until recently, as mentioned later in the report, the NHMRC did nothing to ensure compliance with the Code of Practice by experimenters and institutions.

Legislation

14.9 Except for New South Wales, legislative provisions dealing with animal experimentation are contained in State and Territory prevention of cruelty to animals legislation. Until 1985 and 1986, such provisions were cursory at best, with Tasmania merely exempting animal experimentation from the cruelty

provisions of the legislation. Regulations provided for in the Queensland legislation have never been made rendering that legislation ineffective. Since 1985 three States have revised legislation providing a legislative framework within which animal experimentation can be controlled and monitored by the governments in those States.

14.10 The Committee now briefly describes the main provisions of State and Territory legislation.

New South Wales

14.11 Unlike the other States, the New South Wales Government decided to enact separate legislation to control animal experimentation rather than include it in prevention of cruelty to animals legislation. The New South Wales Government took this decision because it believed that the community's attitude to animals had changed and that it was no longer appropriate to consider animals used in experiments just from the point of view of cruelty. The philosophy of the legislation is summarised in the following terms:

> ... the twin tenets of this legislation are the concepts first of enforced self regulation and second of public participation in the decision-making process.[1]

14.12 The Act requires the accreditation of institutions in which animal experimentation is conducted. Individuals doing experiments on animals must either be authorised by an accredited institution or, if the research is not done within an accredited institution, licensed by the Secretary of the Department of Local Government. It is a precondition for accreditation that an institution have established a properly constituted animal care and ethics committee.

14.13 The animal care and ethics committee required under the NSW legislation has the following functions:

> (a) the making of recommendations concerning the granting of animal research authorities by the establishment;
> (b) the supervision of the carrying out of animal research by holders of animal research authorities granted by the establishment; and
> (c) such other functions may be conferred or imposed on it by the Code of Practice.[2]

14.14 Animal care and ethics committees may also be appointed by the Secretary of the Department of Local Government to supervise the research of the holders of individual research licences.

14.15 The constitution and procedures of these committees will be prescribed by regulation. The Act, however, does require that at least one member of such a committee be a person who is neither associated with any accredited research establishment nor involved in the conduct of, or the supply of animals for, animal research.

14.16 The Act also requires that an animal supplier's licence be obtained by a person wishing to supply animals for use in animal experiments.

14.17 The Act provides for a code of practice to be prescribed in regulations. This may be the NHMRC/CSIRO/AAC Code of Practice, an amended form of it or an entirely different code of practice.

14.18 The Act also establishes the Animal Research Review Panel which has the following responsibilities:

- investigation of applications for accreditation by corporations or for individual licences and reporting on them to the Secretary of the Department of Local Government;

- investigation and report to the Secretary on complaints of breaches of conditions upon which accreditation was granted, or upon which research or animal supplier's licences were issued;

- investigation of matters relating to the conduct of animal research and the supply of research animals;

- investigation and evaluation of the efficacy of the Code of Practice in regulating animal research; and

- such other functions as the Minister may confer upon it.[3]

14.19 The Secretary of the Department of Local Government, not the Panel, issues licences and grants accreditation or cancels or suspends them where breaches of conditions have occurred. The Secretary is obliged to refer matters to the Panel but is not obliged to act in accordance with its reports. Appeals from decisions of the Secretary may be made to the District Court.

14.20 The Act provides for the appointment of inspectors, who must be registered veterinary surgeons. They are given powers to enter research establishments, search for and examine animals, equipment and documents connected with animal experimentation.

Victoria

14.21 The Prevention of Cruelty to Animals Act was revised in 1985 to provide, among other things, a legislative framework for the control of animal experimentation in the State.

14.22 The Act provides for the supervision of animal experimentation at three levels:

a) ethics committees operating within institutions;
b) peer review committees; and
c) authorised inspectors appointed by the Minister.

14.23 Provision is made for the registration of experimenters as well as for the licensing of scientific establishments and breeding establishments.

14.24 To gain registration as an experimenter, a person must be a legally qualified veterinarian, dentist or doctor, or must hold a masters or doctoral degree in animal biology. Experimentation in a licensed scientific establishment must be done under the direction or supervision of a registered experimenter.

14.25 An animal experimentation ethics committee (ethics committee) must be set up by a scientific establishment as a condition of obtaining a licence. The Act does not specify qualifications for membership or the number of members. There is provision to make regulations on such matters. The committee must, however:

- approve all research by persons other than registered experimenters and ensure that such research is supervised by a registered experimenter;

- approve, before commencement, all 'scientific procedures' carried out at a scientific establishment and all field work.

14.26 An ethics committee must also give prior approval to 'scientific procedures' proposed by registered experimenters.

14.27 Ethics committees must report to the licensing authority (the Director-General of Agriculture and Rural Affairs) on all approvals granted for work conducted outside the institution.

14.28 The Act provides that the Minister may establish peer review committees and determine terms of reference for these committees, in relation to any aspect of scientific procedures or scientific research at one or more licensed scientific establishments. These committees are intended to be investigatory and advisory and are to have at least five members - one with experience in animal welfare and the remainder with expert knowledge relevant to the inquiry. A peer review committee on lethal dose testing has been appointed.

14.29 The third level of supervision is provided by inspectors ('authorised officers'). They are appointed by the Minister and may enter premises, inspect animals and facilities, issue orders requiring the treatment, feeding, housing or destruction of animals, and require persons to provide information. Five inspectors have been appointed.

14.30 The Act itself does not set out standards for the welfare of animals. The intention is that standards should be set in codes of practice which may be varied or revoked by the Minister with the approval of the Governor in Council. The NHMRC Code of Practice has been incorporated in the Code of Practice Relating to Animal Experimentation gazetted in the Victorian Government Gazette of 4 March, 1987.

South Australia

14.31 The South Australian Government revised the Prevention of Cruelty to Animals Act in 1986.

14.32 Under the revised Act, institutions or organisations are licensed by the Minister (the Minister for Lands has responsibility for this legislation) and employees of those bodies do not have to be licensed individually to conduct experiments on animals. The Act is worded in a way to allow an individual to be licensed if that person does not belong to a licensed body, provided that the person meets the criteria required for licensing.

14.33 The establishment of an ethics committee of the type specified in the Act may be among the conditions imposed on the licensee at the discretion of the Minister. However, the Minister's second reading speech on the legislation stated:

> Research or teaching institutions will be required to create Animal Ethics Committees to examine and approve all work using animals. Ethics committees will also have responsibility to ensure that animals used in their institutions are humanely treated.[4]

14.34 The composition of an animal ethics committee, at the institutional level, is to consist of at least four members appointed by the Minister - of whom at least one shall be a veterinary surgeon; one a person engaged in teaching or research involving animals; one a person responsible for the daily care of research/teaching animals; and one a person 'with an established commitment to the welfare of animals'.

14.35 The functions of an animal ethics committee include: approve the use of animals in the experiments proposed by the licence holder; approve the acquisition of animals by the licence holder; ensure that animals involved in teaching or research are treated humanely and relevant regulations complied with; and prepare annual returns for the Minister.

14.36 There is a right of appeal to the Minister against any decision of an animal ethics committee, with a further right of appeal to the Supreme Court.

14.37 The Act also establishes an Animal Welfare Advisory Committee, consisting of eight members appointed by the Governor.

14.38 The functions of the Advisory Committee are to advise the Minister on the operation and administration of the Act, which covers a wide range of animal welfare concerns in addition to animal experimentation; to report on legislative proposals; to examine proposed codes of practice; and to report on matters referred to it by the Minister. The Committee has no role in the granting or revoking of licences.

14.39 It is intended that detailed standards be set by way of regulation. This includes incorporation of a code of practice into the regulations.

14.40 Because the current Code of Practice is undergoing revision it has not been incorporated into regulations. Until the revised code is available, it has been a condition of licences that all experiments on animals will be conducted in accordance with the current Code of Practice, where that Code does not conflict with the Prevention of Cruelty to Animals Act 1985.

Tasmania

14.41 The relevant act is the Cruelty to Animals Prevention Act 1925.

14.42 With respect to animal experimentation the Act is permissive rather than regulatory. The relevant section of the Act reads as follows:

5 - (1) Any person who does any act or omits any duty whereby unnecessary suffering is caused, or likely to be caused, to any animal shall be deemed guilty of cruelty to such animal.

(2) Without limiting the generality of subsection (1), but subject to the provisions of subsection (3), the following acts and omissions shall constitute cruelty to the animal concerned ...

(g) Except for medicinal or curative purposes or for the purposes of scientific research, administering to it any drug or any toxic or noxious substance;
(h) Except for the purposes of scientific research, wilfully and unreasonably administering to it any poisonous or injurious drug or substance.

14.43 In Tasmania, therefore, there is no legislative framework for the regulation of animal experimentation.

Queensland

14.44 Legislative requirements for the regulation of animal experimentation are included in the Animals Protection Act 1926-1981.

14.45 The relevant section of the Act contains the following provisions:

7. Exemptions. (1) Except as hereinafter provided, nothing in this Act shall render unlawful ...
(f) Any vivisection or other experiment performed on any animal in accordance with regulations made by the Governor in Council for the humane conduct of such experiments, by any person who is (pursuant to such regulations) duly authorised by the Home Secretary to perform such experiments;
(2) The exemption in this section contained shall not take effect:

(a) In any case of ill-treatment; or
(b) In any case of vivisection or other experiment as described in paragraph (f) of subsection one hereof wherein the following conditions are neglected, that is to say:-
(i) The operation shall be performed in accordance with the said regulations;
(ii) The animal subject to the operation shall, during the whole time thereof, be so under the influence of some anaesthetic as to be insensible to pain;
(iii) When the animal has in the course of the operation been so injured that its recovery would involve serious suffering, it shall be destroyed while still insensible in accordance with the said regulations;
(iv) An animal which has suffered one operation shall not be subjected to another.

14.46 Provision is made for the making of regulations to control both animal experimentation and the granting of authorisations to carry out such experiments. However, no regulations have been made under this section of the Act. Regulation of animal experimentation by the State government has therefore been inoperative.

14.47 The Queensland Police Department, which administers the Animals Protection Act, is reviewing animal welfare legislation and advertised in January this year for written submissions with a closing date of 25 March 1989.

Western Australia

14.48 The regulatory provisions dealing with animal experimentation are contained in the Prevention of Cruelty to Animals Act 1920-1976. These provisions are similar to those contained in the Queensland legislation. They are as follows:

6. (1) Except as hereinafter provided, nothing in this Act shall render unlawful:

(f) any vivisection or other experiment performed on any animal in accordance with regulations made by the Governor for the humane conduct of such experiments, by any person who has (pursuant to such regulations) been duly authorized by the Governor to perform such experiments, and whose authority in this behalf the Governor has not withdrawn; or
(g) any operation of the nature of an inoculation or of a feeding experiment.
(2) The exemption in this section contained shall not take effect:

(a) in any case of ill-treatment; or
(b) in any case of vivisection or other experiment as described in paragraph (f) wherein the following conditions are neglected, that is to say:-
(i) the operations shall be performed in accordance with the said regulations;
(ii) the animal subject to the operation shall, during the whole time thereof, be so under the influence of some anaesthetic as to be insensible to pain;
(iii) when the animal has in the course of the operation been so injured that its recovery would involve serious suffering, it shall be destroyed, while still insensible;
(iv) an animal which has suffered one operation shall not be subjected to another.

14.49 Regulations have been made under this Act. They are entitled: 'Prevention of Cruelty to Animals Act - Control of Vivisection and Experiments Regulations, 1959 ...' They make provision for the issuing of an authority to perform vivisection and experiments, the attachment of conditions to the authority, the withdrawal of an authority, the regulation of operations and the supply of information on experiments by authorised persons to the Commissioner of Public Health.

Australian Capital Territory

14.50 Animal experimentation in the A.C.T. is regulated by the Prevention of Cruelty to Animals Ordinance 1959.

14.51 As in the Western Australia and Queensland Acts experiments and vivisection are excluded from the definition of acts of cruelty and aggravated cruelty. The Ordinance states:

> 7. The last two preceding sections of this Ordinance do not apply to an act done:
>
> (c) in an experiment or vivisection performed on an animal for the purposes of scientific investigation in accordance with conditions, if any, determined by the Minister of State for Health by a person, or by a person acting under the direction, control and supervision of a person, who-
> (i) is a legally qualified medical or veterinary practitioner, or being a graduate of a university, is engaged in biological research; and
> (ii) is authorised by the Minister of State for Health, to perform experiments and vivisections on animals.

14.52 The power to issue authorisations was delegated by the Minister of Health to the Chairman of the A.C.T. Health Authority some years ago. However, the abolition of this office was announced in September 1987, by the Minister for Arts, Sport, the Environment, Tourism and Territories.

14.53 A review of the Ordinance has been completed and the draft revised policy has been subject to public comment. However, with the recent transfer to self-government, the new Legislative Assembly has not yet had time to consider the revised policy and pass legislation to bring the policy into effect.

Northern Territory

14.54 Provision for the regulation of animal experimentation is contained in the Northern Territory of Australia Prevention of Cruelty to Animals Act.

14.55 Animal experimentation is exempted from being classed as acts of cruelty as defined by the Act under certain conditions. The provision reads:

> 21. Exemptions
> (1) Except as hereinafter provided, nothing contained in this Ordinance shall apply to any act done in any of the following cases:
>
> (d) In any experiment or vivisection performed upon any animal by any legally qualified medical practitioner or veterinary practitioner or any officer authorised by the Minister, for purposes of scientific investigation;
> (2) Nothing contained in subsection (1) shall apply to any case where an animal is ill-treated, or pain is unnecessarily caused to any animal, by any person.

14.56 The authorisation provision is, to all appearances, not being used at all.

CHAPTER 15

PROPOSED REGULATORY SYSTEM

Introduction

15.1 There are a number of ways in which animal experimentation can be administered and those are examined in this chapter in the light of Australian and overseas experience. The various administrative systems mainly differ according to the level of government involvement.

15.2 At one end of the spectrum is a system in which there is no government control or intervention, with all decisions on animal experimentation being taken by institutions within which the experiments will be performed. Before 1985, a self-regulatory system similar to that described was in place. The only external control was a requirement by a number of funding bodies for experimenters and institutions to comply with the Code of Practice. However, monitoring by funding bodies for compliance with the Code of Practice was virtually non-existent. It was left to the integrity of institutions and their sense of responsibility to ensure that animal experimentation was performed in accordance with the Code of Practice. In many institutions, responsibility was largely devolved to the experimenters themselves.

15.3 At the other extreme, one can have a totally regulated system where government takes responsibility for approving protocols involving experiments on animals and for monitoring to ensure that stipulated standards of animal use and care are adhered to by experimenters and institutions.

Regulation or Not

15.4 Within most areas of animal welfare, the basic question which is always raised is whether to have some form of government regulation or none at all. Animal welfare organisations have generally advocated government regulation while users of animals have supported self-regulation with little or no government involvement.

15.5 Until recently in Australia, animal experimentation was conducted with virtually no interference from government authorities. Before the introduction of ethics committees, there was no mechanism for reviewing protocols to determine whether research projects were designed in accordance with the provisions of the Code of Practice.

15.6 The history of ethics committees in Australia, as evinced by the Committee, is one of varying levels of success, with some acting merely as a facade to keep authorities and the community at bay. Others have diligently applied themselves to the task of examining protocols to ensure that ethical standards are maintained and that protocols comply with the Code of Practice. There is no doubt, however, that in recent years there has been a marked change in attitude towards the functioning of ethics committees with the result that many more ethics committees now operate in accordance with the Code of Practice.

15.7 In its submission ANZFAS argued:

> In order to achieve uniformity throughout the country in such matters as the assessment of research protocols by AEECs, the issue of licences, animal care and husbandry etc, ANZFAS recommends a comprehensive network of monitoring bodies be established. This network would vest some control at state level while ensuring consistency between states through the establishment of a statutory national body.

> The monitoring network must include checks and balances to achieve the objective of rigorous monitoring of animal experimentation. The network would incorporate:
>
> . institutional animal experimentation ethics committees (AEECs),
>
> . State and Territory Advisory Panels,
>
> . a National Assessment Panel, and
>
> . an independent federal Inspectorate which would report to the National Assessment Panel.[1]

15.8 ANZFAS questioned the effectiveness of the ethics committees to review protocols and to monitor animal houses and research programmes. It acknowledged that some ethics committees fulfil their responsibilities but others do not. In order to ensure that a more consistent approach is taken among ethics committees, it recommended that a National Assessment Panel be established to conduct, among other things, site visits along the lines of those carried out by panels of the Canadian Council for Animal Care. It proposed that the aims of site visits should be to:

> ... review <u>all facets of the use of animals</u> in research, teaching and testing, to assess the procedures and facilities for animal care, to note and comment on situations that are not in compliance with the Guide and to report to the Council and the institution the panel's observations and recommendations. The concern of the assessment panel is to assist the local animal care committees and the administration in achieving and maintaining a high standard of animal care, use, management as well as procurement and expertise.[2]

The National Assessment Panel would be a division of a national statutory authority that ANZFAS had recommended in its earlier submission for the administration of animal welfare generally in Australia. Other functions of the National Assessment Panel include:

- to sponsor (from a budget which should be made available by the Federal Government) regional workshops to improve the function of Animal Experimentation Ethics Committees

- to ensure a significant annual minimum reduction in percentage terms of the number of live animals used in research

- to establish the educational standards required for researchers and other laboratory personnel

- to supervise the effective implementation and maintenance of national standards ... for animal experimentation by, inter alia, a system of site visits

- to disseminate information on non-animal alternative techniques to researchers, Animal Experimentation Ethics Committees and others

- to investigate at its discretion any matters relating to the conduct of research or supply or care of animals in any organisation

- to promote (from a budget which should be made available by the Federal Government) any research into non-animal alternative techniques

- to obtain expert advice relating to the discharge of its functions

- to make an annual report to the responsible Minister to be laid before Parliament

- to receive reports from the federal Inspectorate

- to receive reports from the State and Territory Advisory Panels.[3]

15.9 The federal Inspectorate would be another arm of the national statutory authority. ANZFAS proposed that inspectors appointed by the Inspectorate have wide powers to enter and inspect premises; and to remove, treat or euthanase animals. Inspectors would also have the right to recommend the suspension or revocation of licences.

15.10 The State Advisory Panels, which would be composed of equal numbers of experimenters and animal welfarists, would be responsible for the licensing system and would hear appeals from any member of an ethics committee against a decision of an ethics committee.

15.11 ANZFAS also recommended that both experimenters and institutions in which experiments are conducted on animals be licensed by the State Advisory Panels.

15.12 The monitoring network proposed by ANZFAS allows for a high degree of control over the conduct of experiments on animals, based on a blend of the strict controls imposed over animal experimentation in the United Kingdom and the system which has evolved in New South Wales, Victoria and South Australia. The Committee noted, however, that ANZFAS did not recommend the centralised protocol approval system in the United Kingdom. In that system, protocols are approved by the government Inspectorate. ANZFAS commented that a government Inspectorate did not have the flexibility of the system of ethics committees developed in Australia and questioned whether the Inspectorate had a broad enough expertise to assess protocols.

15.13 In its submission, the AVCC argued principally for a system of self-regulation:

> First, the fundamental issue concerned with animal welfare is that in each instance a decision has to be made whether to use animals in teaching and research and this involves resolution of conflicting ethical claims. The law can only be effective when the community has reached a moral decision or consensus. The limitations of the law, when this consensus does not occur, are exemplified by its failures to be effective in other areas of social and moral conflict.

> Second, legislation can act against good ethical concern. By embodiment of decisions within the law difficult issues are avoided. There is the danger that when actions are approved under legislation in the form of a license or a stamp of approval, the investigator may feel that as long as the law is not contravened there is no need for further ethical consideration of his actions.
>
> Third, previous attempts at legislative control have proven to have serious limitations, and indeed to have been counter-productive ...'[4]

15.14 The AVCC went on to accept the need, in a system of self-regulation, for external monitoring to ensure accountability. Its preference was for this external monitoring to be conducted by a non-government organisation without legislative backing. It suggested a system similar to that developed by the Canadian Council for Animal Care. The AVCC commented:

> The Canadian model attempts to assure accountability first and foremost by an internal review committee and second by an external assessment panel. The mode of operation of both committees is to act primarily in an advisory capacity. The relationship of internal committees to the scientist is as the ethical adjudicate, the consultant and advisor. Similarly the external assessment panel operates primarily in an advisory capacity. However, both committees have considerable powers and can stop or modify animal-based research and can recommend removal of external funding if there is serious evidence of non-compliance ...
>
> Assessment by external advisory panels provides surveillance over animal use and care. Such assessment panels should be chosen from a pool of persons with expertise in a variety of fields, including animal production, care and use. Panels should be selected as far as possible with reference to the predominant research interests in the institution to be reviewed. Members of bona fide animal welfare organisations should be invited to join the site visit team.[5]

It therefore recommended that an autonomous Australian Council on Animal Care be established modelled on the Canadian system.

15.15 The proposed Australian Council on Animal Care has since been established as the Australian Council on Animal Research and Teaching (ACCART). The accreditation functions of the Canadian Council on Animal Care were omitted, however, from the constitution of ACCART. This function has been taken over by some State Governments.

15.16 Although the AVCC preferred non-government monitoring of animal experimentation along the lines of that conducted by the Canadian Council on Animal Care, the reluctance of some organisations involved in the establishment of ACCART to support an accreditation function for the Council and the action taken by three State Governments to legislate for government licensing and monitoring in their States have forced the AVCC to reassess their original position. Nevertheless, the AVCC remains firmly attached to the principle of experimenters and institutions assuming prime responsibility for their use of animals in experiments and are in fact accountable for such use.

15.17 The Australian Society for Medical Research argued in its submission for self-regulation without external monitoring but stated that if external monitoring were considered necessary, it should be done by the NHMRC. However, a representative of the Society supported a position beyond external monitoring by the NHMRC. In answer to a question on the incorporation of codes of practice into government regulations, Dr I.L. Campbell told the Committee:

> This is a good move as long as the people who are involved in policing these regulations are fully qualified and fully aware of scientific procedures and animal use in animal experimentation. We would welcome any

> regulations that improve the use of animals in animal experimentation and oversee the ethical and humane use of animals. We have no objection. We welcome that sort of legislation.[6]

15.18 A similar view was expressed by the Australian Society for Laboratory Animal Science in its submission:

> We believe that the control of the use of animals in research should be in a uniform manner. Where possible we believe a system of self-regulation is preferable but recognise that this may need to be embodied in State legislation. Nevertheless uniformity of intent and standards of practice should apply.[7]

15.19 There was general agreement during the inquiry that neither self-regulation nor a totally regulated system was desirable. It became instead a question of the extent of government regulation and the nature of the administrative structure to control animal experimentation.

15.20 Although the Committee received a wide range of views in submissions and oral evidence at public hearings, there was general endorsement of a number of key elements in a control system for animal experimentation.

15.21 As clearly enunciated in the draft revised Code of Practice and generally supported in evidence, primary responsibility for animal use and care rests with the senior experimenter. The senior experimenter is responsible for the design of the project, the conduct of the experiments and the care and welfare of the animals used in the experiments. A senior experimenter who is conscious of his ethical responsibility towards the use of animals will achieve more for animal welfare than what can be achieved by the most stringent of monitoring or

supervising systems. Conversely, an uncaring senior experimenter can cause much unnecessary pain and distress to animals, even in a system where monitoring occurs. It is vital, therefore, to instil in experimenters early in their careers an ethical, responsible and caring approach to the use of animals in experiments.

Ethics Committees

15.22 The use of ethics committees to consider and approve protocols also received widespread support during the inquiry. Although there were differences of opinion expressed about the operations and membership of ethics committees, the concept was generally acceptable. There was virtually no support for the British system which required government inspectors to approve protocols. As pointed out by ANZFAS, this system lacks flexibility. There was concern that government inspectors do not have the breadth of expertise to make decisions on protocols covering a diverse range of proposed projects.

15.23 The Committee discusses aspects of ethics committees in Chapter 16. It is suffice to say here that ethics committees need to operate properly for the system to be effective. This means that the committees must meet to consider and make decisions on protocols. It is not acceptable for ethics committees to delegate that responsibility to sub-committees or individuals or to fulfil that function by correspondence. The Committee is pleased to note that the draft revised Code of Practice requires ethics committees to conduct its deliberations along these lines.

15.24 There has been a reluctance on the part of institutions to appoint non-scientists to ethics committees. With few exceptions, ethics committee membership has included the minimum number of animal welfare or community representatives. Yet the

institutions which have appointed representatives of animal welfare organisations to their ethics committees spoke favourably of the positive contributions made by those representatives.

15.25 The Committee examined the Swedish system of regional ethics committees. The Swedish system differs markedly from the Australian system in many respects. In Sweden, there are only six regional ethics committees and an additional one for military research. The committees are large, with two having had 45 members. They consist of equal numbers of researchers, animal technicians and lay people. They are advisory but their advice on protocols has generally been accepted. Protocols are considered initially by sub-committees of three people, one from each of the three categories of membership.

15.26 The Swedish system has not been without its critics. The criticism has centred on the performance of lay people, many of whom have been hostile towards the use of animals in experiments. The prolongation of debate, both in sub-committees and in the regional ethics committees, has caused delays in the approval of protocols and this has been a source of frustration to some members of the ethics committee. This has had the effect of dissuading many researchers and technicians from volunteering for membership of the ethics committees. The large size of some committees has accentuated the problem because it had facilitated delaying tactics where they have been pursued by lay members.

15.27 The Committee believes that the institutional ethics committees in Australia have more flexibility and are less cumbersome than the Swedish ethics committees. The Australian system places greater emphasis on individual responsibility and peer pressure. This helps to inculcate in experimenters desirable ethical attitudes to animal use in experiments. It is also desirable that the ethical committees make the decisions rather than act just as advisers to a government department or authority.

15.28 With few animal welfare or community representatives appointed to ethics committees in Australia, there has been little opportunity for intransigence on philosophical lines. The potential for that type of problem is considered to be minimal in Australia. In the first place, the institutions select the members of the ethics committees. People with inflexible views towards animal experimentation will not be chosen to sit on ethics committees. Institutions can always have members of ethics committees removed if they are unreasonably obstructive.

15.29 All members of an ethics committee have a responsibility to act constructively to ensure that protocols are designed in accordance with the Code of Practice. That does not prevent any member from drawing attention to or arguing against protocols which do not seem to comply with the Code of Practice. Often it is a matter of fine judgement whether a protocol is considered to be in compliance with or in breach of the Code of Practice. All members should in those circumstances strive to achieve consensus.

15.30 Apart from the approval of protocols, ethics committees have other important functions to perform. They are required to monitor approved projects within their institutions to ensure that the projects are conducted in accordance with their approvals. This includes monitoring the number and species of animals used and the type of procedures carried out on those animals. Ethics committees are or should be accountable for the conduct of animal experimentation within their institutions to the government units which have responsibility for the legislation.

15.31 Ethics committees also are responsible for ensuring that animal facilities and standards of animal care are maintained in their institutions. Members of ethics committees must regularly visit animal houses and animal holding areas to ensure that everything is in order. Ethics committees must also keep in close

contact with animal house staff to ensure that experimenters adhere to ethics committee approvals and the provision of the Code of Practice. If the director or senior technician of an animal house is not a member of the ethics committee, he should at least attend their meetings.

15.32 It is much more satisfactory for all concerned if problems are dealt with properly within institutions rather than action having to be taken later by inspectors or accreditation panels. Ethics committees need to remain alert for breaches of standards or of the Code of Practice and take swift action to resolve any problems.

15.33 Ethics committees need to keep full records of all decisions made and of animal breeding, purchase and use. These records must be available for inspection by inspectors at any time. The keeping of comprehensive animal house records should not be regarded as an imposition. They are essential for efficient animal house management. Such records, where possible, should be computerised.

Code of Practice

15.34 Although differences of opinion were expressed in evidence on specific provisions in a code of practice, there was general agreement that there should be a national code of practice. A code of practice sets out principles, administrative systems and general standards covering the use and care of animals. In the draft revised Code of Practice, the responsibilities of experimenters, institutions and ethics committees are clearly defined.

15.35 Witnesses argued for a national code of practice so that uniform standards would apply throughout Australia. The Committee believes that this is desirable provided that there is no diminution in standards of animal welfare in order to gain

consensus. However, it would still be within the power of a State or Territory Government to impose stricter conditions in regulations to supplement the code of practice should a Government believe that the current Code of Practice does not provide enough control over animal experimentation. The New South Wales Government considered such a course of action after it received a copy of the draft revised Code of Practice early in 1988. Subsequently, the draft revised Code of Practice was amended to bring it more in line with a draft code of practice prepared by the New South Wales Government.

Enforcement and Accountability

15.36 In the following discussion on enforcement and accountability, it should be remembered that under the Commonwealth Constitution, animal experimentation is primarily a State and not a Commonwealth matter, except where it is being conducted by Commonwealth authorities. The Commonwealth maintains some involvement in animal experimentation through funding by Commonwealth bodies such as the Australian Research Council, the NHMRC and others.

15.37 Until recently, State Governments did not assume administrative control over animal experimentation. In 1985 and 1986, the Governments of New South Wales, Victoria and South Australia enacted legislation and established administrative units within their Governments to control animal experimentation. The Australian Capital Territory and Queensland Governments are presently moving towards revised legislation in this area.

15.38 The Committee received various views on the roles of funding bodies and State and Territory Governments in the administration of animal welfare. It is clear, however, that as the States and Territories are moving to take control of the

administration of animal experimentation, as is their constitutional right to do so, primary responsibility for overseeing animal experimentation should rest with them and not funding bodies.

15.39 Funding bodies still have a role to play in that all protocols for external funding are considered by those bodies and their referees. Where a protocol obviously does not comply with the Code of Practice, the funding body has a responsibility to withhold funds for the project until compliance is achieved. However, the funding bodies do not have a role to set up specific administrative structures to enforce the Code of Practice. Their role is to fund research and in some cases to provide advice to government in accordance with their charters. If funding bodies encroach on the legitimate role of government to administer animal experimentation, it would only cause confusion and be a waste of scarce resources. Of the funding bodies, only the NHMRC has had a direct role in the compilation and revision of the Code of Practice. As it funds only a small percentage of all projects involving the use of animals in Australia, it is anyway not in a position to take over responsibility for enforcement of the Code of Practice.

Legislation

15.40 Each State and Territory should have legislation to control animal experimentation modelled on legislation already enacted in New South Wales, Victoria and South Australia.

15.41 It is worthwhile to compare some of the main provisions of the revised legislation in New South Wales, Victoria and South Australia. Although the three Acts provide a similar framework, there are distinct differences in approach and in specific requirements. ACCART did a simple comparison and this was incorporated in the Committee's Hansard transcript of evidence.[8]

15.42 The New South Wales Government decided to enact separate legislation to control animal experimentation while the Victorian and South Australian Governments included such provisions in their prevention of cruelty to animals legislation. Similarly, the New South Wales Government established an Animal Research Review Panel, separate from the Animal Welfare Advisory Council, to control animal experimentation in that State. In Victoria and South Australia, the Animal Welfare Advisory Councils have responsibility for animal experimentation as well as for other areas of animal welfare.

15.43 The Committee prefers separate legislation to regulate animal experimentation, along the lines of the New South Wales approach, to get away from the notion of prevention of cruelty and substitute one of care of and respect for animals. Although some experiments cause pain or suffering to animals, deliberate cruelty to animals undergoing experiments in Australia is rare. It seems incongruous to include animal experimentation in legislation which is designed primarily to prevent cruelty to animals.

15.44 In many areas of animal welfare, local government or non-government organisations have responsibility for upholding legislation. However, in animal experimentation, State Governments are directly involved in accreditation; licensing; monitoring; preparation of legislation, regulations, guidelines and codes of practice; and consideration of many complicated and contentious ethical issues. Government involvement in animal experimentation is much deeper than in most other animal welfare issues. Although these other issues can reasonably be brought together and considered by a general advisory committee, it is much harder to do this satisfactorily in the case of animal experimentation. One or two members representing scientific interests on an advisory committee would not necessarily have the breadth of expertise or experience to enable the advisory committee to give government the best advice on animal experimentation.

15.45 Although the Committee prefers separate advisory committees for animal experimentation, it believes that a single animal welfare unit within the State bureaucracy should administer all animal welfare functions as happens in New South Wales, Victoria and South Australia.

15.46 A major difference among the three updated State Acts is the matter of licensing or accreditation of institutions. The Victorian and South Australian Governments adopted the approach of licensing institutions and appointing inspectors to visit institutions from time to time to check whether facilities are of the appropriate standard and whether other requirements of legislation and the code of practice are being met.

15.47 The New South Wales legislation provides for licences for institutions and for the appointment of inspectors. Once Regulations are issued, licences will be issued to institutions after they have undergone a process of accreditation.

15.48 Accreditation in New South Wales will be no perfunctory exercise. In its submission, the New South Wales Government stated that accreditation 'incorporates peer review of practices and procedures and therefore mandates critical and informed review and appraisal'. A little later, it went on to say:

> There is no doubt that to be effective the agent/agency responsible for external monitoring must have sufficient knowledge to evaluate the practices and procedures and must be able to reflect in its judgement a 'balanced community view'. Assessment by a panel of persons with appropriate and relevant expertise and including community representative, should achieve this.[9]

15.49 This process will involve some members of the Animal Research Review Panel and other scientists doing a thorough review of animal and experimentation facilities, inspection of records and examination of ethics committees' decisions to ensure compliance with the provisions of the Code of Practice. As several members of the accreditation group will have expert knowledge in various areas under review, a more thorough review

compliance with the provisions of the Code of Practice. As several members of the accreditation group will have expert knowledge in various areas under review, a more thorough review of the self-regulatory performance of the institution will be done compared with the occasional visits by inspectors to institutions in systems which do not accredit institutions.

15.50 Another advantage of accreditation from the point of view of the scientific community is that it will install peer review in the control system at a second level and not just at the level of ethics committees. Accreditation teams will contain a number of senior scientists who will provide scientific expertise to the teams. Monitoring will not be done just by government inspectors who may not have a scientific background and who are not fully familiar with scientific method, experimental techniques and the subtleties of animal experimentation.

15.51 The inclusion of animal welfare or community representatives on accreditation teams will make the monitoring process more publicly accountable. It will also help to allay suspicion on the part of animal welfare organisations that experiments are being conducted in accordance with the Code of Practice and housing and other facilities for animals are of an appropriate standard.

Monitoring

15.52 A system based on the principles of enforced self-regulation depends largely on self-regulatory practices; government controls are not meant to be too intrusive. However, legislation without enforcement soon becomes seen to be ineffective and is treated accordingly. A balance has to be struck between self-regulation and government controls to ensure that the former works without too much interference from the latter.

15.53 In New South Wales, accreditation will provide a thorough review of the performance of the institution, its ethics committee, experimentation and facilities at specified intervals of between one and three years. In addition, in all three States which have revised legislation there is provision for the appointment of inspectors. Their powers and functions are detailed in the relevant legislation. Basically, they have powers to enter premises, check facilities and records and give directions in accordance with the provisions of legislation.

15.54 Inspectors have an important role to play in the system of enforced self-regulation. They need to have had experience in laboratory animal science or relevant veterinary science so that they are familiar with the operations of animal experimentation and animal care. They must be sufficiently experienced to detect non-compliance with codes of practice or other regulations but have qualities of discretion and commonsense to take appropriate action. Often advice or a warning will be preferable to more serious action. They must gain the respect and confidence of the scientific community with which they have dealings. The importance of attitude in animal experimentation is the key to the correct approach being taken by experimenters. With a positive attitude towards ethical use and care of animals, humane treatment is a ready result. Inspectors have a role to play in helping to inculcate the right attitude among experimenters. As is the case in other areas of life, laws are made to prevent exploitation. This is true too for animal experimentation. Most people who believe a law is fair and just will respect it but there will always be someone who will try to circumvent the law for his or her own benefit. It is that person on whom the efforts of inspectors must be concentrated.

Accountability

15.55 On occasions, it is understandable for institutions and experimenters to become defensive and secretive, particularly in the face of violence or malicious allegations of misconduct or cruelty. However, resort to secrecy should be avoided wherever possible. The best defence is full public accountability. The community supports animal experimentation which is conducted within normal humane limits. The community will not support violence against institutions where it can be shown that normal standards of use and care have been followed. In those circumstances, violence would be counter-productive.

15.56 All people and bodies involved in animal experimentation and in its administration and control need to be accountable for their actions, otherwise the system may be brought into disrepute. Each person or body in the system must carry out its function and keep proper records of action taken.

Summary

15.57 The Committee RECOMMENDS that the system of controlling animal experimentation in New South Wales, Victoria and South Australia be extended to the other States and Territories. This system is based on upgraded legislation; incorporation of a code of practice in regulations; the accreditation and licensing of institutions in which animal experimentation is conducted; and the appointment of inspectors to monitor the work of ethics committees, animal house facilities and practices, and the conduct of animal experimentation.

Commonwealth Government

15.58 At the Commonwealth level there have been some problems recently about the administration of animal experimentation which attracted media attention.

15.59 In the first case, the NHMRC tried to monitor research being done by CSIRO with NHMRC grants for compliance with the Code of Practice. The Committee does not wish to become too embroiled in the details of the case but merely comments on aspects which impinge upon the control of animal experimentation at the Commonwealth level. The Committee has already discussed the question of monitoring for compliance with the Code of Practice. It has recommended that, in the States and Territories, the State and Territory Governments do the monitoring under their own legislation in accordance with their constitutional responsibilities. Consequently, funding bodies would not monitor for compliance unless there was doubt arising from consideration of a protocol or other application for a grant that the Code of Practice might not be complied with. The NHMRC would therefore not have the power to demand inspection of CSIRO facilities. In any event, it seemed to the Committee odd that the NHMRC would make such demands on a co-sponsor of the Code of Practice.

15.60 Another case where media attention focussed on animal experimentation was in 1988 when allegations were made about the use of uranium isotopes on penguins and also about other research being conducted in Antarctica. This issue was the subject of a government inquiry which has recommended various procedures to obviate future problems with control and monitoring of experiments on animals in Antarctica. Some of the recommendations of the report on the incident do warrant comment. The Working Party which produced the report concluded that the existing Code of Practice was unsuitable for experiments on animals in Antarctica and recommended that a separate code of practice be prepared for Antarctic research. The Committee believes that the

Working Party has misunderstood the purpose of the Code of Practice. The Code of Practice is meant to cover all experiments on animals, irrespective of whether the experiments are conducted in a laboratory or on wildlife in the field - in the blistering heat of inland Australia or in the cold of Antarctica. The code is a set of principles and administrative arrangements. It is not a set of detailed guidelines for experiments on specific species of animal.

15.61 It has been acknowledged by the NHMRC and other bodies that guidelines need to be compiled on specific species or particular procedures to supplement the Code of Practice. This is a task for ACCART, specialist societies (e.g. the Primate Society) or other expert bodies. The Antarctic Division should arrange with people with experience in dealing with animals in Antarctica to draw up guidelines for future projects involving experiments on Antarctic animals. However, the Code of Practice is still appropriate for overall control of experiments on animals in Antarctica.

15.62 There are organisations at the Commonwealth level which have some involvement in experiments on animals, either as funding bodies or in an experimental capacity. The controversy over the experiments on animals in Antarctica serves as an example to show the lack of co-ordination of experiments in animals at the Commonwealth level.

15.63 There is another dispute simmering, between CSIRO and State Governments, over the constitutional control of a Commonwealth statutory authority which has activities within a State. One or two State Governments have claimed that CSIRO staff working in their States have to obey State laws. CSIRO, on the other hand, has received legal advice from the Commonwealth to the effect that its staff are not bound by State laws. Despite this constitutional impasse, CSIRO has voluntarily agreed that its staff should comply with State laws and regulations.

15.64 In a submission to the Committee the CSIRO argued for the enactment of Commonwealth legislation to put the question of constitutional authority beyond doubt. The CSIRO stated:

> The Act should aim to provide a mechanism by which all members of the community become aware of their duty of respect for animals and of the necessity for humane treatment of them. As such it should go well beyond the conventional notion of aiming such legislation at the prevention of cruelty of animals.[10]

15.65 The CSIRO went on to say in its submission that the legislation would:

- ensure that standards of animal care and use are uniformly high in Commonwealth research and teaching establishments throughout Australia,
- facilitate administration within Commonwealth departments and research funding bodies,
- provide a clearly defined uniform scheme within which Commonwealth researchers and teachers are legally protected, and
- facilitate good relationships with State and Territory animal welfare authorities.[11]

15.66 The Committee notes that most tertiary institutions, such as universities, colleges of advanced education and colleges of technical and further education would continue to come under State or Territory legislation.

15.67 The legislation proposed by the CSIRO would cover all activities of Commonwealth staff irrespective of whether their work is carried out in Commonwealth or State facilities. However, observance of State legislation would be advisable by staff if they are working in State facilities with non-Commonwealth staff to prevent any unnecessary friction between Commonwealth and State authorities.

15.68 The enactment of Commonwealth legislation would enable all Commonwealth staff located throughout Australia to be subject to the same legislative and regulatory provisions. This would obviate possible confusion about the terms of legislation and regulations applying to them by staff moving among the States and Territories. It also helps an organisation such as the CSIRO with research programmes in all States and Territories to promote a uniform set of standards and rules within the whole Organisation.

15.69 The Committee RECOMMENDS that the Commonwealth Government enacts legislation to remove any doubt that the conduct of animal experimentation by Commonwealth employees comes under the control of Commonwealth authorities.

15.70 In Chapter 15, the Committee recommended the establishment of a Commonwealth AWAC responsible to a neutral Minister who had been given responsibility for animal welfare matters by Cabinet. The AWAC would be served by a unit within the Minister's department.

15.71 The Committee considered the question of co-ordination and control of animal experimentation at a Commonwealth level. The Committee believes that control should be vested in the Minister who would seek advice from the Commonwealth AWAC and also from an inter-departmental committee (IDC) consisting of representatives of the various departments and authorities which have an interest in animal experimentation at the Commonwealth level. The animal welfare unit within the department would also serve the IDC.

15.72 Both the Commonwealth AWAC and the IDC could draw upon ACCART for technical advice on animal experimentation and the care of animals.

15.73 The IDC would act as a co-ordinating body under the chairmanship of the head of the animal welfare unit. It would discuss new practices, policies, standards, regulations and legislation and examine problems faced by any of the departments or authorities. Some of the bodies would also be represented on the Commonwealth AWAC which would facilitate communication of the views of the IDC to be considered by the AWAC when issues relating to animal experimentation were raised in that forum.

15.74 The IDC would advise the Commonwealth Minister responsible for animal welfare on animal experimentation matters within the Commonwealth jurisdiction and on other animal experimentation matters which would be the subject of discussions with State and Territory ministers.

15.75 The Committee RECOMMENDS the establishment of an inter-departmental committee consisting of the various departments and authorities which have an interest in animal experimentation at the Commonwealth level to co-ordinate and oversee the conduct of animal experimentation to ensure that it is carried out in accordance with the Code of Practice.

CHAPTER 16

CODE OF PRACTICE AND ETHICS COMMITTEES

Introduction

16.1 In Chapter 15 the Committee recommended the adoption by all States and Territories and the Commonwealth of a regulatory system for animal experimentation based on the systems operating in New South Wales, Victoria and South Australia. The system is based on legislation, the code of practice, ethics committees and government monitoring. During the course of the inquiry, various issues were raised concerning the Code of Practice and ethics committees. These issues are discussed in this chapter.

Code of Practice

16.2 A key element in the regulatory package is the code of practice, within the provisions of which experiments on animals are to be conducted. For the provisions to be enforceable, the code of practice needs to be included in regulations made under relevant legislation. There are always some institutions or individuals who will not comply with the code of practice if it does not have the backing of the law. Not all institutions depend on government funding for their research projects rendering useless the threat of the withholding of grants as a means of ensuring compliance with the code of practice.

16.3 The Victorian Government has included the Code of Practice in its regulations under the Prevention of Cruelty to Animals Act. The South Australian and New South Wales Governments will include the draft revised Code of Practice in their regulations when it has been approved by the sponsoring bodies.

16.4 The New South Wales Government at one stage issued a draft code of practice which varied significantly from the draft revised Code of Practice. The Committee notes that, subsequently, the writing group revising the Code of Practice amended the draft revised Code of Practice by including many key provisions of the New South Wales draft code. The Committee understands that the New South Wales Government will probably now adopt the revised Code of Practice to maintain uniformity with other states.

16.5 It is sensible for there to be a single code of practice applying in all States and Territories and in Commonwealth facilities. That should not prevent a government from imposing extra requirements in regulations to tighten control of animal experimentation. Inevitably, a code of practice is the minimum set of standards which all parties bound by the code are prepared to accept. Some parties may wish to raise the standards within their area of authority. If this improves animal welfare, it should be encouraged.

Revision of the Code of Practice

16.6 Since 1965 when work was begun on the original Code of Practice, the NHMRC has had the main carriage of the preparation and revision of the Code of Practice. During most of this period, the responsibility for the adoption of an ethical approach to experiments on animals and for the welfare of animals was left to the NHMRC. The CSIRO and later the AAC jointed the NHMRC in revising the Code of Practice but it has always been the NHMRC which has provided the administrative support for the Code of Practice.

16.7 The NHMRC has done a good job in establishing the Code of Practice and in carrying out its first three revisions. However, the Committee is aware of difficulties and tensions among the NHMRC, some State Governments and other bodies during the recent revision of the Code of Practice. With the new Code of Practice to be included in regulations in three States and with responsibility for enforcing compliance with the Code of Practice in the hands of those States, a new approach should be taken for conducting future revisions.

16.8 In the past, a new edition of the Code of Practice has come into force when it has received the approval of its sponsoring bodies - the NHMRC, the CSIRO and the AAC. In the future, the State and Territory Governments which will include the Code of Practice in regulations should give it final approval. If the State and Territory Governments were unhappy with a revised Code of Practice, they would withhold their endorsement anyway and not substitute it for the existing Code of Practice. Alternatively, the Governments would simply amend the revised Code of Practice to bring it into line with their policies.

16.9 There are many interested parties in revisions of the Code of Practice - governments, institutions which conduct animal experimentation, experimenters, animal house staff, specialist societies, animal welfare organisations, educational organisations and funding bodies. It would be sensible for all of these interests to have an input into revisions of the Code of Practice. Each party brings a different perspective to bear on the subject matter of the Code of Practice. As with the functioning of ethics committees, it is the mix of these diverse views which will result in a Code of Practice which takes account of all of the interests represented.

16.10 It has been suggested that a national conference be held annually to review the Code of Practice to draw attention to any shortcomings or to technological developments which might impinge on the Code of Practice. The Committee believes that the Code of Practice should be revised about every three years unless there emerges from an annual national conference a clear need to undertake an earlier revision.

16.11 The national conference should have an independent chairman and should include representatives of Commonwealth, State and Territory animal welfare or animal experimentation advisory councils; AVCC; CSIRO; ASLAS; the Australian Association of Animal Technicians; the Australian Research Council; NHMRC; AAC; the Australian Educational Council; ANZFAS; RSPCA Australia; NFF; AVA; experimenters; and the community.

16.12 The national conference should consider and agree on the principles and main points for inclusion in a revised draft of the Code of Practice. It would then select a small writing group to incorporate the changes. When the writing group has completed its task, the revised draft would be considered by the national conference before being submitted to State and Territory Governments for approval. If a Ministerial Council for Animal Welfare were established, the revised Code of Practice would be submitted to it.

16.13 The committee to revise the Code of Practice should draw on the resources of ACCART for technical advice.

16.14 The Committee believes that ACCART should also provide the secretariat for the committee to revise the Code of Practice. ACCART is a neutral body but has many of the interested parties as members.

16.15 The Committee RECOMMENDS that future revisions of the Code of Practice be carried out by a national conference consisting of representatives of governments, institutions which conduct animal experimentation, experimenters, animal house staff, specialist societies, animal welfare organisations, educational organisations and funding bodies and that final approval for those revisions be given by Commonwealth, State and Territory Governments which include the Code of Practice in regulations.

Compliance with the Code of Practice

16.16 Until recently, ensuring compliance with the Code of Practice has been the responsibility of funding bodies. Grants were made to experimenters and institutions for projects involving experiments on animals on the condition that they adhere to the provisions of the Code of Practice. Ethics committees were also required to screen proposals for compliance with the Code of Practice.

16.17 In practice, there was little effort made to secure compliance with the Code of Practice by experimenters and institutions. Many ethics committees did not carry out their responsibilities and some institutions did not even have ethics committees in operation. The NHMRC and other funding bodies had no resources to monitor compliance and they depended on statements of compliance from experimenters and institutions. The NHMRC in its original submission dated February 1984 to the Committee stated:

> ... experience indicates that there is complete compliance with the Code on the part of the medical researchers in Australia.[1]

16.18 By the time that representatives of the NHMRC gave evidence to the Committee on 29 August 1986, the view of the NHMRC about compliance had changed to some extent:

> There was no evidence in 1984 of lack of compliance. It would still be difficult to identify whether or not there is lack of compliance. It became clear to the Council that simply asking people to ensure in the submission of their grant application that their proposal had been examined by an ethics committee and that that ethics committee had put a signature on it was not sufficient for the Council to be able to be completely satisfied that compliance was occurring and it was for that reason that Dr Anderson's committee was asked to provide advice, information and input on this matter to the Council.[2]

16.19 The Committee sent out about 50 questionnaires to universities and other institutions which conducted animal experimentation. From the completed questionnaires, it was quite obvious that many institutions were not complying with the Code of Practice in one way or another. The AVCC, with whom the Committee liaised during the preparation of the questionnaire, analysed the returns from the 19 universities. It acknowledged that there were areas in a number of universities that required changes in practice or procedure.[3] In at least two universities, the Committee noticed during its inspections a disregard for the universities' own procedures.

16.20 There is no doubt that the Code of Practice has not been adhered to in all respects. The Committee has noted, however, that during the course of the inquiry, considerable improvements have been made by many institutions in improving facilities and procedures. There has been a growing awareness of the need to adopt a more ethical and careful approach to the use of animals. This has been not just to reflect changing attitudes within the community but also to acknowledge that improvements in animal care and use result in more reliable data.

16.21 In November 1985 the NHMRC decided to take a more active role in monitoring compliance by appointing its own ethics committee. It was given three functions, the third of which was:

> With the approval of the Council, to develop and implement ways of ensuring that all animal experimentation funded by the NHMRC is in accord with the current 'Code of Practice'.[4]

16.22 The NHMRC admitted in evidence on 29 August 1986 that it allocated one clerical officer to administer the committee although that officer had back-up support within the then Department of Health. Dr Anderson added that the Baker Institute provided secretarial assistance.[5]

16.23 The budget of the NHMRC ethics committee was limited and membership was originally restricted to people based in Melbourne in order to contain costs.[6]

16.24 It is questionable whether the NHMRC or any other funding body should try to ensure adherence to the Code of Practice. Obviously, it should keep the requirement that funds should only be disbursed to experimenters and institutions which agree to comply with the Code of Practice. Any aspect of a proposal for funding which indicates possible non-compliance with the Code of Practice should be queried and amended if necessary to obtain compliance. However, for a funding body to go beyond these measures requires additional resources and runs the risk of causing other problems.

16.25 The NHMRC funds a small proportion of projects in which experiments are carried out on animals. For the NHMRC to establish a unit to monitor compliance with the Code of Practice means that it would only cover a small proportion of projects anyway. Each funding body would need to set aside resources for this purpose. This would make the system cumbersome and expensive to operate. Different standards or interpretations might apply among the funding bodies to add to the other problems.

16.26 Regulation of animal experimentation is a State responsibility. A State government may decide to impose stricter conditions on experimenters and institutions than those contained in the Code of Practice. The Code of Practice may therefore conflict with regulations made under State legislation. This would create problems for a funding body, if it had to police non-compliance with the Code of Practice. If several States had different regulations, it would compound the difficulties faced by a funding body in ensuring compliance.

16.27 Three States have since 1985 revised legislation and established mechanisms to control and monitor animal experimentation. In all three States the legislation has provided for the appointment of inspectors to carry out this monitoring. There are also moves among the other States and Territories for similar provisions to be put in place.

16.28 The Committee firmly believes that the relevant government authorities in the States and Territories and within the Commonwealth should be responsible for ensuring compliance with the Code of Practice or other regulations made under legislation. These authorities have a legislative responsibility to carry out this task. With government authorities taking over monitoring of compliance, funding bodies should avoid causing confusion by trying to duplicate government efforts in this area, except where non-compliance is obvious from proposals or reports of completed or partially completed projects.

Emergencies

16.29 In the draft revised Code of Practice dated 22 February 1989, there is provision for the nomination of a person to respond to emergencies:

> On each site where animals are used, the AEEC should nominate a person who is authorised to respond to emergencies. Where possible, this person should be a member of the AEEC.[7]

16.30 Although an executive committee of an ethics committee may be authorised to deal with emergencies, it may find it impossible to respond to an emergency in a remote facility or even one away from the main campus or headquarters area. The nomination of a person on each site to respond to emergencies enables action to be taken quickly in the event of an emergency. The Committee believes that this is a positive step towards allocating responsibility and authority in the interests of animal welfare. The Committee, however, believes that it should be mandatory rather than optional for such nominations to be made.

Animal Welfare Officers

16.31 In the draft revised Code of Practice which was distributed for comment in 1988, provision was made for the appointment of an animal welfare officer in institutions. In the draft, it was stated:

> Institutions should consider whether an animal welfare officer should be appointed, responsible to the AEEC. An animal welfare officer should have veterinary or other appropriate specialist qualifications, and may act as the executive officer of the AEEC but should not be concerned directly with the day-to-day care or husbandry of the animals. The animal welfare officer must be authorised by the AEEC to ensure compliance with the requirements of this Code and of the AEEC, including the treatment or human killing of any animal.[8]

16.32 The paragraph on animal welfare officers was deleted from the 22 February 1989 draft of the revised Code of Practice. In that draft, it was suggested:

> Large institutions with multiple sites of animal care and use should consider whether an Executive Officer with veterinary or other appropriate specialist qualifications should

> be appointed. An Executive Officer should be authorised by the AEEC to ensure compliance with the Code and decisions of the AEEC.[9]

16.33 In effect an executive officer has been substituted for an animal welfare officer.

16.34 Few institutions have appointed animal welfare officers although a number have purportedly appointed an animal welfare officer by arranging for a local veterinarian to make periodic inspections of animal houses. Such an arrangement cannot be regarded, however, as the appointment of an animal welfare officer. Animal welfare officers are officers who are appointed on a full-time or part-time basis and who, in the latter case, have other duties within the institution. Apart from carrying out monitoring duties to ensure that the care of animals and experimental projects are carried out in compliance with the Code of Practice and institutional policies, the animal welfare officer has advisory and educational roles to fulfil. The animal welfare officer should be developing standards of care and promoting good animal welfare practice, emphasising the correlation between good animal welfare and reliable experimental data derived from experiments on animals. None of these roles, including the primary monitoring role, can be done by an external officer making occasional visits to the institution. There is nothing wrong in having veterinarians in private practice inspecting facilities but such arrangements do not constitute having an animal welfare officer.

16.35 Under the Code of Practice, the ethics committee has responsibility for monitoring animal breeding and holding areas and for ensuring that experimenters comply with the terms of approved protocols. No administrative arrangements diminish that responsibility although arrangements can be made to enhance it. Members of ethics committees individually and collectively have to fulfil this responsibility by personally inspecting animal

houses and experimentation facilities on a regular basis. It is not enough to delegate this function to an animal welfare officer or executive officer, even though either officer, if one has been appointed, may also monitor those animal houses and experimentation facilities more frequently.

16.36 As it is the ethics committee that has the responsibility for monitoring standards and compliance, the Committee believes that it is appropriate for the ethics committee to appoint an executive officer, with veterinary or other appropriate qualifications, to support it administratively and in its roles of monitoring, development of standards and education. Although it may only be a question of nomenclature, the use of 'executive officer' does reflect the responsibilities of the position and the ethics committee more clearly and it precludes the use of 'animal welfare officer' for public relations purposes only as is the case in a number of institutions at present.

Ethics Committees

16.37 The second edition of the Code of Practice required institutions which conducted experiments on animals to establish ethics committees to scrutinise and approve protocols for projects in which animals were involved. Since then, institutions have gradually established ethics committees although the effectiveness of some has been questionable. The Committee is aware of some ethics committees that had not met until recently or that examined protocols in a cursory way to comply with the letter of the 'law' but not its spirit.

16.38 Ethics committees are the lynch pin in the system of responsibility and accountability in the three States with upgraded legislation. The effectiveness of the ethics committees will determine whether the system is successful or not. In the

other States and Territories, they are virtually the only control over animal experimentation. Ethics committees consider all protocols for experiments on animals and they may approve, amend or reject protocols for non-compliance with the Code of Practice. They control, therefore, all experiments on animals and they have the responsibility for ensuring that experiments conform to acceptable ethical principles in accordance with the Code of Practice.

Membership of ethics committees

16.39 Membership of ethics committees is important because it determines the diversity of views that consider protocols and other business of the committees. A narrow spectrum of views consisting mainly of scientific values would tend to appraise proposals less critically than a membership which reflected both scientific and community attitudes.

16.40 The ethics committee is also a key element in the system for public accountability. By having animal welfare and community views on an ethics committee, the community has more confidence that the ethical attitudes of the community are being reflected in the judgements and decisions of the committee. The Committee believes that it is essential not only for community interests and attitudes to be the basis of decisions of an ethics committee but also for those decisions to be perceived by the community as reflecting its views.

16.41 Under the 22 February 1989 draft revised Code of Practice, the ethics committee must comprise at least four members, including one from each of the following categories:

> Category A. a person with qualifications in veterinary science, preferably with experience relevant to the activities of the institution, or a person with qualifications and experience to provide equivalent expertise;

Category B. a person with substantial recent experience in animal experimentation;

Category C. a person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the institution, and who is not involved in the care and use of animals for scientific purposes. The person should where possible be selected on the basis of membership of an animal welfare organisation;

Category D. an independent person who does not currently and has not previously conducted experiments using animals, and who is preferably not an employee of the institution.[10]

16.42 The Code of Practice provides for additional people to be appointed to an ethics committee. Most ethics committees have a larger membership to reflect the diversity of research which has to be considered by the committees.

16.43 Although the person representing Category D may be appointed from within the institution, it becomes mandatory for two people from Categories C and D to be external appointments if the ethics committee has more than seven members.

16.44 The draft which was distributed for public comment required the person appointed under Category D not to be an employee of the institution.

16.45 The Committee sought the views of a number of people at public hearings on the composition of the ethics committees as set out above. At that stage the draft Code of Practice was subject to public comment. The only reservation about the membership categories that was elicited from witnesses was the requirement for the appointment of two people who have no affiliation with the institution. It was argued that a lay person within the institution, such as a professor of philosophy, would be appropriate to represent community interests. It was not

asserted that two people should not be appointed from outside the institution but that there should be more flexibility so that one of those two might be appointed from within provided that the person was suitable.

16.46 Although a suitable person may be found within an institution to fill the lay person category, the Committee believes that, on balance, it is preferable to appoint from outside of institution two people who have no involvement in animal experimentation. There can be no question then of loyalty to the institution clouding their judgement on sensitive or controversial protocols or other issues. An external appointment under Category D is more likely to ensure that community views and attitudes are reflected than an internal appointment, however well qualified the latter may be for membership of an ethics committee. It also means that the one outside member is not overwhelmed by internal members in meetings of the committee. As most ethics committees require unanimous decisions, there may be pressure brought to bear on a single dissenting member. It may put a single dissenter into a difficult position if he or she is the sole outside member on the committee.

16.47 An eminent philosopher within an institution can still be appointed to the ethics committee when an external appointment is made under Category D as there is no upper limit on the number of people appointed from each category. It has been only a matter of institutional policy that has resulted in the number of non-scientists being kept to a minimum on ethics committees.

16.48 The Committee supports the membership provisions of ethics committees as drafted in the draft revised Code of Practice which was originally published for public comment, that required the community representative to be a person not employed by the institution.

16.49 Under the draft revised Code of Practice, there must be at least one person appointed from each of the four categories. At present, as long as each category is represented, one person may represent more than one category. For example, veterinarians in private practice have often been appointed to ethics committees to represent veterinary science, animal welfare and an external appointment in the one person. This will not be allowed when the revised Code of Practice comes into effect. The Committee supports this change in policy.

16.50 The appointment of a member under Category C 'should where possible be selected on the basis of membership of an animal welfare organisation'. There is an obvious need for flexibility in this provision because in some areas there may not be a suitable person who is a member of an animal welfare organisation available for appointment to an ethics committee. However, the flexibility of the provision should not be used as an excuse not to appoint a member of an animal welfare organisation where one is available. Institutions should make appointments within the spirit and not merely the letter of the provision. In emphasising this point, the Committee believes that members of animal welfare organisations who are appointed to ethics committees must fulfil their responsibilities as members in a way that enables the ethics committees to operate effectively. In other words, there is no place on an ethics committee for people who simply want to obstruct the work of ethics committees because they have a philosophical objection to animal experimentation. The Committee noted that a number of members of ANZFAS and RSPCA have been effective members of ethics committees. By having a different perspective, they have persuaded ethics committees to consider some protocols and issues in a different light.[11]

Consideration of Protocols

16.51 The manner of considering and approving protocols became a controversial issue during the course of the inquiry. A number of ethics committees have been dealing with protocols by correspondence and not at meetings of the committees. In some cases, consideration and approval of protocols have been delegated to one or a few members of an ethics committee.

16.52 Under the current Code of Practice, the constitution of ethics committees must include provisions to:

> ... examine written proposals relevant to the use of animals in experiments and approve only those experiments which conform to the requirements of this Code, taking into consideration ethical aspects as well as scientific or educational merit;[12]

16.53 The 19 February 1989 draft revised Code of Practice has four clauses which deal with consideration of protocols. Ethics committees must have terms of reference which include provisions to:

> ... examine and approve, approve subject to modification, or reject written proposals relevant to the use of animals in experiments and approve only those experiments for which animals are essential and which conform to the requirements of this Code, taking into consideration ethical and welfare aspects as well as scientific or educational value;[12]
>
> Proposals must be considered and approved at meetings of the AEEC.[13]
>
> The AEEC may establish an executive (including at least one member from Category C or D) to approve minor modifications to projects, and deal with emergencies, but any decisions by the executive must be reviewed by the AEEC at its next meeting.[14]
>
> The executive may not approve proposals.[15]

16.54 The above four clauses provide a clear direction to ethics committees for the consideration and approval of proposals. The current Code of Practice is unclear on this point and in many institutions advantage has been taken of this lack of clarity whereby protocols have been considered other than at meetings of an ethics committee.

16.55 Copies of protocols need to be distributed to members of an ethics committee prior to a meeting for their consideration. Members may seek additional information or do their own investigation of a protocol with which they have reservations. However, such preliminary consideration must not be a substitute for consideration at a meeting of the ethics committee. The dynamics of a meeting facilitates the raising of issues and encourages discussion. A point made by one member of a committee will often lead to a chain reaction in the thinking of other members. It is the collective wisdom of a committee, with each member bringing his or her own expertise or perspective to bear on the matter together with the other members, that enables a collective judgement to be made.

16.56 Self-regulation, within or without a legislative framework, requires both responsibility and public accountability. The system of ethics committees provides the opportunity for there to be responsibility on the part of the scientific community and also public accountability. Members representing the community or animal welfare will be, if not already are, a way for community interests to be represented in decisions on the use of animals in experiments. The public attitude towards animal experimentation is of tolerance provided that there is responsibility on the part of the scientific community. The public recognises the benefits that have resulted from experiments on animals in the past and the prospect of further benefits in the future. There is a growing feeling that such animal experiments must take place with the minimum number of animals with the least possible suffering. The use of ethics

committees with members reflecting scientific, veterinary, community and animal welfare interests, enables the public to have some confidence that the interests of the animals are being taken account of in a responsible way. The operations of an ethics committee which do not provide the greatest possible protection of the interests of the animals will, in the end, breed suspicion of the system and bring it into disrepute.

16.57 The Committee acknowledges the benefits of an executive committee making minor modifications to an approved protocol and in making decisions in emergencies, both subject to review by the ethics committee. The executive committee cannot approve protocols in any circumstances. This prohibits the practice being carried out in a few institutions where consideration and approval of some or all proposals have been delegated to one or two members of an ethics committee.

16.58 The Committee supports the system of enforced self-regulation based on ethics committees on the basis that ethics committees operate properly as committees and fully consider and make decisions on protocols at meetings of those committees and not by correspondence or delegation to one or a few members of an ethics committee.

Guidelines

16.59 The Code of Practice sets out the principles for the care and use of animals for experimental purposes and the administrative procedures to be followed for the control and supervision of animal experimentation. It does not, however, give details of the care and use of specific species of animal. The NHMRC foresaw the need to prepare and publish additional guidelines to supplement the Code of Practice. There are various

and manuals available for scientific procedures done on some specific species and for the husbandry of those species. Not all are up-to-date. Some species, especially Australian native wildlife, are not adequately covered.

16.60 The NHMRC has draft guidelines for use of native mammals in biomedical research and has prepared another set of guidelines for primates. The latter was regarded as totally inadequate by the Australian Primate Society.

16.61 There is a need to prepare guidelines on specific species of animal to assist experimenters and animal house staff in their use and care. The Committee believes that ACCART is the most appropriate organisation to prepare guidelines in many areas of animal experimentation. It already has several monographs in the process of publication. ACCART should liaise with other specialist societies, including the NHMRC and its committees, in drawing up those guidelines. ACCART is more appropriate to undertake this task than the NHMRC because it is a resource centre whereas the NHMRC is primarily a government funding body.

16.62 The Committee RECOMMENDS that the Australian Council for the Care of Animals in Research and Teaching prepare guidelines on procedures and practices in relation to animal experimentation to supplement the Code of Practice.

Senator A.R. Devlin
Chairman

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APPENDIX I

LIST OF WITNESSES WHO APPEARED BEFORE THE COMMITTEE TO GIVE EVIDENCE ON ANIMAL EXPERIMENTATION

Adams, Mr J., Director, Animal Services, Monash University, Clayton, Victoria
Adams, Mr J., Selby, Victoria
Ahlston, Ms E., President, Australian Association for Humane Research, Broadway, New South Wales
Aitkin, Dr L., Monash University, Clayton, Victoria
Alexander, Dr G., President, Australian Federation for the Welfare of Animals Inc., Division of Animal Production, Ian Clunies Ross Animal Research Laboratory, Blacktown, New South Wales
Anderson, Dr W.P., Chairman, Animal Experimentation Ethics Committee, National Health and Medical Research Council, Canberra, Australian Capital Territory
Barber, Mr P., Director, RSPCA Victoria, Burwood, Victoria
Barnes, Mr D.,Australian and New Zealand Federation of Animal Societies, Collingwood, Victoria
Beazley, Dr L.D., Senior Research Fellow, Department of Psychology, University of Western Australia, Nedlands, Western Australia
Blackshaw, Dr A.W., Head, Department of Physiology and Pharmacology, University of Queensland, St Lucia, Queensland
Blackshaw, Dr J.K., Lecturer in Animal Behaviour, Department of Animal Sciences and Production, University of Queensland, St Lucia, Queensland
Boardman, Dr N.K., Member of Executive, CSIRO, Dickson, Australian Capital Territory
Bond, Professor N.W., Associate Professor, School of Behavioural Sciences, and Member, Animal Experimentation Ethics Committee, Macquarie University, Sydney, New South Wales
Bond, Dr N.W., School of Behavioural Sciences, Macquarie University, North Ryde, New South Wales
Boreham, Dr P.F.L., Principal Research Fellow, Queensland Institute of Medical Research, Herston, Queensland
Boura, Professor A.L.A., Chairman, Department of Pharmacology, Monash University, Clayton, Victoria
Boura, Professor A.L.A., Member, Australian Federation for the Welfare of Animals (Inc.), Blacktown, New South Wales
Bowen, Ms L.M., Layperson, Animal Experimentation Ethics Committee, National Health and Medical Research Council, Canberra, Australia Capital Territory
Bradshaw, Professor S.D., Member, Animal Welfare Committee, University of Western Australia, Nedlands, Western Australia
Bruce, Dr N.W., Associate Professor, Department of Anatomy and Human Biology, University of Western Australia, Nedlands, Western Australia
Burman, Mr S.L., Member, Australian Federation for the Welfare of Animals Inc., Blacktown, New South Wales

Burns, Mr J.P., Secretary, Animal Ethics Committee, University of Tasmania, Hobart, Tasmania
Bushell, Dr G.R., Senior Scientific Officer, Queensland Institute of Medical Research, Herston, Queensland
Campbell, Dr I., Director, Australian Society for Medical Research, Sydney, New South Wales
Carryer, Miss S.E., Administrator, WA Group Against Vivisection (Inc.), Perth, Western Australia
Carter, Mr P.D., Veterinarian, Division of Animal Health, CSIRO, Parkville, Victoria
Chenoweth, Deputy Dean, Clinical, School of Veterinary Science, University of Queensland, St Lucia, Queensland
Clark, Professor W.T., Professor of Small Animal Medicine and Surgery, Murdoch University, Murdoch, Western Australia
Clarke, Mrs P., President, Animal Liberation Tasmania Inc., Hobart, Tasmania
Coleman, Dr G.J., Chairman, Department of Psychology, La Trobe University, Bundoora, Victoria
Collins, Dr T.P., Vice-President, Australian Veterinary Association, Sydney, New South Wales
Cooper, Professor D.W., School of Biological Sciences, and Chairman, Animal Experimentation Ethics Committee, Macquarie University, Sydney, New South Wales
Cotton, Dr W.G., Ethical Animal Research Information Group, Animal Care, Westmead Centre, Westmead, New South Wales
Cotton, Dr W.G., Director of Animal Houses, University of Sydney, Sydney, New South Wales
Crossing, Dr R.J., Acting Principal Veterinary Officer, Bureau of Animal Welfare, Department of Agriculture and Rural Affairs, East Melbourne, Victoria
Cumming, Dr R.W., Secretary, National Health and Medical Research Council, Canberra, Australian Capital Territory
Curtis, Professor D., Department of Pharmacology, John Curtin School of Medical Research, Canberra, Australian Capital Territory
Curtis, Professor D.R., Member, Sub-Committee on Animal Experimentation, Australian Vice-Chancellors' Committee, Braddon, Australian Capital Territory
Daly, Mr D., Australian Council on the Care of Animals in Research and Teaching
Dalziel, Dr F., Senior Lecturer in Psychology, University of Adelaide, North Terrace, Adelaide, South Australia
Darian-Smith, Professor I., Professor of Anatomy, University of Melbourne, Parkville, Victoria
Darian-Smith, Professor I., National Health and Medical Research Council, Canberra, Australian Capital Territory
Davison, Mrs S.P., Secretary, National Council, Australian Animal Technicians Association, Brisbane, Queensland
Dawson, Professor T.J., Faculty of Biological and Behavioural Sciences, University of New South Wales, Kensington, New South Wales
De Cean, Department of Community Services and Health, Canberra, Australian Capital Territory

Deeny, Mr A.A., Director, Animal Resources Centre, Willetton, Western Australia
Dickson, Mr R.W., Member, National Council, Australian Animal Technicians Association, Brisbane, Queensland
Doherty, Professor R.L., Pro-Vice-Chancellor, Health Sciences, University of Queensland, St Lucia, Queensland
Donald, Dr A.D., Chief, Division of Animal Health, CSIRO, Glebe, New South Wales
Dorsch, Professor S.E., Pro-Vice-Chancellor, University of Sydney, Sydney, New South Wales
Dowsett, Dr J., Director of Teaching and Research, Resources and Chairman, Animal Care Committee, Parramatta Hospitals, Westmead Centre, Westmead, New South Wales
Dunlevy, Mr J.M.M., President, W.A. Group Against Vivisection, Perth, Western Australia
Eadie, Professor M.J., Chairman, Ethics Committee, Queensland Institute of Medical Research, Herston, Queensland
Edwards, Dr T., Animal Studies, Bentley College of TAFE, Hayman Road, Bentley, Western Australia
Egan, Professor A.R., Professor of Agriculture and Forestry, University of Melbourne, Parkville, Victoria
Egerton, Professor J.R., Chairman, Animal Welfare Advisory Council, Department of Local Government, Sydney, New South Wales
Fell, Dr L.R., Australian Federation for the Welfare of Animals Inc., Blacktown, New South Wales
Fenwick, Mr D.C., Chief Scientific Officer, Department of Physiology and Pharmacology, University of Queensland, St Lucia, Queensland
Fisher, Mr B.P., Vice-President, Animal Liberation (QLD) Ltd., Brisbane, Queensland
Gleeson, Dr P.J., Executive Officer, Animal Experimentation Ethics Committee, La Trobe University, Bundoora, Victoria
Graham, Dr D., National Biological Standards Laboratory
Hampson, Dr J.E., Consultant, Australian and New Zealand Federation of Animal Societies, Collingwood, Victoria
Harris, Mr I.E., Acting Director, Central Animal Breeding House, University of Queensland, St Lucia, Queensland
Harris, Mr I.E., Member, National Council, Australian Animal Technicians Association, Brisbane, Queensland
Healy, Mr T.J., CSIRO, Campbell, Australian Capital Territory
Hellyer, Dr O., Cosmetic, Toiletries and Fragrance Association of Australia, North Sydney, New South Wales
Howell, Professor J.M., School of Veterinary Studies, Murdoch University, Murdoch, Western Australia
Imray, Dr P., Department of Community Services and Health, Canberra, Australian Capital Territory
Jackson, Dr A., Executive Officer, Standing Committee on Ethics in Animal Experimentation, Monash University, Clayton, Victoria
Jackson, Professor D., University of Sydney, Sydney, New South Wales
Jackson, Dr G.D.F., Associate Professor, School of Microbiology, University of New South Wales, Kensington, New South Wales

Jacobs, Mr D., Curator, Animal House, University of Tasmania, Hobart, Tasmania
Janssens, Dr P.A., Australian National University, Canberra, Australian Capital Territory
Jeffrey, Dr P.L., Principal Research Fellow, Childrens Medical Research Foundation, Camperdown, New South Wales
Jenkin, Dr G., Councillor, Australian Federation for the Welfare of Animals Inc., Blacktown, New South Wales
Johnson, Dr K.G., Senior Lecturer in Physiology, Murdoch University, Western Australia
Jones, Mr M.R., Honorary Secretary, Animal Liberation (Western Australia), Inglewood, Western Australia
Jones, Mr W.L., Inspector, RSPCA Tasmania, Rosney Park, Tasmania
Kehoe, Dr E.J., Senior Lecturer, School of Psychology, Faculty of Biological and Behavioural Sciences, University of New South Wales, Kensington, New South Wales
Kehoe, Dr E.J., Australian Psychological Society, National Science Centre, Parkville, Victoria
Kelly, Dr G.E., Ethical Animal Research Information Group, Animal Care, Westmead Centre, Westmead, New South Wales
King, Professor M.G., Member, Australian Federation for the Welfare of Animals Inc., Blacktown, New South Wales
Kuchel, Dr T., Australian Society for Laboratory Animal Science
Large, Mrs A., Manager, Animal Welfare Branch, Department of Local Government, Sydney, New South Wales
Lawrence, Dr G.W., Senior Research Fellow, Queensland Institute of Medical Research, Herston, Queensland
Lazenby, Professor A., Australian Council on the Care of Animals in Research and Teaching
Lazenby, Professor A., Australian Vice-Chancellors Committee
Lindsay, Professor D.R., Chairman, Animal Welfare Committee, University of Western Australia, Nedlands, Western Australia
Logan, Professor M., Deputy Vice-Chancellor, Monash University, Clayton, Victoria
Lovibond, Dr P.F., Member, Australian Psychological Society, National Science Centre, Parkville, Victoria
Lowther, Professor P., Chairman, Animal Services Committee, Monash University, Clayton, Victoria
Lumbers, Professor E.R., School of Physiology and Pharmacology, Medical Faculty, University of New South Wales, Kensington, New South Wales
Lykke, Professor A.W.J., Chairman, Animal Ethics Committee, University of New South Wales, Kensington, New South Wales
Macey, Dr D.J., Lecturer in Biology and Animal Physiology, Murdoch University, Western Australia
Martin, Dr A.A., Chairman, Department of Zoology, University of Melbourne, Parkville, Victoria
Martin, Professor R., Chairman, Sub-Committee on Animal Experimentation, Australian Vice-Chancellors' Committee, Braddon, Australian Capital Territory
Martin, Dr T., Director of Animal Care, University of New South Wales, Kensington, New South Wales
McColm, Ms S., Animal Welfare Officer, Registrar's Office, University of Western Australia, Nedlands, Western Australia

McKie, Mr D.G., Secretary, Committee on Ethical Use of Animals for Experimentatal Purposes, University of Adelaide, North Terrace, Adelaide, South Australia
McNeil, Mr A., Officer in Charge, Central Animal House, University of Adelaide, North Terrace, Adelaide, South Australia
Manley, Dr S.W.W., Senior Lecturer, Department of Physiology and Pharmacology, University of Queensland, St Lucia, Queensland
Meischke, Dr R., RSPCA Australia, Fyshwick, Australian Capital Territory
Merkelbach, Mr P., Director of Animal Care, Westmead Centre, Westmead, New South Wales
Muller, Professor H., Head of Pathology, University of Tasmania, Hobart, Tasmania
Nelson, Dr D.S., Councillor, Australian Federation for the Welfare of Animals Inc., Blacktown, New South Wales
Nelson, Dr J., Senior Lecturer, Zoology Department, Monash University, Clayton, Victoria
Newman-Martin, Mr G., Principal Chemist, Toxicology Section, Department of Community Services and Health, Canberra, Australian Capital Territory
O'Donovan, Professor J., Member, Animal Welfare Committee, University of Western Australia, Nedlands, Western Australia
Parish, Dr C.R., Australian National University, Canberra, Australian Capital Territory
Pinder, Ms E., Australian Association for Humane Research, Darlinghurst, New South Wales
Porter, Professor R., Director, John Curtin School of Medical Research, Canberra, Australia Capital Territory
Porter, Professor R., Member, National Health and Medical Research Council, Canberra, Australian Capital Territory
Priestley, Dr B., Senior Lecturer, Pharmacology, University of Adelaide, North Terrace, Adelaide, South Australia
Purcell, Dr D.A., Chief Veterinary Pathologist, Animal Health Laboratories, Western Australian Department of Agriculture, South Perth, Western Australia
Reilly, Dr J., Animal Welfare Officer, Faculty of Veterinary Science, University of Queensland, St Lucia, Queensland
Reilly, Dr J., Animal Welfare Officer, Queensland, Institute of Medical Research, Herston, Queensland
Rex, Professor M.A.E., Chairman, Animal Experimentation Ethics Committee, University of Queensland, St Lucia, Queensland
Reynoldson, Dr J.A., Senior Lecuter in Pharmacology and Chemotherapy, Murdoch University, Murdoch, Western Australia
Rijswijk, Mr G. van, Agricultural and Veterinary Chemicals Association, North Sydney, New South Wales
Roach, Mr B.E., Supervising Senior Health Surveyor, Logan City Council, Woodridge, Queensland
Roberts, Mrs I.P., Committee Member, Australian Association for Humane Research, Darlinghurst, New South Wales
Ronayne, Professor J., Deputy Vice-Chancellor, Administration, University of New South Wales, Kensington, New South Wales
Rose, Dr M.A., Ethical Animal Research Information Group, Animal Care, Westmead Centre, Westmead, New South Wales

Rose, Dr M.A., Chairman, Animal Research Review Panel, Department of Local Government, Sydney, New South Wales
Rose, Dr M.A., Member, Sub-Committee on Animal Experimentation, Australian Vice-Chancellors Committee, Braddon, Australian Capital Territory
Rowe, Professor M.J., Associate Professor, School of Physiology and Pharmacology, Medical Faculty, University of New South Wales, Kensington, New South Wales
Rowe, Professor P.B., Director, Childrens Medical Research Foundation, Camperdown, New South Wales
Runciman, Dr W., Senior Lecturer, Intensive Care Unit, Flinders Medical Centre, Bedford Park, South Australia
Ryder, Mr R.D.,Australian and New Zealand Federation of Animal Societies, Collingwood, Victoria
Scott, Dr L., Animal Welfare Officer, University of Melbourne, Parkville, Victoria
Scott, Dr L., Australian Society for Laboratory Animal Science
Setchell, Professor B., University of Adelaide, North Terrace, Adelaide, South Australia
Shackleford, Mr and Mrs R.M., Emerald, Victoria
Sheldon, Dr B., Federation for the Welfare of Animals Inc., Blacktown, New South Wales
Shellam, Professor G.R., Professor of Microbiology, University of Western Australia, Nedlands, Western Australia
Siddle, Dr D.A.T., Associate Professor in Psychology, Australian Psychological Society, Macquarie University, North Ryde, New South Wales
Sim, Mr J.P., Member of Senate, Murdoch University, Murdoch, Western Australia
Singer, Professor P.,Vice-President, Australian and New Zealand Federation of Animal Societies, Collingwood, Victoria
Smith, Dr J., Animal Welfare Officer, Australian National University, Canberra, Australian Capital Territory
Smith, Dr J., Australian Society for Laboratory Animal Science
Smith, Dr J.B., Member, Board of Management, Australian Veterinary Association, Sydney, New South Wales
Stacey, Mr A.H., State President, RSPCA Tasmania, Launceston, Tasmania
Stone, Ms M., Senior Lecturer, Faculty of Law, University of New South Wales, Kensington, New South Wales
Stuart, Dr M.C., Member, Institution's Representative, Australian Federation for the Welfare of Animals Inc., Blacktown, New South Wales
Taylor, Dr I.W., Scientific Manager, Queensland Institute of Medical Research, Herston, Queensland
Taylor, Professor M.G., Deputy Vice-Chancellor, University of Sydney, Sydney, New South Wales
Ternai, Dr B., Chairman, Animal Experimentation Ethics Committee, La Trobe University, Bundoora, Victoria
Titchen, Professor D.A., Professor of Veterinary Physiology, University of Sydney, Sydney, New South Wales
Toia, Dr J., Chairman, National Council, Australian Animal Technicians' Association, South Brisbane, Queensland

Trent, Mrs J.K., Executive Officer, Northern Tasmanian Division, RSPCA Tasmania, Launceston, Tasmania
Vaughan, Mrs A., Australian National University, Canberra, Australian Capital Territory
Wackett, Mr M.S., Senior Administrative Officer, Research and Postgraduate Studies, Murdoch University, Murdoch, Western Australia
Watts, Mr D., Senior Project Officer, Animal Welfare Office, Department of Lands, Adelaide, South Australia
White, Dr R.W., Senior Lecturer in Zoology, University of Tasmania, Hobart, Tasmania
Wiskich, Dr J., Chairman, Executive Committee, University of Adelaide, North Terrace, Adelaide, South Australia
Withell, Mr J., National Biological Standards Laboratory, Canberra, Australian Capital Territory
Worth, Dr H., President, RSPCA Victoria, Burwood, Victoria
Wright, Mr C., RSPCA Australia, Fyshwick, Australian Capital Territory
Young, Dr I., Department of Physiology, Monash University, Clayton, Victoria
Yuncken, Mr T.F., Member, Animal Experimentation Ethics Committee, University of Melbourne, Parkville, Victoria