Animal Research Regulation in Australia – Does it Pass the Test of Robustness?

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1. Introduction

Every year around the world, millions of animals are used in various types of scientific research. A comprehensive global estimate for this figure is 115.3 million.[2] Australia appears to rank highly both in terms of absolute laboratory animal usage figures, and per capita use, being ranked fourth largest in the world in 2005.[3] The most recent statistics available suggest Australian usage figures in the order of 7 million animals.[4]

The extent of this use, the purported benefits to the Australian public, and the fact that the majority of biomedical research is government funded,[5] make this is a public policy issue. As with other animal welfare issues, the surrounding debate is polarised, and involves

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[2] Taylor K et al., 'Estimates for worldwide laboratory animal use in 2005' (2008) 36 *Alternatives to Laboratory Animals* 327.

[3] Ibid.

[4] Humane Research Australia (HRA), *Statistics: Animal use in research & teaching, Australia 2011* < http://www.humaneresearch.org.au/statistics/>.

[5] See, e.g., Australian Research Council (ARC), *About ARC* (18th September 2013) < http://www.arc.gov.au/>; National Health and Medical Research Council (NHMRC), *About* (16th December 2013) <http://www.nhmrc.gov.au/>.

complex cultural, social and personal beliefs.[6] The government has sought to respond to this ethical minefield by creating a framework designed to address concerns around this issue, but allowing such use in ways which it believes are broadly acceptable to the community.[7] Accordingly, does the current system adequately protect animal welfare, or does a cloak of intransparency[8] hide serious underlying actual, or potential animal welfare concerns?

This paper does not attempt to discuss the pros or cons of research using animals. It assumes the practice exists with conditional approval of the wider population. As such, the regulatory system in place must protect animal welfare to the greatest extent possible within this paradigm.

The legal framework surrounding the use of animals for scientific purposes within Australia will be discussed, and contrasted with some international jurisdictions. The author will then discuss some key issues with the current system based on personal observation, international comparison and literature review. Finally, an examination of potential reforms will be undertaken. The author will argue that the system at present fails to protect welfare and that reform is required.

2. The Australian Regulatory Framework

Under the Australian federal system, animal welfare responsibility is devolved to the states.[9] All states and territories have statutes designed to protect animals from cruelty, and in more recent times to promote welfare.[10] This overarching legislation covers all fields of animal use. Additionally, most of these acts have specific clauses pertaining to research animals.[11] New South Wales (NSW) adopts a different legislative framework to all other states and territories by the use of a separate additional statute dedicated to the regulation of research animal use.[12] This delegation of authority is provided for in the primary animal protection act by allowing a defence to prosecution for a cruelty offence should the provisions of the *Animal Research Act 1985* (NSW) be followed.[13] Statutory interpretation of the opening wording of this section, which states that the defence applies 'in the course of, and for the purpose of carrying out animal research' suggests that there may be situations where the infliction of cruelty directed towards a research animal, which can be established as being outside the parameters of the research project, may still be prosecuted under the *Prevention of Cruelty to Animals Act 1979* (NSW). However, no case authority for this assertion exists.

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[6] Margaret Rose and Elizabeth Grant, 'Australia's ethical framework for animals used in research and teaching' (Paper presented at AAWS International Animal Welfare Conference) < http://www.daff.gov.au/animal-plant-health/welfare/aaws/aaws_international_animal_welfare_conference/australias_ethical_framework_for_animals _used_in_research_and_teaching>.

[7] Ibid.

[8] Siobhan O'Sullivan, 'Transparency in Australian animal research regulation- How are we doing?' (2008) 1 *Australian Animal Protection Law Journal* 57.

[9] Under the *Australian Constitution* s 51 there is no head of power for animal welfare.

[10] *Prevention of Cruelty to Animals Act* 1979 (NSW); *Prevention of Cruelty to Animals Act* 1986 (Vic); *Animal Care and Protection Act* 2001 (Qld); *Animal Welfare Act* 1985 (SA); *Animal Welfare Act* 2002 (WA); *Animal Welfare Act* 1993 (Tas); *Animal Welfare Act* 1992 (ACT); *Animal Welfare Act* (NT).

[11] See, e.g., *Animal Welfare Act* 1985 (SA) s 16; *Animal Welfare Act* 2002 (WA) pt 2; *Animal Welfare Act* 1992 (ACT) pt 4.

[12] *Animal Research Act 1985* (NSW).

[13] *Prevention of Cruelty to Animals Act* 1979 (NSW), s 24 (1)(e).

Whilst there does appear to be considerable variability in the extent of statutory provisions relating to animals in research across the jurisdictions,[14] unity is provided by referral to a code of practice, the *Australian code for the care and use of animals for scientific purposes* ('the Code').[15] The Code provides specific detail over and above that provided in the animal protection acts pertaining to research animals. It does this using a principles-based approach, setting the outcome to be achieved yet allowing the user to determine the optimum method to achieve this. In general, this document receives its regulatory power by adoption under the state's delegated animal welfare legislation,[16] or through administrative controls, for example referral to it in licenses issued to research establishments. Administrative controls in this area of animal use abound, and can include the issuance of mandatory research licences to individuals or institutions, and mandatory prior approval by an ethics committee.[17]

The legislation and code seek to achieve a balance which acknowledges that animal interests are subjugated to human interests, but attempts to limit their use and suffering through safeguards provided in the various regulatory provisions.[18] Thus, the jurisprudential ethical foundation is incontrovertibly utilitarian.[19] One other ethical framework features highly in this area, with particularly frequent mention in the code. The Three R's refers to 'replacement' of animals with non-sentient alternatives, 'reduction' of animal use, and 'refinement' of procedures to minimise suffering.[20]

Regulatory styles form a continuum ranging between punitive forms aimed at deterrence, and persuasive forms where cooperation and education predominate.[21] Compromise is achieved through using a combination of these.[22] Enforced self-regulation operates towards the persuasive end of this scale and is the system adopted in Australia for regulation of animal use for scientific purposes. The theory suggests that institutions should take an active role in drawing up the rules under which they will operate,[23] and be responsible for ensuring compliance with them, with little government intervention.[24] The only governmental role is in verification that the internal controls are adequate by the use of government inspections, and in New South Wales through site visits and inspections by the

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[14] Honor Figgis and Gareth Griffith, 'Animal Experimentation' (Background Paper No 3/98) NSW Parliamentary Library, Parliament NSW, 1998) 25.

[15] National Health and Medical Research Council (NHMRC), *Australian code for the care and use of animals for scientific purposes* (Canberra, 8th ed, 2013) ('*NHMRC Code*').

[16] See, e.g., *Animal Welfare Regulations 2012* (SA); *Prevention of Cruelty to Animals Regulations 2008* (Vic); *Animal Care and Protection Regulation 2012* (Qld).

[17] Animal Experimentation, above n 13, 34.

[18] Margaret Rose, supra note 6.

[19] Jeremy Bentham, *A Fragment on Government; being an Examination of what is delivered on the Subject of Government in General, in the Introduction to William Blackstone's Commentaries: with a Preface in which is Given a Critique of the Work at Large* (London, 1 ed, 1776).

[20] W.M.S. Russell and R.L. Burch, *The Principles of Humane Experimental Technique* (Methuen, London, 1959).

[21] Jed Goodfellow 'Animal Welfare Law Enforcement: To Punish or Persuade' in Peter Sankoff, Steven White and C Black (eds), *Animal Law in Australasia* (Federation Press, 2nd ed, 2013) 185.

[22] Ibid.

[23] See, generally, Ayres, I and Braithwaite, J, *Responsive regulation: Transcending the Deregulation Debate* (Oxford University Press, 1992).

[24] Animal Experimentation, supra note 14, at 34.

Animal Research Review Panel.[25] In practice, researchers assume primary responsibility for animals on their studies, with a degree of vicarious responsibility taken by their employers.

Central enforcement activities differ between states but may include inclusion of government appointed personnel on code external review panels,[26] or routine accreditation visits by government inspectors or review panels.[27]

3. The International Regulatory Landscape

3.1. The European Union

The EU and the Council of Europe both provide documents concerning the use of animals in research. These include EU Directive 2010/63/EU,[28] and the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes.[29] The former document is not directly binding on member states in this format but requires adoption into domestic legislation. Unlike EU Regulations, Directives are only binding as to their outcomes and the member state can ascertain the optimal way to achieve such outcomes. On this basis, it is evidently feasible for member states to adopt standards which are higher than those required by the Directive. Hence the harmonisation brought about through this regulatory format merely provides a minimum threshold or level playing field across member states. It should be noted that the overriding purpose of this document as expounded in (1) is to provide further *detailed* rules over and above those provided in the previous Directive (86/609) to reduce disparities between member states which are ' liable to constitute barriers to trade in products and substances, the development of which involves experiments on animals'. This opening paragraph provides clear evidence of the overriding motive in drafting which might suggest a cautionary use of this document when referring to animal protection.

The Convention has been ratified by the EU as a whole and several other states, acting through the Council of Europe. Despite the extension beyond EU borders, providing a farther –reaching effect, it has no legislative credence and essentially forms a set of guidelines to follow. However, the text of the Directive does largely follow that of the Convention.

The Directive clearly sets out the type of animals to be covered, which includes all non-human vertebrates and cephalopods as well as foetal forms. It provides a detailed description of the type of procedures encompassed by the term 'experimental and other scientific purposes', doing so by using an exclusionary approach which lists those areas of animal use not covered by the provisions.[30] It also sets itself a lofty goal of representing: an important step towards achieving the final goal of full replacement of procedures on live animals for

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[25] Animal Experimentation, supra note 14, at 34.

[26] NHMRC Code, supra note 15, at s 6.

[27] For example, the Animal Research Review Panel in NSW see
http://www.dpi.nsw.gov.au/agriculture/livestock/animal-welfare/research-teaching/factsheets/awfact07.

[28] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes [2010] OJ L 276, 20.10.2010/33 (' Directive 2010/63/EU').

[29] *Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes*, opened for signature 18 March 1986, ETS No. 123 (entered into force 1 January 1991), as amended by ETS No. 170 (entered into force 2 December 2005).

[30] Directive 2010/63/EU, art 1(5).

scientific and educational purposes as soon as it is scientifically possible to do so.[31] However it fails to use the commonly recognised term of 'ethical review' in regard to the decision-making procedure for approval of projects. There is however provision of this through the 'animal welfare body' which comprises of animal care personnel, a scientist and the designated veterinarian.[32]

Whilst adopting EU legislation as a foundation,[33] the UK animal research legislation has been considered the most rigorous in the world.[34] The *Animals (Scientific Procedures) Act 1986* (UK) provides for a centrally administered licensing system which authorises scientific procedures at three levels, namely authorisation of; the person carrying out the procedures, the program of work and the establishment where animals are held and procedures performed. A special inspectorate is responsible for granting licences and inspecting premises.[35] The system has been criticised by scientists for its complexity and bureaucratic nature with concern that, through exclusion of ethics committee involvement, it renders the decision making capacity in the hands of those with little ethical training, who are distanced from the true issues.[36] However, an ethical review process is required to be established.[37] Whilst the form of this is not dictated it is likely to be represented by a committee with designated members, similar to other countries' ethics committees. In reality all protocol applications are required to be considered by this process prior to submission to the Home Office, and there is mention of balancing the input arising from this review with those of the inspectorate.[38] The advantages provided by this central oversight in terms of uniformity of decision-making are considerable. This uniformity would be expected to create clear minimum welfare standards, and enhance transparency to the general public.

3.2 United States of America

With the adoption of a self-regulation model and the federal system, the US is an excellent comparative model for Australia. On the face-of-it the system appears relatively simple with animal use being governed by two federal acts; the *Animal Welfare Act 1966* (AWA)[39] and the *Health Research Extension Act 1985*.[40] However, scratching beneath the surface reveals a complex array of policies, codes and guidance documents covering different animal species, types of institutions and funding arrangements.[41]

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[31] Directive 2010/63/EU, art 1(10).

[32] Ibid art 26.

[33] Directive 2010/63/EU.

[34] Animal Experimentation, supra note 14, at 38.

[35] The UK Home Office is charged with establishing the inspectorate and administering the Act.

[36] P Townsend and D Morton, 'Laboratory Animal Care Policies and Regulations: United Kingdom' (1995) 37 *ILAR Journal* 72.

[37] United Kingdom, *Guidance on the Operation of the Animals (Scientific Procedures) Act 1986* (TSO, Norwich, 2000) app J.

[38] Ibid.

[39] 7 USC 2131-2157 (1966).

[40] 42 USC 289d (1985).

[41] See, e.g., Institute of Laboratory Animal Resources, *Guide for the Care and Use of Laboratory Animals* (National Academies Press, 2011) ('*The Guide*'); Office of Laboratory Animal Welfare, *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington DC, 2002).

The advantages brought about by a federal system of governance are largely negated by the complexity and overlapping nature of these additional documents, and the fact that the majority of animals used in research are exempted from protection. This includes cold-blooded animals such as fish, and rats and mice through exemption under the delegated legislation.[42] Additionally, the AWA is only concerned with the *care* of protected animals in research establishments, as opposed to the scientific validity of procedures performed upon them.[43] Inspectors are appointed to provide central oversight and control.[44]

Much criticism of the US system has been advanced by animal advocates based on the variable protection afforded to different animal species, the lack of prescriptive regulation, and the absence of ethical review. However, whilst this assertion is correct based on consideration of statutory requirements, the use of self-enforcement also plays an important role. In the US the main medical research funding body is the National Institute of Health which administers the Public Health Service (PHS) policy. Non-compliance with this renders the institution at risk of losing access to this valuable funding source, and hence acts as the 'carrot' for compliance. PHS policy requires the formation of an ethics committee equivalent, the Institutional Animal Care and Use Committee (IACUC), plus adherence to a detailed and prescriptive manual pertaining to research animal care and use, the 'Guide'.[45] Thus, in conjunction with the AWA, this policy effectively brings most species and animal procedures under control of an IACUC. It is also of note that a large majority of US research facilities are members of a strict voluntary accreditation scheme.[46]

4. Issues Identified

4.1. The Code

Returning to the Australian jurisdiction, the main focus of attention needs to be directed at the Code since this is the principle governing document for animal use in research and contains the detail pertaining to animal care and ethical review. Whilst the Code itself is a national document, it is of note that it sits beneath State and Territory delegated animal welfare legislation and therefore has no Federal regulatory power. In fact, the provisions therein have no ability to be enforced first-hand; instead acting in the form of a defence (or lack-off) to cruelty prosecution under the primary Act.

The Code in this area of animal use appears to provide refreshing simplicity and uniformity to Australia's complex state-based animal protection system. As a document drafted with input from the industry itself, as well as animal welfare groups, and refined in light of public consultation, surely use of this document represents best practice in animal research? However, a closer look at the primary legislation in a number of jurisdictions suggests that there are a range of legal loopholes and inconsistencies which suggest that the

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[42] *Animal Welfare Regulations*, 7 U.S.C. 2131-2159.
[43] Animal Experimentation, supra note 14, at 44.
[44] The Animal and Plant Health Inspection Service (APHIS), a division of the United States Department of Agriculture (USDA), oversees compliance with the Animal Welfare Act see < http://www.aphis.usda.gov/>.
[45] The Guide, supra note 41.
[46] Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), < http://www.aaalac.org/accreditation/index.cfm>.

Code may not actually be as compulsory as first thought. For instance in NSW, 'the regulations *may* prescribe a Code of Practice'[47] contra an 'animal research authority shall not authorise, or purport to authorise, the carrying out of animal research otherwise than: …..in accordance with the Code of Practice'.[48] The amended regulations do however stipulate the Code as the prescribed one for the purposes of this Act.[49] Yet, the regulations may allow this to be adopted 'wholly or in part, and with or without modification'.[50]

Similarly in South Australia, the sole mention of the Code in the primary act refers to licensing and again implies discretion by use of the word 'may'.[51] This clause (as in NSW) suggests that the Minister may take a piecemeal approach to code incorporation. Additionally in this jurisdiction the Code is not one listed as a prescribed code under the regulations.[52] Similar referral to regulations and use of discretionary language is also seen in other states.[53] Whilst this finding is disappointing in terms of its effect on public transparency and country-wide harmonisation, it could simply have arisen out of political motivation to retain the state's legislature-making ability. It should also be considered that for large academic institutions the risk of loss of government funding due to non-Code compliance may be a bigger stick than any penalty applied under the relevant state legislation. Not so perhaps for non-government funded bodies?

Setting aside the above and turning to the document itself, a cursory glance reveals an abundance of well-considered principles and reassuringly definitive statements such as, '…the use of animals for scientific purposes *must* have scientific merit'.[54] However, it is not quite so clear how this document ensures that these admirable sentiments are achieved. Without even delving into the substance of the document it is evident that there are two general problems which have both legislative and practical effect. Firstly, the language used is littered with the terms 'must' and 'should' which to the ordinary lay person are often regarded as synonymous.[55] However, the Code uses the former to imply an obligation and the latter to imply a strongly recommended provision. Other expressions used include: *regularly, suitable, essential, adequate,* and *necessary* and they are never defined.[56] Secondly, the document is a classic example of a performance-based document,[57] in character with the self-regulatory enforcement model it operates under. Such documents provide the outcomes that need to be achieved and allow the responsible personnel to decide the optimal way of

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[47] *Animal Research Act 1985* (NSW) s 4(1).

[48] Ibid s 26 (2)(b).

[49] *Animal Research Regulation 2010* (NSW) s 4.

[50] *Animal Research Act 1985* (NSW) s 4(2).

[51] *Animal Welfare Act 1985* (SA) s 19(2)(f).

[52] *Animal Welfare Regulations 2012* (SA) sch 2.

[53] See, e.g., *Prevention of Cruelty to Animals Act 1886* (Vic) s 7; *Animal Care and Protection Act* 2001 (Qld) s 15; *Animal Welfare Act* (NT) s 34.

[54] NHMRC Code, supra note 15, at s 1.

[55] See, Charrow, Veda R, Erhardt, Myra K and Charrow, Robert P, *Clear & Effective Legal Writing* (Aspen Publishers, 4th ed, 2007) 183-4. The term 'should' is not quite as contentious as the term 'shall' in legal circles but to non-legal scholars is likely to be confusing.

[56] Katrina Sharman, 'Opening the Laboratory Door: National and International Legal Responsibilities for the Use of Animals in Scientific Research--An Australian Perspective' (2006) 2 Journal of Animal Law 67.

[57] Klein HJ, Bayne KA, 'Establishing a culture of care, conscience, and responsibility: addressing the improvement of scientific discovery and animal welfare through science-based performance standards' (2007) 48 *ILAR Journal* 3.

achieving this. For example: 'animals must be provided with accommodation, physical and social environmental conditions, food, water and care to meet species-specific or strain-specific physical and behavioural needs'.[58] This can be contrasted with a prescriptive document such as the US Guide which provides tables of specific data on numerous husbandry issues, including the temperature at which different species should be housed, and the minimum cage floor required by different weight of rodent.[59] Advocates of the performance-based model cite advantages such as reduced regulatory burden, consideration of local factors, and the fostering of a culture of care through active staff involvement.[60] It is also clear that in such a system it is feasible for standards above that of the minimum to be implemented. However, the reverse also applies, and it would be exceptionally difficult to mount a legal challenge for non-compliance based on the Code wording above. The behavioural needs of animals are widely disputed by eminent animal welfare scientists,[61] is it reasonable to expect researchers and animal carers to be fully cognisant of these needs, and readily able to implement provisions to safeguard them? Interestingly, the EU Directive, perhaps in recognition of this issue, has created a new statutory role for a person 'to ensure that staff dealing with animals have access to information specific to the species housed in the establishment'.[62] An efficient use of performance-based documents requires not only a highly educated and experienced workforce, clear reporting lines and an exemplary organisational culture of care, but an efficient system of outcome monitoring and improvement.[63] Are we secure in the knowledge that this is present in most scientific institutions in Australia?

4.2. Ethics Committees

Animal Ethics Committees (AECs) are of paramount importance in this system of governance. They have been designed to provide community accountability by the inclusion of a 'lay' member and a person with a demonstrated commitment to animal welfare.[64] This committee composition may make our AECs superior to those internationally.[65]

AECs are sanctioned to evaluate research proposals to determine the fundamental question of their necessity.[66] However, there are numerous factors which affect their ability to do this. This includes the quality of the protocols submitted, the individual ideologies of members, and the willingness of members to voice their concerns.[67] More troublingly members are being asked to make decisions involving complex scientific procedures and statistical validity which are far outside their expertise. The nature of today's scientific

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[58] NHMRC Code, supra note 15, at s 2.13.
[59] The Guide, supra note 41, at 57.
[60] Klein and Bayne, supra note 57.
[61] MS Dawkins, 'Using behaviour to assess animal welfare' (2004) 13 *Animal Welfare* S3.
[62] Directive 2010/63/EU, art 24.1(b).
[63] Ibid.
[64] NHMRC Code, supra note 15, at s 2.2.4. The category D member on the AEC is often described as a 'lay' member whilst the category C member is committed to furthering the welfare of animals.
[65] The US IACUC composition varies depending on the document perused but 'the Guide' requires four members which include one public member and one non-scientist, the EU 'animal welfare body' only requires a minimum of an animal carer, scientist and input from the designated veterinarian.
[66] *Animal Research Act 1985* (NSW) s 14(1); NHMRC Code, above n 12, ch 2.3.
[67] Sharman, supra note 56.

pursuits is so variable and specialised that even the scientist member is unlikely to bring detailed knowledge on every protocol considered.

The lack of centralised oversight leads to a number of other concerns. Firstly, different committees' decisions can be highly variable and one proposal may receive different outcomes on consideration by each. Since committees are made up of individuals who bring their own experience and prejudices to the table this result is hardly surprising. It does however do little for public accountability. The lack of detailed prescriptive guidelines on minimum recommendations or refinements does not aid the situation. The status quo when there is disagreement amongst members is also unclear. The Code requires that decisions are made on the basis of consensus.[68] This, it seems provides a good welfare safeguard and allows all members a voice. However, this safeguard is defeated, since 'if consensus cannot be reached after compromise, then decisions can proceed by majority'.[69] Still, the broad stated aim of the Code that, ' the use of animals for scientific purposes must have scientific or educational merit; must aim to benefit humans, animals or the environment; and must be conducted with integrity…'[70] renders it unlikely that a consensus in decision-making could not be achieved.

Despite AECs functioning as government-appointed committees under most state acts, their retention of independence may also be called into question especially when chairs and members may be senior university officials responsible for other conflicting portfolios. This was raised as a potential issue in a recent animal welfare scandal at Charles Darwin University.[71]

4.3. Training and Competence

A key determinant in promotion of animal welfare (and scientific outcomes) during research procedures is the competence of the research personnel carrying out the procedure. Competence is defined in the Code as 'the consistent application of knowledge and skill to the standard of performance required regarding the care and use of animals. It embodies the ability to transfer and apply knowledge and skill to new situations and environments'. It has however been suggested that the main element of 'competency' is a person's behavioural characteristics which underlie their competent performance.[72] Attainment of competence is likely to come about through a combination of formal training, supervision and experience which are elements that legislation can only impact upon minimally. However, law can provide the tools to mandate formal training requirements, and for implementation of systems for its review.

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[68] NHMRC Code, supra note 15, at s 2.3.11.

[69] Ibid.

[70] Ibid 1.

[71] Jane Bardon, 'Not enough done to prevent cattle starvation: ombudsman', ABC News, 29/10/10 <http://www.abc.net.au/news/2010-10-28/not-enough-done-to-prevent-cattle-starvation/2315928>. The ombudsman reported an irreconcilable conflict of interest held by the AEC Chair due to also being deputy vice-chancellor of research, and that this had led to reports being changed prior to review by the vice-chancellor.

[72] Wooodruffe, C., 'Competent by any other name' (1991) 23 *Personnel Management* 30.

The Code requires that all people who use and care for animals *must* be competent in the procedures performed or supervised by others with the requisite competency.[73] Some responsibility for this is devolved to the institution which must ensure that they provide 'adequate resources for appropriate education, training, and assessment of competence of investigators, and certification of such competence to the satisfaction of the AEC.[74] There is no further elucidation on what topics should be considered as part of training programs or how competency outcomes should be measured. Also of concern is that on closer analysis of the Code wording surrounding training it is clear that the Institution's main responsibility is to offer training to investigators, and not to ensure that they have availed themselves of it.[75] As already discussed, the use of undefined terms such as 'adequate' and 'appropriate', and the outcome requirement of being to the 'satisfaction of the AEC' provides a large degree of flexibility and variability in terms of what resources may be offered and processes accepted under the Code. This contrasts with the European model which appears relatively advanced by the requiring of a person(s) on site with responsibility for 'ensuring that staff are educated, competent and continuous trained'.[76] In addition, investigators should be supervised until they have demonstrated the requisite competence. The UK has formalised this requirement by the creation of a new statutory role, the 'Named Training and Competence Officer'.[77] The EU Directive requires that member states publish their minimum requirements with respect to education and training and their requirements for obtaining, maintaining and demonstrating competence.[78]A list of topics for inclusion as part of educational programs is also provided. [79]

Another interesting and relatively unexplored area is the requirements for attainment of surgical competence during research procedures, and even the ability of researchers to be able to legally perform surgery on a research animal. Ordinarily, the performance of surgery on an animal could be construed as an act of cruelty since this would be expected to cause pain. [80] It would be expected that the general defence to cruelty for procedures conducted in the pursuance of research outcomes would apply to research surgical procedures.[81] This however requires consideration of this exemption in the relevant state legislation governing veterinary practitioners and the practice of acts of veterinary science. This is provided for in NSW,[82] but does not appear to be provided for specifically in all jurisdictions.[83]

Given the previous discussion, and that the legality of performance of surgery on research animals appears to be a grey area, the mandating of surgical training for researchers should receive even greater priority. It however receives no greater emphasis in the Code than any other forms of training despite the serious adverse welfare outcomes that can arise due to negligent performance of it. In the centralised UK system of governance all those researchers wishing to perform surgery on animals must provide evidence of completion of a

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[73] NHMRC Code, supra note 15, at s 1.29.
[74] Ibid s 2.1.8(ii).
[75] See also NHMRC Code, supra note 15, at s 2.1.2 (v).
[76] Directive 2010/63/EU, art 24.1(c).
[77] *The Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012* (UK), s 2C (5) (d).
[78] Directive 2010/63/EU, art 23.3.
[79] Directive 2010/63/EU, annex V.
[80] *Prevention of Cruelty to Animals Act* 1979 (NSW), ss 4-5.
[81] Ibid, s 24 (1)(e).
[82] *Veterinary Practice Act 2003* (NSW), s 9 (2) (e).
[83] See e.g. *Veterinary Surgeons Act 1936* (Qld) s 25M (2)(b); *Veterinary Practice Act 2003* (SA) s 39 (2).

specific surgical training course in order to satisfy the Home Office requirements for issuance of a personal licence.[84] The wording of the US Guide in respect to training is analogous to the Code requiring that investigators are trained and competent, however it does provide specific recommendations for training or qualifications that should be expected of various types of staff members involved in research. Nonetheless, many of these requirements are listed in conjunction with the 'should' terminology.[85]

4.4. Veterinary Care

Somewhat uniquely, in comparison to international counterparts, there is no requirement under either primary or delegated legislation to appoint a dedicated veterinary surgeon who is responsible for the health and wellbeing of research animals. Instead there is a Code requirement for institutions to ensure 'availability and access to veterinary advice for the management and oversight of a program of veterinary care, quality management and project design to safeguard animal wellbeing'.[86] There are other parts of the Code where veterinary input is suggested, for example in providing advice on animal health protocols,[87] or in veterinarians fulfilling roles as animal facility managers,[88] and the Institutions should consider appointment of personnel with veterinary qualifications, but at no point is there a requirement for an appointed individual with a relatively fixed set of responsibilities. This contrasts with the statutory appointed Named Veterinary Surgeon role in the UK, the designated veterinarian of the EU and attending veterinarians in the US.[89] It must be considered that the public has a general duty of care to seek veterinary advice for sick animals in their charge under relevant state animal protection legislation,[90] and it would be expected that a parallel duty would exist for animals in research. This is probably provided for by the wording of the Code used above, but given the characteristic separation of research animal regulation from all other animal uses, it would be beneficial to specifically establish this duty to seek advice, and strengthen the role of the veterinarian in research environments. The role of the Named Veterinary Surgeon in the UK is well-defined by the use of supportive guidance notes issued by the Veterinary Surgeons professional body.[91] This not only aids those acting in the role, but provides another impetus to perform the role competently; the bringing of the role under the remit of professional conduct rules. Other international jurisdictions also make reference to the specific expertise required of laboratory animal veterinarians and training programs which allow attainment of this.[92] This, no doubt included,

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[84] Draft guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (as amended), 31. Module 4 training is specifically designed to cover anaesthetic and surgical procedures on animals.
[85] The Guide, supra note 41, at ch 2.
[86] NHMRC Code, supra note 15, at s 2.1.5 (vi).
[87] Ibid s 3.2.1 (iv).
[88] Ibid s 2.5.14.
[89] Javier Guillén (ed), *Laboratory Animals-Regulations and Recommendations for Global Collaborative Research* (Elsevier Academic Press, 2014).
[90] For example, *Prevention of Cruelty to Animals Act* 1979 (NSW), s 5.
[91] RCVS, Code *of Professional Conduct for Veterinary Surgeons*. http://www.rcvs.org.uk/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/supporting-guidance/named-veterinary-surgeons/>.
[92] The Guide, supra note 41, at 24.

in recognition of the diverse range of species and husbandry practices encountered in laboratory animal practice, as distinct from routine veterinary general practice.

4.5. Enforcement

Effective enforcement requires mechanisms for detecting legislative breaches and a readiness to respond appropriately. This may be through administrative sanction (suspension or revocation of licenses) or criminal prosecution.[93] The Code sets out institutional requirements for dealing with complaints or non-compliance in its principles-based fashion. However, what remains largely uncertain is the process for detecting issues in the absence of whistle-blower reports. The majority of states, with NSW as the notable exception, employ little use of outside inspectors and rely on internal monitoring of compliance.[94]

Institutions rarely report on the format used for their internal monitoring of compliance. The Code notes that compliance must be achieved through the AEC,[95] but as a committee composed of a range of internal and external members that may meet only several times a year, it is unlikely that they would have the day-to-day level of oversight required to ensure compliance. In most cases then, the role of detecting and investigating compliance or welfare issues falls to animal facility staff, and the facility veterinarian (often called the animal welfare officer). This latter individual occupies no statutory role, in contrast with the UK,[96] and is merely a suggested institutional appointment under the Code.[97] There also appears to be an inherent conflict of interest in using such internal compliance models. Firstly, these people work closely with the researchers and may lose their impartial decision-making ability. Additionally, in order to safeguard animal welfare and prevent animal suffering we need researchers to consult veterinarians for advice, and not fear punitive action should they do so. This has been resolved in some large US institutions by employing clinical veterinarians, in addition to compliance officers.[98]

AECs are required to participate in facility inspections but this is at a frequency to be determined by themselves,[99] and in reality is unlikely to be greater than semi-annually. These visits are usually announced due to planning requirements. Visit outcomes may show inconsistency across time and across institutions.[100] Committee members are not trained auditors, and with no checklist of criteria, outcomes will largely be dependent on individuals' knowledge and biases. This issue would be resolved if the legislation was more prescriptive

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[93] Sharman, supra note 56.

[94] Animal Experimentation, supra note 14, at 34.

[95] NHMRC Code, supra note 15, at s 2.1.5.

[96] Under the *Animals (Scientific Procedures) Act 1986* (UK) the Named Veterinary Surgeon (NVS) and Named Animal Care and Welfare Officer (NACWO) are required roles under the Act.

[97] NHMRC Code, supra note 15, at s 2.1.5 (vii).

[98] See, e.g., John Hopkins University, *Animal Care and Use Committee* <http://web.jhu.edu/animalcare/about.html>; University of Missouri, Care *and Use of Vertebrate Animals as Subjects in Research and Teaching* <http://www.umsystem.edu/ums/rules/collected_rules/research/ch400/400.020_care_and_use_of_vertebrate_animals_as_subjects_in_research>.

[99] NHMRC Code, supra note 15, at s 2.3.21.

[100] Animal Experimentation, supra note 14, at 37.

in nature, or if institutions adopted established audit templates such as that provided by AAALAC.[101]

Whilst most state acts empower inspectors to perform both routine and unannounced inspections,[102] it is not clear how often this occurs in respect to research establishments. Given that this role is delegated to the RSPCA and the resource constraints of this organisation it is unlikely to be a frequent occurrence.[103] The Code puts in place a system of external review that must be conducted at least once every four years.[104] Whilst this is a useful form of assessment for the institution and could improve practice, there is no requirement for recommendations to be implemented.[105]

The greatest test of enforcement strength is perhaps seen in the number of prosecutions or legal proceedings commenced. Proceedings have been commenced in NSW in relation to animal supply for research, but on no other grounds.[106] The previously mentioned Charles Darwin University case may have been prosecuted under the Northern Territory Act,[107] but the time limit for mounting proceedings was missed.[108] Aside from this no other case law in this area could be sourced. It has been suggested that if such low prosecutions levels were occurring in other areas of self-regulation, that serious concerns would be raised about the efficacy of monitoring and enforcement.[109]

5. Areas for Reform

The critique above provides a number of areas for possible reform. These range between being evidently possible, to requiring some significant shift in political and legal thinking. A number are considered below.

If we are set on the use of a document such as the Code it should at least be given true legal effect in its entirety to allow national harmonisation of the system. States need to trust in the system of code writing and consultation, and remove clauses in their primary acts which allow them to retain decision-making power relating to its implementation. Rendering compliance with the Codes mandatory through the use of administrative means such as licensing arrangements would achieve a similar goal. Although, this would not allow the range of enforcement mechanisms currently available under statute. A superior solution, although requiring considerable jurisprudential development, would be to bring the provisions of the Code out of the delegated legislation and place them in the state's primary animal protection act. This change would allow Code provisions to be enforced directly by rendering a breach of them to be an offence under the Act. Criminal penalties existing under the Act could therefore be applied. This contrasts with the current indirect enforcement of

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[101] Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International, *Accreditation* < http://aaalac.org/accreditation/resources.cfm>.
[102] See, e.g., *Animal Welfare Act* 1985 (SA) s 30; *Animal Welfare Act* 1993 (Tas) pt 5; *Animal Welfare Act* 1992 (ACT) pt 7.
[103] Goodfellow, supra note 21, at 190.
[104] NHMRC Code, supra note 15, at s 6.1.
[105] Ibid s 6.
[106] Sharman, supra note 56.
[107] *Animal Welfare Act* (NT).
[108] Bardon, supra note 70.
[109] Sharman, supra note 56

provisions by use of them as a defence to prosecution. An elevated position in the legislative hierarchy would also give prominence to the sentiments contained within provisions and serve as a beacon for their importance.

Again, controversial, but it is asserted that the principles-based format of the Code is not effective at safeguarding welfare in the current research management climate within Australia. Consideration should be given to creating a more prescriptive-based document based on science-based recommendations used overseas. Indeed there is precedent for this, with such a document already existing in Victoria.[110] Provision of more rigid training guidelines within the Code should be a priority and consideration should turn to the administrative systems that would aid their implementation. Strengthening the role of the veterinarian would also further benefit animal welfare and scientific outcomes.

The cost-benefit analysis role of AECs would be made easier by the inclusion of a mandatory statistician and data-mining role on the committee. Mandating a pre-review of applications for scientific validity by a well-constituted committee of expert scientists would also be beneficial. The background of the AEC chair needs further consideration by institutions and committee-appointment personnel in government, to ensure that the individual can maintain institutional independence, yet is positioned well-enough to receive institutional support in their role.

The Code should be more prescriptive about how compliance may best be monitored. Suggestions include independent compliance inspectors, increased frequency of AEC facility visitations, and the use of specific checklists when visiting facilities to ensure standards are in-keeping with international best practice. In terms of public accountability, government resourcing of more external inspections (and the reporting of these) or encouraging organisations to join voluntary best-practice accreditation schemes would be welcomed. The latter may be achieved through some agreed-upon trade-off in terms of reduced governmental intervention. Greater use of the punitive criminal sanctions available in the framework for cases of clear animal cruelty, would help assure the public about the use of animals in research, and would reduce the risk of regulatory capture occurring.[111]

Australia is not unique in facing such problems; many issues are experienced overseas, or are in fact problems in animal law in general. The very nature of self-regulation suggests that some institutions will have better standards than others due to a variety of factors. However, law should create an equal playing-field, even if that merely sets minimum standards, which are arguably preferential to *no enforceable* standards. It is concluded that there are inadequacies in the current system which have the potential to impact on animal welfare. Additionally, in many cases these issues could be easily rectified if the forces for change were present.

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[110] Department of Environment and Primary Industries Victoria, *The Code of Practice for the Housing and Care of Laboratory Mice, Rats, Guinea Pigs and Rabbits* (Department of Primary Industries, 2004).This is a mandatory code under the *The Prevention of Cruelty to Animals Act 1986* (Vic).

[111] Regulatory capture was described in George Stigler, 'The Theory of Economic Regulation' (1971) 2 *Bell Journal of Economics* 3. The concept describes the process by which regulatory agencies, formed in the public interest, eventually come to be dominated by the industries they were charged with regulating.