

CHAPTER 6

Use of animals in scientific research and teaching

Summary and Overview

6.1 Legislative regulation of the use of animals in scientific research and in particular vivisection was a major focus in the early development of anti-cruelty laws in England. The English *Cruelty to Animals Act 1876* was the response to concerns about vivisection. It included provisions making it an offence to carry out an experiment on an animal which was calculated to cause pain, save where the experiment was carried out with the object of advancing physiological knowledge, saving or prolonging life or reducing suffering.¹

Many people are concerned about the use of animals for the testing of pharmaceuticals and particularly for the testing of cosmetics and the like. This is perhaps less of a concern in Australia, given that the majority of pharmaceutical and other product testing occurs in the United States, Europe and Japan. For example, Australia has no major pharmaceutical development facility carrying out testing on animals.

The growth of use of animals in scientific research has, unfortunately, occurred in parallel with the growth of what one may call the “scientific research industry”. This is a post-war phenomenon, associated with the explosion of physiological and biochemical knowledge and a huge increase in the number of pharmaceutical developments which made hitherto untreatable diseases treatable. For example, it is hard to imagine (but nevertheless true) that pre-war there were no really effective antibiotics and no widespread acceptance by scientists of the principle of chemical transmission between nerves (in other words, the basis of nerve and brain function).

Put bluntly, the modern “research industry” educates and employs many people who simply would not have made the grade forty or fifty years ago. This is because universities and other research and educational institutions have been forced to “dumb down” in order to accommodate ever-increasing numbers of students. The aspect of this industry which obtains funding for research has become a cynical exercise in overblowing the relevance and prospects of success of the research, and an uncomfortable and strained necessity to make the proposed research have a commercial angle. The monotonously repetitive media stories featuring the prospects of yet another miracle cure for cancer, diabetes and the like (but where are they?) are ample evidence that biological scientists are more engaged in ensuring job

¹ See the excellent review in Radford's 2002 book *Animal Welfare Law in Britain* (Oxford: Oxford University Press)

security than in doing good science.² The upshot of this is that much research using animals is simply a waste of those animals' lives and suffering.

6.2 In Australia, the cornerstone of regulation of use of animals in scientific research is the *Australian code of practice for the care and use of animals for scientific purposes* published by the National Health and Medical Research Council. The most recent edition (the 7th) was published in 2004. In the author's opinion it represents a very fair attempt to improve the welfare of animals used in scientific research and teaching. While it has no legal effect *per se*, it is incorporated in various ways in the relevant legislation of the States and Territories. There follows a brief summary of some of its more important features.

The responsibilities for those using animals are said to be to:

- ensure that the use of animals is justified, taking into consideration the scientific or educational benefits and the potential effects on the welfare of the animals;
- ensure that the welfare of animals is always considered;
- promote the development and use of techniques that replace the use of animals in scientific and teaching activities;
- minimise the number of animals used in projects; and
- refine methods and procedures to avoid pain or distress in animals used in scientific and teaching activities.

This reflects the application of the “3Rs”, being replacement of use of animals with other methods; reduction in number of animals used and refinement of techniques to reduce the adverse impact of the techniques on the subject animals.

6.3 A very important aspect of the Code (and the statutes which refer to it) is the role of the Animal Ethics Committee (“AEC”) (or equivalent) in approving and overseeing projects. Institutions using animals for scientific purposes must ensure compliance with the Code and one of the ways in which that must be done is by establishing AECs. Investigators wishing to propose projects must submit written proposals to the appropriate AEC and those proposals must take into account the expected value of the knowledge to be gained, the project justification and all ethical and animal welfare aspects taking into consideration the 3Rs. Projects must not commence until the AEC has given written approval. Factors which must be taken into account in approving proposed projects include ethics.

An AEC must comprise at least 4 persons, with at least one each of the following: a

² Webster has pointed out that one of the reasons for studying any form of science is that it may be necessary to achieve academic advancement; ie self-interest: AJF Webster (1998) What use is science to animal welfare? *Naturwissenschaften* 85, 262

person with qualifications in veterinary science and experience relevant to the activities of the institution; a suitably qualified person (usually meaning possession of a higher degree in research) in the use of animals in scientific or teaching activities; an “animal welfare” person and an independent person (who has never been involved in scientific or teaching activities).

6.4 The Code differs from several anti-cruelty laws in that it defines “animals” to include fish, amphibians and reptiles and includes cephalopods such as octopus and squid. It has an interesting definition of “animal welfare”: “an animal's quality of life based on an assessment of an animal's physical and psychological state as an indication of how the animal is coping with the ongoing situation as well as a judgment about how the animal feels.” Again, this represents a significant difference from definitions of terms such as “cruel” in the anti-cruelty laws.

Scientific and teaching use of animals can only be done to obtain and establish significant information relevant to “the understanding of humans and/or animals”, for the maintenance and improvement of human and/or animal health and welfare, for the improvement of animal management or production, to obtain and establish significant information relevant to the understanding, maintenance or improvement of the natural environment or for the achievement of educational objectives. One important condition which is imposed on a person proposing a project is to identify whether any of the proposed studies have been performed previously and if so, state why they should be repeated.

The potential effects of the work on the welfare of the subject animals must be considered before deciding that a project will be performed.

6.5 The “reduction” aspect of the Code requires a consideration of the “statistical power” of the proposed study. This means that an investigator, in proposing a project, must establish how many animals must be used in order to make the results statistically meaningful; no more than that number should be used.

6.6 The “refinement” section includes provisions relating to the transportation, housing and feeding (etc) of animals. It is said that the welfare of the animals must be a “primary consideration” and this should be based on “behavioral and biological needs.” There is an explicit requirement to avoid pain and distress to animals and where this is not possible, to minimise pain and distress. This necessarily means that where possible, experiments on living animals must include the use of appropriate anaesthetics and analgesics, and this is expressly stated in a later section. This section contains the very important statement that

“pain and distress cannot be evaluated easily in animals and therefore investigators and teachers must assume that animals experience these in a

manner similar to humans unless there is evidence to the contrary. Decisions regarding the animals' welfare must be based on this assumption.”³

This is virtually an “animal welfare precautionary principle”. In other words, even where there is no firm scientific evidence that a procedure is causing an animal pain or distress, the animal must be given “the benefit of the doubt”. Note that this flies directly in the face of the position usually adopted by the animal farming industry (and is a feature of the regulatory impact statement associated with the development of the Commonwealth code of practice for pigs), which is that legislation seeking to improve animal welfare should only be implemented where there is clear scientific evidence that the proposed change will improve animal welfare.

The NHMRC has recently published “Guidelines to promote the wellbeing of animals used for scientific purposes – the assessment and alleviation of pain and distress in research animals”. This document says it is to be read in conjunction with the Code. However, the Code contains no reference to these Guidelines, so without more the Guidelines will not have legal effect (for example, unless they are picked up by references in the relevant State and Territory legislation).

6.7 Animals must not be used for teaching activities unless there are no suitable alternatives. The Code specifically protects “whistleblowers” who complain about use of animals in teaching and acknowledges the right of students and others to question the use of live animals in teaching.

Also relevant to animal welfare issues in research and teaching is the Australian and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART).⁴ This organisation publishes various reports and guidelines intended to be of assistance to those using animals in research and teaching.

6.8 There is no centralised agency responsible for collating and publishing data on animal use in research and teaching. The Australian Association for Humane Research has figures on its website for 2005, which do not include numbers for Queensland,⁵ Western Australia or the Northern Territory.⁶ These data indicate that during this period just under 670,000 mice and 92,000 rats were used. Nearly 900,000 chickens are listed as having been used.

6.9 The responsible agency in New South Wales publishes information on

3 “Distress” is defined as “the state of an animal that has been unable to adapt completely to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions”

4 see <http://www.adelaide.edu.au/ANZCCART>

5 the most recent Queensland annual report is for 2004:
<http://www2.dpi.qld.gov.au/animalwelfare/17286.html>

6 see <http://www.aahr.asn.au/statistics.html>

animal use on its website.⁷ The annual report for 2006 shows:

- about 600,000 animals were used for the purpose of “education”, of which the majority were “stock”;
- about 3,000 lab animals (mostly rats and mice) were used for the purpose of “education”;
- about 85,000 lab animals (mostly rats and mice) were used for research (human or animal biology);
- about 40,000 lab animals were used for research (human or animal health or welfare);
- about 45,000 “stock” animals were used in research concerning “animal management or production”;
- regulatory product testing involved about 50,000 animals.

6.10 The South Australian Department of the Environment publishes statistics on animal use in research and teaching.⁸ Figures for 2006 show that a total of 378,889 animals were used for these purposes. About 20,000 laboratory rodents were used in “understanding biology”, while slightly more than that number were used in research related to “health and welfare”. About 120,000 livestock animals (mostly sheep) were used in teaching or research.

To conclude, the regulation and oversight of animal welfare in research and teaching is fragmented and poorly coordinated. The author thinks there is every reason for this to be done on a national basis. The NHMRC Guidelines represent a very good starting point, but there is no uniformity regarding implementation and enforcement. Similarly, animal use statistics should be reported on a national basis.

The Law

Licence

6.11 In the ACT⁹ it is an offence if a person uses or breeds an animal for research or teaching and does not have a licence¹⁰ to do so.¹¹ An application for a licence must be made to the Animal Welfare Authority.¹² The licence is subject to

7 see <http://www.animaethics.org.au/reader/annualreports>

8 see http://www.environment.sa.gov.au/animalwelfare/pdfs/tr_using_animal_2006.pdf

9 s25(1) *Animal Welfare Act* 1992

10 A “licence” is for the use or breeding of animals for research or teaching (or both) at stated premises: s26. It is for a period of not longer than 3 years: s30

11 Exceptions are a person holding an “authorisation” or a person assisting that person, a person who uses or breeds an animal in the course of employment or engagement by a licensee, a person who uses an animal prescribed by regulation for teaching purposes in a preschool or primary school (prescribed by Regulation 6 and Schedule 2 of the *Animal Welfare Regulation* 2001 as axolotl, frog, budgerigar, chicken, cockatiel, finch, pigeon, quail, goldfish, guppy, platy, silver perch, sword tail, guinea pig, mouse, rabbit, rat), an “interstate researcher” (s49B(1)), a person who uses or breeds an animal in the course of employment or engagement by an interstate researcher

12 The “Animal Welfare Authority” is a public servant appointed by the chief executive under s5 of the *Animal Welfare Act*; in deciding whether to grant the licence (which includes grant by renewal) the authority must

the condition that the licensee must establish and maintain an animal ethics committee.¹³

6.12 In New South Wales the use of animals in scientific research¹⁴ is governed by the *Animal Research Act* 1985.¹⁵ The Act applies to all non-human vertebrates.¹⁶ The Act establishes an Animal Research Review Panel,¹⁷ which may appoint advisory committees and has functions including the investigation of matters relating to the conduct of animal research.¹⁸ “Animal care and ethics committees” may be set up.¹⁹ The functions of a committee include those conferred or imposed on it by the “Code of Practice”.²⁰ A corporation may apply for accreditation²¹ as a research establishment.²² There is a mechanism for making a complaint concerning use of animals at an accredited research establishment.²³ Suppliers of animals for

consider matters including the applicant's experience and competency in caring for and handling animals, the adequacy of the premises, equipment etc for caring for and handling animals, adequacy of arrangements for provision of veterinary care at the premises, whether the applicant has (within 3 years before the date of application) been convicted or found guilty of a defined offence (which means an offence against the Act or an offence in relation to animal welfare under another territory law or a Commonwealth or State law): s26

13 Act s28; Regulations 6A: or make appropriate arrangements with an existing animal ethics committee for that committee to exercise the functions of an animal ethics committee in relation to the licensee's activities

14 Section 3 defines “animal research” to mean any procedure, test, experiment, inquiry, investigation or study in connection with which an animal is used and, without limitation, includes any procedure, test, experiment, inquiry, investigation or study in the course of which an animal is subjected to surgical, medical, psychological, biological, chemical or physical treatment; abnormal conditions of heat, cold, light, dark, confinement, noise, isolation or overcrowding; abnormal dietary conditions or electric shock or radiation treatment; or any material or substance is extracted or derived from the body of an animal (but does not include any procedure, test, experiment, inquiry, investigation or study which is carried out in the course of the administration of veterinary treatment to an animal for the purpose of protecting the welfare of the animal or the conduct of normal animal husbandry operations)

15 Section 2A says the object of the Act is to protect the welfare of animals used in connection with research by requiring persons or organisations carrying out animal research or supplying animals for research to be authorised under the Act and by regulating the carrying out of animal research and the supply of animals for research by those persons or organisations

16 Section 3

17 See also reg 5 *Animal Research Regulation* 2005

18 See ss6– 12 *Animal Research Act* 1985

19 ss13 – 16 *Animal Research Act* 1985

20 s14 *Animal Research Act* 1985; which is the *Australian code of practice for the care and use of animals for scientific purposes* published by the Australian Government” and Schedule 1 of the *Animal Research Regulation* 2005: reg 4 (and section 4 of the Act). Schedule 1 concerns additional conditions to be observed: in relation to animal research conducted in schools; by licensed animal suppliers in relation to dogs and cats; in relation to the supply of dogs and cats to licensed animal suppliers and the delegation of functions of ethics committees

21 Which is for 12 months (but may be less in certain circumstances): s21 *Animal Research Act* 1985; it is an offence to carry on the business of animal research unless accredited: s46

22 Application is to the Director-General of the Department of Primary Industries: s18 *Animal Research Act* 1985; applications must be referred to the Panel for investigation: s19; After considering the report of the Panel, the Director-General must determine the application (there is a right of application to the Administrative Decisions Tribunal for review of a failure to determine the application): s20

23 ss22 – 24 *Animal Research Act* 1985 (complaints are investigated by the Panel, which makes a report to the Director-General of the Department of Primary Industries, who determines the complaint; this may involve cancellation or suspension of accreditation)

research must be licensed.²⁴ There is a complaints procedure in relation to licensed animal suppliers.²⁵

6.13 Section 29 of the *Animal Welfare Act 1999* (NT) says that a person may use premises for teaching or research²⁶ (defined by section 4 to mean teaching or research involving the use or breeding of animals) only if the person holds a licence.²⁷ Application for a licence is to the “Authority”²⁸ A licence²⁹ is subject to the condition that the licensee must establish and maintain an ethics committee in accordance with the Regulations.³⁰ The Authority may cancel or suspend the licence.³¹ A person aggrieved by the Authority's decision to vary, cancel or suspend a licence or refusal to grant, renew or vary a licence may appeal to the Local Court against the decision.³²

6.14 In Queensland a person must not use an animal for a scientific purpose or allow an animal to be used for a scientific purpose³³ unless the person is registered.³⁴

24 ss37 – 41 *Animal Research Act 1985*; it is also an offence for a person to keep animals with the intention of using them in connection with animal research unless the person is authorised (“authorised” means a person is an accredited research establishment, the holder of an authority or a licensed animal supplier): s47A; it is an offence to supply animals other than exempt animals for use in connection with animal research unless the person is the holder of an animal supplier's licence: s48

25 ss42 – 44 *Animal Research Act 1985*

26 Which is defined by s4 to mean an experiment, procedure, test or study in which an animal is used and includes subjecting an animal to surgical, medical, psychological, biological, chemical or physical treatment

27 There is an exception relating to animals in schools etc

28 Which is a “single person authority”, being a Chief Executive Officer or an employee as defined in the *Public Sector Employment and Management Act*: s26 *Animal Welfare Act 1999*. The Authority's functions may be delegated (s27); in considering whether or not to grant a licence the Authority must consider matters including whether the applicant is a fit and proper person to hold a licence including whether the applicant has been found guilty of an offence under animal welfare legislation in Australia, the experience and competency of the applicant in the care and handling of animals, the adequacy of the premises etc, adequacy of arrangements for provision of veterinary treatment (references to applicants include references to an officer of a body corporate applicant and each partner of a partnership applicant)

29 Which continues in force for 3 years: s35 *Animal Welfare Act 1999* and which may be renewed (ss2) or varied (s36)

30 and additional conditions the Authority considers desirable: s34 *Animal Welfare Act 1999*; or enter into an arrangement with an established ethics committee

31 On reasonable grounds, said to include that the licensee has been found guilty of an offence under the Act, that the Authority believes on reasonable grounds that the licensee obtained the licence improperly, failed to comply with a licence condition or is not a fit and proper person to continue holding the licence: s38 *Animal Welfare Act 1999* (the Authority must give the licensee a written notice of the proposed cancellation or suspension and the licensee may reply in writing as to why the licence should not be cancelled or suspended)

32 s40 *Animal Welfare Act 1999*

33 s48 *Animal Care and Protection Act 2001*: an animal is used for a scientific purpose if it is used in an activity performed to acquire, demonstrate or develop knowledge or a technique in a scientific discipline or in connections with such an activity (but does not include banding a bird or tagging a fish, but does include the use of any of the remains of an animal that was killed for the purposes of such an activity)

34 s51 *Animal Care and Protection Act 2001* (or is an individual retained by a registered person acting in the course of the individual's retainer or a student at a college, institute, school, university or other institution that is registered and acting in the course of the person's studies with the institution; retained means employed or engaged whether or not for remuneration); the procedure for application for registration is set out in Division 2, Part 2 of Chapter 4. In deciding an application, the chief executive (who is the Chief Executive of the

Registration is for 3 years;³⁵ the Chief Executive may impose conditions on the registration.³⁶ Interestingly, the Chief Executive must keep a register of persons registered to use animals for scientific purposes and that register must be open for public inspection.³⁷ However, a registered person or an applicant for registration may apply to the Chief Executive for an exemption from compliance with the public disclosure requirement.³⁸ The Chief Executive may cancel or suspend a person's registration.³⁹ He or she must give notice of the proposed action and the holder of a registration may make representations to show why that action should not be taken.⁴⁰ Those representations must be considered by the Chief Executive who after making a decision must give the relevant person notice of that decision.⁴¹ Division 5 of Chapter 4 contains provisions⁴² allowing the Chief Executive to request the commissioner of the police service to provide information about animal welfare offences (both in Queensland and in other Australian jurisdictions) in relation to an application or in connection with proposed action concerning a registration. The holder of a registration must provide the Chief Executive with an annual report.⁴³

6.15 Part 4 of the *Animal Welfare Act* 1985 (SA) deals with teaching and

Department of Primary Industries and Fisheries by virtue of the effect of s33 of the *Acts Interpretation Act* 1954) must be satisfied the applicant and the nominated animal ethics committee is likely to comply with the NHMRC Code; in considering the application the chief executive must consider whether a disqualifying event has happened in relation to the applicant or any proposed member of an animal ethics committee and if the applicant is a corporation whether a disqualifying event has happened in relation to any of its executive officers or another corporation of which any of its executive officers is or has been an executive officer and another (sic) matter prescribed under a regulation

35 s58 *Animal Care and Protection Act* 2001

36 s56 *Animal Care and Protection Act* 2001

37 ss60 – 62 *Animal Care and Protection Act* 2001

38 ss64 – 70 *Animal Care and Protection Act* 2001

39 s73 *Animal Care and Protection Act* 2001: if the registration was because of a materially false or misleading representation or declaration, the person has not complied with a registration condition, the person has not paid a relevant fee, if the person is an individual, a disqualifying event happens in relation to the individual or he or she becomes an undischarged bankrupt or as a debtor takes advantage of any law about bankruptcy or insolvent debtors; “animal welfare offence” means an offence against the Act (other than chapter 6, part 2, divisions 2, 3, 4 and 7 and chapter 8 part 1 or the Criminal Code, section 468); “disqualifying event” means a conviction for an animal welfare offence or cancellation or suspension of registration or cancellation or suspension under a law of another State or the Commonwealth of an authority, instrument, licence permit or registration, however called, that is the same as or similar to registration; for the relevant Chapter, “conviction for an animal welfare offence” includes not only conviction for an offence against the Act (as defined) but includes conviction for an offence against a law of the Commonwealth or another State if the act or omission that constitutes the offence would, if it happens in Queensland, be an animal welfare offence or an offence committed anywhere in Australia before the part commence that, apart from the non-commencement of the part would have been a conviction for an offence as defined.; if the person is a corporation a disqualifying event happens in relation to any of its executive officers or another corporation oa which any of its executive officers is or has been an executive officer or it becomes insolvent as defined in the Commonwealth *Corporations Act* s95A; a disqualifying event happens in relation to a member of an animal ethics committee for the person; an animal ethics committee for the person has not performed any of its functions under the NHMRC code or complied with that code to the extent it is relevant to the committee

40 s75 *Animal Care and Protection Act* 2001

41 ss76 – 78 *Animal Care and Protection Act* 2001

42 ss81 – 86 *Animal Care and Protection Act* 2001

43 s87 *Animal Care and Protection Act* 2001, which must contain information as prescribed by regulation

research using animals. It is an offence for a person to use an animal for the purposes of teaching any science or research or experimentation without a licence.⁴⁴ A licence is subject to conditions imposed by the Minister.⁴⁵ Those may include compliance with the NHMRC Code.⁴⁶ The Minister may revoke or suspend a licence.⁴⁷ Regulation 14 of the *Animal Welfare Regulation* 2000 in effect prohibits the Draize eye test and the LD₅₀ toxicity test, but allows those tests to be carried out where “the assessment relates to research that has the potential to benefit human or animal health and the objectives of the assessment cannot practicably be achieved by means that will cause less pain to animals.” These caveats seem superfluous, given the equivalent requirements of the *Australian code of practice for the care for the care and use of animals for scientific research* (see 6.2-6.6).

6.16 The *Animal Welfare Act* 1993 (Tas) prohibits a person from carrying out animal research⁴⁸ unless it is carried out by an institution licensed under the Act.⁴⁹ Suppliers of animals for scientific research may only supply the animal to a licensed institution and in accordance with the NHMRC Code of Practice.⁵⁰ A licence for use of animals in scientific research is subject to conditions including that the research be conducted in accordance with the Code of Practice.⁵¹ The Minister may cancel a licence if the Minister considers that the institution should no longer hold the licence or has not complied with the licence conditions.⁵²

44 s16; an employee carrying out such activities in the course of employment by a licence holder is not required to have a licence; application for a licence is dealt with by s17 – applications are to the Minister; under s18 the Minister must determine whether a licence should be granted having regard to matters including the suitability of the applicant, the adequacy of the relevant premises and the adequacy of arrangements for the provision of veterinary attention to animals (and other prescribed matters); a licence is for 2 years and may be renewed for successive periods of 2 years: s20

45 s19; which may include requiring the holder to establish an animal ethics committee and seek its approval for experiments; animal ethics committees are dealt with in ss23 – 25; an animal ethics committee must comply with the Code and relevant approvals for use of animals must be in accordance with the Code: s25; decisions of a committee may be appealed to the Minister: s26; there is a right of appeal to the Supreme Court concerning any decision of the Minister under Part 4 of the Act: s27

46 defined by s3 of the *Animal Welfare Act* to mean the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (2004) NHMRC, 7th edition, as amended from time to time

47 s22: where the holder of a licence has been found guilty of an offence under the Act, has obtained the licence improperly or has failed to comply with a condition of the licence

48 “animal research” is defined to mean a procedure, test, experiment, inquiry or study on an animal which is undertaken to develop, demonstrate or acquire knowledge, or techniques, in an area of science or teaching and is likely to, or may, adversely affect the welfare of the animal

49 Application for a licence is to the Minister: s29 *Animal Welfare Act* 1993, who on the advice of an inspector may grant a licence, but only if satisfied the institution has an Animal Experimentation Ethics Committee constituted in accordance with the NHMRC Code: s30; licences can be for up to 3 years: s31; a licensed institution must submit an annual report on research using animals: s35

50 Approved by the Minister under s34 *Animal Welfare Act* 1993

51 s30(3) *Animal Welfare Act* 1993; other conditions include that research must be approved by the relevant Ethics Committee, that there be inspections (at least once each year) and any other condition imposed by the Minister

52 s32 *Animal Welfare Act* 1993; where the Minister is acting on the advice of an inspector; a decision to refuse to grant a licence or cancel a licence or impose a constitution may be the subject of a review by the Magistrates Court: s33

6.17 Section 26 of the *Prevention of Cruelty to Animals Act 1986* (Vic) provides that a person who occupies a scientific premises must not cause or allow scientific procedures⁵³ on animals⁵⁴ to be carried out on those premises unless that person holds a relevant scientific procedures licence.⁵⁵ There are similar provisions relating to scientific field work involving animals and breeding animals for research.⁵⁶ Prescribed conditions for scientific procedures licences⁵⁷ include that all scientific procedures must be carried out in accordance with the NHMRC Code,⁵⁸ the *Code of Practice for the Housing and Care of Laboratory Mice, Rats, Guinea Pigs and Rabbits*,⁵⁹ and the relevant Code of Practice for the use of animals from municipal pounds in scientific procedures.⁶⁰ Scientific procedures must be done in

53 s3: “scientific procedure” means any procedure, test experiment, inquiry, investigation or study which is carried out on or in connection with an animal in the course of which an animal is subjected to surgical, medical, psychological, biological, chemical or physical treatment or conditions of heat, cold, light, dark, confinement, noise, isolation or overcrowding to which an animal of that species is not accustomed, abnormal dietary conditions, electric shock or radiation treatment, any tissue, material or substance is extracted or derived from the body of an animal and which is for the purpose of acquiring, demonstrating or developing knowledge in the field of medical, dental, veterinary, agricultural, behavioural or biological science or in any other field of science or the purpose of acquiring demonstrating, exercising or developing techniques used in the practice of medical, dental, veterinary, agricultural, behavioural or biological science or in any other field of science or the purpose of developing or testing the use, hazards, safety or efficiency of vaccines, substances, drugs, materials or appliances intended for use in, on or in connexion with human beings or animals or any other prescribed purpose, but does not include the treatment of an animal for the purpose of promoting its health or welfare by or in accordance with the instructions of a veterinary practitioner or the conduct of animal husbandry carried out in accordance with a Code of Practice, the collection, taking, banding and marking of wildlife within the meaning of and in accordance with the *Wildlife Act 1975* or any or any type of procedure, test, experiment, inquiry, investigation or study prescribed.

54 s25 defines an animal to mean a live member of a vertebrate species including any fish or amphibian or reptile, bird or mammal other than any human being or any reptile, bird or other mammal that is below the normal mid-point of gestation or incubation for the particular class of reptile, bird or mammal or a live adult decapod crustacean that is a lobster, crab or crayfish or a live adult cephalopod including an octopus, squid, cuttlefish or nautilus

55 Prescribed particulars for an application are in regulation 91

56 The occupier must nominate a “responsible person” in relation to scientific procedures who must not cause or allow scientific procedures to be carried out unless appropriate authorisation has been given; s27 relates to scientific procedures field licences, required for work on animals outside of a scientific premises; s28 relates to specified animals breeding licences required (in essence) for breeding of laboratory animals (“specified animal” means guinea pig, rat, mouse, rabbit and non-human primate); provisions relating to grant, application, duration and conditions for a scientific procedures licence are in ss29 – 32; similar provisions relating to scientific procedures field work licences are in ss32A – 32D; and for specified animals breeding licences in ss32E – 32H; ss32I – 32R deal with renewal, variation, suspension and cancellation of licences. Applications for licences are to the Department Head. The licences are for not more than 3 years duration. They are subject to prescribed conditions are those imposed by the Department Head. If satisfied there are grounds for cancelling a licence, the Department Head may suspend the licence but must first give notice before suspending a licence and the holder may make submissions as to why the licence should not be suspended. The Department Head after considering the submissions may cancel the licence if satisfied the licence holder is not a fit and proper person to hold the licence, may cancel the licence; see also regulation 92 *Prevention of Cruelty to Animals Regulations 2008* (Vic) for conditions on licences; regulation 96 sets out standards for field work, while regulations 97 - 99 relate to animal breeding licences;

57 s32 *Prevention of Cruelty to Animals Act 1986* (Vic); reg 92 *Prevention of Cruelty to Animals Regulations 2008* (Vic)

58 *Australian code of practice for the care and use of animals for scientific purposes* 7th edition (2004)

59 as gazetted 16 December 2004

60 as gazetted 7 December 1988

accordance with the approval given by an Animal Ethics Committee.⁶¹ Section 34 of the Victorian Act provides that the Minister may establish Peer Review Committees in relation to any aspect of scientific procedures or research at relevant premises. The Minister may also appoint “authorised officers”, who have power to enter licensed premises, issue orders requiring destruction or treatment of animals, power to file charges for any offence under the relevant Part of the Act or regulations and power to require any person at the relevant premises to give information.⁶² Authorised officers may serve an infringement notice relating to a prescribed offence.⁶³ Section 36 of the *Prevention of Cruelty to Animals Act 1986* (Vic) is a provision specifically concerning activities at licensed premises.⁶⁴ Regulations 100 – 102 of the *Prevention of Cruelty to Animals Regulations 2008* deal with requirements regarding returns in relation to use of animals in scientific research. Regulation 12 of the *Prevention of Cruelty to Animals Regulations 1997* in essence outlaws the Draize eye irritancy and LD₅₀ tests.⁶⁵

6.18 The Western Australian *Animal Welfare Act 2002* sets out provisions dealing with use of animals for scientific purposes⁶⁶ in Part 2. A licence is required.⁶⁷ A licence is also required to carry on business supplying animals for

61 regulation 18 *Prevention of Cruelty to Animals Regulations 1997* (Vic)

62 s35 *Prevention of Cruelty to Animals Act 1986* (Vic)

63 s37A *Prevention of Cruelty to Animals Act 1986* (Vic)

64 It says it is an offence for a person who knowingly or negligently does or omits to do any act with the result that unnecessary, unreasonable or unjustifiable pain or suffering is caused to any animal kept at a licensed premises; it is an offence if a person carries out any surgical operation on an animal unless during the entire length of the operation the animal is under the influence of an anaesthetic so as to be insensible to any pain it might otherwise have suffered and the operation is carried out in accordance with any relevant Code of Practice; and if an animal has been so injured in the course of a scientific procedure that it would seriously suffer if it remained alive, it must be destroyed painlessly

65 Any eye irritancy test can only be done under terminal anaesthesia; any procedure involving death as an endpoint measure is prohibited unless the procedure is related to a potentially lifesaving treatment for animals or human beings, research in connection with animal or human cancer, development and assessment of the humaneness of lethal vertebrate pest control agents or investigation of environmental contaminants and the objectives of the procedures cannot be achieved by any other scientific means (the procedures must be approved by the Minister and carried out in accordance with any conditions determined by the Minister)

66 s5: “scientific purposes” means acquiring, developing or demonstrating knowledge or techniques in a scientific discipline, other than in prescribed circumstances and includes teaching, research, product development or testing and carrying out a prescribed activity (regulation 3 of the *Animal Welfare (Scientific Purposes) Regulations 2003* prescribes the use of an animal to demonstrate a product or a technique

67 s6: A person must not use animals for scientific purposes unless the person is a scientific establishment that holds or a member of staff of or a student at a scientific establishment that holds a licence; the relevant animal ethics committee must have given approval (in accordance with the scientific use code); the duration of a licence is 3 years (or specified shorter period): s15; an application for a licence is made to the Minister: s8; the Minister, in considering whether to issue a licence must be satisfied the scientific establishment has an animal ethics committee or has made appropriate arrangements with another animal ethics committee and will comply with the scientific use code, the Minister is to have regard to whether the applicant and the applicant's staff are experienced and competent (relevantly) in using animals for scientific purposes and in caring for and handling animals of the kind to be used or supplied; whether the applicant has or any of the applicant's staff or students have been convicted of an offence under the Act in the previous 3 years, whether a licence held by the applicant has ever been suspended or revoked or the applicant has ever been disqualified from holding a licence, whether the welfare, safety and health of the animals is adequately protected and any prescribed matters. There is provision for licence conditions to be prescribed (s11) or imposed by the Minister (s12); it a

scientific purposes.⁶⁸ The Minister may suspend a licence for up to 3 months;⁶⁹ a court convicting an offender may suspend or revoke or impose conditions on a licence.⁷⁰ The Chief Executive Officer of the responsible Department must keep a register of licences and that register can be inspected by the public.⁷¹

Personal authorisations etc

6.19 The ACT legislation requires a person employed or engaged by a licensee, and which person is conducting a programme of research or teaching which involves using or breeding animals, to have an authorisation.⁷² Application for authorisation is to the relevant animal ethics committee.⁷³ There are no conditions (prescribed by the Act or Regulations) for an authorisation.⁷⁴

The *Animal Research Act* 1985 (NSW) provides for the issue of an authority⁷⁵ to an individual to carry out animal research for the purpose of a particular research project.⁷⁶ There is a complaints procedure in relation to authorities.⁷⁷

In the Northern Territory a person employed or engaged by a licensee may conduct

condition of each licence that animals must not be used for scientific purposes unless in accordance with the scientific use code (which is defined by regulation 2 of the *Animal Welfare (Scientific Purposes) Regulations* 2003 as the *Australian code of practice for the care and use of animals for scientific purposes* (latest edition) published by the National Health and Medical Research Council

68 s7

69 s17: including, if satisfied that the licensee has or any of the licensee's staff or students have committed an offence under the Act since the licence was issued or renewed, in the case of a scientific use licence, the relevant animal ethics committee has failed to comply with the scientific use code or for any other reason the welfare, safety and health of an animal would be under threat if the licence remained in force

70 s55 *Animal Welfare Act* 2002

71 s18

72 s36(1) *Animal Welfare Act* 1992. An authorisation is granted for a period of not longer than 3 years (s41); the requirement for an authorisation does not apply to a person providing research or teaching assistance for the programme or an interstate researcher or a person who uses or breeds an animal in the course of employment or engagement by an interstate researcher

73 s37 *Animal Welfare Act*. In deciding whether to grant (which includes grant by renewal) the application the committee must consider matters including the applicant's experience and competency in caring for and handling animals and whether the applicant has within 3 years before the date of the application been convicted or found guilty of a defined offence (which includes an animal welfare offence under another territory law or a Commonwealth or State law: ss2

74 Although conditions may be imposed by the Animal Ethics Committee: s39 *Animal Welfare Act*

75 It is an offence for an individual to carry out animal research unless the individual is the holder of an authority: ss46, 47 *Animal Research Act* 1985

76 ss25 – 26; authority may be issued by the Director-General of the Department of Primary Industries or an accredited research establishment (s25); an authority must only be in relation to research carried out in accordance with the Code of Practice; it must not approve research involving the use of the LD50 or Draize eye tests: s26 (although these tests may be permitted in certain circumstances); an authority remains in force for 12 months: s27

77 ss28 – 28C *Animal Research Act* 1985; complaints may be made to the Director-General of the Department of Primary Industries, who must refer the complaint to the Panel for investigation; the Panel must report to the Director-General who must determine the complaint and may take action including cancellation or suspension of the authority

a teaching or research programme only if the person holds a permit.⁷⁸ The ethics committee may impose conditions on the permit.⁷⁹ A person aggrieved by a decision of an ethics committee in relation to the permit may appeal to the Authority.⁸⁰

In Queensland the only requirement in relation to individuals who are carrying out scientific work on animals (and who are not holders of a registration) is that the use of an animal for a scientific purpose must be approved by an animal ethics committee, any requirements of the committee made under the NHMRC code has been complied with and the provisions of that code (to the extent they are relevant to the use) have been complied with.⁸¹ The use of certain tests is forbidden⁸² without specific approval.⁸³

Interstate researchers

6.20 In the ACT section 49A of the *Animal Welfare Act 1992* requires an interstate researcher⁸⁴ to apply for authorisation to use or breed animals in the ACT for research purposes. A person who has complied with that section may use or breed animals in the same way as that person is permitted to use or breed animals in their “home” State.⁸⁵

78 s43 *Animal Welfare Act 1999*; applications are to the relevant ethics committee: s44, which must, in determining whether or not to grant a permit, consider whether the applicant is a fit and proper person to hold it, including whether the applicant has been found guilty of an offence under animal welfare legislation in Australia and his or her experience and competency in the care and handling of animals; permits are granted under s47 of the Act and the ethics committee may refuse to grant a permit: s46; a permit continues in force for a period not exceeding 2 years: s49; it may be varied either by the holder (s50) or by the ethics committee (s51); it may be cancelled or suspended for reasons similar to those permitting cancellation of a licence, and the ethics committee must give the permit holder notice of the proposed cancellation, to which he or she can respond with reasons why the permit should not be cancelled or suspended (s52)

79 s48 *Animal Welfare Act 1999*

80 s55 *Animal Welfare Act 1999*: in relation to a decision to vary, cancel or suspend a permit or refusal to grant, renew or vary a permit

81 s91 *Animal Care and Protection Act 2001*

82 s92 *Animal Care and Protection Act 2001*: Draize eye test or similar; LD50 or similar or use of an animal for a scientific purpose if the use involves a cosmetic, a sunscreen product or an ingredient of a cosmetic or sunscreen product

83 s93 *Animal Care and Protection Act 2001*

84 defined as a person who has an authorisation to conduct research or teach using animals granted under a State law

85 s49B *Animal Welfare Act*