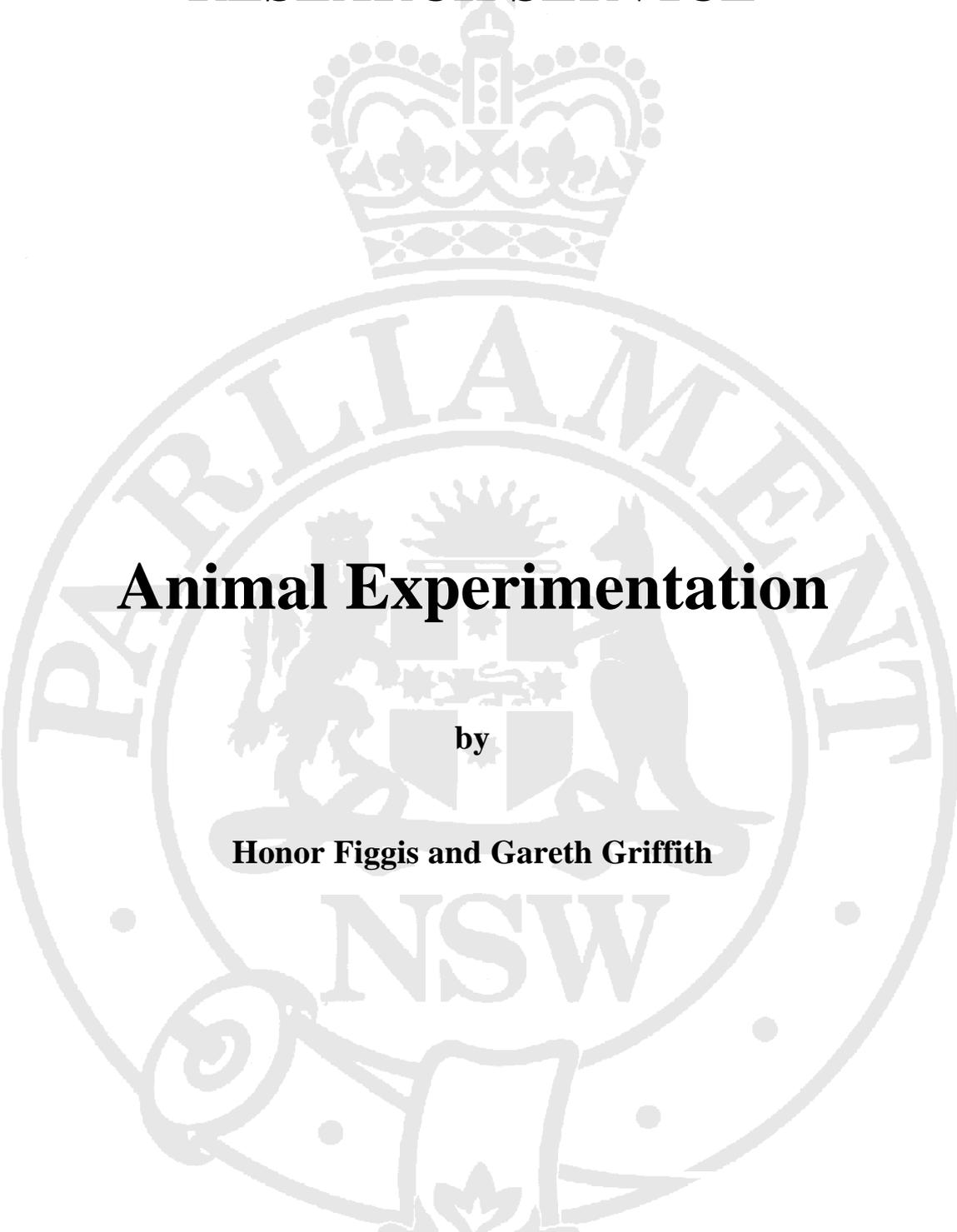


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Animal Experimentation

by

Honor Figgis and Gareth Griffith

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Honor Figgis and Gareth Griffith

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EXECUTIVE SUMMARY

The purpose of this background paper is to look at the facts and arguments relating to several aspects of the scientific use of animals in New South Wales, with some interstate and international comparisons. The main points can be summarised as follows:

- For a large number of people, the use of animals in research raises **difficult moral questions**. A spectrum of attitudes towards the use of animals can be found. At one end are those who believe that animal experimentation for any reason is simply wrong, and at the other end are those who do not find the use of animals in research problematic in any way. Many people find themselves somewhere towards the middle of the spectrum, seeking to protect the welfare of animals as far as possible without compromising the welfare or, possibly, the convenience of humans (pp 1-3).
- Attitudes to the use of animals are generally shaped by personal convictions as to whether animal experimentation has benefitted human and/or animal welfare; whether some or all animals do in fact experience pain, stress or anxiety; and what the moral status of animals is in relation to humans. These questions are all the subject of debate in scientific and philosophical circles (pp 3-16).
- There are three principles central to the humane conduct of animal research: the **replacement** of animals with other experimental techniques; the **reduction** of the number of animals used in experiments; and the **refinement** of procedures to minimise the impact of experiments on animals. These principles guide the continuing efforts to develop alternatives to animal experiments. The extent to which existing alternatives can replace animal experiments is a controversial question. Another area of debate is how the three principles should be incorporated into animal research systems (pp 57-70).
- **Animal use figures** in New South Wales tend to vary from year to year. The use of animals may decline in some research areas, but increase in others. While there is no clear downward trend in the number of animals used, there are specific instances of reduction in the use of animals and refinement of experiments to reduce the impact on the animals involved. In New South Wales, a total of 2, 481,031 animals were used in research and teaching in 1995-96. Almost 78% of these animals were fish, followed by domestic fowl (7.7%), mice (5%), sheep (3.1%) and rats (2%). Altogether 2728 cats, dogs and primates were used, about 0.1% of the total number of animals. Several other Australian States collect animal use figures, but these are not directly comparable as the methods of collecting information vary widely among the States (pp 21-25).
- The **adequacy of the available animal usage figures** has been criticised on several grounds. It is said that the published statistics do not inform people about critical aspects of the research being conducted, such as how invasive the animal research procedures are, their justification, or their potential to cause pain or distress.

Criticisms have also been made about a lack of publicly available information on how many animal experiments are actually producing significant or valuable results (pp 21-23).

- **Australian State and Territory legislation regulating animal research** varies considerably, but the regulatory systems generally share similar basic features. The animal research legislation in New South Wales, South Australia, Victoria and the ACT is more comprehensive and up to date than that of Queensland, Western Australia and the NT, although these last three jurisdictions are currently reviewing their legislation. Common features of State regulatory systems are: mandatory research licences for individuals or institutions, and mandatory prior approval by an ethics committee of procedures involving animals. Community representatives and animal welfare supporters are brought onto institutional animal ethics committees in order to ensure community participation in decisions about what animal research should be allowed (pp 25-33).
- A unifying force linking the various State systems is the **Australian Code of Practice for the Care and Use of Animals for Scientific Purposes** produced by the National Health and Medical Research Council. The guiding principles of the Code are: the requirement to establish the necessity of the proposed study; the requirement to make an ethical judgment that the proposed experiment is justified, weighing its scientific and educational value against the potential effects on the animals; the obligation to treat animals with respect and to consider their welfare; and strategies to apply the principles of replacement, refinement and reduction (pp 26-27).
- There are a number of possible **regulatory models** for controlling animal research. At one end of the regulatory spectrum is a system in which there is no government control or intervention, with all decisions on experimentation being taken by researchers and their institutions; at the other end is a totally regulated system where government takes responsibility for approving experiments and for monitoring the conduct of research. In between these two extremes is 'enforced self-regulation', the type of system adopted in New South and other Australian jurisdictions, and commonly adopted in other countries. The selection of an animal research regulatory regime is generally informed by arguments about the relative effectiveness of self-regulation and government intervention in controlling the conduct of animal research (pp 34-47). Similar arguments arise in determining how the animal research laws should be enforced (pp 54-57).
- **Animal ethics committees** play a key role in the operation of the New South Wales animal research laws. Although the benefits of these committees are generally accepted, there is debate about their effectiveness in practice. Questions centre around: what the role of the community and animal welfare members should be; the selection of these members, and the level of institutional and administrative support given to them; and how ethics committees should approach their task of weighing the costs and benefits of animal experiment proposals (pp 47-53).

1. INTRODUCTION

The purpose of this background paper is to look at the facts and arguments relating to several aspects of animal experimentation in New South Wales, with some interstate and international comparisons. The paper begins with a discussion of the philosophical and moral issues surrounding the use of animals. The next part of the paper sets out what constitutes 'animal experimentation' in Australia, and what kinds of animals are covered by animal research legislation in various jurisdictions. It also outlines the purposes for which animals are used, and looks at some concerns about a lack of publicly available information on the nature and extent of animal experimentation in Australia. Part 4 summarises the animal research legislation in the Australian States and Territories, with particular attention to the New South Wales legislation. Part 5 looks at the various models for regulating animal research, and summarises the regulatory systems in several other countries, including the United Kingdom, the United States of America, Canada and New Zealand.

Parts 6 and 7 of this background paper look in more detail at some aspects of the New South Wales animal research system, in particular the operation of animal ethics committees, and some proposals made by the Regulation Review Committee of the New South Wales Parliament for reforms to the administration of the legislation. Finally, this background paper looks at some legislative and scientific developments in alternatives to animal use, with specific reference to three areas of particular community concern: cosmetics testing, the LD50 lethality test, and the Draize rabbit eye test. The paper does not look at the use of animals in education or training, or at the source of animals used for research (pound, purpose-bred or wild-caught animals).¹

2. PHILOSOPHICAL AND MORAL ISSUES

Conflicts and dilemmas in balancing human and animal welfare: It is said sometimes that in life we can be faced with dilemmas and conflicts to which there do not appear to be any clear and morally satisfactory answers; in such situations whatever good is produced by a course of action, there seems to be a corresponding evil. As the philosopher Thomas Nagel stated, 'The world can present us with situations in which there is no honourable or moral course for a man to take, no course free of guilt and responsibility for evil'.² For a growing number of people the question of the use of animals in biomedical research may be an issue

¹ The use of stray or pound animals in research is currently the subject of an inquiry by a working party established by the Minister for Agriculture. The NSW Animal Research Review Panel is also reviewing the supply of animals from pounds to research establishments. It has been reported that Cabinet is due to debate the question soon: 'Experiments on stray dogs face total ban', *Sydney Morning Herald*, 9/6/98, p 5. For more information on this issue, see Regulation Review Committee, NSW Parliament, *Report on the Animal Research Regulation 1995*, Report No 13/51, November 1997 pp 50-51; Senate Select Committee on Animal Welfare, Commonwealth Parliament, *Animal Experimentation*, AGPS, Canberra, Chapter 10.

² Quoted in G Griffith, *Socialism and Superior Brains: The Political Thought of Bernard Shaw*, Routledge 1993, p 240.

of this sort, where it is hard to be consistent, coherent and truly disinterested in one's moral thinking. Moreover, it may be that the more we think about the matter, the more we bring the analytical tools of philosophy to bear upon it, the more we imagine we understand what is at issue, the harder it is to construct a position which is not free from moral dilemma.

Not everyone finds him or herself in this difficult position. For some people animal experimentation, be it for biomedical or other reasons, is simply wrong: in which case the only morally satisfactory course is to oppose any such experimentation and abolish it altogether. At the other end of the spectrum, there are those who do not find the use of animals in biomedical (and possibly other) research problematic in any way and would propose its continuation and sometimes its extension.

As with most complex matters, however, it may be that the tendency is for most of those who have given the issue of animal experimentation some thought to find themselves at a mid-point on the spectrum, in a state of more or less discomfort and indecision. Presumably most people tend to assume that some benefit flows from the use of animals in biomedical research. Likewise, with a little imagination most people can place themselves in a situation where any real or potential benefits may be of vital importance to oneself or to those closest to them, for example, in relation to cancer or HIV research. Yet, it can also be presumed that some of us would feel some discomfort if we were to learn that those benefits had been gained at the cost of pain and suffering to, let us say, a thousand dogs or ten thousand chimpanzees. In stark terms, then, the question from this mid-point is how are we to balance the competing claims of human and animal welfare?

How legislation balances human and animal welfare: At this stage it can be noted that the relevant legislation in NSW, as well as in most other comparable jurisdictions, seeks to achieve a balance which tacitly acknowledges the superior moral status of humans, thereby permitting animal experimentation in certain well-defined situations. On the other hand, the legislation also seeks as far as possible to limit the use of animals in biomedical research and to offer protections and safeguards for those animals which are used on the assumption that they do experience pain and suffering. In other words, legislation in this field is typically something of a mid-point compromise between the welfare of humans and animals, in which the balance is weighted in favour of humans.

The 'three Rs': Informing much of this middle ground approach is the principle of the 'three Rs', as formulated in the 1950s by British zoologist William Russell and microbiologist Rex Burch in their book *The Principles of Humane Experimental Technique*. Russell and Burch had the following goals: *replacement* of animal experiments whenever possible; in the absence of complete replacement, researchers should strive for a *reduction* in the number of animals used in each procedure, consistent with the requirements of statistical analyses; and the *refinement* of experiments to minimise the suffering involved. The 'three Rs' principle is now widely accepted: see Part 8 of this background paper.

Different kinds of animal experimentation and the question of welfare: It can also be noted that the debate about animal experimentation is rendered more complex by the fact that it is not always conducted for the proposed benefit of human welfare. In veterinary

research, for example, it is the welfare of animals themselves which is (or should be) the point at issue, thus presenting a different perspective on the moral and philosophical problems concerned. Alternatively, if animals are used in safety testing in the cosmetics industry, for instance, then any claim that such testing serves the purpose of human welfare must be open to serious questioning; indeed, such research may be impossible to defend on the ground of welfare which, arguably, presupposes *needs* not *wants*. Then again, to further complicate the discussion, some forms of research using animal experimentation may claim to serve the purposes of both human and animal welfare, as in the case of some toxicity testing on fish which may provide information about the safety levels of chemicals for humans as well as for fish and other aquatic life forms. Indeed, adding still another dimension to the discussion, the welfare of the environment as a whole may also be at issue in some circumstances.

Three questions: The foregoing discussion raises at least three important questions. One is the practical question as to whether it can be shown that animal experimentation has benefitted human and/or animal welfare. A second is the threshold question as to whether some or all animals do in fact experience pain, stress or anxiety and can, therefore, be said to suffer more or less as humans suffer when undergoing physical or mental deprivation or invasion. The third question relates to the moral status of humans and animals and its implications for undertaking animal research.

The benefits of animal experimentation: As with every issue in the animal experimentation debate, the question as to its practical benefits is the subject of some controversy. A minority view is that the value of animal experimentation for advancements in biomedical science has been grossly overstated. In a forum conducted recently by the journal, *Scientific American*, this case was argued by two practising physicians, ND Barnard and SR Kaufman. Concentrating on the unique biology of each species and the consequent pitfalls involved in extrapolating animal data to other species, including humans, they maintain that:

although animal experiments are sometimes intellectually seductive, they are poorly suited to addressing the urgent health problems of our era, such as heart disease, cancer, stroke, AIDS and birth defects. Even worse, animal experiments can mislead researchers or even contribute to illness or deaths by failing to predict the toxic effects of drugs.³

Barnard and Kaufman present a range of examples to support their case, noting for example that many animals have been used in AIDS research, 'but without much in the way of tangible results'. It is noted, too, that cancer research is 'especially sensitive to differences

³ ND Barnard and SR Kaufman, 'Animal research is wasteful and misleading', *Scientific American*, February 1997, p 64. A recent edition of *Four Corners* discussed research into the complex problems that may arise from the use of animals in biomedical research. The program dealt with the possibility that the early polio vaccines from the 1950s had been contaminated by a virus carried by the monkeys used in the research, the SV.40 virus, and the as yet unsubstantiated claim that that virus may be a cause of mesothelioma cancer in humans - *Four Corners*, 14 April 1998.

in physiology between humans and other animals'.⁴ On the subject of the use of animals to test the safety of drugs and other chemicals, Barnard and Kaufman comment:

many substances that appeared safe in animal studies and received approval from the US Food and Drug Administration for use in humans later proved dangerous to people. The drug milrinone, which raises cardiac output, increased survival of rats with artificially induced heart failure; humans with severe chronic heart failure taking this drug had a 30 per cent increase in mortality. The antiviral drug fialuridine seemed safe in animal trials yet caused liver failure in seven of 15 humans taking the drug...The commonly used painkiller zomepirac sodium was popular in the early 1980s, but after it was implicated in 14 deaths and hundreds of life-threatening allergic reactions, it was withdrawn from the market. The antidepressant nomifensine, which had minimal toxicity in rats, rabbits, dogs and monkeys, caused liver toxicity and anemia in humans - rare yet severe, and sometimes fatal, effects that forced the manufacturer to withdraw the product a few months after its introduction in 1985.⁵

Barnard and Kaufman add that 'Researchers have better methods at their disposal',⁶ and explain that, because animal 'models are, at best, only analogous to human conditions, they cannot be used to prove or refute any theory. As a result, it is claimed, animal experiments 'serve primarily as rhetorical devices' in scientific debates: 'And by using different kinds of animals in different protocols, experimenters can find evidence in support of virtually any theory'.⁷

The 1989 Senate Select Committee on Animal Welfare also heard evidence to this effect,

⁴ Indeed, scientists have been able to cure cancer in mice for many years but not in humans. Recent reports that a major breakthrough was imminent in the treatment of breast cancer were shown to be premature. Dr Richard Klausner, head of the US National Cancer Institute, was quoted as saying, 'The history of cancer research has been a history of curing cancer in the mouse...We have cured mice of cancer for decades - and it simply didn't work in people':- C Gorman, 'The hope', *Time*, 18 May 1998 p21.

⁵ Barnard and Kaufman, n 3, p 65. For further commentary on the problems and limitations of animal experimentation see for example - R Sharpe, 'Animal experiments - a failed technology' in *Animal Experimentation: The Consensus Changes* edited by G Langley, Macmillan 1989; H Ruesch, *Naked Empress or the Great Medical Fraud*, Civis 1982; Hon R Jones MLC, *NSWPD*, 16/6/97, pp 10250ff.

⁶ Barnard and Kaufman, n 3, p65. They continue: 'These techniques include epidemiological studies, clinical intervention trials, astute clinical observation aided by laboratory testing, human tissue and cell cultures, autopsy studies, endoscopic examination and biopsy, as well as new imaging methods. And the molecular science of epidemiology, which relates genetic, metabolic and biochemical factors with epidemiological data on disease incidence, offers significant promise for identifying the causes of human disease'.

⁷ *Ibid*, p 66. It is said that 'researchers have used animal experimentation to show that cigarettes both do and do not cause cancer'.

notably from representatives of the Australian Association for Humane Research.⁸ However, both in relation to fundamental and applied research in the biomedical field, the Select Committee was persuaded by the arguments of the proponents of animal experimentation who maintained that ‘biomedical science, largely dependant on animal experimentation, has made many advances over the last century in developing cures for diseases and for the relief of pain and distress’.⁹ The same view was adopted in the 1991 report of a Working Party of the British Institute of Medical Ethics which stated, ‘There can be no doubt that the use of animals in medical research in the past has proved worthwhile for human purposes, with consequent benefit to human and animal health’.¹⁰ Both the British Working Party and the Australian Select Committee agreed that, for the foreseeable future and in the absence of credible scientific and moral alternatives, some animal experimentation is necessary for the advancement of biomedical science. For the Working Party this argument of necessity was developed only in relation to research of which it can be said that ‘a benefit accruing to the prevention, diagnosis or treatment of disease, ill health or abnormality in humans or animals must be *possible and intended*’.¹¹

On the issue of the benefits flowing from animal experimentation, the UK based Research Defence Society has stated:

There is ample evidence to show that animal research has been vital for medical advances in the past. For example, it has helped provide antibiotics and vaccines, insulin for diabetes, treatments for leukaemia, local and general anaesthetics, and has made possible advances in medical technology such as blood transfusion, kidney dialysis, and the heart lung machine.¹²

JH Botting and AR Morrison, writing in the *Scientific American*, said they could ‘not think of an area of medical research that does not owe many of its most important advances to animal experimentation’.¹³ One example was the recent development of a ‘vaccine against *Hemophilus influenzae* type B (Hib), a major cause of meningitis, which before 1993 resulted in death or severe brain damage in more than 800 children each year in the US. Early versions of a vaccine produced poor, short-lived immunity. But a new vaccine, prepared and tested in rabbits and mice, proved to be powerfully immunogenic and is now

⁸ Senate Select Committee on Animal Welfare, *Animal Experimentation*, AGPS 1989, p 66.

⁹ Ibid, p 67.

¹⁰ JA Smith and KM Boyd eds, *Lives in the Balance: The Ethics of Using Animals in Biomedical Research - The Report of a Working Party of the Institute of Medical Ethics*, Oxford University Press 1991, p 25.

¹¹ Ibid, p 31.

¹² Research Defence Society - Today’s research for tomorrow’s treatments, [Http://www.uel.ac.uk/research/rds/today.htm](http://www.uel.ac.uk/research/rds/today.htm)

¹³ JH Botting and AR Morrison, ‘Animal research is vital to medicine’, *Scientific American*, February 1997, p 67.

in routine use'.¹⁴ They note, too, that open-heart surgery was the consequence of 20 years of animal experimentation, and that replacement heart valves also emerged from years of animal experiments. Animal research is also said to have been instrumental in generating solutions to the problems confronting doctors in the field of kidney or other major organ transplantation. 'The list continues', write Botting and Morrison:

Before the introduction of insulin, patients with diabetes typically died from the disease. For more than 50 years, the lifesaving hormone had to be extracted from the pancreas of cattle or pigs; these batches of insulin also had to be tested for safety and efficacy on rabbits and mice.¹⁵

As the 1989 Senate Select Committee Report acknowledged, the argument for using animal experimentation is less compelling outside the field of biomedical science. The use of animals in the psychological and behavioural sciences was one area where the benefits accruing from animal experimentation were not as clear cut;¹⁶ toxicological testing was another difficult area.

Do animals experience pain, stress and anxiety?¹⁷ Much of the literature on this subject discusses the problems involved in assessing pain, stress and anxiety in animals. Briefly, it can be noted that: (a) the relevant terms are hard to define; (b) pain involves some private or subjective aspect and it is therefore hard to measure; (c) the grounds for supposing that animals have a subjective life similar to that of humans may not be as self-evident as is sometimes supposed, in large because of differences in ways of life and in how animal bodies work; (d) while there may be general agreement that many animals, mammals in particular, have the capacity to experience pain and suffering, the situation may be less clear-cut where other non-human species are concerned; (e) the question, then, is one of deciding where to draw the line, let us say between vertebrates and invertebrates for example and, for the sake of argument, on which side of the line should a fish, an octopus, an insect and a shrimp fall; (f) in drawing that line and in discussing animal suffering generally we should avoid adopting an anthropomorphic concept of suffering, that is personifying and treating

¹⁴ Ibid.

¹⁵ Ibid, p 68.

¹⁶ The Committee did not recommend a complete ban on the use of animals in this area, but it did call for careful consideration by the relevant ethics committees and funding bodies to determine the necessity of animal experimentation.

¹⁷ For further reading on this subject see: RA Jenkin, *Invertebrates and Pain*, 10 April 1994, the text of which is set out at Appendix A to this paper; Smith and Boyd, n 10, Chapter 4; M Rose and D Adams, 'The evidence for pain and suffering in other animals' from *Animal Experimentation: The Consensus Changes* edited by G Langley, Macmillan 1989; M Rose, 'The problem of pain: concepts and issues' (December 1996) 9 *ANZCCART News* 2-4; Animal Welfare Committee of the National Health and Medical Research Council, *Ways of minimising pain and distress in animals in research*, AGPS 1994; LR Rogers, 'What do animals think and feel?' (1994) 7 *ANZCCART News* 1; G Vines, 'Who's suffering now?', *New Scientist*, 22 March 1997, p 31.

other species as if they were actually human when in fact they are not.¹⁸

In terms of the general debate about the capacity of non-human species to experience pain and suffering, the once influential hard-line argument that animals cannot experience pain is associated with the seventeenth century French philosopher, Rene Descartes. He maintained that non-human animals are automata who go through the external motions which in humans are symptomatic of pain without experiencing its mental sensation. It is fair to say that this is now a minority standpoint and that it has been superseded by a 'benefit of the doubt' view which holds that animals do have the capacity to experience pain and suffering, but that the capacity is limited to sentient creatures only. The problem then becomes one of how to define sentience and, again, to settle on a cut-off point. For example, Peter Singer declared at first that sentience stops at the level of the oyster: creatures higher than the oyster in terms of the species order (for example, the lobster) are conferred with a degree of sentience; those at or below the level of the oyster excluded.¹⁹

In the relevant protective legislation, such as the New South Wales Animal Research Act, a division is often drawn between vertebrates and invertebrates. However, significant variations remain from one jurisdiction to another (see Part 3.1 of this background paper). The interesting point is that legislation of the sort in force in NSW, along with the relevant codes of practice in force in this country and elsewhere,²⁰ imply a continuity as far as the experience of pain and suffering is concerned between most creatures capable of mere sentience, at one end of the spectrum, and we humans with our capacity for full reflective consciousness, at the other. At the same time, however, by explicitly excluding humans from the definition of 'animal' such legislation maintains a discontinuity in moral status between humans as against all non-human vertebrates and invertebrates, sentient or otherwise. How,

¹⁸ One perspective on this is to ask whether different species have different forms of consciousness to our own and that the suffering of such animals may be magnified by the perception of the suffering of others: LR Rogers, 'What do animals think and feel?' (1994) 7 *ANZCCART News* 1 at 2. By way of an alternative, could it be that to unravel how and when an animal suffers the subjective aspect of the experience should be downplayed and we should ask instead if evolution has designed the animal to deal with the conditions it faces - animals suffer, it is sometimes argued, where they are forced to perform outside their design criteria and the question then is whether experimental procedures, intensive farming techniques and the like infringe the design criteria of a particular species and prevent that species from acting in line with the inbuilt evolutionary rules of thumb which guides its behaviour: G Vines, 'Who's suffering now?', *New Scientist*, 22 March 1997, pp 31-33.

¹⁹ For Singer's changing views on the subject see - P Singer, *Animal Liberation*, 2nd ed, The New York Review of Books 1990, p 174. In 1980 Singer wrote, 'To the question as to where precisely the limit is to be drawn, I can only plead agnosticism. I presume that fish can feel pain, but I do not know whether shrimps and insects can' - RM Baird and SE Rosenbaum, *Animal Experimentation: The Moral Issues*, Prometheus Books 1991, p 64.

²⁰ Animal Welfare Committee of the National Health and Medical Research Council, *Ways of minimising pain and distress in animals in research*, AGPS 1994, p 7. It is noted that the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes 'is based on the view that pain in animals, at our current state of knowledge, cannot be easily evaluated, and therefore investigators must, for practical purposes, assume that animals experience pain in a manner similar to humans'.

if at all, can this be justified?

The campaign for animal welfare:²¹ The campaign against cruelty to animals is longstanding, dating at least as far back as 1824 with the establishment in Britain of the Society for the Prevention of Cruelty to Animals (after 1840 the RSPCA). There followed campaigns against vivisection and for the regulation of animal experimentation which, in 1876, resulted in the passing of the *Cruelty to Animals Act* (UK). The cause of anti-vivisection continued to be heard in the vigorous public debate before World War One, finding a notable champion in George Bernard Shaw. After the War, however, perhaps as a result of the public's regard for the spectacular medical advances of the period, the cause of complete abolition declined, to be replaced by small pressure groups with more moderate goals and a public which was for the most part uncritical of science and its methods. Not until the 1970s, with the publication of Peter Singer's *Animal Liberation*, was the debate on animal welfare renewed with real intensity and, it should be said, with a greater intellectual rigour than had previously been the case. The key to this debate was the question of the relative moral status of humans and animals.

Speciesism and the moral status of humans and animals: The central challenge of Singer's work is found in the concept of 'speciesism'. As explained by the Working Party of the British Institute of Medical Ethics this alleges that the mere fact of membership/non-membership of the human race cannot in itself be the criterion for judging some creatures to have an enhanced moral status. The argument is developed by analogy. It states that, in rejecting racism, we accept that mere membership of an ethnic group does not in itself justify greater burdens or less benefits in one's social lot: 'Discrimination in benefits and burdens must relate to specific facts about the subject discriminated against (or for)'.²² The question posed by the proponents of animal rights, therefore, 'is whether there is any morally significant feature which all humans, but no animals, possess, and which hence could justify treating them differently'.²³ Often discussed in the literature are such morally significant features as self-consciousness, rationality²⁴ and language. The proponents of animal rights

do not claim that any other animal possesses these features in as developed a form as do adult human beings:

²¹ This account is based on V Monamy, *Animal Experimentation: A Student Guide to Balancing the Issues*, Osmond SA, Australian and New Zealand Council for the Care of Animals in Research and Teaching, 1996, Chapter three.

²² Smith and Boyd, n 10, p 317.

²³ Ibid, p 301.

²⁴ In the rationalist tradition, which has its origins in Aristotle's work, it is the capacity to reason which is decisive in answering the question, 'who belongs to the moral community?'. In this tradition, direct duties are only owed to fellow members of the moral community and, as animals are judged to lack the capacity to reason, they are placed outside the sphere of direct duty. According to this tradition, there may be indirect duties to animals, but these are not owed to them, for no one outside the moral community can either be owed a direct duty or possess a correlative right - LC Becker and CB Becker eds, *Encyclopedia of Ethics*, Volume 1, St James Press 1992, p 42.

But some of these features are possessed, to a greater or lesser extent, by some animals; and they are absent in some human beings, for example infants, the severely mentally retarded and the senile. If we believe that the interests or rights of these humans should be respected, these philosophers argue, then it is inconsistent not to respect analogous interests and rights in animals.²⁵

This is the challenge posed by Peter Singer and other radical animal rights philosophers, notably Tom Regan. It was developed in opposition to the more traditional views which can be summarised as follows: (a) the now largely abandoned views associated with the philosopher, Rene Descartes, which were discussed earlier in this part of the paper; (b) the interpretation of Darwinian theory which places humans at the top of the evolutionary ladder and therefore superior to animals;²⁶ (c) various interpretations of the Christian tradition in which man is given an absolute or limited dominion over other creatures; and (d) consistent with that 'limited dominion' view there is the 'humane' interpretation of the right of humans to use animals in which humans must exercise a responsible stewardship over other creatures, thus avoiding tyrannical practices and any avoidable cruelties. This last view, derived as it is from the Christian tradition, was described by the Working Party of the British Institute of Medical Ethics as reflecting 'common morality's perspective on the status of animals' in twentieth century Western society.²⁷ The challenge posed by radical philosophy to this 'common morality' is the claim that it is a form of special pleading riddled with the moral inconsistencies associated with speciesism.

Singer's utilitarian argument based on interests: Although the critics of speciesism all agree on the general thrust of their argument, on closer analysis important differences in detail emerge between them. For example, while many of the critics of speciesism attempt to show that animals have rights, Singer on the other hand prefers to base his utilitarian argument on the concept of 'interests',²⁸ that is, all creatures capable of suffering can claim

²⁵ Smith and Boyd, n 10, p 301.

²⁶ For an alternative view of the implications of Darwinian theory for the moral status of humans and animals see - J Rachels, *Created from Animals: The Moral Implications of Darwinism*, Oxford University Press 1990. Rachels contends that Darwinism serves to establish the continuities between humans and animals and, therefore, to undermine the placing of humans in a special moral category. Arguing against speciesism and for a form of moral individualism, Rachels maintains that distinctions can only be made between individual creatures 'where there are relevant differences that justify differences in treatment' (page 222).

²⁷ Smith and Boyd, n 10, p 316.

²⁸ Utilitarianism is a form of consequentialism, which means that it the consequences of actions which determine their rightness or wrongness. For the classical utilitarianism associated with Jeremy Bentham (1748-1832) morality consists of maximising pleasure and minimising pain of the greatest number of individuals. Moreover, in this scheme of things 'each is to count as one and none as more than one' in any moral calculation of the rightness or wrongness of a course of action. Singer, it is said, operates with a form of 'preference utilitarianism' in which utility is to be measured in terms of satisfaction or preferences. His argument is that self-conscious, rational human beings are capable of having a specific preference for continued existence, a factor which can make their lives of more than equal worth compared

an equal consideration as far as their interest in avoiding pain is concerned.²⁹ For Singer, it does not follow from this that all creatures will be treated equally: 'The basic principle of equality does not require equal or identical *treatment*; it requires equal consideration. Equal consideration for different beings may lead to different treatment and different rights'.³⁰ Singer does not claim, for instance, that life is of no greater value to a normal adult human than to a being with no self-awareness, or that it is necessarily as wrong to kill a dog as it is to kill a human being in full possession of his or her faculties.³¹ Viewed in this light, in theory at least Singer is not an absolute abolitionist as far as animal experimentation is concerned. He is prepared to accept, for example, that if a single experiment could cure a major disease, then it would be justified on the basis of a utilitarian cost benefit analysis of the balance of pleasure and pain involved. However, the sting in the tail of Singer's argument is that a justification of this sort must avoid the arbitrariness of speciesism, so that justice must be done between an adult chimpanzee, let us say, and a severely retarded or hopelessly senile human. This consideration leads him to formulate the test that 'an experiment cannot be justifiable unless the experiment is so important that the use of a retarded human being would also be justifiable'.³² In other words, from Singer's utilitarian standpoint, animals may be used for purposes which serve the common good, but only if we are prepared to use humans in the same way.

Regan's rights based argument: Tom Regan's version of the animal rights argument was formulated in his book, *The Case for Animal Rights*, published in 1983. This argument is 'categorically abolitionist',³³ at least as far as experimentation on mammals is concerned. Fundamental to it is the Kantian³⁴ idea that individuals who have inherent value must be treated, not as a means, but as ends in themselves: such individuals have morally significant value in themselves, apart from their possible usefulness to others and independently of any utilitarian calculation of the episodic or overall value of their mental states. Regan's argument has been summarised as follows:

to the lives of other creatures. His further contention is that, due to his abandonment of speciesism, he cannot make the same claim on behalf of those humans who are not fully self-conscious and rational, as in the case of the severely retarded or hopelessly senile.

²⁹ Jeremy Bentham, in a much-quoted statement, wrote, 'The question is not, can they [animals] reason? Nor, can they talk? But *can they suffer?*'.

³⁰ P Singer, *Animal Liberation*, 2nd ed, The New York Review of Books 1990, p 2.

³¹ Ibid, p 18.

³² L Gruen, 'Animals' from *A Companion to Ethics* edited by P Singer, Basil Blackwell Ltd 1993, p 349.

³³ T Regan, 'The case for animal rights' from *In Defence of Animals* edited by P Singer, Basil Blackwell 1985, p 24.

³⁴ After the German philosopher, Immanuel Kant (1724-1804). The term 'deontology' is used to describe his ethical theory, based as this is on the duty we have to respect fundamental principles (for example, that autonomous and rational persons have a moral dignity which prevents them from being treated as a means to an end). The Greek word for duty is '*deon*', hence the name deontology.

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- rights can be claimed for all individuals who possess ‘inherent value’, whether or not they are ‘persons’ in the full sense;
 - inherent value rests on being the ‘subject of a life’ rather than merely being alive or being conscious. Regan’s criteria for this are quite extensive, but briefly they entail having desires, memory, a sense of the future and an emotional life including feelings of pleasure and pain;
 - there is sufficient evidence to suggest that all mammals (aged at least one or more) possess these attributes. Therefore they have a right to respectful treatment and may not be casually used or harmed without good cause. Although such mammals cannot be moral agents, they are moral patients. We respect their rights even though they cannot respect ours.³⁵

Criticisms of the Singer and Regan arguments: Both the utilitarian and rights based arguments against animal experimentation have drawn a wide range of criticisms. Some examples of the difficulties found with Singer’s work are as follows:

- that the reliance on the analogy between racism and speciesism is unsound. There is no morally relevant distinction among the races and therefore racism does not have any rational basis. Between species of animate life, on the other hand, there are morally relevant differences. As Carl Cohen explains, unlike animals, ‘Humans engage in moral reflection; humans are morally autonomous; humans are members of moral communities, recognizing just claims against their own interest’.³⁶
- it is suggested that Singer’s insistence on sentience as the thing that matters, together with his reliance on a utilitarian theory of ethics, would seem to permit experimentation on any creatures that cannot, for whatever reason, feel pain. Thus, in the absence of any underlying animal right to life or liberty, Dr Michael Walsh, Senior Lecturer in Bioethics at the University of Technology, Sydney, states that if it were possible to make animal experimentation pain free, we would seem to be ‘justified in conducting research that would produce benefits in terms of health, well-being, safety, or knowledge’.³⁷
- any strong form of utilitarianism (or any other consequentialist ethical theory) can lead to conclusions which go against our moral instincts, as in the idea that brain-damaged human infants can be used in research if this would minimise the level of suffering overall. Strong utilitarianism is in danger, therefore, of what Andrew

³⁵ AV Campbell, ‘The animal rights debate’ (March 1995) 8 *ANZCCART News* 1 at 2.

³⁶ C Cohen, ‘The case for the use of animals in biomedical research’ (1987) 18 *Proceedings of the Australian Physiological and Pharmacological Society* 38 at 41.

³⁷ M Walsh, ‘The ethics of acute toxicity testing’ from *Scientific and Ethical Aspects of Ecotoxicity Testing on Living Organisms*, UTS 1994, p 53.

Brennan calls 'moral irrelevance'. On the other hand, 'if we modify utilitarianism so as to maintain contact with our commitment to other values that are widely accepted, then it is not clear that there is a blanket opposition between utilitarianism and animal research'.³⁸

Regan's argument has also been subjected to extensive criticism, including the claim that animals cannot be said to have rights which, according to Carl Cohen, can 'arise, and can be intelligibly defended, only among beings who actually do, or can, make moral claims against one another'. Against Regan, Cohen has argued that rights must be looked upon as 'claims or potential claims, within a community of moral agents...they are necessarily human; their possessors are persons, human beings'.³⁹ A factual challenge to Regan's views is that the scanty evidence we possess about the subjective experiences of non-human mammals cannot justify the claim that they are individuals who are 'subjects of a life' in the way that Regan employs that notion.⁴⁰

Alternative viewpoints - Cohen's animal welfare argument: Such criticisms notwithstanding, there is no doubt that the work of Singer and Regan, in particular, has generated a vigorous debate on the moral status of animals. This, in turn, has required those who support the continued use of animal experimentation, if only in a limited way, to reconsider and restate the basic elements of their case. Various alternatives have been proposed. Central to many of these is the argument that animals cannot be said to have either interests⁴¹ or rights (the contention of Singer and Regan respectively) and are therefore not members of the moral community; on the other hand, it is also said that there is a duty of some kind to consider the welfare of animals.

This, in essence, is the alternative proposed by Carl Cohen who formulates his argument, first, by rejecting the notion that animals have rights on the ground that they lack the capacity for moral judgement and, secondly, by maintaining that capacity for moral judgement and hence the moral status issue generally should not be looked at in individual terms - the status of this chimpanzee compared with that hopelessly senile human - but as one of 'kind'. In other words, the decisive factors in the argument are the unique capacities of the human species, on one side, and membership of that species, on the other. Cohen explains:

Humans are of such a kind that they may be the subject of experiments only with

³⁸ A Brennan, 'Animal ethics: time for a new approach' from *Animals and Science in the Twenty-First Century: New Technologies and Challenges* edited by RM Baker et al, ANZCCART 1995, p 88.

³⁹ C Cohen, 'The case for the use of animals in biomedical research' (1987) 18 *Proceedings of the Australian Physiological and Pharmacological Society* 38.

⁴⁰ AV Campbell, 'The animal rights debate' (March 1995) 8 *ANZCCART News* 1 at 2.

⁴¹ For a critique of this aspect of Singer's claim, but also of Regan's rights based argument, see - RG Frey, *Interests and Rights: The Case Against Animals*, Clarendon Press 1980, pp 157-167.

their voluntary consent. The choices they make freely must be respected. Animals are of such a kind that it is impossible for them, in principle, to give or withhold voluntary consent or to make a moral choice. What humans retain when disabled, animals have never had.⁴²

As for the duty or obligation to treat animals humanely, this is said to rest on such grounds as the general obligation to do no gratuitous harm to sentient creatures, or the obligation to do good to sentient creatures when that is reasonably within one's power.⁴³ Cohen concludes:

We surely do have obligations to animals, but they have, and can have, no rights against us on which research can infringe. In calculating the consequences of animal research, we must weigh all the long term benefits of the results achieved - to animals and to humans - and in that calculation we must not assume the moral equality of all animate species.⁴⁴

Aspects of this argument have not escaped criticism.⁴⁵ Nonetheless versions of it have proved to be quite influential in that it serves as a basis for arriving at what is considered to be a reasonable balance between the claims of human and animal welfare, in which the conduct of animal experimentation is to be informed by the principle of the 'three Rs' - replacement, reduction, refinement. The influence of Cohen is evident, for instance, in the conclusion reached by the Senate Select Committee in its 1989 report where it was stated that 'human beings, as moral agents, have real and substantial obligations and duties' toward animals.⁴⁶

But where does this leave animal experimentation, bearing in mind that the Senate Select Committee also accepted that the obligations owed by humans are based on a recognition of 'the autonomy and capacity to experience distress that animals possess in varying capacities' ?⁴⁷ Even if these capacities are not sufficient to bring any animal aboard the ark of the moral community, as this is understood by Cohen, once recognised they would seem

⁴² C Cohen, 'The case for the use of animals in biomedical research' (1987) 18 *Proceedings of the Australian Physiological and Pharmacological Society* 38 at 40.

⁴³ Ibid at 39.

⁴⁴ Ibid at 45.

⁴⁵ For example see - EC Hettinger, 'The responsible use of animals in biomedical research' from RM Baird and SE Rosenbaum, *Animal Experimentation: The Moral Issues*, Prometheus Books 1991, pp 116-118. Among other things, Hettinger states that Cohen 'simply assumes that being a member of a biological species guarantees that one has certain capacities, despite overwhelming evidence that marginal members of species often lack capacities normal for that kind of creature. We need a strong argument before we should reject the obvious point that some animals have a greater capacity for moral behavior (however minimal) than do some severely retarded human beings'.

⁴⁶ Senate Select Committee, n 8, p 41.

⁴⁷ Ibid.

to erect formidable restraints against causing deliberate suffering to such creatures, even in the name of the common good. In other words, has the case for animal experimentation been made out in a consistent and persuasive way?

The troubled middle ground - the Working Party of the British Institute of Medical Ethics: As noted earlier, the Senate Select Committee's conclusions were also informed by the notion that animal experimentation can only be justified on the basis of *necessity*. The implications of this finding were developed more fully by the Working Party of the British Institute of Medical Ethics. In summary, the Working Party constructed its argument in this way:

- that what is called 'common morality' (as embodied in intelligent, reflective and rationally defensible practice) is the appropriate basis for reasoning about our treatment of animals;
- that this common morality reflects the view that there is a difference in the moral status of humans and animals, which means that a contrast exists between the ethics governing research using human subjects and the ethics governing research on animals;
- this difference in moral status is based on the possession of self-consciousness and rationality by the human subject and their absence in the animal subject;
- the grounding of relevant moral differences in these distinctions begins with noticing the unique harm that pain, distress and death represent to a self-conscious, rational creature;
- belonging to the human species is a *sufficient* condition of this enhanced moral status, on the basis that possessing the *nature* of a rational self-conscious creature may be sufficient for being awarded this status even though this nature is impaired or underdeveloped in the individual case;
- species membership is therefore a relevant moral criterion;
- but if the moral status of animals is inferior to that of humans, it does not mean that humans may treat animals in a cruel or tyrannical way;
- common morality recognises that humans have a duty to care for the welfare of animals;
- having regard to that duty, not everything that happens to laboratory animals, taken in isolation, falls into the category of actions that ought to be done;
- all things considered, however, medical research (the benefits of which must be possible and intended) ought to proceed on the basis that necessity outweighs the deliberative judgement that research using animals ought not to take place;
- in this way, the goals of biomedical research and animal welfare are a good example of a moral conflict;
- however, this moral conflict is resolvable on rational grounds;
- thus, although it can be said that we ought to pursue the goals of medical progress as well as the avoidance of distress, pain and disruption to animals, due to the claims of necessity the balance is weighted in favour of medical advancement;
- hence the conclusion that 'a controlled, critical, questioning use of animals in biomedical research is warranted by common morality when supported by the

requisite facts about animal and human consciousness'.⁴⁸

Practical wisdom and animal experimentation: The Working Party's argument has been summarised in some detail, not because it is free of difficulty, but because it is a good example of the kind of reasoning used by many contemporary moral philosophers who occupy 'the troubled middle ground' in the debate concerning animal experimentation. For this reason, some of the features of the argument are worth noting:

- in basing the argument on 'common morality' the Working Party was avoiding any attempt to resolve the practical ethical questions concerning animal experimentation by reference to the rules of a grand theory, universal in scope and application, such as utilitarianism or deontology;
- instead, the common morality approach was described as 'a reflective attempt to examine practice and sift out the best and worst it'. In doing so, the Working Party's report was drawing upon the *practical wisdom* approach to moral reasoning about human actions, which is associated with Aristotle. In this tradition, moral deliberation and judgement is not determined by fixed rules or principles. Instead, the moral reasoning associated with practical wisdom must engage the particularities of any situation and must decide on what is the good and right course of action in those circumstances. On the other hand, if it is to rise above mere subjectivism, practical wisdom must be guided by some scheme of established values and practices. Thus, as the report of the Working Party of the British Institute of Medical Ethics notes, practical wisdom takes as its starting point 'an agreed aspect of reflective, intelligent practice' and proceeds by 'reasoning from the values implicit in that to the desired conclusion'.⁴⁹
- what emerges from this is a form of moral pluralism characterised by a situational or contextualist approach to ethics;
- the common morality appealed to here is not static. Quite the reverse, in fact: 'Common morality on respect for non-human life continues to be on the move, as facts from ecology, evolutionary biology and animal behaviour spread through the moral community'.⁵⁰ The present conclusions of common morality may not be the same as those reached in ten or twenty years time. Added to this, the argument of necessity may also be only temporary in nature, that is, as the need for animal experimentation decreases, due to technological advances, so the balance of

⁴⁸ Smith and Boyd, n 10, Chapter 11.

⁴⁹ Ibid, p 313. Dr Michael Walsh of the University of Technology, Sydney, has explained that practical wisdom involves 'the capacity to know how to act in particular circumstances. It enables us to weigh up the likely consequences of an action and to decide how to strike a balance between competing duties' - M Walsh, 'The ethics of acute toxicity testing' from *Scientific and Ethical Aspects of Ecotoxicity Testing on Living Organisms*, UTS 1994, p 43.

⁵⁰ Smith and Boyd, n 10, p 327.

practical wisdom will shift in favour of abolition;

- however, from the standpoint of practical wisdom the requirement to consider each case on its merits will remain, so that conclusions may vary as between one circumstance and another;
- in deciding the question of necessity, as well as in other respects, this line of reasoning holds that we ‘must depend on the good faith of the scientific community in its stewardship of the public interest and the welfare of animals’;⁵¹
- but at the same time, by sifting out the best practices available at any given moment, those features which should be taken into account in assessing the potential and likely benefits of a research project involving animals can be articulated. For example, an assessment would need to be made of the potential benefits of the proposed project in terms of its potential social, scientific, economic, educational and/or other value. Consideration would also need to be given to the quality of the proposed approach and the likelihood that the potential benefits will be realised. These features can then serve as the basis for deciding whether animal experimentation is warranted in any particular case.

Concluding comments: Viewed from a certain standpoint, the appeal of this argument is that it seems to dovetail neatly enough into the regulatory regimes which operate in New South Wales and elsewhere. Thus, animal experimentation in biomedical research is permitted but only where this is deemed necessary and then only in accordance with the principle of the ‘three Rs’ - replacement, reduction, refinement. It may also be the case that an argument of this kind can be used to permit toxicity testing outside the medical field in some situations, for example, where it is deemed necessary to test the safety of a new chemical before introducing it onto the market. On the other side, the argument of necessity may also be used to ask hard questions of current practices (perhaps even those which may be permitted under established regulatory regimes). This is because the test of necessity is a rigorous one, being far more difficult to satisfy than a test of mere ‘usefulness’, for example. Another observation to make is that an approach to practical ethical questions which rests ultimately on the judgment of those making decisions in particular contexts emphasises the need for integrity on the part of those persons and the system in which they operate. What is proposed, after all, is a controlled, critical questioning of the use of animal experimentation.

Determined advocates of animal rights will not be convinced by any of this. For them, arguments of this sort are based, not on necessity, but on the arbitrariness of speciesism and the demands of convenience and self-interest. Moreover, this chasm cannot be bridged because it spans the fundamental differences that exist between those who hold different views about the relative moral status of humans and animals. This underlines the point that, even if a common morality can be said to exist in this context, it is not shared by everyone.

⁵¹

Ibid, pp 35-36.

Indeed, the Working Party itself acknowledged the differences of opinion that existed among its members. The most that some would say is that the argument advanced on behalf of the use of animal experimentation was an acknowledgement of a ‘necessary evil’, whereas others were more convinced that the moral conflict involved is resolvable on rational grounds. Either way, for those who occupy the troubled middle ground, where a balance is sought between the conflicting claims of human and animal welfare, the demands of morality are met ‘only with difficulty’. Indeed, according to the philosopher Roger Scruton, where animal experimentation is concerned these demands are only met ‘on the assumption that the experiments in question make an unmistakable contribution to the welfare of others’.⁵²

3. USE OF ANIMALS IN RESEARCH

3.1 What is animal experimentation

In New South Wales, Victoria, Tasmania, and Queensland, the legal definitions of animal research cover a comprehensive range of scientific activities.⁵³ These jurisdictions in general regulate the use of animals in any procedure, test, experiment, inquiry, investigation or study which is carried out in connection with an animal in the course of which:

- (a) an animal is subjected to:
 - (i) surgical, medical, psychological, biological, chemical or physical treatment; or
 - (ii) abnormal conditions of heat, cold, light, dark, confinement, noise, isolation, or overcrowding; or
 - (iii) abnormal dietary conditions; or
 - (iv) electric shock or radiation treatment; or
- (b) any tissue, material or substance is extracted or derived from the body of an animal.

There is some variation among the States as to the kinds of animals whose use in experimentation is regulated by legislation. As a general rule, the use of vertebrates is regulated, while the use of invertebrates is not.⁵⁴ The national code of practice governing the use of animals for scientific purposes⁵⁵ applies to any live non-human vertebrate (including domestic animals, purpose-bred animals, livestock and wildlife). The Code does not apply to invertebrates or embryos, but it states that eggs, fetuses and embryos must be treated in a humane manner where development of an integrated nervous system is evident, and suggests that investigators should consider forwarding proposals to use higher order

⁵² R Scruton, *Animal Rights and Wrongs*, Demos 1996, p 99.

⁵³ South Australia, Western Australia, the Australian Capital Territory and the Northern Territory do not define what activities constitute animal research or experimentation.

⁵⁴ A ‘**vertebrate**’ is an animal that has a backbone or spinal column. It includes mammals, birds, reptiles, amphibians and fish. An ‘**invertebrate**’ is an animal that does not have a backbone, such as octopus, molluscs, crustaceans, and insects.

⁵⁵ National Health and Medical Research Council, *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*, 6th edition, 1997.

invertebrates to their animal ethics committees.⁵⁶

New South Wales follows the Australian Code of Practice by regulating the use of non-human vertebrates,⁵⁷ as does Tasmania⁵⁸ and the ACT.⁵⁹ In Victoria, the definition of ‘animal’ in the *Prevention of Cruelty to Animals Act 1986* includes live crustaceans, but research involving crustaceans and fish is excluded from the provisions regulating scientific procedures.⁶⁰ The South Australian *Prevention of Cruelty to Animals Act 1985* applies to all non-human vertebrates except fish. Queensland, Western Australia and the Northern Territory use more old-fashioned language in their animal welfare legislation. Both the *Animals Protection Act 1925* (Qld) and the *Prevention of Cruelty to Animals Act 1920* (WA) apply to ‘captive’ and ‘domestic’ animals ‘of whatsoever species’. The *Prevention of Cruelty to Animals Act* (NT) applies to ‘every species of quadruped and every species of bird, whether in a natural or domestic state, and all other animals dependent upon man for their care or sustenance or in a state of captivity’.

Like New South Wales, most European countries regulate the use of non-human vertebrate animals in experimentation.⁶¹ The most inclusive legislation is the British *Animals (Scientific Procedures) Act 1986* which defines ‘a protected animal’ to include any ‘living vertebrate’ in its ‘foetal, larval or embryonic form’ from the stage where, in the case of a mammal, bird or reptile, ‘half the gestation or incubation period for the relevant species has elapsed’, and in any other case where the animal ‘becomes capable of independent feeling’; moreover, under the Act any invertebrate of the species *Octopus vulgaris* is protected ‘from the stage of its development when it becomes capable of independent feeding’.⁶² Much more restrictive in approach is the US federal legislation which excludes ‘cold-blooded’ animals (invertebrates, fish, amphibia and reptiles) from its protective regime, as well as rats, mice, birds, horses and other farm animals. More comparative information on the regulation of animals in research is contained in Part 5.2 of this background paper.

3.2 Purposes of animal research

⁵⁶ Ibid p 1.

⁵⁷ *Animal Research Act 1985* (NSW) s 3.

⁵⁸ *Animal Welfare Act 1993* (Tas) s 3.

⁵⁹ *Animal Welfare Act 1992* (ACT) s 4.

⁶⁰ *Prevention of Cruelty to Animals Regulations 1997* reg 11.

⁶¹ The Council of Europe *Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes 1986* in article 1 defines an animal as ‘any live non-human vertebrate, including free-living or reproducing larval forms, but excluding other foetal or embryonic forms’. The same definition of ‘animal’ is used in European Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (see Part 5.2 of this paper).

⁶² Section 1(1)-(2).

The basic scientific purposes for which animals are used in Australia are fundamental and applied biological research, behavioural research, the production of biological substances, and toxicity testing. These fields are described in more detail below.

Fundamental and applied biological research: Fundamental research is aimed at advancing general knowledge of biological processes, while applied research is undertaken with a specific aim, such as to produce a vaccine for a particular disease. In practice, fundamental and applied research are interwoven, and one can lead to the other. There are many different fields of research in the areas of medicine, surgery, and agricultural and veterinary studies where animals may be used, such as in developing new pharmaceuticals, new treatments such as gene therapy, development and testing of medical and surgical materials or procedures, study of disease or pathology, development and production of antisera and vaccines, and development of diagnostic techniques.⁶³

Behavioural research: Research on animal behaviour may be used to understand human or animal psychologies. Animals have been used to study depression, drug addiction, aggressive behaviour, communication, learning and problem solving, normal and abnormal social behaviour, reproduction and parental care.

Production of substances for research or therapeutic purposes: There are a range of biological substances that can be obtained from animals for scientific or therapeutic purposes. For example, monoclonal antibodies, which have clinical and diagnostic uses, can be produced in mice, and anti-venenes used to treat snake bites can be produced in animals such as horses.

Toxicity testing: Toxicity testing is concerned with identifying the potential of chemicals to cause adverse effects. Regulatory authorities such as the Commonwealth Therapeutic Goods Administration require companies wanting to market goods in Australia to establish that the goods are safe and effective for their intended use. Much toxicity testing requires adverse effects to be produced in animals, often leading to considerable pain and distress.⁶⁴ Which tests are carried out depends on the particular substance concerned.

- **Acute toxicity tests** examine the adverse effects caused by a single dose of a test substance. It is used for chemicals which might be ingested or absorbed into the body either directly or indirectly via the general environment.⁶⁵ The most controversial kind of acute toxicity test is the LD50 test, which is used to determine the dose or concentration of test substance (the 'lethal dose') which will kill 50% of the animals tested.
- **Sub-acute and chronic toxicity tests.** These tests are used to examine the effects

⁶³ Smith and Boyd, n 10, p 11.

⁶⁴ Ibid, p 183. The following descriptions of various toxicity tests are drawn from Smith and Boyd, *ibid*, pp 189-194.

⁶⁵ Ibid, p 189.

of long term or repeated exposure to chemicals. Animals may be exposed to the test chemical for, say, seven, 28 or 90 day periods, or where rats and mice are used, for a 'life-time' of up to 2 years. The effects of the substance on the animals' behaviour and blood and tissue biochemistry are investigated.

- ***Skin and eye irritation tests.*** These assess the potential of a substance to irritate or damage eyes or skin. Albino rabbits are usually used. The most controversial of the tests is the Draize eye irritation test, in which the normal procedure is to place a small amount of the substance into the conjunctival sac of the eye of a rabbit. Observation of the other eye of the animal serves as a control. The reactions of the eye to the test substance are observed, and the redness of the rabbit's eye membranes and the effects of the substance on the cornea are noted and graded.
- ***Sensitisation tests.*** These tests are used to examine the sensitising or allergenic potential of substances, commonly using guinea-pigs. The tests generally involve attempting to induce allergy by repeatedly applying the test substance, and then challenging the animal with a single re-exposure to the test substance.
- ***Carcinogenicity and mutagenicity tests.*** These test involve repeated exposure of animals, usually rats and mice, to chemicals over their life times to detect whether the chemical causes cancer or genetic mutations.
- ***Reproductive toxicity tests.*** Examination of the effects of chemicals on reproductive processes involves dosing animals, usually rodents and rabbits, with test substances before mating and during and after pregnancy. Research includes fertility studies (effects on production and function of eggs and sperm); teratogenicity studies (effects on the early development of embryos and fetuses); pre- and post-natal studies (effects on later development of fetuses and on the new-born).
- ***Neurotoxicity tests.*** These tests determine the extent of toxic effects on vertebrate nervous systems. Animal behaviour is observed to detect any lack of co-ordination, motor disorders, altered learning abilities or other behavioural changes.⁶⁶

3.3 Information on animal use in Australia

Most States collect and publish data on the use of animals in research, generally from annual returns provided by research institutions or animal ethics committees.⁶⁷ Some recent animal use figures are set out later in this section. It must be noted that the figures published for

⁶⁶ Monamy, n 21, p 29.

⁶⁷ The Australian Capital Territory, the Northern Territory and Queensland do not currently make animal use data available.

each jurisdiction are not directly comparable, since the methods of collecting information vary widely among the States. The lack of consistency in animal use statistics has been explained as follows:

In 1989, the Australian Senate Select Committee on Animal Welfare recommended that a summary of the animals used should be produced by each State and Territory and that these should be collated on a national basis. This recommendation has been extremely difficult to put into practice for several reasons. The definition of 'research and teaching' varies between States. In some cases, wildlife environmental studies are not included. Similarly, animals held in schools and kindergartens are often not included. ... The biggest impediment to the collation of statistics has been the sheer volume of projects considered by the Animal Ethics Committees ... The final problem, which is currently being considered by the NHRMC Code Liaison Group, is that different States require different information and report this in ways which are not compatible.⁶⁸

The adequacy of the available information has been the subject of widespread criticism.⁶⁹ In New South Wales, the Animal Research Review Panel has acknowledged that the data collected does not provide a satisfactory picture of how animals are being used in science. The Panel stated, among other concerns, that the published statistics do not inform people about critical aspects of the research being conducted, such as how invasive the animal research procedures are, their justification, or their potential to cause pain or distress.⁷⁰

Another concern is that comparison of total numbers of animals used does not provide a meaningful indication of progress towards refinement, reduction and replacement of animal use.⁷¹

⁶⁸ Office of Animal Welfare, Department of Environment and Natural Resources, *Animal Usage Report 1995/96: A Summary of Animal Use in Research and Teaching in the State of South Australia from 1 July 1995 to 30 June 1996*, p 5.

⁶⁹ See for example K Edwards, 'Animal-Use Statistics: Are they meaningless? Could they be meaningful?', *Animals Today*, August-October 1995, pp 16, 17, 29.

⁷⁰ Animal Research Review Panel, *Annual Report 1993-94*, NSW Agriculture, 1994, p 32. In contrast, the records required in New Zealand include grading the severity of every animal use on a scale ranging from 'no suffering or virtually no suffering', 'little suffering', 'moderate suffering', 'severe suffering' to 'very severe suffering': Animals Protection (Codes of Ethical Conduct) Regulations (NZ) reg 5(1)(fa).

⁷¹ Animal Research Review Panel, *Annual Report 1993-94*, NSW Agriculture, 1994, p 32. For example, an increase in the total number of mice used may be due to the introduction of a new procedure using large numbers of animal, but with little impact on them, to replace a procedure using smaller numbers with significant impact on individual animals See also M Rose, 'Statistics - are the expectations too great?', (1994) 7(2) *ANZCCART News* p 1, where it is pointed out that using the minimum number of animals necessary, and only using

Criticisms have also been made about a lack of publicly available information on how many animal experiments are actually producing significant or valuable results.⁷² This problem may be partly due to the inherent uncertainty and serendipity of the scientific process,⁷³ which can mean that there may not be a clear-cut 'success' or 'failure' of an experiment, or that the significance of experimental results may not be immediately apparent. Commercial confidentiality requirements can also hinder public access to information.

To address the lack of transparency in animal data, the Regulation Review Committee of New South Wales Parliament has recommended that animal ethics committees be required to document why they have approved a research proposal, including why the information to be obtained is significant and why the experiment is scientifically valid.⁷⁴ As well, a national scheme is underway to establish a comprehensive national database of animal use statistics, in order to develop an accurate, clear and simple mechanism to obtain meaningful data relating to animal use in research and teaching.⁷⁵ The new system is being developed by the South Australian Office of Animal Welfare, with funding from the National Health and Medical Research Council. The system will be administered by ANZCCART (the Australian and New Zealand Council on the Care of Animals in Research and Training). The database is intended to be incorporated into the home page of the ANZCCART web site.

The proposed national database will contain information on the number and kinds of animals used, the broad purpose of the project, and the type of procedure undertaken. The categories of procedures will indicate the impact that the procedure has on the animals.⁷⁶ The new system will also clarify some problematic areas of data collection, such as how to count animals which are used in more than one procedure. An explanation of the proposed national scheme by the South Australian Office of Animal Welfare is attached to this paper as Appendix C.

It is hoped that eventually all States and Territories will join the proposed national scheme,

animals where necessary, will not necessarily lead to a decrease in the overall number of animals used.

⁷² Mr A Cruickshank MP, *NSWPD*, 21/5/97, p 8980; Hon R Dyer MLC, *NSWPD*, 16/6/96, p 10257.

⁷³ M Rose, 'Of science, scientists and animals - knowledge, values and political dilemmas' in R Baker, J Burrell and M Rose (eds), *Effective Animal Experimentation Ethics Committees*, ANZCCART, 1995 p 79.

⁷⁴ Regulation Review Committee, Parliament of New South Wales, *Report on the Animal Research Regulation 1995*, Report No 13/51, November 1997, p 21 and Appendix 6.

⁷⁵ SA Office of Animal Welfare, n 68, p 3. See also D Kelly, 'The National Statistics package - background and progress', (1997) 10(3) *ANZCCART News*, p 1.

⁷⁶ The categories are: 'observational studies involving minor interference', 'animal unconscious without recovery', 'minor conscious intervention without anaesthesia', 'minor surgery under anaesthesia with recovery', 'major surgery under anaesthesia with recovery', 'minor physiological challenge' and 'major physiological challenge'.

and will co-ordinate their animal data collection to be compatible with the new system. The package is intended to be in place by late 1998. Progress in gaining agreement from all the States and Territories is slow, however. South Australia and Tasmania have already begun to collect data in accordance with the new system, and Victoria, Queensland and the ACT intend to introduce it. New South Wales supports a national database, but appears to be waiting until agreement is reached among all the States and Territories.⁷⁷ Western Australia and the Northern Territory have not committed themselves to joining the national database.

There has been much criticism of the continued delay in making available coherent and accurate animal use data.⁷⁸ The Regulation Review Committee of NSW Parliament has recommended that the proposal for a national reporting format should be actively pursued by the Minister. If agreement cannot be reached with the other States within 12 months, the Committee recommended that NSW should introduce its own revised regulatory scheme.⁷⁹

The proposed national database may not fully answer all the concerns of animal welfare groups about lack of public information on animal research. For example, it seems that it will not contain information about how long animals are held for experiments, and the eventual fate of the animals (such as any unplanned deaths, and the disposal of animals used in non-fatal experiments). It also does not contain information on the numbers and species of animals bred by animal suppliers, and the fate of animals bred in excess of demand. The current reporting requirements of individual States' may be more detailed in some respects than the information to be collected for the national database. For example, in Victoria, data for all animal experiments include specific information on the reason for the experiment, and on the fate of the animals, and in New South Wales extensive information on lethality tests is required.⁸⁰

A brief outline of Australian animal use data is set out below.

New South Wales: A total of 2, 481,031 animals were used in research and teaching in 1995-96. Almost 78% of these animals were fish, followed by domestic fowl (7.7%), mice (5%), sheep (3.1%) and rats (2%). It is worth noting that chick embryos are counted as animals in the New South Wales statistics, accounting for 1.8% of animals used. Altogether 2728 cats, dogs and primates were used, about 0.1% of the total number of animals. The areas of research in which the most number of animals were used included 'education', 'immunology', 'nutrition', 'breeding', and 'ecology'. For more detail, see Appendix B to this background paper.

⁷⁷ Hon R Amery MP, Minister for Agriculture, *NSWPD*, 21/5/97, p 8993.

⁷⁸ For example, Mr A Cruickshank MP supported NSW amending its own data collection practices, to avoid waiting years for national arrangements to be agreed upon and put in place: *NSWPD*, 21/5/97, p 8981.

⁷⁹ Regulation Review Committee, n 74, p 65.

⁸⁰ A lethality test is a procedure by which a material or substance is administered to animals for the purpose of determining whether any (or how many) will die: s 56A (not yet in force).

The annual total of animals for 1995-96 is larger than that for 1994-95 (1, 420 937 animals)⁸¹ and for 1993-94 (1 726 163 animals)⁸². It has been observed that the highly variable annual totals are largely attributable to the variation in the numbers of fish and domestic fowl, and that when these species are discounted, the totals are more consistent.⁸³ The Hon R Dyer MLC has stated that 'annual statistics on animal use in research and teaching in New South Wales show no clear downward trends in the number of animals used', but 'that does not mean that the legislation is not effective in reducing the number of animals used per experiment and does not reflect the reduced impact on those animals as a result of the legislation... Specific examples show clearly that the current legislation has led to reduction in the number of animals used in research. For example, there has been a 95% reduction in the number of animals used for teaching at the University of Sydney, and a 75% reduction in the number of animals used in toxicology tests at universities.'⁸⁴

Victoria: A total of 409 426 animals were used in 1996. Most animals used were mice (70.4%), followed by rats (10.2%), domestic fowl (8.6%), guinea pigs (3.2%) and sheep (2.4%).⁸⁵

South Australia: A total of 77 404 animals were used in research and teaching in 1995-96. Poultry were most commonly used (33.7%), followed by mice (22.1%), sheep (13%) and rats (5.7%).⁸⁶

WA: A total of 160 167 animals were used in research and teaching in 1996. Most used were fish (58.9%), followed by mice (13.7%), rats (8.6%) and sheep (4.2%).⁸⁷

Tasmania: A total of 15 460 animals were used in research and teaching in 1996-97. Most of these were aquatic animals (fish, amphibians etc) (56.1%), followed by lab mammals (mice, rats, rabbits, guinea pigs etc) (22.7%), native animals (10.8%), birds (4.9%), reptiles

⁸¹ Animal Research Review Panel, *Annual Report 1994-95*, p 30.

⁸² Animal Research Review Panel, *Annual Report 1993-94*, p 64.

⁸³ Edwards, n 69, p 16.

⁸⁴ NSWPD, 16/6/97, p 10257.

⁸⁵ Bureau of Animal Welfare, Department of Natural Resources and Environment, *Statistics of Animal Experimentation, Victoria, Fifteenth Report, 1 January 1996 to 31 December 1996*.

⁸⁶ Office of Animal Welfare, Department of Environment and Natural Resources, *Animal Usage Report 1995-96*.

⁸⁷ Department of Health, *Annual Statistical Vivisection and Experiments Return for the Calendar Year 1996*.

(3%) and stock animals (cattle, sheep etc) (2.4%).⁸⁸

4. AUSTRALIAN ANIMAL RESEARCH LEGISLATION

4.1 Overview of Australian animal research legislation

Under the Australian federal system, animal welfare is mainly a State responsibility, although the Commonwealth Government has some interests and responsibilities in questions of animal welfare.⁸⁹ All States and Territories have some form of legislation regulating scientific research using animals. These State regulatory systems generally share similar basic features, although they vary considerably in their detail. The only State that has a separate statute dedicated to regulating animal research is New South Wales, where more animals are used in research than in any other State or Territory. In other jurisdictions, animal research is dealt with in the general animal welfare legislation.

New South Wales, Victoria, South Australia and the ACT have detailed, up-to-date animal research legislation, while legislation in the other States and Territories is not as extensive. Western Australia, Queensland and the Northern Territory are currently reviewing their animal welfare legislation, including their animal research provisions. Each State and Territory system is briefly described later in this Part.

The features that are common in State regulatory systems are: mandatory research licences for individuals or institutions; and mandatory prior approval by an ethics committee of procedures involving animals. A licence or authorisation to carry out animal research is required in every jurisdiction except Queensland. Animal ethics committees are required by legislation or regulations in every State and Territory except Western Australia and the Northern Territory. Community representatives and animal welfare supporters are brought onto these institutional animal ethics committees and (in some jurisdictions) ministerial advisory committees⁹⁰ in order to ensure community participation in the practice of animal research, and in the development of policy and legislation.

A unifying force linking the various State systems is the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (referred to hereafter as the Australian Code of Practice). This code of practice is produced by the National Health and Medical Research Council in conjunction with research organisations and State and Territory Governments. The purpose of the Code is to ensure the humane care of animals used for

⁸⁸ Public Health & Animal Welfare Section, Department of Primary Industry and Fisheries, *Animal Research Statistics Tasmania, Annual Report, Report No 1 1996/97 [1 April 1996-31 March 1997]*.

⁸⁹ See Senate Select Committee, n 8, pp 201-202.

⁹⁰ Ministerial advisory committees on animal welfare, including animal research, have been established in New South Wales (the Animal Research Review Panel) and in Victoria, South Australia, Tasmania and the ACT, which each have an Animal Welfare Advisory Committee.

scientific purposes. The Code encompasses:

all aspects of the care and use of, or interaction with, animals for scientific purposes in medicine, biology, agriculture, veterinary and other animal sciences, industry and teaching. It includes their use in research, teaching, field trials, product testing, diagnosis, the production of biological products and environmental studies. The Code provides general principles for the care and use of animals, specifies the responsibilities of investigators and institutions, and details the terms of reference, membership and operation of institutional AECs [Animal Ethics Committees]. It also provides guidelines for the humane conduct of scientific and teaching activities, and for the acquisition of animals and their care, including their environmental needs.⁹¹

The Chairman of the New South Wales Animal Research Review Panel, Assoc Prof Margaret Rose, has explained that the guiding principles of the Code are:⁹²

- the requirement to establish the necessity of the proposed study;
- the requirement to make an ethical judgment that the proposed experiment is justified, weighing its scientific and educational value against the potential effects on the animals;
- the obligation to treat animals with respect and to consider their welfare; and
- strategies to apply the principles of replacement, refinement and reduction so that the minimum number of animals are used with the least possible impact. (These principles are explored in Part 8 of this background paper).

The Australian Code of Practice is adopted in various forms into the regulatory system of every jurisdiction except Western Australia and the Northern Territory, both of which are currently reviewing their animal welfare legislation with a view to adopting the Code. The influence of the Code is enhanced by funding bodies such as the National Health and Medical Research Council, which generally require compliance with the Code as a condition to granting funds for research. The effect is that every Australian jurisdiction has a system of institutional ethics committees to approve and oversee animal research in accordance with some form of the Australian Code of Practice.

The Australian Code of Practice and State legislation generally adopt a system of ‘enforced self-regulation’ of animal research. That is, the primary responsibility for the welfare of animals is placed with the individual researchers undertaking work using animals. The concept of enforced self-regulation is discussed further in Part 5 of this background paper, which looks at different regulatory models for controlling animal research.

4.2 New South Wales

⁹¹ National Health and Medical Research Council, *Australian code of practice for the care and use of animals for scientific purposes*, 6th edition, 1997 p 1.

⁹² M Rose, ‘Striking the balance: the practitioner and the animal ethics committee’, (1996) 9(3) *ANZCCART News* 1, p 2.

Animal research in New South Wales is governed by the *Animal Research Act 1985*, the *Animal Research Regulations 1995*, and the Australian Code of Practice. New South Wales is the only State in Australia to have a separate statute dealing with animal research. The NSW Government decided to enact separate animal research legislation rather than include it in prevention of cruelty legislation because it believed that it was no longer appropriate to consider animals used in experiments just from the point of view of cruelty.⁹³

The Animal Research Act establishes the framework for the regulation of animal research. In brief, this framework consists of:

- a licensing and accreditation system for the conduct of research or the breeding or supply of animals for research;
- institutional animal ethics committees to approve and supervise research using animals;
- an Animal Research Review Panel to oversee research and animal ethics committees, and to advise the Minister; and
- inspection of research facilities by the Animal Welfare Unit of NSW Agriculture.

The Animal Research Act operates in conjunction with the *Prevention of Cruelty to Animals Act 1979* (NSW). The Act, the regulations and the Code apply to all individuals, groups, institutions, organisations, schools and companies that use animals for research or teaching. It should be noted that an overall review of the *Animal Research Act* has been foreshadowed by the Minister for Agriculture, who has stated that the Government is planning to review all aspects of the Act in the light of the Hilmer competition policy agreement.⁹⁴

Accreditation and licensing: The Animal Research Act currently provides for several types of approval for the use of animals in research:

- *accreditation of research establishments* for companies, universities etc that undertake animal research;
- *animal research authorities* issued by accredited establishments to individual researchers;
- *animal research licences* for individuals undertaking research who are not affiliated with an accredited research establishment; and
- *animal suppliers licences* for persons who breed or supply animals for research.

Accreditations and licences are issued by the Director-General of NSW Agriculture, upon the recommendation of the Animal Research Review Panel.⁹⁵ The accreditation and licensing

⁹³ Senate Select Committee, n 8, pp 215, 241.

⁹⁴ Hon R Amery MP, *NSWPD*, 21/5/97, p 8993.

⁹⁵ The New South Wales accreditation system was mentioned with approval by the Commonwealth Senate Select Committee on animal welfare. The Select Committee saw the accreditation process as a useful additional means to supplement and check the operation of institutional animal ethics committees: Senate Select Committee, n 8, p 243.

provisions of the Animal Research Act are currently in a state of flux. Two statutes amending the Act were passed in 1997: the *Animal Research Amendment Act 1997* altered the research licensing and accreditation system, among other changes; and the *Administrative Decisions Legislation Amendment Act 1997* altered the provisions dealing with review of decisions about animal research, transferring review of decisions to the new Administrative Decisions Tribunal. However, the *Animal Research Amendment Act 1997* has only commenced in part,⁹⁶ and the *Administrative Decisions Legislation Amendment Act 1997* has not commenced at all. As a result, the substantive changes to the system of licensing and accreditation and to the review of decisions have not yet come into force. It is understood that the changes have been postponed pending amendment of the Animal Research Regulations to accord with the amendments to the Act. Draft amendments to the regulations are being prepared for public consultation.

When the amendments to the Animal Research Act come into force, they will streamline the current licensing and accreditation system. The amendments abolish animal research licences for individuals. Instead, the Director-General of NSW Agriculture or an accredited research establishment will be able to issue an authority to any individual to carry out animal research for the purpose of a particular research project. An animal research authority may only be issued by the Director-General or an accredited research establishment on the recommendation of an animal care and ethics committee. Each accredited research establishment must have an ethics committee, and there is a separate ethics committee established by the Director-General. Research carried out under an animal research authority must be:

- in accordance with the directions of the animal care and ethics committee;
- in accordance with the Australian Code of Practice;

- for a recognised research purpose;⁹⁷ and
- in connection with animals that have been obtained from a licensed animal supplier.⁹⁸

The uncommenced amendments to the Animal Research Act also require licenced animal suppliers to establish an animal care and ethics committee and to comply with the Australian Code of Practice. The Minister for Agriculture has stated that the amendments will 'ensure that an approval for research becomes a one-stage process with animal research authorities

⁹⁶ NSW Government Gazette No. 130, 28 November 1997, p 9475.

⁹⁷ A 'recognised research purpose' is the purpose of acquiring, demonstrating or developing knowledge in the field of medical, veterinary, agricultural, behavioural or biological science; or the purpose of acquiring, demonstrating, exercising or developing techniques used in the practice of medical, veterinary, agricultural, behavioural or biological science; or the purpose of developing or testing substances intended for therapeutic use: *Animal Research Act 1985*, ss 2A and 3.

⁹⁸ There are some exemptions to this requirement: *Animal Research Act*: s 3.

linked to specific research projects.’⁹⁹ He further explained that the amendments will allow ‘industry and government resources that are currently tied up in licensing to be better used to make sure that animals are treated humanely. Independent researchers will be inspected at the same time as their ethics committee and it will remain an offence to carry out research without animal care and ethics committee approval’.¹⁰⁰

Animal care and ethics committees: Research projects involving animals must be approved by an animal ethics committee, either the committee of an accredited research establishment or the Director-General’s committee. The committees also have a continuing role of supervising the animal research that they have approved.¹⁰¹ Each committee must have at least one member with scientific research experience, one with veterinary expertise, one with a demonstrated commitment to animal welfare, and one independent community representative. Animal ethics committees are discussed in more detail in Part 6 of this background paper.

Animal Research Review Panel: Responsibility for enforcing the Animal Research Act generally lies with the Animal Research Review Panel and NSW Agriculture. The Panel consists of 12 members who are appointed by the Minister on the basis of nominations received from industry, academic, government and animal welfare groups. Its functions include:

- investigating matters relating to the conduct of animal research and the supply of animals for use in research;
- investigating and evaluating the efficacy of the Australian Code of Practice; and
- investigating applications for accreditation, and complaints referred to it under the Act.

The Panel reports to the Director-General of NSW Agriculture on its investigations, and advises the Minister on the operation of the legislation.

Complaints: Complaints may be made to the Director-General about research establishments, individual researchers and animal suppliers on several grounds, including contravention of the directions of an animal care and ethics committee, or contravention of the Code of Practice. Complaints are investigated by the Animal Research Review Panel. After considering a report by the Panel, the Director-General may cancel or suspend an accreditation, research authority or licence, or caution or reprimand the research establishment, researcher or animal supplier. An animal research authority that was issued by an accredited research establishment may be cancelled at any time by the establishment. A person may be prosecuted for committing an offence under the Animal Research Act,¹⁰²

⁹⁹ Hon R Amery MP, *NSWPD*, 7/5/97, p 8246.

¹⁰⁰ *Ibid.*

¹⁰¹ *Animal Research Act 1985* (NSW) ss 14(1)(b), 14(2)(a).

¹⁰² The *Animal Research Act 1985* (NSW) Part 5 sets out several offences, such as unlawfully carrying out animal research.

or under the *Prevention of Cruelty to Animals Act 1979* (NSW).¹⁰³

Inspections: Inspections of research establishments and animal suppliers are carried out by inspectors of NSW Agriculture appointed under the Animal Research Act. Three different types of inspections are conducted: accreditation site visits; inspection of the facilities of animal researchers and suppliers; and investigation of complaints. Inspection of accredited and licensed premises are performed approximately every three years by members of the Animal Research Review Panel and veterinary officers of the Animal Welfare Unit. In 1996-97, 30 inspections were carried out under the *Animal Research Act*, and several complaints were investigated.¹⁰⁴

4.3 Victoria

Research on animals is regulated by Part 3 of the *Prevention of Cruelty to Animals Act 1986* (Vic). The Act requires scientific establishments to obtain a licence in order to carry out a 'scientific procedure'. To be licensed:

- the establishment must have an Animal Experimentation Ethics Committee (AEEC);
- the scientific procedure must be carried out in accordance with statutory requirements and the Australian Code of Practice;
- the AEEC must have approved the carrying out of the procedure;
- procedures must be carried out at the premises specified in the licence;
- the facilities and equipment at the premises specified in the licence must comply with the prescribed minimum standards; and
- animals used in scientific procedures must be either bred at the establishment or obtained from a licensed breeding establishment, or obtained in accordance with the regulations.

The Act also regulates the breeding and supply of animals for sale or delivery to a scientific establishment for use in scientific procedures. Inspections of licensed research or breeding establishments are carried out by officers authorised by the Minister. The Minister is advised on animal research by the Animal Welfare Advisory Committee, a general animal welfare body with representatives from industry, academia, government and animal welfare groups.

The Minister is also empowered to establish a Peer Review Committee to inquire into any aspect of scientific procedure or scientific research at any licensed scientific establishment. A Peer Review Committee must have at least five members appointed by the Minister, one of whom is a person with experience in the area of animal welfare, and the remainder of whom are persons with expert skill or knowledge in an area relevant to scientific procedures or research.

4.4 Queensland

¹⁰³ Prosecutions under the Animal Research Act and the Prevention of Cruelty to Animals Act are discussed in Part 7 of this background paper.

¹⁰⁴ New South Wales Agriculture, *Annual Report 1996-97*, p 24. See Part 7 of this background paper for an outline of some proposals to alter inspection practices.

The Queensland legislation governing animal research is fairly brief and has not been updated for some time. Under the *Animals Protection Act 1925* (Qld) it is lawful to carry out a 'scientific experiment' in accordance with the regulations, except in 'any case of ill treatment': s 7(1)(f). The Animals Protection Regulation 1991 provides that a scientific establishment or a person proposing to conduct a scientific experiment must comply with the 5th edition of the Australian Code of Practice. The 5th edition of the Code has since been replaced by the 6th edition, published in 1997, with the result that the Code incorporated into the Queensland regulatory system differs in some respects from the current Code of Practice that applies in New South Wales.

Queensland is currently reviewing its animal welfare legislation, with a view to developing a system of registration for carrying out scientific experiments. The regulations are also to be updated to incorporate the new edition of the Code of Practice.

4.5 South Australia

Animal research in South Australia is regulated by Part 4 of the *Prevention of Cruelty to Animals Act 1985* (SA). Under the Act a person must be licenced by the Minister in order to use an animal for research or experimentation. The Minister may impose conditions on the grant of a licence, such as requiring a licence holder to consult or seek the approval of an animal ethics committee before using animals for the purposes of teaching, research or experimentation. In the second reading speech for the legislation the Minister stated that research institutions will be required to create animal ethics committees to examine and approve all work using animals.¹⁰⁵

An ethics committee must not approve the use of an animal for the purposes of research or experimentation unless it is satisfied that the use of the animal is essential in order to obtain significant scientific data, and that the person who proposes to use the animal has appropriate experience and qualifications. The regulations to the *Prevention of Cruelty to Animals Act 1985* provide that animal ethics committees have the functions assigned to them by the 1990 edition of the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes. That Code of Practice has since been replaced by a new edition published in 1997, so the Code incorporated into the South Australian regulatory system differs in some respects from the current Code as it applies in New South Wales.

The Minister is advised on animal research by the Animal Welfare Advisory Committee, a general animal welfare body with representatives from industry, academia, government and animal welfare groups. The Act is enforced by inspectors nominated by the RSPCA and appointed by the Governor.

4.6 Western Australia

The current Western Australian legislation regulating animal research is not extensive, and it has not been updated for some time. The *Prevention of Cruelty to Animals Act 1920*

¹⁰⁵ Hon R Abbott MHA, *SAPD*, 9/10/85, p 1224.

provides an exemption to the Act for persons who have been authorised by the Governor to perform any vivisection or other experiment on any animal: s 6(1)(g). In order to be exempt:

- the operation must be in accordance with the regulations;
- the animal subject to the operation must be under the influence of anaesthetic so as to feel no pain;
- if the animal has been so injured that its recovery would involve serious suffering, it must be destroyed while still insensible; and
- an animal which has suffered one operation must not be subjected to another one.

The *Control of Vivisection and Experiments Regulations 1959* provide that the Governor may include conditions in the authority relating to the premises at which operations may be conducted, the persons who may be present, the keeping of records and other matters. There is no legislative requirement for institutions carrying out research to have an ethics committee or to comply with the Code of Practice. Inspections of premises may be carried out with the authorisation of a court.

The WA Department of Local Government is currently preparing new animal welfare legislation dealing with both prevention of cruelty and animal research. A green paper on the proposed legislation is expected to be released soon. The new legislation is intended to regulate animal research in a more comprehensive and up to date fashion than the current Act. It will require compliance with the Code of Practice, and there will be a system of licencing of institutions and provision for inspection of research facilities.

4.7 Tasmania

Research on animals is regulated in Tasmania by Part 4 of the *Animal Welfare Act 1993* (Tas). In order to carry out animal research, an institution must be licenced by the Minister. A condition of each licence is that institutions must comply with the Australian Code of Practice in conducting animal research. Each institution must have an Animal Experimentation Ethics Committee, and no animal research may be commenced until it is approved by the institution's ethics committee. The procedures and functions of the committees are governed by the Australian Code of Practice. The supply of animals for research must also be in accordance with the Australian Code of Practice. Inspections are carried out by inspectors appointed by the Minister.

4.8 Australian Capital Territory

The *Animal Welfare Act 1992* (ACT) Part 4 deals with animal research, teaching and breeding. A person must have a licence granted by the Animal Welfare Authority in order to use or breed animals for research or teaching. Each licence holder must establish and maintain an Ethics Committee, and an ethics committee may authorise a person employed or engaged by a licence holder to use animals in research or teaching. Animal research programs cannot be carried out without the approval of an ethics committee. The Act is enforced by inspectors and authorised veterinary surgeons.

The 5th edition of the Australian Code of Practice (with some modification) has been approved under the *Animal Welfare Act 1992*.¹⁰⁶ The NHMRC has since replaced the 5th edition of the Code with a 6th edition, published in 1997, with the result that the Code incorporated into the ACT regulatory system differs in some respects from the current Code of Practice that applies in New South Wales.

4.9 Northern Territory

The legislation regulating animal research in the Northern Territory is fairly brief. The *Prevention of Cruelty to Animals Act s 21* provides that it is lawful for a medical practitioner, veterinary surgeon or officer authorised by the Minister to perform any experiment or vivisection upon any animal for the purposes of scientific investigation. The exemption does not apply where an animal is ill-treated, or pain is unnecessarily caused to any animal by any person. There is no legislative requirement for institutions undertaking animal research to establish animal ethics committees. There are currently only two animal ethics committees in the Northern Territory.

The Department of Local Government and Housing is in the process of developing new prevention of cruelty to animals legislation. The provisions in the new statute dealing with animal research will follow the New South Wales model. There will be a system of licenses to conduct procedures involving animals, and approval of research by animal ethics committees. The legislation will adopt the Australian Code of Practice.

5. REGULATORY MODELS AND INTERNATIONAL COMPARISONS

As seen in Part 4 above, there is considerable variation in the animal research legislation of the Australian States and Territories. Nevertheless it is true to say that the philosophy underlying most State animal research systems is one of 'enforced self-regulation'. This Part will explore further the concept of enforced self-regulation, and compare it to the systems used to control animal research in other countries. It will be seen that countries with comprehensive animal research legislation tend to opt for a regulatory system that, like Australian systems, combines self-regulation with elements of government supervision or control. The variations between countries lie in the nature and degree of government intervention.

5.1 Regulatory models

The Commonwealth Senate Select Committee on Animal Welfare observed that there are

¹⁰⁶ *Australian Capital Territory Gazette*, No. S90, 31 May 1993.

a number of ways in which animal experimentation can be administered.¹⁰⁷

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.... 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. 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 generally supported self-regulation with little or no government involvement.

Another perspective is provided by Associate Professor Loane Skene of the University of Melbourne, who has identified a hierarchy of animal research controls and sanctions.¹⁰⁸ At the top of the hierarchy is the strictest form of regulation: legislative control of animal research, with external monitoring of compliance by government inspectors, and criminal sanctions such as imprisonment or fines for breach of the statutory scheme. Further down the hierarchy is a licensing system, which has a civil rather than a criminal basis. Failure to comply with the conditions of a licence may result in suspension or cancellation of the licence. There may still be criminal sanctions for offences such as conducting research without a licence, or in breach of a licence. At the bottom of the hierarchy are voluntary controls, such as guidelines and codes of practice, monitored by a committee within the institution itself. Sanctions for non-compliance with voluntary regulation are of a 'professional' kind, such as withdrawal of funding, demotion, dismissal, reprimand or loss of reputation through peer criticism.

Enforced self-regulation of animal research is located towards the bottom half of this hierarchy. In brief, the theory of enforced self-regulation¹⁰⁹ is that organisations should be involved in drawing up the rules that they will have to comply with and should be responsible for ensuring that the rules are followed, rather than the government writing the rules and imposing them on the organisation. Compliance is monitored by an officer or committee internal to the organisation, with the government verifying that these internal monitors are operating effectively.

¹⁰⁷ Senate Select Committee, n 8, pp 227-8.

¹⁰⁸ L Skene, 'Animal experimentation ethics committees - what are we trying to achieve?' in R Baker, J Burrell and M Rose (eds), *Effective Animal Experimentation Ethics Committees*, ANZCCART, 1994 pp 2-3.

¹⁰⁹ The theory is explained in detail in I Ayres and J Braithwaite in *Responsive Regulation: Transcending the Deregulation Debate*, Oxford University Press, 1992, pp 106-107. See also Regulation Review Committee, NSW Parliament, *Some aspects of international regulatory programs and practices*, Report No 14/51, May 1998, for a discussion of regulatory initiatives.

The New South Wales animal research legislation generally applies this self-regulatory approach. The researcher must present an application to an animal ethics committee that sets out the details of the proposal.¹¹⁰ It is up to the researcher and the ethics committee to work out how to meet the requirements of the Australian Code of Practice in relation to the particular research proposed. Approvals of research licences and authorisations can be seen as a form of rule-writing between the researcher and the ethics committee representing the public interest. The Australian Code of Practice itself can be seen as an example of self-regulating rules being drawn up by the scientific community in consultation with governments and animal welfare groups; indeed, the Code has been described as a 'public contract'.¹¹¹ The 'enforcement' element of 'enforced self-regulation' is provided by means such as supervision by animal ethics committees, government inspections and, in New South Wales, site visits and accreditation inspections by the Animal Research Review Panel.

The Commonwealth Senate Select Committee on Animal Welfare supported this self-regulatory approach. The Committee considered what kind of regulatory system for animal research should be adopted in Australia, and outlined a number of proposed models including:¹¹²

- institutional ethics committees monitored by state and federal advisory panels and a federal inspectorate;
- institutional animal ethics committees monitored by a body such as ANZCCART¹¹³ (Australian and New Zealand Council for the Care of Animals in Research and Teaching), or the NHMRC (National Health and Medical Research Council); and
- self-regulation without external monitoring.

The Select Committee found that there was general agreement that neither self-regulation nor a totally regulated system was desirable. Instead, the question was the extent of government regulation and the nature of the administrative structure to control animal experimentation.¹¹⁴ The Committee found widespread support for the use of ethics committees to approve and supervise research. After considering various possible regulatory models, the Senate Select Committee eventually recommended one that corresponds closely to the current NSW system. The Senate Committee was in favour of all States and Territories adopting comprehensive animal research legislation, (preferably in a statute separate to the prevention of cruelty legislation); incorporation of a code of practice in

¹¹⁰ Animal Research Regulation 1995 reg 14(2).

¹¹¹ M Rose, 'Striking the balance: the practitioner and the animal ethics committee', (1996) 9(3) *ANZCCART News* 1 p 2.

¹¹² Senate Select Committee, n 8, Chapter 15.

¹¹³ ANZCCART is an umbrella organisation made up of representatives from many bodies including State, Territory and National Governments, major research and teaching organisations and scientific societies.

¹¹⁴ Senate Select Committee, n 8, p 234.

regulations; accreditation and licensing of institutions in which animal experimentation is conducted; and the appointment of inspectors to monitor the work of AECs, animal care facilities, and the conduct of procedures using animals.¹¹⁵

The focus on self-regulation in animal research generally arises from the perception that it forces researchers to accept the responsibilities expected of them by the community towards the animals in their care. The Senate Select Committee made the point that primary responsibility for animal use and care rests with the experimenter, emphasising that it is vital to instil in experimenters early in their careers an ethical, responsible and caring approach to the use of animals in experiments.¹¹⁶

As well as fostering this thoughtful attitude in researchers, enforced self-regulation is said to have several advantages over regulation by stricter legislative schemes.¹¹⁷ The ethics committees which monitor compliance with the Australian Code of Practice generally include someone who is familiar with the institution and its staff and who is likely to be on site. This can make ethics committees better monitors of research activities: while government inspectors may only visit occasionally for short periods, ethics committees have a continuing presence in the institution and they meet regularly. Additionally, animal researchers may be more responsive to directions and advice from an 'insider' who is familiar with their particular circumstances than from an outside 'policeman'. Another consideration is that the representatives of a research institution on a committee will have a particular interest in upholding the reputation of the institution by ensuring that all animal research is in order. Ethics committees can also be a less expensive method of monitoring compliance than government inspectors, since the members are generally volunteers or are paid by the institution, and there are few travelling expenses.

A system of enforced self-regulation can also have disadvantages. Some weaknesses with the use of animal ethics committees to enforce self-regulation have been identified,¹¹⁸ including:

- Potential lack of independence of an AEC: animal ethics committees that include scientists and members from within an institution may be 'co-opted' by the institution, losing their objectivity and their capacity to police their personnel

¹¹⁵ Ibid, n 8, p 245.

¹¹⁶ Ibid, n 8, p 235.

¹¹⁷ These paragraphs are drawn from Skene, n 108, pp 5-6.

¹¹⁸ Skene, n 108, p 6; M Rose, 'Striking the balance: the practitioner and the animal ethics committee', *ANZCCART News*, vol 9 no 3, September 1996 p 3. Part 6 of this background paper discusses in more detail some criticisms of the practical operation of animal ethics committees in New South Wales.

effectively.¹¹⁹

- Tendency to avoid dissent: where decisions are made by committees, there may be a reluctance among members of the committee to voice dissenting opinions. Lay members of an animal ethics committee may not feel free to question researchers or expert members who appear to have greater expertise or experience than they do.
- Lack of consistency: if monitoring is conducted by individual in-house committees, there may be a piece-meal approach to monitoring and inspections.

The rest of this Part sets out brief outlines of animal research legislation in Europe (both Europe-wide provisions and some national legislation), the United States of America, Canada, and New Zealand.

5.2 Europe

The European Union has two main documents setting out the standards for animal research: the *European Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes*, and the *Council of Europe Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes 1986*. The Directive is legally binding on all EU Member States, but in order for it to become effective it must be adopted by each country into its domestic legislation. The Convention has been signed by the EU as a whole and a number of individual member states. The Council of Europe has a larger membership than the EU, but its power is limited in comparison: it has no means to impose any of its rules on Member States. The relationship between the two texts has been described as follows:

The overlap between the two regulations is considerable, the Directive being largely based on the text of the Convention. Both establish a framework for the control of animal experiments and provide minimum standards for housing and care. Although the Convention is fundamentally superfluous to the control of animal experiments in the EU (the Directive is the regulation which must, by European law, be enforced in Member States), it remains functional, including as it does countries outside the EU. It is important to note that the standards set out in both regulations are minimal, as Member States can impose higher standards if they choose, a form of self-regulation which some countries have implemented... The main provisions of both regulations are the same... Despite some inconsistencies in interpretation and implementation between Member States, the introduction of the Directive and the Convention have had a significant effect on the regulation of animal experiments across Europe. However, as with any legislation, the effectiveness of these measures

¹¹⁹ For example, the Animal Research Review Panel in its *Annual Report 1995-96* noted that a research institute had its licence suspended for a number of reasons, including that its ethics committee had failed to demonstrate adequate consideration of research proposals (p 22).

relies upon adequate implementation of their provisions. There is still a wide variation between countries in the level of scrutiny of experimental protocols, measures taken to ensure adequate standards of housing and care, and consideration of techniques to refine, reduce and replace animal use.¹²⁰

The Council Directive applies to experiments undertaken for the purposes of developing, manufacturing and testing the safety and efficacy of drugs, foodstuffs and other substances or products, and to experiments for the protection of the environment. Although it does not apply to experiments carried out in connection with fundamental research and education, a Council Resolution adopted at the same time as the Directive urges Member States to apply equally strict national provisions to these areas.

The European regulations do not require the use of animal ethics committees. Some countries use animal ethics committees to meet their EU obligations, and others use an inspectorate system.¹²¹

United Kingdom: The animal research system in the United Kingdom relies more on government regulation than self-regulation. The *Animals (Scientific Procedures) Act 1986* (UK) in some ways exceeds the requirements of the European Union Directive, and it is widely viewed as the most rigorous piece of animal research legislation in the world. The United Kingdom protects (in addition to live vertebrates):

- any octopus from the stage of its development when it becomes capable of independent feeding; and
- any vertebrate in its foetal, larval or embryonic form when, in the case of a mammal, bird or reptile, half the gestation or incubation period for the relevant species has elapsed, and in any other case, it becomes capable of independent feeding.

Britain does not have a mandated system of animal ethics committees. The responsibility for approving animal research and ensuring that animal welfare standards are maintained lies with the Home Office. Under the *Animals (Scientific Procedures) Act 1986*, animal research is controlled by a licensing system: the Home Office issues project licenses for those responsible for directing research programmes, personal licences for those performing scientific procedures, and certificates for those responsible for establishments where laboratory animals are bred, kept or used. A project licence specifies the programme of work in which regulated procedures are to be carried out and each personal licence allows an individual to carry out identified procedures on specified types of animals. Project licences are valid for up to five years.

All procedures within a project licence are assigned a severity limit - either mild, moderate

¹²⁰ B Jones, 'European legislative control of animal experiments', *ANZCCART News*, vol 9 no 4, December 1996, pp 10-11. For more information on the European position see D Wilkins, *Animal Welfare in Europe: European Legislation and Concerns*, Kluwer Law International Ltd, 1997.

¹²¹ Ibid.

or substantial. No animal procedure used under a project licence should exceed the severity limit unless an alteration to the licence has been agreed by the inspector. The Act provides that in determining whether and on what terms to grant a project licence, the Home Office is to weigh the likely adverse effects on the animals concerned against the benefit likely to accrue as a result of the research programme.

There is a special inspectorate of civil servants to advise the Home Office on the granting of licences, and to carry out inspections of premises to ensure licences are complied with. The inspectorate functions as a source of professional and scientific expertise in the formulation of policy on the care and use of animals in laboratories. There is also an Animal Procedures Committee set up under the Act to advise the Home Secretary on matters concerned with the Act and the functions it imposes on the Secretary.

The UK system has been criticised as possibly too complex and bureaucratic. Researchers have raised concerns that since it is very difficult to predict the way that a fundamental research project will develop, researchers may need to submit several requests to vary the project licence to the Home Office, which can delay the progress of the research.¹²² Difficulties may also arise from the vesting of the responsibility for making ethical decisions in a small group of civil servants:

The Home Office inspectors all have a scientific background but no formal training in ethics... Decisions made by a single person may make the inspector a scapegoat for anything that goes wrong or can be contested, particularly considering the history of anti-vivisection movements in the UK. Ethics committees, on the other hand, can provide a forum to debate these issues, raise awareness on both sides, and perhaps defuse tensions and lead to a greater mutual understanding... Ironically, despite high standards employed in animal research in the UK, the top-down approach of the legislation, because it specifically excludes those who have a serious interest in the debate, leads to discontent. Little opportunity arises for mutual education, unlike in countries where ethics committees have an active role to play... The system of control of the Animals Procedures Committee and the Home Office inspectors gives an overwhelming scientific bias to the implementation of the 1986 Act.¹²³

Sweden: The Swedish system of regulating animal research is established by a general law controlling animal welfare, the Animal Protection Act and the Animal Protection Ordinance, both from 1988.¹²⁴ The legislation delegates the power to create specific regulations on

¹²² European Biomedical Research Association - The regulation of animal research and testing in United Kingdom, <http://www.uel.ac.uk/research/ebra/regulate/uk.htm>.

¹²³ P Townsend and D Morton, 'Laboratory Animal Care Policies and Regulations: United Kingdom' in the *ILAR Journal* (Institute of Laboratory Animal Resources), vol 37 no 2, Spring 1995 p 72.

¹²⁴ The information about Sweden is taken from the European Biomedical Research Association - Laboratory animal research legislation in Sweden, <http://www.uel.ac.uk/research/ebra/regulate/swedish.htm>, and information provided by the

animal research to the National Board for Laboratory Animals. The Swedish legislation covers all animals, not just vertebrates, and provides that only purpose-bred animals can be used in experimentation.

The National Board is responsible for granting permission for animal experiments, following approval by one of the seven regional ethical committees. Scientific and medical experts make up half of the membership of each committee with the other half being lay members. Animal welfare representatives can make up to one third of the committee. The committees are large, some having had 45 members.¹²⁵ The chairman of each committee is a senior lawyer, usually a judge. All animal research and testing proposals are considered by these committees which are required to weigh up the importance of the experiments against the animal suffering involved. Projects can be approved for a maximum of three years. Although these committees only have advisory power, their recommendations are always followed. All animal research projects require ethical committee approval, including feeding studies, experiments under terminal anaesthesia and the killing of animals to remove tissues for use in *in vitro* biomedical research. Veterinary inspectors from local or regional authorities check research establishments to ensure compliance with the committee decisions.

An interesting feature of the Swedish system is the requirement for all animal researchers, technicians and animal carers to undergo training in animal care and research techniques. Until they have completed this training and passed a test on it, they are required to work under supervision.

The Netherlands: The Dutch *Experiments on Animals Act 1997* provides that animal research projects must be approved by an ethical review committee, which has to consider the benefit to come from the experiments and whether this justifies the distress caused to the animals to be used.¹²⁶ Each committee must have at least seven members made up from equal numbers of experts in (i) animal experiments, (ii) alternative methods, (iii) animal welfare, and (iv) ethical assessment. At least two members must not be conducting animal experiments and at least three members, including the chairperson, must not be employed by a scientific organisation applying to the committee. The relevant Minister is advised on the operation of ethical review committees by a central animal review committee. The Act requires licensing for animal breeders and suppliers.

The Dutch legislation applies to vertebrates, (although there is provision for an invertebrate to be given the same protection as vertebrates by an administrative order, where it may reasonably be supposed to suffer distress if used in an experiment). Like Sweden, the Netherlands requires scientists conducting research on animals to be trained in animal care

Swedish Parliamentary Research Service.

¹²⁵ Senate Select Committee, n 8, p 236.

¹²⁶ The information in this section is taken from European Biomedical Research Association, - Animal experimentation legislation in Holland, <http://www.uel.ac.uk/research/ebra/regulate/holland.htm>.

and research techniques.¹²⁷

A notable feature of the Dutch legislation is the provision that the intrinsic value of animal life is to be recognised. This represents a move away from the traditional position under European legislation: the Treaty of Rome, the legal document which created the EEC, classifies animals as 'agricultural goods.' Animal welfare groups argue that the Treaty should be amended to re-define animals as sentient beings, to provide a firmer basis for animal welfare legislation. A 1996 protocol to the Treaty of Rome referred in its prologue to animals as sentient beings but did not actually change the status of animals.¹²⁸ Whether the Dutch provision will have a significant effect on the conduct of animal research remains to be seen. The Research Defence Society, a UK organisation established to defend the use of animals in research, has observed that the Dutch legislation does not require animal review committees to take this point into account when assessing research plans.¹²⁹

Germany: Animal research is covered in Germany by the Animal Protection Law. Although this is a national law, it is applied by the 16 regional governments (Länder), resulting in some regional differences in the conduct of animal research.¹³⁰ Generally researchers submit an application for a research project to their regional authority, with details of all the experiments to be carried out. Any alterations to these details during the course of a project have to be submitted to the authority. Each regional authority is advised on applications to conduct animal research projects by a commission composed of at least one-third animal welfarists. The advice of this commission is not binding on the regional authority, but it is treated with respect. There is a different mechanism for animal testing which is required by law, such as testing of pharmaceuticals or chemicals.

Experimentation on both vertebrates and invertebrates is regulated by the Animal Protection Law. However, licences are only required for research involving the use of vertebrates. All institutions carrying out animal experiments have to appoint an internal Animal Welfare Officer to advise on animal use. Veterinary officers from the regional authority have the right to inspect the work being conducted at all animal research institutions.

Lengthy delays in the approval process for animal research programs have recently led Germany to make some changes to the animal protections laws. For example, small changes to a protocol required during the course of a research project need be notified only to the authorities, rather than having to go through the full approval procedure.

¹²⁷ Hon R Jones, *NSWPD*, 16/6/97, pp 10252-3.

¹²⁸ European Biomedical Research Association - IGC agrees protocol on animal welfare, <http://www.uel.ac.uk/research/ebra/news/aug97/igc.htm>.

¹²⁹ European Biomedical Research Association, - Animal experimentation legislation in Holland, <http://www.uel.ac.uk/research/ebra/regulate/holland.htm>.

¹³⁰ The information in this section is taken from the European Biomedical Research Association - the regulation of animal research in Germany, <http://www.uel.ac.uk/research/ebra/regulate/germany.htm>.

5.3 Canada

Canada has a largely self-regulating system of animal research, based on institutional ethics committees monitored by a non-government body without legislative backing.¹³¹ The Canadian Council on Animal Care (CCAC), a national peer-review organisation founded in 1968, issues guidelines and policies on animal care, and assesses compliance with these guidelines. The Council's members represent a number of industry, agricultural, academic, medical, environmental and animal welfare organisations. The national guidelines¹³² on the use of animals in science apply to all animals except humans. However, certain procedures, such as experiments on most invertebrates, egg embryos, and experiments that only involve observation of animals, are not 'counted' by the Canadian Council on Animal Care in their annual statistics.¹³³

Canadian federal legislation covers the prevention of cruelty to animals, but research is exempt from the legislation if it can be shown to be necessary. Several provinces have their own animal research legislation. The most comprehensive of these provincial statutes is the Ontario *Animals for Research Act 1971*, which regulates the use of animals in connection with research, teaching, testing and production. Saskatchewan also has legislation regulating animal research, and Alberta regulates animal research in universities. Legislation in Nova Scotia and Prince Edward Island require institutions conducting animal research to follow CCAC guidelines. The CCAC Guide to the Care and Use of Experimental Animals¹³⁴ states that:

The CCAC carries out its national responsibility for animal care through education in the form of workshops, publications, presentations etc, and its assessment program, which focuses on animal care and use, and the evaluation of the effectiveness of local Animal Care Committees. These institutional committees are responsible for assuring ethical animal use and compliance with CCAC guidelines at the local level, and must evaluate the ethical aspects of proposed research before the study may commence... Assessments are based on volumes 1 and 2 of this Guide and CCAC position papers. In-depth assessments are normally scheduled approximately every three years. In addition, a number of Special or Unannounced Visits are conducted if a panel and/or the Council feels that the conditions at an institution so warrant, or upon request by the institution. The scientific members of an assessment panel are chosen by CCAC from an inventory of individuals with experience and special knowledge of various aspects of animal experimentation and care.

¹³¹ The information in this section is taken from J Wong, 'Laboratory Animal Care Policies and Regulations: Canada' in the *ILAR Journal* (Institute of Laboratory Animal Resources), vol 37 no 2, Spring 1995 pp 57-59.

¹³² Canadian Council on Animal Care, *Guide to the Care and Use of Experimental Animals*, 2nd edition, 1993.

¹³³ Correspondence with Dr Griffin of the Canadian Council on Animal Care, 29 May 1998.

¹³⁴ Vol 1, 2nd ed, 1993, p 3.

The local institutional animal care committees are usually constituted according to the terms of reference recommended by the CCAC. These Terms of Reference state that committee members should include: scientists experienced in animal care and use; a veterinarian; an institutional non-animal user; and at least one person representing community interests and concerns.

The major granting agencies in Canada require researchers and their institutions to comply with CCAC guidelines or risk losing all research grants to the institution. The position is more difficult where the institution concerned does not depend on public funding. The CCAC does not have an enforcement system for such institutions, describing this issue as 'contentious',¹³⁵ and it is currently exploring mechanisms for mandatory participation in the self-regulatory system. The CCAC has introduced a Certificate of Good Animal Practice, which is given to institutions which are found to be in a state of 'compliance' or 'conditional compliance' following a CCAC assessment, as a tangible symbol of their animal care and use programs.

5.4 United States of America

The US system of regulating animal research leans heavily towards self-regulation. The oversight of animal care and use in the United States is provided mainly by two overlapping federal laws: the Animal Welfare Act¹³⁶ and the Health Research Extension Act.¹³⁷

The Animal Welfare Act is implemented by regulations published in the Code of Federal Regulations. The Health Research Extension Act is implemented by the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). This policy applies to all activities conducted and supported by the Public Health Service involving any live vertebrate animal used in research, biological testing or related purposes. The PHS policy requires compliance with the Animal Welfare Act and requires institutions to use the *Guide for the Care and Use of Laboratory Animals* (published in 1985 by the National Research Council) as a basis for developing and implementing an institutional program for activities involving animals. All States have their own laws governing the humane treatment of animals, but animal use by research institutions is usually exempted.¹³⁸

¹³⁵ Correspondence with Dr Griffin of the Canadian Council on Animal Care, 29 May 1998.

¹³⁶ 7 USC 2131-2157.

¹³⁷ 42 USC 289d

¹³⁸ The information in this section is drawn from T Hamm Jr, R Dell, R Van Sluyters, 'Laboratory Animal Care Policies and Regulations: United States' in (1995) 37 *ILAR Journal* (Institute of Laboratory Animal Resources) pp 75-77.

The scope of protection offered to laboratory animals in the United States is much narrower than in most other western countries. The Animal Welfare Act covers ‘any live or dead dog, cat, monkey (nonhuman primate animal), guinea pig, hamster, rabbit or other such warm-blooded animal as the Secretary of State [of the US Department of Agriculture] may determine’. Cold-blooded animals, such as invertebrates, fish, amphibia and reptiles are by definition not covered by the federal legislation. Regulations under the Act have further excluded rats, mice, birds, horses and other farm animals from the definition of ‘animal’. These exclusions mean that the majority of animals used in research in the United States are not afforded federal legislative protection.¹³⁹

The Animal Welfare Act and regulations focus on the care and handling of animals used in research, rather than on the actual procedures performed on the animals. The regulatory authority is prohibited from interfering with the conduct or design of actual research or experimentation, although every research facility covered by the Animal Welfare Act must certify that ‘professionally acceptable standards’ of animal care, treatment and use are being used in research.¹⁴⁰ In this respect the United States is a notable exception to the general trend in many countries towards controlling the design of animal studies.¹⁴¹

The Animal Welfare Act is administered by the US Department of Agriculture’s Animal and Plant Health Inspection Service (APHIS). Research facilities are required to register with APHIS, which employs veterinary medical officers to conduct unannounced inspections at institutions that use animals in research, education and testing. If deficiencies are not corrected after a warning, or if severe deficiencies are found, administrative legal proceedings may be initiated which can result in fines and loss of registration to operate as a research facility. The Act requires research facilities to provide for scientists and animal technicians to be trained in the humane practice of animal maintenance and experimentation, in methods that minimise or eliminate the use of animals or limit animal pain and distress, and in the use of the National Agricultural Library information service. This service provides information that could prevent the unintended duplication of animal experiments, and information on minimising the use of animals, or pain and distress in animals.

The PHS Policy is administered by the National Institutes of Health (NIH). No activity involving animals may be conducted or supported by the PHS until the institution conducting the activity has provided a written assurance to the PHS that complies with the PHS Policy. The PHS Policy and the Animal Welfare Act both make an institutional official responsible for the animal care and use program, and both require institutional animal care and use committees (IACUC). Taken together, the PHS Policy and Federal statutes bring

¹³⁹ Smith & Boyd, n 10, p 267. It has been reported, however, that the USDA is considering extending the federal regulations to include rats, mice and birds: M Mukerjee, ‘Trends in Animal Research’, *Scientific American*, February 1997, 86 p 91.

¹⁴⁰ Office of Technology Assessment (OTA), US Congress, *Alternatives to animal use in research, testing and education*, Washington DC, 1986 p 279.

¹⁴¹ Smith & Boyd, n 10, p 260.

the overwhelming majority of animal users in the United States under the oversight of IACUCs.¹⁴² The IACUC must have at least one member not affiliated with the institution, representing the general community.

The IACUC is responsible for performing a semi-annual review of the institution's animal care and use program, and of the facilities where the animals are housed, using the *Guide* and the standards of the Animal Welfare Act as a basis for evaluation. The IACUC reviews prospectively all protocols designed to use animals in research, education or testing to ensure that they will be conducted in accordance with the USDA regulations and the PHS Policy, unless acceptable justification for a departure is approved.

Criticisms of the US system have focused on:

- The broad exemptions of many classes of animals from protection by the Animal Welfare Act and regulations, including cold-blooded animals, birds, rats, and mice.
- An absence of rules or standards concerning the actual practice 'inside the laboratory door' of research involving animals.
- The emphasis on 'performance standards' (specified goals, such as 'ensuring animal well-being'), rather than 'engineering standards' (precise specifications such as the size of cages). Researchers generally defend performance standards as a 'great strength'¹⁴³ of the current system that allows the professional judgment of the researchers and IACUC to devise suitable means to meet the standards. Animal welfare groups are concerned that performance standards are vague and unenforceable.
- A lack of reliable and meaningful information available to the public about the use of animals in research.¹⁴⁴ For example, the estimated 17 million rats, mice and birds that are used in research each year are not included in reporting requirements.¹⁴⁵
- A lack of adequate funding for APHIS (the US Department of Agriculture's inspection service), and the cautious approach of APHIS to enforcement has led to concerns that the legislation is not being properly enforced.¹⁴⁶

¹⁴² Office of Technology Assessment, n 140, p 281.

¹⁴³ T Hamm Jr, R Dell, R Van Sluyters, 'Laboratory Animal Care Policies and Regulations: United States' in (1995) 37 *ILAR Journal* (Institute of Laboratory Animal Resources) p 77.

¹⁴⁴ Office of Technology Assessment, n 140, p 297.

¹⁴⁵ M Mukerjee, 'Trends in Animal Research', *Scientific American*, February 1997, 70 p 75;

¹⁴⁶ *Ibid*, p 76; Office of Technology Assessment, n 140, p 286.

5.5 New Zealand

The use of animals in research is governed by the *Animals Protection Act 1960*, a general animal welfare statute. Amendments in 1983 introduced a comprehensive system based on self-regulation for research involving animals. All manipulations of live animals for the purposes of research, experimental, diagnostic, toxicity and potency testing, the production of antisera or other biological agents, or teaching must be carried out in accordance with an approved code of ethical conduct relating to the welfare and humane treatment of the animal involved. New Zealand's animal research legislation applies to any vertebrate animal kept in a state of captivity or dependent upon man for care and sustenance.¹⁴⁷ Invertebrates are not protected. The New Zealand legislation is under review, and an Animal Welfare Bill is currently before a Select Committee. The Bill would extend protection to any live fish, octopus, squid, crab, lobster or crayfish.

There is a National Animal Ethics Advisory Committee (NAEAC), which has the task of advising the Minister on matters relating to codes of practice, and on ethical issues in animal use. There is also an Animal Welfare Advisory Committee (AWAC), whose overall task is to advise the Minister on all matters relating to animal welfare other than which fall within the jurisdiction of NAEAC. The AWAC has published a code for the care and use of animals for scientific purposes.¹⁴⁸ This code does not deal with ethical aspects of their experimentation, which is the concern of the NAEAC.

The Act legislates only for the use of codes of ethical conduct and their content: it does not prescribe how the codes are to be implemented. Institutions are encouraged to write their own animal ethics codes, incorporating the items required by law, some features imposed by the NAEAC, and matters specific to the individual institution. All proposed codes are inspected by the NAEAC, which recommends to the Minister whether codes should be approved. The NAEAC guidelines require codes to provide for an institutional ethics committee which includes three people not affiliated with the institute: a lay person, a veterinarian, and a nominee of an animal welfare group.¹⁴⁹

In 1995 there were 35 institutional animal ethics committees in New Zealand, and by 1997 the NAEAC had recommended for approval more than 70 codes of ethical conduct.¹⁵⁰ (Some committees supervise more than one code). The *Animals Protection Act 1960* does not require the licensing of institutes, premises, researchers or their projects. Failure to comply with an institution's approved code of conduct is an offence that renders a person

¹⁴⁷ *Animals Protection Act 1960* (NZ) s 2

¹⁴⁸ AWAC, *Code of Recommendations and Minimum Standards for the Care and Use of Animals for Scientific Purposes*, Code of Animal Welfare No. 17, August 1995.

¹⁴⁹ The information in this section is taken from C Reid, 'Laboratory Animal Care Policies and Regulations: New Zealand' in the *ILAR Journal* (Institute of Laboratory Animal Resources), vol 37 no 2, Spring 1995 pp 62-67.

¹⁵⁰ D Bayvel, 'Animal Welfare in New Zealand - Concepts, Committees, Consultation and Codes of Practice', (1997) 10(4) *ANZCCART News*, p 5.

liable to prosecution under the *Animals Protection Act*.

6. ANIMAL ETHICS COMMITTEES IN PRACTICE

From Parts 4 and 5 of this background paper, it can be seen that institutional animal ethics committees (AECs) are an important part of the systems for regulating animal research in most Australian states, and in most countries that have comprehensive animal research legislation. In Australia, AECs are generally used not only to enforce animal protection laws at the institutional level, but also to involve community representatives and animal welfare interest groups in the approval and supervision of animal research. AECs are a ‘key element in the system for public accountability’,¹⁵¹ and the effective operation of AECs is vital to regulation of animal research. This Part looks at AECs in New South Wales, and at some criticisms that have been made about their operations.

The New South Wales *Animal Research Act 1985* sets out the general functions of AECs, while the *Animal Research Regulation 1995* governs the constitution, procedures and responsibilities of AECs. An AEC for an accredited research establishment and licenced animal researchers must have at least 4 members. Of these, one must be a person who is not involved in the conduct of animal research and is not associated with any accredited research establishment. Membership of an AEC must comply with the requirements of the Australian Code of Practice; that is, there must be at least four members, including one person from each of the following categories:

- Category A:* a veterinarian with experience relevant to the activities of the institution (or in special circumstances a person with comparable expertise);
- Category B:* a person with substantial recent experience in the use of animals in scientific or teaching activities;
- Category C:* a person with a demonstrable commitment to, and established experience in, furthering the welfare of animals, who is independent of the institution (preferably nominated by an animal welfare organisation).
- Category D:* an independent person who has never conducted scientific or teaching activities using animals and who is not an employee of the institution. The Australian Code suggests distinguished public figures, business people, teachers, retirees, accountants, lawyers and so on.

The functions of Animal Care and Ethics Committees (ACECs) in NSW have been described as follows by the Animal Research Review Panel:

ACECs are responsible for monitoring research within the institution, including inspections of animals and facilities. The committees must consider and evaluate requests to conduct research, on the basis of the researchers’ responses to a

¹⁵¹ Senate Select Committee, n 8, p 262.

comprehensive set of questions, including the justification for the research, its likely impact on the animals; and procedures for preventing or alleviating pain or distress. On behalf of the institution, ACECs have the power to stop inappropriate research and to discipline researchers by withdrawing their research approvals. They can require that adequate care, including emergency care, is provided. They can also provide guidance and support to researchers on matters relevant to animal welfare, through preparation of guidelines and dissemination of relevant scientific literature. They are also responsible for advising the institution on changes to physical facilities which are needed to meet required standards.¹⁵²

Animal ethics committees meet regularly,¹⁵³ and must keep full and accurate minutes of the proceedings of each meeting. The Regulations and the Australian Code of Practice also require each AEC to report annually on its work and activities to its institution. Decisions are made by majority vote, with the person presiding at a meeting to have a casting vote. The members of AECs may often be faced with difficult ethical and practical problems, and there are several avenues of support for AECs to assist them in making decisions (see p 51 below). The Australian Code of Practice provides that irreconcilable differences between an AEC and a researcher must be referred to the governing body of the institution for review.

In 1995-96, there were 3403 approvals and reapprovals of research proposals by ACECs. There were 15 rejections. The Animal Research Review Panel noted that 'rejection' meant only those proposals rejected outright; many proposals are approved or reapproved only after significant alterations are made to them in consultation with the ACEC.¹⁵⁴

Animal ethics committees are a relatively recent development in Australia, and they have not always had support from the scientific community. The Senate Select Committee on Animal Welfare observed in 1989 that the history of ethics committees in Australia is one of varying levels of success, with some acting merely as a facade to keep authorities and the community at bay, while others have diligently applied themselves to the task of ensuring that ethical standards are maintained. The Senate Select Committee went on to find 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 Australian Code of Practice.¹⁵⁵ The AEC system has generally been accepted as successfully introducing public oversight of animal research.

There has nevertheless been some criticism from animal welfare groups and others in New South Wales about the effectiveness of AECs in ensuring that the aims of the *Animal Research Act 1985* are met. The Regulation Review Committee of the Parliament of New

¹⁵² Animal Research Review Panel, *Annual Report 1995-96*, p 8.

¹⁵³ The Australian Code of Practice (cl 2.2.14) states that meetings must be as frequent as the volume of business demands, but normally scheduled not less than quarterly.

¹⁵⁴ Animal Research Review Panel, *Annual Report 1995-96*, pp 31-32.

¹⁵⁵ Senate Select Committee, n 8, p 228.

South Wales has recently recommended that the Animal Research Review Panel carry out in the next two years an in-depth review of the operation of AECs to determine whether they are carrying out their duty under the Australian Code of Practice to ensure that all animal care and use within research institutions incorporate the principles of replacement, reduction and refinement.¹⁵⁶ Some of the concerns about AECs are set out below.

Role of the community/animal welfare members of AECs. A common criticism of AECs in New South Wales is that scientists and researchers often greatly outnumber the community and animal welfare members of AECs, making the votes of these members ineffectual. Indeed, the RSPCA no longer nominates persons to act as Category C members, citing concerns that the presence of RSPCA nominees on AECs was being used to reassure the public about research activities while the RSPCA itself may have little knowledge of or control over those activities.¹⁵⁷ Criticisms have focused on questions of:

- *Membership proportions.* In New South Wales there is no maximum number of members of an AEC, nor is there a mandatory proportion between member categories. The Australian Code of Practice (clause 2.2.6) states that if an AEC has more than four members, Categories C and D should represent no less than one third of members. The Regulation Review Committee of New South Wales Parliament criticised the absence from the Code of a **mandatory** one third proportion of community and animal welfare members, particularly in light of the Code's reference to the requirement for balance of membership of AECs.¹⁵⁸ The Committee recommended that the Animal Research Regulations 1995 should be amended to make it mandatory that in any case where an AEC has more than four members, Categories C plus D represent no less than one third of the members.¹⁵⁹
- *Voting procedures.* The New South Wales Animal Research Regulations 1995 provide for AECs to make decisions by majority vote, and allow a quorum for an AEC to include less than one member from each of the four categories of membership. It has been argued that the regulations should provide for decisions by consensus, rather than by majority vote. The Regulation Review Committee decided

¹⁵⁶ Regulation Review Committee, n 74, p 32.

¹⁵⁷ '7:30 Report', ABC Television, 13 May 1998; see also G Oogjes, 'The need for change', in (1996) 9(3) ANZCCART News, p 4.

¹⁵⁸ Regulation Review Committee, n 74, p 16.

¹⁵⁹ In some jurisdictions there are prescribed proportions between member categories. For example, in South Australia, the *Prevention of Cruelty to Animals Act 1985* provides that in selecting the members of an animal ethics committee, the Minister should act with a view to ensuring that the membership of the committee is, as nearly as possible, equally representative of each of the four classes of members: s 23(4). There are also mandatory membership proportions in Germany, Sweden and the Netherlands: see Part 5.2 of this background paper.

that as most AECs voluntarily favour a unanimous voting method there is no practical justification at this stage to consider altering the regulations to make such a practice mandatory.¹⁶⁰

These debates may reflect deeper tensions about the role of AECs in regulating animal research. On one view, the AEC is responsible for controlling and monitoring the conduct of animal research, to enforce compliance with the Australian Code of Practice. On another view, ultimate responsibility for compliance with the Code lies with individual researchers; the role of an AEC should not be to control projects but to work with researchers to ensure that they appreciate their obligations and that they address areas of ethical concern identified by the AEC.¹⁶¹ Those who take this approach find that the process of debate and dissent in an AEC is valuable in itself, because it helps to ensure that all aspects of a decision are looked at and carefully reviewed.¹⁶² Questions about the balance of voting power in an AEC have less importance where this approach is taken. The Regulation Review Committee acknowledged the importance of ‘good dialogue’ in an AEC, but still considered that a balanced membership was important to the effective operation of AECs.

Delegation of approvals: The problem of AECs delegating approval of animal research projects to subcommittees or executive committees was raised by the Senate Select Committee. The Select Committee did not approve of this practice, on the grounds that subcommittees are not representative of the full AEC, and so it would be contrary to the purposes of the legislation for a subcommittee to perform the principal functions of an AEC.¹⁶³ In New South Wales, reg 10 of the Animal Research Regulations 1995 permits an AEC to delegate any of its functions to subcommittees. The Regulation Review Committee of New South Wales Parliament found that this provision was in conflict with the Australian Code of Practice and with the *Animal Research Act 1985*. The Committee recommended that reg 10 be repealed.¹⁶⁴

Lack of support for independent/animal welfare members of AECs: Animal welfare groups have reported occasional problems with the Category C or D members being neglected or intimidated by other members of AECs, not receiving relevant documents, or not being backed up by the institution. It has been argued that institutions must support the AEC by providing resources such as secretarial and veterinary support, and by backing AEC

¹⁶⁰ Regulation Review Committee, n 74, p 18. See also A Brennan, ‘Australian Animal Experimentation Ethics Committees: some proposals for effectiveness’, (1996) 9(2) *ANZCCART News* 1-3.

¹⁶¹ These differing approaches to the role of AECs are explored by M Rose, Chair of the Animal Research Review Panel, in ‘Striking the balance: the practitioner and the animal ethics committee’, (1996) 9(3) *ANZCCART News*, p 1.

¹⁶² M Rose, *ibid*, citing S Abbasi and K Hollman, ‘Dissent: An Important but Neglected Factor in Decision Making’, (1991) 29 *Management Decision* pp 7-11.

¹⁶³ Senate Select Committee, n 8, p 268.

¹⁶⁴ Regulation Review Committee, n 74, p 26.

recommendations.¹⁶⁵ Access to an impartial expert adviser has also been proposed as a means of assisting the members of AECs in their deliberations.¹⁶⁶

Support for AECS is available from a number of existing sources, such as the Animal Research Review Panel and the Animal Welfare Unit of NSW Agriculture, which produce policies, guidelines and fact sheets relating to the use of animals and research, and issue a newsletter, *Animal Ethics Update*. An annual meeting is also held for Chairs and Executive Officers of ACECs. Another resource for AECs is ANZCCART (the Australian and New Zealand Council for the Care of Animals in Research and Training), a non-government body that issues a newsletter, *ANZCCART News*, that contains information about developments in animal research and laboratory animal welfare. ANZCCART also holds conferences and

produces publications relating to the welfare of animals in research. The Animal Welfare Committee of the National Health and Medical Research Council also issues guidelines and other publications.

The lack of remuneration for voluntary members has also been pointed to as a disincentive to join an AEC. Members frequently spend many hours in preparing for and deliberating at AEC meetings without any compensation for their time and effort. This can make it difficult to find lay people who are willing to sit on AECs as Category C or D members. Mr D Shedden MP has stated that there is strong argument in favour of providing fees for the voluntary services currently provided by the independent member and the welfare member of ethics committees.¹⁶⁷

Who are the animal welfare members of AECs? Concerns have been expressed that some people who are appointed as Category C members of AECs are not affiliated with a recognised animal welfare body such as the RSPCA or ANZFAS, and that these peak animal welfare groups do not have any control over or knowledge of the committee activities of these animal welfare members.¹⁶⁸ Acting as the animal welfare member of an AEC is a difficult task that requires diligence and access to other sources of information and support. Are all the Category C members who do not belong to a recognised animal welfare group fulfilling their expected role?

The Animal Research Review Panel, which oversees AECs in NSW, has a policy on criteria for assessment of AEC membership. The Panel pays particular attention to assessing the

¹⁶⁵ G Oogjes, 'The need for change', (1996) 9(3) *ANZCCART News*, p 4.

¹⁶⁶ J Strachan, 'RSPCA - its influence on public opinion and its interaction with AEECs' in R Baker, J Burrell and M Rose (eds), *Effective Animal Experimentation Committees*, ANZCCART, 1994, p 63.

¹⁶⁷ *NSWPD*, 21/5/98, p 8989.

¹⁶⁸ G Oogjes, 'Are animal experimentation committees delivering?' in R Baker, J Burrell and M Rose (eds), *Effective Animal Experimentation Committees*, ANZCCART, 1994, p 68.

credentials of animal welfare and independent members, to ensure that animal welfare and community perspectives are adequately represented. In checking the credentials of the animal welfare members, the Panel looks for animal welfare society membership, active involvement in promoting animal welfare, and nomination by an animal welfare society.¹⁶⁹ It has been suggested by the NSW Branch of the RSPCA that perhaps a register of volunteers who have had some relevant experience or training could be established, from which the Category C representative could be selected.

Weighing the costs and benefits of research on animals: There have been concerns from animal welfare groups that some AECs are dealing with research proposals without sufficiently considering the basic question of whether the research is actually justified. The Australian Code of Practice provides that studies using animals may be performed only if they are necessary for specified purposes, and if they are justified, weighing the scientific or educational value of the study against the potential effects on the welfare of the animals. The Regulation Review Committee in its review of the Animal Research Regulations 1995 recommended that AECs should be required to document the basis of their decisions with respect to every research proposal.¹⁷⁰ This recommendation was made to ensure that in each decision every AEC is turning its attention to its obligations under the *Animal Research Act 1985* and the Australian Code of Practice.

Judgments about the costs and benefits of proposed research can be very difficult to make. Evidence to the Regulation Review Committee inquiry into the Animal Research Regulations 1995 pointed out that AECs are required to reach some decision on the essential and significant nature of research before it is actually carried out. This can be particularly difficult where the proposal is for fundamental research (that is, research not aimed at solving a particular problem but at gaining greater general knowledge about a particular subject).

The Regulation Review Committee agreed with the approach taken by one of the witnesses to its enquiry, Professor Perry. Professor Perry was of the view that in reaching a decision as to whether a particular research project justified the use of animals, an AEC should not place a low value on basic research, as major advances in science have come as much from basic research as from applied research. According to Professor Perry, the difficulty of the decision for the AEC will depend on the impact of the proposed experiment on the animal. If the animal is to experience considerable discomfort then the process of weighing cost versus benefit will be longer and more difficult than where the experiment causes the animal minimal if any discomfort.

The British Working Party of the Institute of Medical Ethics considered in detail the

¹⁶⁹ Animal Welfare Unit, *Criteria for Assessment of ACEC Membership*, Policy Statement No. 9, 1997.

¹⁷⁰ Regulation Review Committee, n 74, p 19. Currently AECs document the reasons for rejecting a proposal, but not for approving one.

question of how to weigh the costs and benefits of research proposals, and it developed two schemes designed to help make the judgment in particular cases: a scheme for assessing the likely benefit of research, and one for assessing the likely cost to animals. The Working Party acknowledged that while many empirical questions have to be answered before arriving at the overall assessment, it also inevitably involves making contestable moral, or value, judgements. The adequacy of an assessment scheme, it suggested, lies not so much in the final judgements as in the moral adequacy of the procedures used to arrive at these final judgments.¹⁷¹

7. ENFORCEMENT OF THE ANIMAL RESEARCH ACT - SOME PROPOSALS FOR REFORM

In November 1997, the Regulation Review Committee of the New South Wales Parliament published a report that made a number of recommendations about the NSW animal research system.¹⁷² Among these recommendations were several proposals to improve the administration and enforcement of the system.¹⁷³ This Part of the background paper commences by summarising some of these proposals, followed by a description of two conflicting approaches to the implementation of the animal research legislation. These different attitudes towards how to enforce the legislation form a background to some of the proposals of the Regulation Review Committee outlined below.

Accreditation: The Animal Research Review Panel has the task of investigating applications for accreditation by research institutions, and reporting to the Director-General of NSW Agriculture. The Regulation Review Committee criticised some aspects of the accreditation process: for example, that the accreditation process is paper-based, with the first inspection of an accredited institution often occurring a year or more after accreditation. The Committee recommended that the current accreditation practices of the Panel should be reviewed by the Minister for Agriculture. An examination should be made of options that would ensure a detailed assessment of institutions and licensees is carried out in conjunction with the act of accreditation or licensing, and a regulation should be made setting out the procedures to be followed by the Panel in relation to the investigation of applications for

¹⁷¹ Smith & Boyd, n 10, Chapter 7.

¹⁷² Regulation Review Committee Report, n 74.

¹⁷³ Some of the report's other recommendations have been referred to elsewhere in this background paper: see Part 6 in relation to animal ethics committees, and Part 3 in relation to animal use statistics.

accreditation or licensing.¹⁷⁴

Prosecutions: The Regulation Review Committee observed that there have been no prosecutions initiated under the NSW animal research legislation, and that the Panel does not have a policy on prosecution of breaches of the Act.¹⁷⁵ In general, administrative sanctions are imposed where the Panel finds breaches of the legislation, such as suspending a licence or accreditation, or requiring an institution to draw up an ‘action plan’ for compliance.¹⁷⁶ The Regulation Review Committee did not make any recommendations about prosecutions, but it drew attention to the importance of prosecutions in maintaining compliance with the legislation. It can also be argued that a reluctance to use criminal sanctions may undermine public confidence in animal research legislation.¹⁷⁷ During debate on the Animal Research Amendment Bill 1997, the Minister undertook to address the lack of prosecutions in his follow-up review of legislation.¹⁷⁸

Inspectorate: The Regulation Review Committee observed that animal research is not exempt from the provisions of the *Prevention of Cruelty to Animals Act 1979* (POCTA), although it is a defence in any proceedings under POCTA if the accused was carrying out research (or supplying animals for research) in accordance with the Animal Research Act. However, the Committee found that the POCTA is currently not being enforced in relation to animal research, since inspectors appointed under POCTA are not permitted to enter the land of accredited research establishments or licence holders, and inspectors under the Animal Research Act, who can inspect these premises, do not have a role in enforcing the POCTA Act. The Committee recommended that the POCTA Act be amended so as to permit inspectors to make announced and unannounced visits to research institutions.¹⁷⁹ The Minister has indicated that the RSPCA will be given increased powers to inspect research institutions which use animals in experiments to ensure that animals are receiving adequate care and that they are housed in suitable conditions.¹⁸⁰

Some concerns have been expressed that inspections of research facilities are not occurring frequently enough. For example, in relation to accreditations site visits, the Regulation

¹⁷⁴ Regulation Review Committee, n 74, p 43.

¹⁷⁵ It is worth noting that prosecutions in relation to animal research seem to be extremely rare, both in Australia and in other countries such as the United Kingdom: see the Smith & Boyd, n 10, p 279.

¹⁷⁶ For example, ARRP Annual Report 1995-96 pp 18 and 22; ‘Anger grows over tests on monkeys’, *Sun Herald*, 21/9/97, p 3.

¹⁷⁷ Smith & Boyd, n 10, pp 279-280.

¹⁷⁸ Hon R Amery MP, *NSWPD*, 21/9/97, p 8993.

¹⁷⁹ Regulation Review Committee, n 74, p 56.

¹⁸⁰ Hon R Amery MP, ‘Government moves to tighten animal research laws’, Media release, 16/9/97.

Review Committee commented that ‘it is not in the spirit of the Act for that detailed examination to take place a year or more after accreditation or up to 5 years after re-accreditation’.¹⁸¹ Kevin Rozzoli MP has argued that the provisions of the Act relating to the inspection of areas where animal experimentation is carried out should be strengthened, and that random inspections should be undertaken regularly, at least every six months.¹⁸²

Power to enter research premises: The Regulation Review Committee pointed out that although the Animal Research Review Panel carries out inspection, investigations and other monitoring activities, the Panel does not have any separate power to enter land where research is being undertaken. If a Panel member wishes to enter such land, it has to request the Director-General of NSW Agriculture to cause an inspection to be made of the research establishment, and the Panel may then authorise a member of the Panel to accompany the inspector. The Committee recommended that the Animal Research Act be amended to give members of the Panel the right to enter designated land in the course of their duties.¹⁸³

Monitoring animal housing: The Regulation Review Committee heard differing evidence about whether current animal housing in institutions complies with the Australian Code of Practice. The Committee recommended that the Animal Research Review Panel should:¹⁸⁴

- take action to ensure the availability of species-specific codes of best practice for the housing of common laboratory animals;
- ensure that NSW manufacturers and retailers of pens, cages and containers used in animal research are clearly advised as to the requirements of the Australian Code of Practice;
- advise each research institution and ethics committee of their obligations to ensure that animal accommodation complies with the Code; and
- within the next three years, complete a survey of the adequacy of housing in each of the accredited research institutions and prepare a report on the findings and action taken by it. That survey should also examine the feasibility of introducing a system for the accreditation of animal housing.

The Regulation Review Committee’s recommendations were made in the context of a continuing tension between two approaches to the administration of animal research laws: an approach that focuses on the strict enforcement of the rules by an independent, external authority; and a more flexible approach where the responsible authority works with researchers to assist them to appreciate their obligations and to correct themselves any breaches of the rules. In general, it can be said that animal welfare representatives favour the strict enforcement of animal research laws, while researchers support the more collaborative approach. The need to find a balance between these two approaches was pointed out by the

¹⁸¹ Regulation Review Committee, n 74, p 42.

¹⁸² *NSWPD*, 21/5/97, p 8983.

¹⁸³ Regulation Review Committee, n 74, p 44.

¹⁸⁴ *Ibid*, p 37.

Regulation Review Committee, in the context of prosecutions:

So far the [Animal Research Review] Panel's practice of achieving compliance has been based exclusively on educating institutions and researchers to voluntarily meet the requirements of the code and regulations. This is central to the scheme of self-regulation but it must be balanced by enforcement, in appropriate cases, through the courts.¹⁸⁵

This debate raises questions about how to measure whether the Animal Research Act, as implemented by the Panel and NSW Agriculture, is effectively protecting animals used in research. Are quantitative measures such as the number of prosecutions, or the number of licence suspensions or cancellations, a meaningful guide to whether the Animal Research Act is working properly? Would it be more useful to ask whether the Act is successfully instilling in researchers a caring and responsible attitude towards the animals in their care? If so, how is progress in developing such an attitude to be assessed? These questions bring us back to the point made in Part 3.3 of this background paper, that there is inadequate publicly available information about what is happening to animals used in experiments, and what the justifications are for these procedures. Greater transparency of animal research activities would assist in determining whether the Animal Research Act is being effectively implemented.

8. ALTERNATIVES TO ANIMAL USE

This Part of the background paper begins with a discussion of three principles central to efforts to minimise animal suffering in experiments, together with some examples of recent developments in alternatives to animal use. This is followed by an outline of approaches to incorporating the three principles into animal research systems, and finally, some procedures that have caused particular community concern are considered: cosmetics testing; the Draize rabbit eye irritation test; and the LD50 acute toxicity test.

As noted earlier (see footnote 71), the development of alternatives may not necessarily result in a decline in the overall numbers of animals used in experiments. Alternatives take many forms, and while some methods do away with the need to use animals at all, others are used alongside animal experiments (for example, non-animal alternatives may be used as preliminary screening devices, to determine which drugs need to undergo further testing on animals). Alternatives may still involve some use of animals (such as using cells, tissues or organs from humanely killed animals). It should also be noted that despite the continuing advances in alternatives to animal use, there may well be more call for animals as the frontiers of research expand in areas that require the use of animals, such as genetic engineering.¹⁸⁶

¹⁸⁵ Ibid, p 57.

¹⁸⁶ Research Defence Society, 'Animal research in context - are there alternatives?', <http://www.uel.ac.uk/research/rds/altern.htm>.

8.1 Replacement, reduction, refinement

The three principles guiding the humane conduct of research are: the *replacement* of animals with other experimental techniques; the *reduction* of the number of animals used in experiments; and the *refinement* of procedures to minimise the impact of experiments on animals. These ‘three R’ principles were formulated in 1959,¹⁸⁷ and they have since been adopted by both the scientific community and animal welfare groups.

Replacement: It has often been recognised that there is a scientific advantage as well as a humanitarian one in the use of replacement methods to animals.¹⁸⁸ Using animals in research can bring many complex variables into the experiment (such as the genetic makeup of the animals, and their feeding and housing conditions), which may affect or complicate experimental results. Many alternatives offer a simpler and more straightforward testing methods. Additionally, non-animal alternatives may also be more economical than other methods.¹⁸⁹ animal experiments tend to be time-consuming as well as expensive in terms of financial and human resources, and non-animal experiments can sometimes provide considerable savings.¹⁹⁰

There is a great deal of debate in the scientific community over the extent to which existing alternatives can replace animal experiments. While some argue that scientific and technological advances are rapidly making animal experiments unnecessary in many areas,¹⁹¹ others point out the limitations and disadvantages of existing alternatives.¹⁹² It has been observed that many anti-vivisectionists may tend to overstate the current availability of replacement alternatives, while scientists may tend to overemphasise their limitations.¹⁹³ It appears that alternatives are more likely to be developed in the area of toxicity testing than in fundamental biomedical research.¹⁹⁴

There have been many substantial advances and promising developments in the use of alternative replacements, but progress in replacing animals has been slow. Developing an alternative and establishing its acceptability to regulatory authorities and the scientific community is often difficult and time-consuming. This process has been described as

¹⁸⁷ WMS Russell and RL Burch, *The principles of humane experimental technique*, Methuen, London, 1959.

¹⁸⁸ Smith and Boyd, n 10, p 125.

¹⁸⁹ Ibid, p 126.

¹⁹⁰ For example, bacterial tests for potential to cause genetic mutations are generally a quicker and less expensive method than whole animals tests.

¹⁹¹ Barnard and Kaufman, n 3, p 65.

¹⁹² Botting and Morrison, n 13, p 69.

¹⁹³ Smith and Boyd, n 10, p 134.

¹⁹⁴ Ibid, p 135.

follows:¹⁹⁵

Validation is an examination of the scientific quality of the proposed replacement method, aimed at assessing its reproducibility and relevance, and whether, scientifically, it is as good as (or better than) the animal procedure it is intended to replace. Such an assessment involves asking whether or not the method is able to achieve its stated scientific aims, whether it is reliable, and whether reproducible in different laboratories. *Evaluation* of the validated replacement alternative method involves examining wider questions, such as its applicability to real problems, the feasibility of implementing it (including cost and personnel considerations) and its value when compared with other potential alternatives...Only when a proposed replacement method has been shown to be valid, and has been favourably evaluated, should it be adopted.

There are several organisations which are dedicated to developing and promoting the use of alternatives to animals, such as FRAME (Fund for Replacement of Animals in Experiments, a UK body); ECVAM (European Centre for Validation of Alternative Methods, a European Commission body based in Italy), CAAT (Centre for Alternatives to Animal Testing at John Hopkins University in the USA) and the NCA (Netherlands Centre for Alternatives to Animal Use). There are also a number of books, journals and newsletters devoted to informing researchers about methods of replacing animals in procedures.¹⁹⁶ Outlined below are some areas where successful alternatives to animals have been found.

- *Access to information*: Improved storage, exchange and use of information about animal experiments already carried out can prevent the unnecessary repetition of animal procedures,¹⁹⁷ and can also assist researchers to design their experiments so as to minimise or avoid the use of animals. Several databases have been set up to allow researchers to search for information on their proposed procedures and on potential alternatives.¹⁹⁸

However, much important information has been developed with a great deal of time and expense by private companies for commercial purposes. It may not be reasonable to expect these researchers and companies to provide this information to potential competitors. The British Working Party of the Institute of Medical Ethics observed that the use of animals in experiments is to be justified for biomedical reasons and not because of commercial considerations, but that nevertheless the interests of individuals or companies doing innovative research must be protected. The Working Party suggested that it might be possible to reach a compromise, whereby data obtained from animal procedures would be made

¹⁹⁵ Ibid, p 127.

¹⁹⁶ A bibliography on alternatives to animals is found in the Australian Code of Practice.

¹⁹⁷ Smith and Boyd, n 10, p 123.

¹⁹⁸ ANZCCART News, vol 9 (4), December 1996 p 5 gives details of a number of databases and directories, as does *Animal Ethics Update*, vol 5(1), May 1998.

available after a certain interval.¹⁹⁹

- *Physical or chemical techniques:* It is possible to use techniques and predictions based on the physical and chemical properties of molecules to assess the likely biological effects of substances in humans. For example, enzymes are being used to test the efficacy of vaccines.²⁰⁰
- *Mathematical and computer models:* Mathematical and computer models can be used to predict potential effects of chemicals in biological systems. Models are being developed of biochemical, physiological, pharmacological, toxicological and behavioural systems and processes.²⁰¹ These models are frequently used for pre-screening potential drugs. In some cases the models may be based on data obtained from real animal experiments, so that some initial use of animals is required. Also, the use of animals may result in hypotheses that need to be tested in animals as a basis for improving the overall quality and predictive value of the models and reducing animal use in future.
- *In vitro cell, tissue and organ culture:* The term ‘*in vitro*’ (‘in glass’) refers to experiments performed in laboratory containers, such as test tubes or petri dishes, with living tissues, organs or cells obtained from animals or humans. There are many different *in vitro* methods. While some methods can use cells from long term cultures, other methods require fresh tissue. This may involve killing animals, or surgically removing tissue such as skin samples from live animals.

In vitro cultures, both human and animal, have become one of the most important whole-animal alternatives, and they are being widely used for biomedical research and for toxicity testing. For some purposes, *in vitro* methods may have advantages over whole-animal methods.²⁰² Despite their many uses, however, they have considerable limitations:

Cell cultures and micro-organisms allow researchers to study a single effect or action of a substance in an isolated environment, thereby eliminating interference from other biological phenomena, such as hormones or immune responses. These models are most effective during the early and intermediate stages of the laboratory research process. They are used by researchers to

¹⁹⁹ Smith and Boyd, n 10, p 128.

²⁰⁰ M Dawson, ‘Alternatives to the Use of Animals’ in AA Tuffery (ed), *Laboratory Animals: an introduction for experimenters*, 2nd edition, John Wiley & Sons, Chichester, 1995, p 16.

²⁰¹ See Smith and Boyd, n 10, p 129; A Coghlan, ‘Model alternative to animal testing’, *New Scientist*, v 150, 27 April 1996 p 22; B Blaauboer, ‘*In vitro* and other non-animal experiments in the biomedical sciences’, *ANZCCART News*, vol 9 no 4, December 1996.

²⁰² For example, hormones or vaccines manufactured in cell cultures can be purer than those made in live animals: M Mukerjee, n 139, p 74.

obtain a preliminary indication of how and why a specific chemical may affect a living system. However, the fact that these tests are conducted in isolated systems, independent of other complex biological systems, creates limitations in their interpretation. In the end, the validity of such tests must be established by comparing their performance with the results of testing conducted in appropriate mammalian model systems.²⁰³

In vitro tests using human tissue are becoming more widespread.²⁰⁴ While these tests have obvious advantages over the use of animals, they can raise their own ethical and practical problems. On the practical side, human tissue can be difficult to obtain and store, and may also contain dangerous viruses (such as AIDS or hepatitis). Some tissue can be obtained from volunteers, such as skin, hair and blood. Others (such as liver, muscle or kidney tissue) can be taken in small amounts from biopsies or with diseased tissues during operations. However, significant amounts of important tissues such as liver can only be obtained from patients having organs removed or from deceased humans such as organ donors.²⁰⁵ It has been suggested that human placenta may be a source of tissue for various types of research.²⁰⁶

On the ethical side, there is the question of obtaining consent from patients or the relatives of deceased donors to use their tissue for research, perhaps for commercially motivated research. Cells and tissues from human fetuses may also be very useful in research, but this leads to further ethical problems, such as the moral questions concerning therapeutic and non-therapeutic abortions. Nevertheless, it has been suggested that there may be a moral obligation to use human tissue, properly and safely obtained, whenever possible.²⁰⁷

- *Use of 'lower' organisms:* 'Lower order' animals may be used to replace 'higher' ones - for example, replacing primates with lower-order mammals, or replacing mammals with invertebrates. For example, it may be possible to use brine shrimps in testing insecticides, and horseshoe crabs can be used to replace the rabbit pyrogen

²⁰³ National Institute of Environmental Health Sciences and the Use of Alternative Methods in Toxicological Research and Testing, <http://niehs.nih.gov/oc/factsheets/analt.htm>.

²⁰⁴ For example, it has been reported that a British pharmaceutical company, Pharmagene, is planning to use only human tissue for testing purposes, and will not conduct any research on animals: A Coghlan, 'Pioneers cut out animal experiments', *New Scientist*, v 151, 31 August 1996 p 4. See further Research Defence Society, - Drug development without animals?, <http://www.uel.ac.uk/research/rds/news/dec96/pharm.htm>.

²⁰⁵ Smith and Boyd, n 10, p 133.

²⁰⁶ Fund for the Replacement of Animals in Medical Experiments (FRAME) - <Http://www.frame-uk.demon.co.uk/altern.htm>.

²⁰⁷ Smith and Boyd, n 10, p 133.

test.²⁰⁸ Advances in genetic engineering may also open up new possibilities of replacing animals. For example, it has been suggested that genetically engineered roundworms which carry human disease genes may prove to be useful in identifying new drugs.²⁰⁹

- *Use of the early developmental stages of vertebrates:* Embryos and fetuses of mammals or other vertebrates may be used for some purposes to replace living animals. Many studies on development and growth can be carried out on animal embryos *in vitro* rather than in the pregnant animal. Rat embryos or fetuses can be used to screen chemicals for potential to cause birth defects, and the use of frog embryos for this purpose is being validated.²¹⁰
- *Human studies:* Where humans are the intended user of a product, information from human studies can be very valuable. Human studies include the use of human volunteers (for example, cosmetics with known ingredients increasingly are being tested directly in human volunteers); post-marketing surveillance of consumer reactions to products; and epidemiological studies (studying the incidence and distribution of a disease in a community - for example, a group of people with a known exposure to a particular chemical may be compared against a control group on such factors as symptoms and hospital admissions).

It has been observed that human volunteer studies are fraught with ethical questions, including the questions of how volunteers should be recruited and selected, whether they should be offered financial inducement, what level of risk of harm to the subject might be acceptable in such work, and how best to ensure that the subject's consent is based on a full understanding of the risks involved.²¹¹

Reduction: Methods to reduce the number of animals used in experiments include:

- Appropriate design of experiments and analysis of the resulting data. These methods can allow fewer animals to be used to generate meaningful data. For example, a small pilot study may be used to indicate whether or not it is appropriate to proceed to a major experiment, and sophisticated statistical methods can minimise the number of animals required to produce valuable results.²¹²

²⁰⁸ M Dawson, 'Alternatives to the Use of Animals', in Tuffery, n 200, pp 17 and 21.

²⁰⁹ FRAME, n 206.

²¹⁰ National Institute of Environmental Health Sciences and the Use of Alternative Methods in Toxicological Research and Testing, <http://niehs.nih.gov/oc/factsheets/analt.htm>.

²¹¹ Smith and Boyd, n 10, p 134.

²¹² A Chamove, 'Reducing animal use: sequential sampling techniques', *ANZCCART News*, vol 9 no 3 September 1996, pp 6-8. These statistical techniques have been made more accessible by the availability of specially designed computer programs for researchers

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- Harmonisation of international regulatory requirements, to prevent pharmaceutical and biomedical research companies being required to conduct variations on trials for each country in which they seek to market a product. Regulatory testing requirements can differ widely between jurisdictions as to matters such as which products require testing, which tests are to be undertaken, the period over which the tests are to be conducted, the number and kinds of animals which are to be used, the dose levels to be administered, and other variables. Standard international guidelines can substantially reduce the number of animals used in testing.²¹³ Drug companies are reported to be campaigning to get all the major countries to agree on a single, common approvals procedure for new drugs.²¹⁴ Australian guidelines for the registration of drugs follow European standards.²¹⁵
 - Using an animal more than once. For example, some laboratories alert all their researchers when animals are going to be killed, so that if one researcher intends to carry out a study on livers, other researchers may be able to make use of other parts of the same animals. However, it may not be ethically acceptable to use a living animal in more than one study, if this involves the animal undergoing repeated painful procedures.
 - Using animals that have been bred to be genetically uniform. The number of animals required in an experiment is thus reduced because the genetic uniformity reduces the variability of reactions and produces more reliable and reproducible results.²¹⁶

Refinement: The principle of ‘refinement’ is that techniques used in the research and maintenance of animals should be refined so to reduce the impact on animals as far as possible. This applies not only to the design and implementation of experimental procedures, but also to the conditions in which animals are housed and maintained, and the manner in which animals are disposed of when no longer required. Refinement techniques include:²¹⁷

- Use of appropriate anaesthetic during all surgical procedures, and analgesia to alleviate pain where possible.

²¹³ For example, in 1997 at the International Conference on Harmonisation, several agreements were reached among medicine licensing agencies in Japan, the USA and Europe, such as an agreement to require only one long-term animal carcinogenicity study for each new compound. These agreements were expected to reduce the number of animals used by 30%: P Mitchell, ‘Drug evaluation harmonisation will lead to fewer animal tests’, *The Lancet*, v 350, 26 July 1997 p 274.

²¹⁴ *Ibid*; see also the Regulation Review Committee Report, n 74, pp 30-32.

²¹⁵ Therapeutic Goods Administration, *Australian guidelines for the registration of drugs*, AGPS, 1995.

²¹⁶ J Gregory, ‘Principles of Animal Husbandry’ in Tuffery, n 200, p 101.

²¹⁷ Monamy, n 21, pp 37-38.

- Use of least invasive techniques possible. For example, advances in techniques such as nuclear magnetic resonance permit non-invasive observations of processes occurring in internal organs, and some techniques even enable observations of intracellular events to be carried out on the whole, living animal.²¹⁸
- Appropriate design of procedures to minimise the effect on animals. For example, it may be possible to use non-animal screening methods to identify toxic chemicals at an early stage in the testing process. If such screens suggests that the chemical is likely to be very toxic, whole animal tests could therefore be used only to confirm the absence of significant toxicity, or to grade low or moderate levels of toxicity.²¹⁹
- Selecting an end-point to the experiment that minimises animal suffering. For example, in a toxicity test it may be possible to kill the animals humanely when evidence of toxic effect is clear, rather than waiting for the animals to die.
- Appropriate method of disposal of the animals. This may be a question of selecting the most humane method of euthanasia, or of arranging some other care of the animal. For example, there are programs to have horses or great apes cared for after they are no longer needed in experiments.
- Ensuring that housing and maintenance of animals meets their physical and behavioural needs, in terms of factors such as space, complexity of environment, and social grouping.²²⁰ Appropriate animal husbandry practices are recognised as having a scientific as well as humanitarian advantage, since animals that are stressed, unhealthy or suffering are unlikely to yield valid experimental results.²²¹ Knowledge of the needs and behaviour of each species is still developing, and there are books and journals devoted to questions of laboratory animal welfare.²²²

8.2 Legal requirements to consider alternatives

As noted above, the principles of reduction, replacement and refinement have been widely

²¹⁸ FRAME, n 206.

²¹⁹ Smith and Boyd, n 10, p 202.

²²⁰ See for example M S Dawkins, *Animal Suffering: the Science of Animal Welfare*, Chapman & Hall, London, 1980.

²²¹ For example, a 1986 study found that rats acclimatised to their laboratory environment tolerated doses of uranium 60 times greater than those placed in an unfamiliar environment. E G Damon, A F Eidson, C H Hobbs, F Hahn, 'Effect of acclimation on nephrotoxic response of rats to uranium' (1986) 36 *Laboratory Animal Science* 24, cited in T Poole, 'The Welfare of Laboratory Animals' in Tuffery, n 200, p 34.

²²² The Australian Code of Practice has a bibliography of literature on laboratory animal care and husbandry. *ANZCCART News* also regularly publishes information about studies on methods of housing and entertaining laboratory animals.

recognised as an essential guide to maximising both the humaneness and the quality of scientific research using animals. However, concerns have been expressed about the effectiveness of the New South Wales animal research legislation in implementing the three Rs.²²³ This section looks at approaches to incorporating the three Rs into animal research regulatory systems.

The principles of replacement, reduction and refinement are currently included in the animal research systems in most Australian jurisdictions by way of incorporation of the Australian Code of Practice into the relevant legislation. For example, in New South Wales the Code is prescribed as a code of practice governing the functions of animal ethics committees.²²⁴ The principles of replacement, reduction and refinement are central to the Australian Code of Practice. As a result, animal ethics committees are required to apply the three Rs in considering research project applications, and in supervising the conduct of research. The Animal Research Review Panel also encourages the implementation of the three Rs.²²⁵

To ensure that animal ethics committees are addressing the three Rs, the Regulation Review Committee of New South Wales Parliament has recommended that committees be required to document the basis of each decision in regard to a research proposal, addressing questions such as whether in the design of the experiment techniques have been used to replace animal experiments, and whether the experiment has been designed to use the minimum number of animals and to avoid pain or distress to animals.²²⁶

Another approach is to place the onus on the researcher, rather than on the ethics committee, to investigate and apply the three Rs to his or her proposed research. In the United States, for example, the Animal Welfare Act requires that researchers declare that no suitable alternative exists in experiments which might involve causing pain to animals. In New South Wales, the Animal Research Review Panel has developed a model research application form that focuses attention on the need to use animals, and places the responsibility on the researcher to explain why alternatives cannot be used.

The three Rs can also be directly imposed on researchers and ethics committees by making the three principles part of animal research legislation, rather than part of a code of practice.

²²³ Ms G Oogjes, Director, Australian and New Zealand Federation of Animal Societies Inc, and Mr K Edwards, member of the Animal Research Review Panel, quoted by the Regulation Review Committee, n 74, pp 29-30.

²²⁴ Animal Research Regulation 1995 reg 4.

²²⁵ The activities of the Panel in promoting alternatives to animal use are set out in its annual report to the Minister.

²²⁶ Regulation Review Committee, n 74, p 21 and Appendix 6.

This approach has been adopted in some European countries;²²⁷ in addition, the three Rs are incorporated into the 1986 European Council *Directive on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes* (Article 7). The Hon R Jones MLC has unsuccessfully attempted to amend the NSW Animal Research Act to expressly include these principles.²²⁸

A very restrictive approach to animal experimentation was proposed by Kevin Rozzoli MP in debate on the Animal Research Amendment Bill 1997. After stating that the current Animal Research Act ‘acts as a support mechanism for researchers rather than seeking to achieve its principal objective, that is, the welfare of animals used in experimentation’, he argued that ‘a bill is needed that adopts as its main aim and objective the fundamental premise that there should be no animal experimentation, but, if there is a need to use animals in experiments, it should be done by exclusion from that basic principle ... The basic premise should be that no experimentation is carried out on animals, although under some circumstances there may well be a need to conduct such an experiment. If that is so, the circumstances should be exceptional and the researcher should be required, under stringent conditions, to justify the need for the experimentation.’²²⁹

Another radical approach is that taken by the European Commission, whose Fifth Environmental Action Programme set a target to achieve a 50% reduction in animal experimentation by the year 2000. This target has been criticised as uncertain and unrealistic.²³⁰ It seems likely that the target will not be met.

8.3 Some controversial procedures

This section discusses some experimental procedures which have given rise to particular community concern: cosmetics testing; the Draize eye irritancy test; and LD50 lethality testing. It looks at what kinds of legislative controls apply to them, and developments in finding alternatives.

²²⁷ For example, in the Netherlands the *Experiments on Animals Act 1997* provides that no animal experiment may be conducted for a purpose that, by expert consensus, can be achieved by means other than an animal experiment, or by means of experiment using fewer animals or entailing less distress than the experiment in question; or the importance of which does not justify the distress caused to the animal. In the UK, the *Animals (Scientific Procedures) Act 1986* provides that the Home Secretary must not grant a licence unless the applicant has given adequate consideration to the feasibility of achieving the purpose of the research by means not involving animals.

²²⁸ *NSWPD*, 16/6/97 pp 10255ff.

²²⁹ *NSWPD*, 21/5/97, p 8983.

²³⁰ European Biomedical Research Association - Target 2000, the conference on the 50% reduction target, <http://www.uel.ac.uk/research/ebra/news/may97/target.htm>. For more information on this target see D Wilkins, *Animal Welfare in Europe: European Legislation and Concerns*, Kluwer Law International Ltd, 1997, p 93.

Cosmetics testing: A number of tests are generally involved in the approval of cosmetics, including tests for acute toxicity, sub-chronic toxicity, skin irritation, eye irritation, skin sensitisation, mutagenicity, photosensitivity, teratogenesis, reproductive toxicity, carcinogenicity and genetic toxicity. Although it seems that no cosmetic testing is carried out in Australia,²³¹ cosmetics sold in Australia may have been tested on animals overseas.

A number of alternative techniques to test cosmetics are under development, but it appears that animal testing will still be necessary for at least the foreseeable future. The European Centre for the Validation of Alternative Methods is conducting validation studies of a number of alternatives. Although no alternative method has yet been finally accepted, the ECVAM has reported that in relation to the testing of cosmetic ingredients, some promising progress is being made. For finished cosmetics products, it seems that it may be possible in several areas to evaluate them on the basis of existing knowledge, without using animals.²³²

There is little legislation specifically directed at cosmetics testing in Australia, probably because few if any such tests are undertaken. In Victoria and Queensland the prior written approval of the Minister is required before a scientific experiment using a sunscreen product or cosmetic toiletry (or an ingredient thereof) can be carried out.²³³ This approval is in addition to the requirement for approval by an animal ethics committee.

In Europe there tends to be more legislative control of cosmetics testing. For example, in the Netherlands the use of animal experiments for the purpose of developing new or testing existing cosmetics is prohibited, and in the United Kingdom, the Blair Labour Government plans to end cosmetic testing on animals.²³⁴ The European Union has attempted to ban cosmetics testing by enacting an amendment (Directive 93/35/EEC) to the 1976 EC Cosmetics directive (Directive 76/768/EEC). The amendment would have banned the sale of cosmetic products tested on animals after 1 January 1998 unless non-animal replacement methods of safety testing for cosmetics had not yet been developed and validated. The ban has been postponed 30 June 2000,²³⁵ due to the absence of fully satisfactory alternatives. However, the European Commission is reported to be preparing an amending directive seeking to make it possible to ban the testing of finished cosmetic products.²³⁶

²³¹ Mr T Rumble MP, *NSWPD*, 21/5/97 p 8982.

²³² *1996 Report from the Commission on the development, validation and legal acceptance of alternative methods to animal experiments in the field of cosmetic products*, COM(97) 182, 12 May 1997 - see C Barclay and P Hughes, *Animal Welfare*, House of Commons Library Research Paper 98/12, pp 28-29.

²³³ Animals Protection (Use of Animals for Scientific Experiments) Regulations 1991 (Qld) reg 5; Prevention of Cruelty to Animals Regulations 1997 (Vic) reg 12.

²³⁴ Currently there are four existing cosmetics testing licences in the UK. The Government is reaching an agreement with the four licence holders for them to give up their licences voluntarily, and the Government will not licence further cosmetic testing: Barclay and Hughes, n 232, p 27.

²³⁵ Directive 97/18/EEC.

²³⁶ See Barclay and Hughes, n 232, p 28.

Eye irritancy (Draize) test: This test for the potential of substances to irritate eyes was described earlier in this background paper (see p 20). The test was devised in the 1940s and has been modified over the years; for example, researchers can begin by applying a low dose of the test substance, stopping when a dose causing irritation is reached.²³⁷ The test has been criticised on several grounds, such as its distressing effect on rabbits, the reliability and reproducibility of its results, and the applicability of its results to human eye irritation.²³⁸ It is difficult to know to what extent the Draize test is used in Australia, but in 1989 the Commonwealth Senate Select Committee on Animal Welfare stated that as far as it could determine, the test has been little used in Australia.²³⁹

Alternatives to the Draize test are being developed, such as using the eyes of dead chickens or cows obtained from slaughterhouses, the chorioallantoic membrane of fertilised chicken eggs, blood vessels from chick embryos, and plant-derived substances. However, it seems that there are currently no fully reliable non-animal alternatives to the Draize test. A 1994 joint British Home Office and European Commission project on replacing the Draize method has tested several potential alternatives, but could not reliably reproduce the results of the rabbit eye test.²⁴⁰ It has however been argued that the difficulty of replacing the rabbit eye test results from its inherent variability and subjectivity.²⁴¹

In 1989, the Commonwealth Senate Select Committee on Animal Welfare recommended that the Draize test should be banned in Australia.²⁴² This has not occurred, but most Australian States have legislation imposing particular controls on carrying out the Draize eye irritancy test.²⁴³ In Victoria and Queensland, this takes the form of a requirement that the Draize test is not to be carried out without the prior approval of the Minister, in addition to the approval required from an animal ethics committee. In New South Wales, an animal ethics committee must not approve the carrying out of a Draize test unless the test is to be carried out for the sole purpose of establishing that prophylactic or therapeutic materials or substances ordinarily intended for use by application to the eye are not irritants to the eye. In South Australia, an animal ethics committee must not approve the use of a Draize test unless it is satisfied that the assessment relates to research that has the potential to benefit

²³⁷ Dawson, 'Alternatives to the Use of Animals' in Tuffery, n 200, p 21.

²³⁸ Senate Select Committee, n 8, pp 114-115.

²³⁹ Ibid p 115.

²⁴⁰ (1995) 9 *Toxicology in Vitro* 871-929; see H Blankesteyn, 'Chickens could save rabbits from painful tests', *New Scientist*, v 152, 2 November 1996 p 10.

²⁴¹ H Blankesteyn, 'Chickens could save rabbits from painful tests', *New Scientist*, v 152, 2 November 1996 p 10.

²⁴² Senate Select Committee, n 8, p 124.

²⁴³ *Animal Research Act 1985* (NSW) s 26(3) and (4); *Prevention of Cruelty to Animals Regulations 1997* (Vic) reg 12; *Animals Protection (Use of Animals for Scientific Experiments) Regulations 1991* (Qld) reg 5; *Prevention of Cruelty to Animals Regulation 1986* (SA) reg 31.

human or animal health, and that the objectives of the assessment cannot practically be achieved by means that will cause less pain to the animals.

LD50 test: This test for the acute toxicity of a substance was described earlier in this background paper (see p 20). Substantial modifications to the test have been made to reduce its impact on animals, but it remains controversial. The test has been criticised for its distressing effect on the animals involved, and doubts have been raised about the usefulness of LD50 test results.²⁴⁴

Modifications to the classical LD50 test have included imposing an upper limit on the dose given to an animals, refining the degree of precision required from the test, and using sophisticated statistical techniques to reduce the number of animals required to produce valuable results.²⁴⁵ An alternative approach to the assessment of acute toxicity is the Fixed Dose Procedure, which does not set the death of the animals as its objective. The test aims to establish the dose at which clear signs of toxicity are detectable, rather than determining the lethal dose.²⁴⁶ The Fixed Dose Procedure has been accepted by the OECD as a substitute for the LD50.²⁴⁷

The Senate Select Committee recommended that the classical LD50 test should be banned, but that acute toxicity tests be allowed with ministerial approval. Although LD50 tests have not been banned, most Australian States and Territories have legislation to control the test.²⁴⁸ In New South Wales, an animal ethics committee cannot approve the carrying out of an LD50 test without the concurrence of the Minister, given on a recommendation for concurrence by the Animal Research Review Panel. In 1995-96, ten approvals for LD50 testing were given in New South Wales. No approvals were granted in 1994-95, three approvals were granted in 1993-94, and three in 1992-93.²⁴⁹ The reasons for approval or rejection of each application are set out in the annual reports of the Animal Research Review Panel, along with any conditions on the approval. For example, the 1995-96 LD50 tests were permitted on condition that the institution involved provide the panel with a program for the development of alternatives. The plan must specify the means by which the institution

²⁴⁴ See Senate Select Committee, n 8, p 117.

²⁴⁵ Smith and Boyd, n 10, pp 190-191.

²⁴⁶ Smith and Boyd, n 10, p 191-2.

²⁴⁷ European Biomedical Research Association, 'Target 2000, the conference on the 50% reduction target', <http://www.uel.ac.uk/research/ebra/news/may97/target.htm>.

²⁴⁸ *Animal Research Act 1985* (NSW) s 26(3) and (4); *Prevention of Cruelty to Animals Regulations 1997* (Vic) reg 12; *Prevention of Cruelty to Animals Regulation 1986* (SA) reg 31.

²⁴⁹ Animal Research Review Panel *Annual Reports 1995-96, 1994-95, and 1993-94*.

intended to keep abreast of international developments in alternatives, and the tests must be scheduled to maximise the possibility of intervention by euthanasia where necessary.²⁵⁰

In Queensland, the prior written approval of the Minister is required to carry out an LD50 test. In South Australia an LD50 test requires approval by an animal ethics committee, which can only be given if the test relates to research that has the potential to benefit human or animal health, and the objectives cannot practically be achieved by means that will cause less pain. In Victoria, lethality testing for the toxicity of a chemical or a cosmetic, toilet, household or industrial preparation is prohibited unless:

- the test is related to potentially lifesaving treatment for animals or human beings, or research in connection with cancer in animals or human beings; and
- the objective of the scientific procedure cannot be achieved by any other scientific procedure; and
- the procedure is recommended for approval by a Peer Review Committee; and
- the procedure is approved by the Minister; and
- the procedure is carried out in accordance with any conditions determined by the Minister.

9. CONCLUSION

Any experiment using animals can be debated on many levels: fundamental moral questions about the use of animals for the benefit of humans; scientific questions about the validity of particular experiments; detailed practical questions about the appropriate design of experiments and of animal housing. At the level of fundamental morality, a spectrum of attitudes towards the use of animals can be found. At one end are those who believe that animal experimentation for any reason is simply wrong, and at the other end are those who do not find the use of animals in research problematic in any way. Many people find themselves somewhere towards the middle of the spectrum, seeking to protect the welfare of animals as far as possible without compromising the welfare or, possibly, the convenience of humans.

The legislation regulating animal research in New South Wales and other States adopts this 'troubled middle ground' position. Thus, animal experimentation is permitted provided that it is **essential** for a purpose such as obtaining significant information relevant to the understanding of animals or humans, and that it is **justified**, weighing the scientific or educational value of the study against the potential effects on the animals. The impact of an experiment on animals must be minimised by following the principles of replacement, reduction and refinement.

This approach of weighing the costs to animals against the likely benefits provides a framework for deciding which experiments should be allowed, but the necessity of making hard decisions cannot be avoided. A series of questions then arises: who should make these

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Animal Research Review Panel, *Annual Report 1995-96*, p 15.

decisions about which experiments will be allowed? What role should community and public representatives have in making these decisions? How can the public be assured that the decision-makers and the researchers are complying with the regulatory legislation?

At this point, debate centres on the selection of an appropriate regulatory regime. There are a number of ways in which animal experimentation can be administered. Again, these can be placed on a spectrum. At one end is a system in which there is no government control or intervention, with all decisions on experimentation being taken by researchers and their institutions; at the other end is a totally regulated system where government takes responsibility for approving experiments and for monitoring the conduct of research. In between these two extremes is 'enforced self-regulation', the type of system most commonly adopted. The selection of an animal research regulatory regime, and the approach to enforcing that regime, is generally informed by arguments about the relative effectiveness of self-regulation and government intervention in controlling the conduct of animal research.

Questions about the effectiveness of an animal research regulatory system cannot be separated from the issue of whether the community has access to meaningful, accurate information about animal research. Public scrutiny of and debate about animal research is an essential element of public confidence in animal research legislation. As the Senate Select Committee observed:²⁵¹

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.