

CHAPTER 14

CURRENT REGULATORY SYSTEM

Introduction

14.1 Significant changes in the regulation of animal experimentation in Australia have occurred within the last ten years. These changes have been made both by the scientific and educational community and by government. The former has developed a code of practice, set up ethics committees and has generally taken steps to promote a more ethical approach to animal experimentation and animal welfare. The latter has begun to update legislation and improve the regulation of animal experimentation.

14.2 In this chapter, the evolution and the current state of the regulatory system are described.

Evolution of the Code of Practice

14.3 Until recently, government had taken a mainly non-interventionist role in the control of animal experimentation. It was left to the scientific and educational community to regulate itself. In 1965 the NHMRC began work on a code of practice which was issued in 1969. Its stated aim was to define a code of conduct which would encourage humane treatment of experimental animals. The code was designed to promote awareness of animal ethics and welfare but not to provide mechanisms for accountability.

14.4 In 1979, the NHMRC and CSIRO jointly revised the Code of Practice. An important inclusion in this edition was the requirement for institutions to establish ethics committees.

14.5 In the 1982 revision of the Code of Practice, provisions were included to make ethics committees more accountable to the wider community. The ethics committee had to include a person not employed by the institution to represent community interests and the committee had to maintain a register of all approved research.

14.6 The next edition of the Code of Practice was issued in April 1985. This edition was endorsed by the Australian Agricultural Council as well as by the NHMRC and CSIRO.

14.7 The fifth edition of the Code of Practice is in draft form. It has been endorsed by the NHMRC but is awaiting the endorsement of its other sponsor bodies and State Governments. It both tightens up and clarifies some of the provisions of the previous edition. It also sets out more clearly the responsibilities of institutions, ethics committees and experimenters in relation to animal experimentation.

14.8 The NHMRC, as now do many other funding bodies, requires applicants for funds and their institutions to comply with the provisions of the Code of Practice. Until recently, as mentioned later in the report, the NHMRC did nothing to ensure compliance with the Code of Practice by experimenters and institutions.

Legislation

14.9 Except for New South Wales, legislative provisions dealing with animal experimentation are contained in State and Territory prevention of cruelty to animals legislation. Until 1985 and 1986, such provisions were cursory at best, with Tasmania merely exempting animal experimentation from the cruelty

provisions of the legislation. Regulations provided for in the Queensland legislation have never been made rendering that legislation ineffective. Since 1985 three States have revised legislation providing a legislative framework within which animal experimentation can be controlled and monitored by the governments in those States.

14.10 The Committee now briefly describes the main provisions of State and Territory legislation.

New South Wales

14.11 Unlike the other States, the New South Wales Government decided to enact separate legislation to control animal experimentation rather than include it in prevention of cruelty to animals legislation. The New South Wales Government took this decision because it believed that the community's attitude to animals had changed and that it was no longer appropriate to consider animals used in experiments just from the point of view of cruelty. The philosophy of the legislation is summarised in the following terms:

... the twin tenets of this legislation are the concepts first of enforced self regulation and second of public participation in the decision-making process.¹

14.12 The Act requires the accreditation of institutions in which animal experimentation is conducted. Individuals doing experiments on animals must either be authorised by an accredited institution or, if the research is not done within an accredited institution, licensed by the Secretary of the Department of Local Government. It is a precondition for accreditation that an institution have established a properly constituted animal care and ethics committee.

14.13 The animal care and ethics committee required under the NSW legislation has the following functions:

- (a) the making of recommendations concerning the granting of animal research authorities by the establishment;
- (b) the supervision of the carrying out of animal research by holders of animal research authorities granted by the establishment; and
- (c) such other functions may be conferred or imposed on it by the Code of Practice.²

14.14 Animal care and ethics committees may also be appointed by the Secretary of the Department of Local Government to supervise the research of the holders of individual research licences.

14.15 The constitution and procedures of these committees will be prescribed by regulation. The Act, however, does require that at least one member of such a committee be a person who is neither associated with any accredited research establishment nor involved in the conduct of, or the supply of animals for, animal research.

14.16 The Act also requires that an animal supplier's licence be obtained by a person wishing to supply animals for use in animal experiments.

14.17 The Act provides for a code of practice to be prescribed in regulations. This may be the NHMRC/CSIRO/AAC Code of Practice, an amended form of it or an entirely different code of practice.

14.18 The Act also establishes the Animal Research Review Panel which has the following responsibilities:

- investigation of applications for accreditation by corporations or for individual licences and reporting on them to the Secretary of the Department of Local Government;

- investigation and report to the Secretary on complaints of breaches of conditions upon which accreditation was granted, or upon which research or animal supplier's licences were issued;
- investigation of matters relating to the conduct of animal research and the supply of research animals;
- investigation and evaluation of the efficacy of the Code of Practice in regulating animal research; and
- such other functions as the Minister may confer upon it.³

14.19 The Secretary of the Department of Local Government, not the Panel, issues licences and grants accreditation or cancels or suspends them where breaches of conditions have occurred. The Secretary is obliged to refer matters to the Panel but is not obliged to act in accordance with its reports. Appeals from decisions of the Secretary may be made to the District Court.

14.20 The Act provides for the appointment of inspectors, who must be registered veterinary surgeons. They are given powers to enter research establishments, search for and examine animals, equipment and documents connected with animal experimentation.

Victoria

14.21 The Prevention of Cruelty to Animals Act was revised in 1985 to provide, among other things, a legislative framework for the control of animal experimentation in the State.

14.22 The Act provides for the supervision of animal experimentation at three levels:

- a) ethics committees operating within institutions;
- b) peer review committees; and
- c) authorised inspectors appointed by the Minister.

14.23 Provision is made for the registration of experimenters as well as for the licensing of scientific establishments and breeding establishments.

14.24 To gain registration as an experimenter, a person must be a legally qualified veterinarian, dentist or doctor, or must hold a masters or doctoral degree in animal biology. Experimentation in a licensed scientific establishment must be done under the direction or supervision of a registered experimenter.

14.25 An animal experimentation ethics committee (ethics committee) must be set up by a scientific establishment as a condition of obtaining a licence. The Act does not specify qualifications for membership or the number of members. There is provision to make regulations on such matters. The committee must, however:

- approve all research by persons other than registered experimenters and ensure that such research is supervised by a registered experimenter;
- approve, before commencement, all 'scientific procedures' carried out at a scientific establishment and all field work.

14.26 An ethics committee must also give prior approval to 'scientific procedures' proposed by registered experimenters.

14.27 Ethics committees must report to the licensing authority (the Director-General of Agriculture and Rural Affairs) on all approvals granted for work conducted outside the institution.

14.28 The Act provides that the Minister may establish peer review committees and determine terms of reference for these committees, in relation to any aspect of scientific procedures or scientific research at one or more licensed scientific establishments. These committees are intended to be investigatory and advisory and are to have at least five members - one with experience in animal welfare and the remainder with expert knowledge relevant to the inquiry. A peer review committee on lethal dose testing has been appointed.

14.29 The third level of supervision is provided by inspectors ('authorised officers'). They are appointed by the Minister and may enter premises, inspect animals and facilities, issue orders requiring the treatment, feeding, housing or destruction of animals, and require persons to provide information. Five inspectors have been appointed.

14.30 The Act itself does not set out standards for the welfare of animals. The intention is that standards should be set in codes of practice which may be varied or revoked by the Minister with the approval of the Governor in Council. The NHMRC Code of Practice has been incorporated in the Code of Practice Relating to Animal Experimentation gazetted in the Victorian Government Gazette of 4 March, 1987.

South Australia

14.31 The South Australian Government revised the Prevention of Cruelty to Animals Act in 1986.

14.32 Under the revised Act, institutions or organisations are licensed by the Minister (the Minister for Lands has responsibility for this legislation) and employees of those bodies do not have to be licensed individually to conduct experiments on animals. The Act is worded in a way to allow an individual to be licensed if that person does not belong to a licensed body, provided that the person meets the criteria required for licensing.

14.33 The establishment of an ethics committee of the type specified in the Act may be among the conditions imposed on the licensee at the discretion of the Minister. However, the Minister's second reading speech on the legislation stated:

Research or teaching institutions will be required to create Animal Ethics Committees to examine and approve all work using animals. Ethics committees will also have responsibility to ensure that animals used in their institutions are humanely treated.⁴

14.34 The composition of an animal ethics committee, at the institutional level, is to consist of at least four members appointed by the Minister - of whom at least one shall be a veterinary surgeon; one a person engaged in teaching or research involving animals; one a person responsible for the daily care of research/teaching animals; and one a person 'with an established commitment to the welfare of animals'.

14.35 The functions of an animal ethics committee include: approve the use of animals in the experiments proposed by the licence holder; approve the acquisition of animals by the licence holder; ensure that animals involved in teaching or research are treated humanely and relevant regulations complied with; and prepare annual returns for the Minister.

14.36 There is a right of appeal to the Minister against any decision of an animal ethics committee, with a further right of appeal to the Supreme Court.

14.37 The Act also establishes an Animal Welfare Advisory Committee, consisting of eight members appointed by the Governor.

14.38 The functions of the Advisory Committee are to advise the Minister on the operation and administration of the Act, which covers a wide range of animal welfare concerns in addition to animal experimentation; to report on legislative proposals; to examine proposed codes of practice; and to report on matters referred to it by the Minister. The Committee has no role in the granting or revoking of licences.

14.39 It is intended that detailed standards be set by way of regulation. This includes incorporation of a code of practice into the regulations.

14.40 Because the current Code of Practice is undergoing revision it has not been incorporated into regulations. Until the revised code is available, it has been a condition of licences that all experiments on animals will be conducted in accordance with the current Code of Practice, where that Code does not conflict with the Prevention of Cruelty to Animals Act 1985.

Tasmania

14.41 The relevant act is the Cruelty to Animals Prevention Act 1925.

14.42 With respect to animal experimentation the Act is permissive rather than regulatory. The relevant section of the Act reads as follows:

5 - (1) Any person who does any act or omits any duty whereby unnecessary suffering is caused, or likely to be caused, to any animal shall be deemed guilty of cruelty to such animal.

(2) Without limiting the generality of subsection (1), but subject to the provisions of subsection (3), the following acts and omissions shall constitute cruelty to the animal concerned ...

(g) Except for medicinal or curative purposes or for the purposes of scientific research, administering to it any drug or any toxic or noxious substance;

(h) Except for the purposes of scientific research, wilfully and unreasonably administering to it any poisonous or injurious drug or substance.

14.43 In Tasmania, therefore, there is no legislative framework for the regulation of animal experimentation.

Queensland

14.44 Legislative requirements for the regulation of animal experimentation are included in the Animals Protection Act 1926-1981.

14.45 The relevant section of the Act contains the following provisions:

7. Exemptions. (1) Except as hereinafter provided, nothing in this Act shall render unlawful ...

(f) Any vivisection or other experiment performed on any animal in accordance with regulations made by the Governor in Council for the humane conduct of such experiments, by any person who is (pursuant to such regulations) duly authorised by the Home Secretary to perform such experiments;

(2) The exemption in this section contained shall not take effect:

- (a) In any case of ill-treatment; or
- (b) In any case of vivisection or other experiment as described in paragraph (f) of subsection one hereof wherein the following conditions are neglected, that is to say:-
 - (i) The operation shall be performed in accordance with the said regulations;
 - (ii) The animal subject to the operation shall, during the whole time thereof, be so under the influence of some anaesthetic as to be insensible to pain;
 - (iii) When the animal has in the course of the operation been so injured that its recovery would involve serious suffering, it shall be destroyed while still insensible in accordance with the said regulations;
 - (iv) An animal which has suffered one operation shall not be subjected to another.

14.46 Provision is made for the making of regulations to control both animal experimentation and the granting of authorisations to carry out such experiments. However, no regulations have been made under this section of the Act. Regulation of animal experimentation by the State government has therefore been inoperative.

14.47 The Queensland Police Department, which administers the Animals Protection Act, is reviewing animal welfare legislation and advertised in January this year for written submissions with a closing date of 25 March 1989.

Western Australia

14.48 The regulatory provisions dealing with animal experimentation are contained in the Prevention of Cruelty to Animals Act 1920-1976. These provisions are similar to those contained in the Queensland legislation. They are as follows:

- 6. (1) Except as hereinafter provided, nothing in this Act shall render unlawful:

- (f) any vivisection or other experiment performed on any animal in accordance with regulations made by the Governor for the humane conduct of such experiments, by any person who has (pursuant to such regulations) been duly authorized by the Governor to perform such experiments, and whose authority in this behalf the Governor has not withdrawn; or
 - (g) any operation of the nature of an inoculation or of a feeding experiment.
- (2) The exemption in this section contained shall not take effect:

- (a) in any case of ill-treatment; or
- (b) in any case of vivisection or other experiment as described in paragraph (f) wherein the following conditions are neglected, that is to say:-
 - (i) the operations shall be performed in accordance with the said regulations;
 - (ii) the animal subject to the operation shall, during the whole time thereof, be so under the influence of some anaesthetic as to be insensible to pain;
 - (iii) when the animal has in the course of the operation been so injured that its recovery would involve serious suffering, it shall be destroyed, while still insensible;
 - (iv) an animal which has suffered one operation shall not be subjected to another.

14.49 Regulations have been made under this Act. They are entitled: 'Prevention of Cruelty to Animals Act - Control of Vivisection and Experiments Regulations, 1959 ...' They make provision for the issuing of an authority to perform vivisection and experiments, the attachment of conditions to the authority, the withdrawal of an authority, the regulation of operations and the supply of information on experiments by authorised persons to the Commissioner of Public Health.

Australian Capital Territory

14.50 Animal experimentation in the A.C.T. is regulated by the Prevention of Cruelty to Animals Ordinance 1959.

14.51 As in the Western Australia and Queensland Acts experiments and vivisection are excluded from the definition of acts of cruelty and aggravated cruelty. The Ordinance states:

7. The last two preceding sections of this Ordinance do not apply to an act done:

- (c) in an experiment or vivisection performed on an animal for the purposes of scientific investigation in accordance with conditions, if any, determined by the Minister of State for Health by a person, or by a person acting under the direction, control and supervision of a person, who-
 - (i) is a legally qualified medical or veterinary practitioner, or being a graduate of a university, is engaged in biological research; and
 - (ii) is authorised by the Minister of State for Health, to perform experiments and vivisections on animals.

14.52 The power to issue authorisations was delegated by the Minister of Health to the Chairman of the A.C.T. Health Authority some years ago. However, the abolition of this office was announced in September 1987, by the Minister for Arts, Sport, the Environment, Tourism and Territories.

14.53 A review of the Ordinance has been completed and the draft revised policy has been subject to public comment. However, with the recent transfer to self-government, the new Legislative Assembly has not yet had time to consider the revised policy and pass legislation to bring the policy into effect.

Northern Territory

14.54 Provision for the regulation of animal experimentation is contained in the Northern Territory of Australia Prevention of Cruelty to Animals Act.

14.55 Animal experimentation is exempted from being classed as acts of cruelty as defined by the Act under certain conditions. The provision reads:

21. Exemptions

(1) Except as hereinafter provided, nothing contained in this Ordinance shall apply to any act done in any of the following cases:

(d) In any experiment or vivisection performed upon any animal by any legally qualified medical practitioner or veterinary practitioner or any officer authorised by the Minister, for purposes of scientific investigation;

(2) Nothing contained in subsection (1) shall apply to any case where an animal is ill-treated, or pain is unnecessarily caused to any animal, by any person.

14.56 The authorisation provision is, to all appearances, not being used at all.