Problems with Part 6: Fixing New Zealand's Animal Research, Testing and Teaching Regime

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Introduction

Few topics create controversy and divide opinions like animal testing. Since the early twentieth-century anti-vivisection societies have attempted to prevent animals suffering for the sake of knowledge, yet animals continue to play a central role in scientific research, testing and teaching ('RTT') around the globe.[1] Legislative response to the issue was slow, but where present, the law often acts as an arbitrator, accepting arguments from both opponents and proponents of animal use; allowing animals to be used provided some benefit is be gained and harm is minimised.[2] In New Zealand, the Animal Welfare Act 1999 ('AWA') created a regulatory framework for animal use in RTT that has been hailed as world leading.[3] However in the past three years two very public protests have led Parliament to sidestep this framework and ban animal testing in specific contexts.[4] This raises the distinct possibility that fifteen years after it was formally established, New Zealand's framework is failing and cannot generate fair and balanced arbitration between animal welfare and research.

This paper critically examines New Zealand's RTT framework, and offers solutions for its flaws. Exploring the background to this balancing act, Chapter 1 begins by clarifying the potential harms to animals and benefits from scientific research and testing. It then establishes four key aims for an effective RTT regulatory framework: proper information gathering and processing; flexibility; consistency; and accountability. Chapter 2 surveys the AWA's framework, introducing key regulatory bodies and processes. As the complex system is explored, it becomes clear that decentralised animal ethics committees ('AECs'), are the main decision-making and compliance monitoring bodies within the system. The recent bypasses of this framework adopted by the Animal Welfare Amendment Act (No 2) 2015 ('the

[1] For a summary of the infamous 'Brown Dog Affair' beginning 1903, see: Peter Mason *The Brown Dog Affair: The Story of a Monument that Divided the Nation* (Two Stevens, London, 1997).
[2] Animals (Scientific Procedures) Act 1986, s 5(4); Animal Welfare Act 1999 s 80; Australian code of practice for the care and use of animals for scientific purposes 2004, s 1.
[3] "Ground-breaking Animal Protection Index assesses animal welfare around the world" World Animal Protection International <http://www.worldanimalprotection.org/news/ground-breaking-animal-protection-index-assesses-animal-welfare-around-world>.
[4] Animal Welfare Amendment Act (No 2) 2015; Psychoactive Substances Amendment Act 2014.

Amendment Act'), and the Psychoactive Substances Amendment Act 2014 ('PSAA') are also investigated.

The second half of this paper turns a critical eye to the regulatory framework, comparing the structure outlined in Chapter 2 to the aims from Chapter 1. Chapter 3 outlines poor information systems and poor accountability as weaknesses, alongside an opacity that renders informed commentary frustratingly difficult. The chapter fleshes out these criticisms by drawing appropriate comparisons to more widely studied contexts, highlighting a dearth of compliance monitoring, and widespread conflicts of interest. Chapter 4 proposes a solution to these issues based on a comprehensive restructuring of the framework. Centralisation of AECs and their current functions forms the main theme of the chapter, constructing a system fulfilling the aims described in Chapter 1. The paper also proposes widespread standardisation to achieve consistency across the system, alongside heavily tightened oversight to ensure decision-making and undertaking of RTT activity involving animals in New Zealand is morally acceptable.

Currently, the regulatory system created by Part 6 of the AWA cannot guarantee that RTT involving animals is ethically permissible. This papers proposed systematic changes will construct a more robust framework, generating more ethically acceptable outcomes for animals in New Zealand RTT.

Chapter 1: Research, Animals, and the Law

A: The Balancing Act

The admissibility of using an animal to expand human knowledge is a question of ethical and scientific importance, generally expressed as a utilitarian equation ('the balancing act'): animal use should be allowed in an experiment *only if* the benefit to society of the information gained outweighs the suffering of the animal.[5] Balancing this equation is central to most legislation concerning animal testing and research in first-world countries, including New Zealand.[6] The balancing act can be written simply, but 'animal suffering' and 'benefit to society' are amorphous concepts that can be extremely difficult to calculate and balance. So before exploring the correct legislative approach to the balancing act, clarification and expansion of both components is necessary.

B: Animal Suffering

In 1789, Jeremy Bentham - when writing on animal interests in moral philosophy - famously penned: "The question is not, 'Can they reason?' nor 'Can they talk?' but, 'Can they suffer?'"[7] Today, it is widely known that animals do suffer; and the Nuffield Council on Bioethics lists "morally relevant" considerations, revealing how certain actions will induce suffering by focussing on animal characteristics.[8] These criteria allow departure from a crude assessment of animal suffering based on close an animal is to a human in evolutionary terms. Instead, these characteristics provide a

[5] Simon Festing and Robin Wilkinson "The ethics of animal research" (2007) 8 EMBO Rep 526; Frank Gannon "Animal rights, human wrongs?" (2007) 8 EMBO Rep 519; Peter Singer *Animal Liberation* (Random House, 1995) at ch 1.
[6] Animals (Scientific Procedures) Act, s 5(4); Animal Welfare Act, s 80; Australian code of practice for the care and use of animals for scientific purposes, s 1.
[7] J Bentham *An Introduction to the Principles of Morals and Legislation*, JH Burns and HLA Hart (eds) (Oxford University Press, Avon, 1996).
[8] Nuffield Council on Bioethics *The Ethics of Research Involving Animals* (2005) at 41.

more nuanced approach to determining animal suffering. Sentience, intelligence, and species typical behaviour are the most relevant characters for the balancing act.[9]

i) Sentience

A sentient animal is capable of experiencing its own existence. If a human action engages with a sentient animals pain or pleasure, the human is morally obliged to consider its interests.[10] In higher animals, such experience is beyond doubt. The Cambridge Declaration on Consciousness 2012; issued by eminent neuroscientists, states: [11]

> Convergent evidence indicates that non-human animals have the neuroanatomical, neurochemical, and neurophysiological substrates of conscious states along with the capacity to exhibit intentional behaviours…non-human animals, including all mammals and birds, and many other creatures including octopuses possess these [conscious generating] substrates.

If a conscious animal has nociceptive networks,[12] logically they will subjectively experience pain. The Cambridge Declaration on Consciousness excludes fish and some other vertebrates, and substantial debate exists over whether fish 'feel' pain as opposed to simply reacting to nociception.[13] However fish and other 'lower' vertebrates possess complex sensory systems; show surprisingly complex intelligence; have capacities for social learning; retain long term memories; display tool use and

[9] *The Ethics of Research Involving Animals* raises five "morally relevant considerations": sentience, higher cognitive capacities; the capacity to flourish; sociability; and the possession of a life. Only three are mentioned here as 'sociability' and 'capacity to flourish' are combined in 'species typical behaviour'; and possession of a life is left aside as while no doubt relevant; the extent to which it needs consideration is extremely hard to quantify and philosophically justify. For further discussion, see: Nuffield Council on Bioethics, above n 8, at 47.

[10] Singer, above n 5, at ch 1.

[11] Philip Low, David Edelman and Christof Koch "The Cambridge Declaration on Consciousness" (paper presented to Francis Crick Memorial Conference on Consciousness in Human and non-Human Animals, Churchill College, University of Cambridge).

[12] Nociception is defined as: "The registration, transmission, and processing of harmful stimuli by the nervous system." "*Guidelines for the recognition and assessment of animal pain*, College of Medicine and Veterinary Medicine, University of Edinburgh" <http://www.vet.ed.ac.uk/animalpain/Pages/glossary.htm.> Accessed 3/82015.

[13] This is mainly because fish lack a frontal cortex, which is responsible for feeling conscious experiences in humans. For recent debate, see: Lynne Sneddon "Pain Perception in Fish" (2011) 18 Journal of Consciousness Studies 209; JD Rose and others "Can fish really feel pain?" (2014) 15 Fish Fish 97.

numerical reasoning; and respond to painful stimuli, all indications of sentience.[14] In all likelihood these vertebrates sentient, so waiting for conclusive proof before considering their interests will likely lead to widespread morally reprehensible acts.

ii) Intelligence

Animals with higher intelligence can suffer in unique ways, expanding the range of treatments which will cause harm. For example, rats and monkeys can develop depressive symptoms if unpredictably exposed to repeated stress, an irrelevant concern for less intelligent species.[15] More intelligent animals can also display empathy, and will suffer if aware of other animals in distress,[16] and scared animals can communicate and spread their fear to nearby individuals.[17] These examples demonstrate the importance of considering the animal used and its level of intelligence.

iii) Species-typical Behaviour

Species-typical behaviour becomes ingrained in animals over millennia of evolution, and displaying certain behaviours frequently becomes essential for their welfare. Environmental enrichment can often simply meet these needs; rabbits and rats are both common laboratory animals and are both extremely predator averse.[18] They become far more relaxed in enclosures where they can hide, and also like to explore, forage, and gnaw.[19] Naturally social animals require social interaction to lead 'fulfilled' lives,[20] so depriving sociable species from developing and maintaining

[14] For a full summary of evidence for fish sentience see: Culum Brown "Fish Intelligence, sentience and ethics" (2015) 18 Animal Cognition 1; D Broom "Cognitive ability and sentience: Which aquatic animals should be protected?" (2007) 75 Diseases of Aquatic Organisms 99.
[15] Matthew Boyko and others "Establishment of an animal model of depression contagion" (2015) 281 Behavioural brain research 358; Christopher R Pryce and others "Long-term effects of early-life environmental manipulations in rodents and primates: potential animal models in depression research" (2005) 29 Neuroscience & Biobehavioral Reviews 649.
[16] Preston SD, and De Waal F "Empathy: Its ultimate and proximate bases" (2002) Behavioral and Brain Sciences 25(1), p 1-20.
[17] Kim EJ *et al.* "Social transmission of fear in rats: the role of 22-kHz ultrasonic distress vocalization" (2010) 5 PLoS ONE e15077.
[18] Vera Baumans "Environmental Enrichment for Laboratory Rodents and Rabbits: Requirements of Rodents, Rabbits, and Research" (2005) 46 ILAR J 162 at 162.
[19] At 162.
[20] At 165.

complex social interactions can lead to untreatable and consistent distress.[21] This harm is extremely serious as unlike physiological pain it cannot be alleviated with painkillers. Each species tends to have its own idiosyncrasies, and animal users must accommodate these in order to minimise animal stress.

C: The Benefits of Animal Use in Scientific Research and Testing

Animals are indispensible for current biological and medical research and used widely for teaching and safety testing. Types of use are often split into three categories: basic research; medical research; and testing. The benefits of using animals in each of these areas, along with the particular concerns for welfare that each raises are discussed below.

i) Basic Biological Research

Basic biological research, or 'blue sky research', is research without a direct application. Viewing these studies in isolation often underestimates their overall merit because the benefits of basic research usually accrue from the building of knowledge, rather than the results of any given experiment. Animal research has led to most human knowledge of animal behaviour; the endocrine, immune, and nervous systems; gene functions; and molecular and cellular development.[22]

Animals are excellent subjects for much of this research. For example, developmental researchers discovered that permanent blindness can be induced in the first six weeks of development but not thereafter, after placing eye-patches on kittens.[23] These findings led to the formulation of treatments to maintain vision in children with lazy-eyes. Animal studies can also directly benefit the animals researched; in New Zealand, deer have been grazed with sheep and cattle to investigate the implications that cross and co-grazing has on parasites. Researchers hope that this could help

[21] Michaela Reimers, Franz Schwarzenberger and Signe Preuschoft "Rehabilitation of research chimpanzees: Stress and coping after long-term isolation" (2007) 51 Hormones and Behavior 428.
[22] Nuffield Council on Bioethics, above n 8, at ch 5.
[23] Torsten N Wiesel and David H Hubel "Comparison of the Effects of Unilateral and Bilateral Eye Closure on Cortical Unit Responses in Kittens" (1965) 28 Journal of Neurophysiology 1029; Torsten N Wiesel and David H Hubel "Extent of Recovery from the Effects of Visual Deprivation in Kittens" (1965) 28 Journal of Neurophysiology 1060.

control internal parasite loads inside the deer.[24] More generally, basic biological research on animals has led to almost all biological insights of the last century. Most medical and surgical advances rely on a deep understanding of such systems, and animals have an irreplaceable role in expanding this knowledge base. [25]

ii) Medical Research

Medical and pharmaceutical development and testing often have more obvious benefits than basic research. In contrast to basic research, medical experiments lead to more tangible benefits and more applicable results, determining whether a drug, treatment, or surgical procedure is succeed.[26]

This research has led to enormous benefits for human and animal health. Drug and vaccine development relies on animals;[27] for example the measles vaccine has reduced measles deaths from 2.6 million in 1990, to 145,700 in 2013.[28] Monkeys were used in isolating of the virus, and developing and testing of the vaccine.[29]. Today, monkeys still remain essential tools in vaccine research for malaria.[30] In such drug development, animals are commonly used as disease models, which should mean the symptoms, causes, and mechanics of a disease are the shared between the animal and humans. How well these disease models fulfil these assumptions varies with the type and complexity of the targeted disease.[31] Some argue that *in silico* or systems approach models are more effective at correctly identifying potential treatments than animal models,[32] however is no evidence as yet of their equivalence.[33] In the absence

[24] AgResearch Corporate Office "Final response to S Tomkins" (28 August 2015) at p 8 (Obtained under the Official Information Act 1982 Request to AgResearch Limited).
[25] Nuffield Council on Bioethics, above n 8, at 103.
[26] At 138.
[27] J Rick Turner *New Drug Development* (John Wiley & Sons, 2007), see ch 3 for summary of modern drug development techniques.
[28] "WHO | Measles Factsheet" WHO <http://www.who.int/mediacentre/factsheets/fs286/en/> Accessed Oct 3 2015.
[29] John F Enders and others "Studies on an Attenuated Measles-Virus Vaccine" (1960) 263 New England Journal of Medicine 153 at 154.
[30] Jittawadee R Murphy and others "Using infective mosquitoes to challenge monkeys with *Plasmodium knowlesi* in malaria vaccine studies" (2014) 13 Malar J 1.
[31] Paul McGonigle and Bruce Ruggeri "Animal models of human disease: Challenges in enabling translation" (2014) 87 Biochemical Pharmacology 162 at 163.
[32] Eugene C Butcher, Ellen L Berg and Eric J Kunkel "Systems biology in drug discovery" (2004) 22 Nat Biotech 1253; EE Schadt "Molecular networks as sensors and drivers of common human diseases" (2009) 461 Nature 218 at 163.
[33] McGonigle and Ruggeri, above n 31, at 163.

of more accurate methods, researchers are encouraged to maximise the precision of animal models by using molecular comparison of a disease between potential animal models and humans when selecting a model.[34] From this, researchers can properly design their experiments in order to increase their predictive validity if a treatment appears to succeed.[35]

Even when treatments are discovered without using animal models they are extensively improved and developed using traditional animal research. An example of this is ampicillin, a more powerful and more widely used derivative of penicillin.[36]

iii) Toxicological Testing

Health and safety legislation requires the toxicological testing of substances and medicines to prevent human harm. Accounting for around 20% of the total animals used in drug development, this step is extremely important in ensuring drug, chemical, and food safety.[37] Improperly tested drugs can do serious harm - thalidomide caused birth defects in approximately 10,000 children worldwide, and is put forward as an example of why toxicological testing on animals does not work.[38] However, animal studies detected and helped to prove thalidomide's teratogenicity,[39] but there is no evidence that thalidomide was tested on pregnant animals before it was released to the public.[40] At the time, drug researchers also asserted the initial animal testing was so poor it "should not have been accepted for print".[41] This tragedy is

[34] At 164.
[35] At 164; H Bart van der Worp and others "Can Animal Models of Disease Reliably Inform Human Studies?" (2010) 7 PLoS Med e1000245; Malcolm R Macleod and others "Reprint: Good laboratory practice: preventing introduction of bias at the bench" (2008) 29 J Cereb Blood Flow Metab 221; Michael FW Festing and Douglas G Altman "Guidelines for the Design and Statistical Analysis of Experiments Using Laboratory Animals" (2002) 43 ILAR J 244; Kenneth F Schulz, Douglas G Altman and David Moher "CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials" (2010) 8 BMC Medicine 18; Carol Kilkenny and others "Improving Bioscience Research Reporting: The ARRIVE Guidelines for Reporting Animal Research" (2014) 4 Animals 35.
[36] P Acred and others "Pharmacology and chemotherapy of ampicillin—a new broad-spectrum penicillin" (1962) 18 Br J Pharmacol Chemother 356.
[37] Nuffield Council on Bioethics, above n 8, at 135.
[38] "The Failure of the Animal Model - National Anti-Vivisection Society" <http://www.navs.org/science/failure-of-the-animal-model>.
[39] Anon, "Drugs and the Human Embryo" (1963) 281 The Lancet 705; CTG King and FJ Kendrick "Teratogenic effects of thalidomide in the Sprague Dawley Rat" (1962) 280 The Lancet 1116.
[40] Jack Botting "The History of Thalidomide" (2002) 15 Drug News Perspect 604.
[41] W Lenz "A short history of thalidomide embryopathy" (1988) 38 Teratology 203 at 203.

partially responsible for triggering a regulatory tightening around testing to ensure drug and chemical safety.[42]

Testing the toxicity and dosage of drugs is now mandatory before they are given to human subjects or released to the public.[43] Tests employed vary with the product and toxicity being investigated, however all such tests induce some overt toxicity as a control for experiment methodology, invariably causing suffering in some animals.[44] Moreover, the vast majority of animals are immediately euthanised once testing is completed.[45] Because of the repetitive nature of toxicological testing, replacement of animal tests with non-sentient alternatives have been easier to develop and these alternatives are more widely adopted in testing than other areas of research.[46]

Animal research continues to play an essential role in furthering human biological understanding. In addition to basic research, animals are currently invaluable for making medical discoveries and required for regulatory testing. However, alternatives are slowly being developed, especially where animal use is repetitive and commonplace.

D: The Role of Regulation

The Nuffield Council for Bioethics defines the law's role in regulating animal use as creating a morally acceptable research environment.[47] Many Western systems attempt to achieve this by framing their legislation around the balancing act,[48] assuming if benefit outweighs harm; the research will be widely perceived as morally acceptable.[49] For this reason, much of the following will assess New Zealand's approach to the balancing act, and how this can be improved. However it is argued

[42] Nuffield Council on Bioethics, above n 8, at 135.
[43] At 143.
[44] At 163.
[45] At ch 9.
[46] Jen-Yin Goh and others "Development and use of in vitro alternatives to animal testing by the pharmaceutical industry 1980–2013" [2015] Toxicol Res.
[47] Nuffield Council on Bioethics, above n 8, at 245.
[48] Animal Welfare Act s 80; Animals (Scientific Procedures) Act, s 5(4); Australian code of practice for the care and use of animals for scientific purposes (Australia), s 1; for summary of the balancing act; see above, page 5.
[49] Singer, above n 5, at ch 1.

that the balancing act alone is not enough. To ensure a morally acceptable balance is struck, a number of additional features are essential for the regulatory system. Decision-makers must obtain up-to-date information regarding potential animal suffering and the merit of the proposed use, and the existence of any non-sentient alternatives. Decision-making should be impartial and consistent, creating a somewhat predictable series of decisions. Transparency of, and compliance with these decisions is necessary to ensure that animal use remains morally acceptable, and that outsiders can properly assess the outcomes of the system. Additionally, regulatory systems should also attempt to integrate the Three R's; replacement, reduction and refinement, which focus on the minimisation of animal harm.

i) Information Systems

Firstly, any decision must incorporate up-to-date technical knowledge about the scientific merit of the animal use, the study design, and the moral considerations of the animals concerned. This information should be processed through an unbiased consideration of whether the likely benefit derived from the activity would outweigh the likely suffering.

The role of public opinion in this balance is moot. Generally, opinion is used to bolster pre-existing arguments for or against animal use, and varies widely depending on survey wording and collection methods.[50] In 2007, only 33% of New Zealanders were generally interested in the issue, and approval ratings swung heavily depending on the type of activity.[51] Medical research into seriously debilitating and life-threatening diseases both had 90% approval ratings, whereas testing enjoyed 70% support, dropping further to 40% for cosmetic testing.[52] Bioethicists maintain this should be ignored as the public generally lack a deep understanding of the costs and benefits of experimentation and the moral status of animal interests.[53] However, democratic ethics demand widespread public opinion receives some weight in decision-making.

[50] P Hobson-West "The role of 'public opinion' in the UK animal research debate" (2010) 36 J Med Ethics 46 at 47.
[51] VM Williams, IT Dacre and M Elliott "Public attitudes in New Zealand towards the use of animals for research, testing and teaching purposes" (2007) 55 New Zealand Veterinary Journal 61 at 64.
[52] At 65.
[53] Hobson-West, above n 50, at 48.

ii) Flexibility

The breadth of possible animal use is staggering. In research alone it varies from field surveys,[54] to determining treatments for facial eczema in cows,[55] to complex AIDS research in chimpanzees.[56] Different experiments require different types of information and different expertise, so the system must afford decision-makers enough flexibility to appropriately collect and process information for the relevant range of decisions.[57]

iii) Consistency

Treating like cases alike is a centrepiece of administrative justice.[58] 'Like' in this context refers to animal uses with a similar balance between benefit and harm. Consistency should pervade the system, regardless of the specific decision-maker, representing both a lack of bias among individual decision-makers, and fairness between applicants. Consistency creates predictability, which further benefits applicants by allowing them to determine the likelihood of their proposals approval and saving resources from being wasted on unacceptable proposals.

iv) Compliance

Any regulatory framework of animal use sanctions harm to sentient beings. Therefore rigorous oversight is necessary to prevent any excess harm from being done, either by poor adjudication of the balancing act, or through poor technique employed by animal users. Approval of animal use must be strictly monitored and outside scrutiny must be allowed. Some transparency is essential to enable this oversight.

[54] Simon Tomkins and others "Nest re-use by Dunnocks (*Prunella modularis*) in New Zealand: an uncommon behaviour revealed through a long-term study" (2015) 62 Notornis 96.
[55] AgResearch Corporate Office, above n 24, at 2.
[56] Bénédicte Puissant-Lubrano and others "Modulation of gene expression in CD4+ T lymphocytes following in vitro HIV infection: a comparison between human and chimpanzee" (2015) 26 VirusDis 62.
[57] Ministry of Agriculture and Forestry *Users Guide to Part 6 of the Animal Welfare Act 1999* (2000) at 32.
[58] HLA Hart "Positivism and the Separation of Law and Morals" (1958) 71 Harv L Rev 593 at 624.

v) The Three R's

In 1959, before most countries legally restricted the use of animals in research,[59] two forward-thinking British scientists laid down three principles which have since become a central focus of animal welfare legislation and scientific practice.[60] Known as 'The Three R's', they help to ensure legislation consistently minimises harm to animals. These principles are set out below in order from most to least beneficial for reducing animal harm.

a) Replacement

Replacing animals with non-sentient alternatives while maintaining scientific validity is the chief goal of the Three R's. It is also the most difficult principle to implement as viable alternatives for many animal models or uses do not exist.[61] Moreover, there is little incentive for researchers to replace animals, and meagre funding for the discovery of alternatives.[62] However, in areas such as toxicity testing where tests are specific, repetitive, and widespread pressure for change exists, rapid adoption of alternatives is occurring.[63]

b) Reduction

The principle of reduction commands that experiments use the minimum possible number of animals while maintaining statistical validity. This is usually achieved by reducing variation amongst animals used in experiments, robust study design, appropriate statistical techniques and careful animal choice.[64] Systematic reviews of animal research, which are becoming essential in medical research are a prevalent example of reduction in study design, using less animals, saving costs, and increasing scientific accuracy.[65]

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[59] The first legislation concerning animal welfare was the United Kingdom Cruelty to Animals Act 1876.
[60] William Moy Stratton Russell and Rex Leonard Burch *The Principles of Humane Experimental Technique* (Methuen, 1959).
[61] Fenwick N *et al.* "Survey of Canadian Animal-Based Researchers' Views on the Three R's: Replacement, Reduction and Refinement" (2011) 6 PLoS ONE e22478.
[62] Nuffield Council on Bioethics, above n 8, at 196–198.
[63] Goh and others, above n 46.
[64] Hooijmans CR and Ritskes-Hoitinga M "Progress in Using Systematic Reviews of Animal Studies to Improve Translational Research" (2013) 10 PLoS Med e1001482 at ch 2: Translational Challenges.
[65] At ch 3: Scientific Rationale for Systematic Reviews of Animal Studies.

c) Refinement

This third principle states that any animals which cannot be replaced or excluded must be exposed to as little harm as possible. All aspects of animal use should be undertaken in the least stressful manner by fully trained practitioners. Current best practice aims to refine a broad area including husbandry, storage, pre- and post-procedural care, pain relief during experimentation, and termination.[66]

[66] HM Buchanan-Smith and others "Harmonising the definition of refinement" (2005) 14 Animal Welfare 379 at 381.

Chapter 2: New Zealand's Regulatory Framework

New Zealand's governing legislation is the AWA, which creates a regulatory framework that controls RTT activities involving animals.[67] Organisations wishing to undertake RTT activities require a code of ethical conduct ('CEC') approved by the Director-General of the Ministry of Primary Industries ('MPI').[68] This CEC creates an animal ethics committee ('AEC') for that code holder, which can authorise RTT upon finding a proposed activity passes the 'balancing act' test.[69] This framework is explored in detail below.

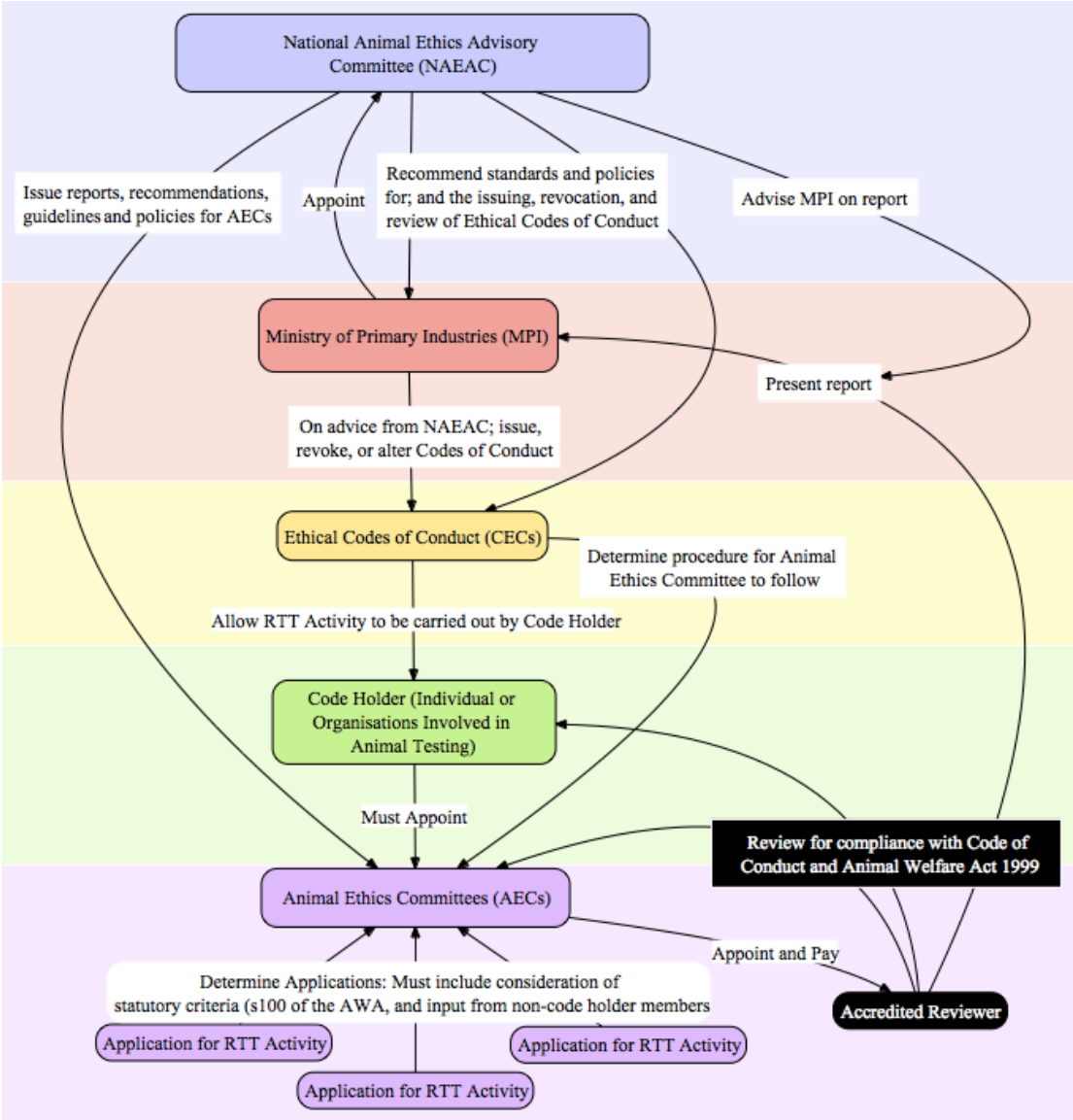

Figure 1: Diagram of the current regulatory framework created by Part 6 of the Animal Welfare Act 1999.

[67] Animal Welfare Act 1999, pt 6.
[68] Animal Welfare Act 1999, s 89(3); 91.
[69] For summary of the balancing act; see above, page 5.

The Amendment Act has introduced slight changes to the regulatory system, which are examined below, alongside restrictions the PSAA placed on RTT activity.

Devised in the early 1990s, the AWA was perceived as a long overdue update of its predecessor, the Animal Protection Act 1960. Its introduction to the House of Representatives stalled until Labour MP Pete Hodgson introduced a private members Bill in 1997.[70] This prompted the National-led Government to introduce its own, very similar Bill through John Luxton; the Minister for Food, Fibre, Biosecurity and Border Control. The Bill became the AWA in 1999, codifying the system of in-house ethics committees, and the National Animal Ethics Advisory Committee ('NAEAC') that oversaw them, which both emerged from a series of statutory amendments in the 1980s.[71]

Jeanette Fitzsimons, reviewing the Bill on the Transport and Environment Select Committee, suggested the Bill was a reaction to international trade pressure from Europe in particular.[72] Nevertheless, she joined her fellow Select Committee members Eric Roy and Luxton in praising the Bill as forward thinking, particularly applauding the flexibility of the AWA, which will allow the AWA to maintain its relevance with changes in the perception of animal welfare.[73] The RTT system created by the AWA was left unchanged until 2014, when the PSAA was passed, causing indirect effects on RTT activity in New Zealand. This was followed by the Amendment Act in 2015.

A: Part 6 of the Animal Welfare Act

Part 6 of the AWA directly concerns the use of animals in any RTT activity. It is separate from the rest of the AWA, and if RTT activity is approved under the regulatory framework, it becomes exempt from Parts 1 and 2 of the AWA,[74] which

[70] Peter Hodgson (16 June 1999) 578 NZPD 17432.
[71] Peter Beatson *Falls the Shadow: The Animal Welfare Debate in New Zealand* (2008) at 5.
[72] Jeanette Fitzsimons (16 June 1999) 578 NZPD 17440.
[73] Eric Roy (16 June 1999) 578 NZPD 17438; John Luxton (16 June 1999) 578 NZPD 17434.
[74] Animal Welfare Act 1999, s 82.

concern general standards of conduct towards animals,[75] and their care.[76] Section 80 of the AWA defines the purpose Part 6; also distinct from the wider purposes of the AWA. Firstly, Part 6 is to ensure a finding or result from using an animal in RTT will enhance understanding of a broad range of scientific aims or achievement of educational objectives.[77] Secondly, any approved RTT activity must pass the balancing act; having benefits that outweigh the suffering or distress an animal is subjected to in the course of the activity. Potential benefit is widely defined, including benefits accruing from planned or co-existing research and literature.[78]

All reasonable steps must be taken to meet an animal's physical, behavioural and health needs,[79] and animals must be treated if they become ill or injured. If the nature of a RTT activity renders treatment impossible, then pain and distress are to be minimised as far as possible.[80] Finally, Part 6 promotes efforts to implement the 3R's in research and teaching.[81]

B: Research, Testing and Teaching in the New Zealand Context

RTT has a wide scope, defined as including any work or teaching that involves the "manipulation" of an "animal".[82] A manipulation is defined as any abnormal or unusual procedure deliberately performed on an animal outside of normal management or practice.[83] It must interfere with the physiological, behavioural or anatomical integrity of the animal,[84] and involve exposure to a parasite, micro-organism, drug, chemical, biological product, radiation, electrical stimulation or environmental condition.[85] Further, it can be an enforced activity, restraint, or

[75] Animal Welfare Act 1999, Part 2.
[76] Animal Welfare Act 1999, Part 1.
[77] Animal Welfare Act 1999, s 80(1)(a).
[78] Animal Welfare Act 1999, s 80(1)(b).
[79] Animal Welfare Act 1999, s 4; defines health needs as including: (a) proper and sufficient food and water; (b) adequate shelter; (c) the opportunity to display normal patterns of behaviour; (d) physical handling which minimises pain; and (e) protection and diagnosis of injury or disease.
[80] Animal Welfare Act 1999, s 80(2).
[81] Animal Welfare Act 1999, s 80(2)(b).
[82] Animal Welfare Act 1999, s 5(1)(a),(b),(c).
[83] Animal Welfare Act 1999, s 3(1)(a).
[84] Animal Welfare Act 1999, s 3(1).
[85] Animal Welfare Act 1999, s 3(1)(a)(i).

nutritional or surgical intervention.[86] Notwithstanding the above, manipulation also includes simply depriving an animal of usual care.[87]

The Amendment Act expands this definition of RTT. From 1 January 2018 "manipulation" will include two new activities; the first of which is killing of animals to use their body or tissues in RTT activity. The second is the creation of animals that are more susceptible to, or at greater risk of pain or distress during their life as a result of their breeding or production.[88] This places the breeding of genetically modified animals, for example mice with immunological defects, within the Part 6 of the AWA; clarifying a long-standing grey area.[89] The definition of RTT was expanded to reflect these changes, but excludes breeding strains for non-scientific work or where it is part of normal animal management or practice.[90]

Not every member of *Metazoa* falls within the ambit of the AWA. "Animal" is defined in s 2 as including most vertebrates; that is non-human mammals, birds, reptiles, amphibians, and bony and cartilaginous fish; as well as any octopus, squid, crab, lobster or crayfish. Pre-natal, pre-hatched, or larval stages of "animals" are excluded,[91] unless they are mammalian foetuses or avian and reptilian pre-hatched young in the latter half of their development or gestation, or marsupial pouch young.[92]

The total number of animals falling within this definition of RTT in New Zealand has oscillated around 280,000 *per annum* for two decades.[93] In comparison, the European Union used 11,480,000 animals in 2011.[94] This appears unsurprising, due to the larger population of the European Union, however *per capita* New Zealand's small

[86] Animal Welfare Act 1999, s 3(1)(a)(ii).
[87] Animal Welfare Act 1999, s 3(1)(b).
[88] Animal Welfare Amendment Act (No 2) 2015, s 6(2).
[89] For discussion of issues see: National Animal Ethics Advisory Committee *NAEAC Policy Statement on the Production of Genetically-Modified Animals* (2002); Melvin B Dennis "Welfare Issues of Genetically Modified Animals" (2002) 43 ILAR J 100.
[90] Animal Welfare Amendment Act (No 2) 2015, s 8.
[91] Animal Welfare Act 1999, s 2(d).
[92] Animal Welfare Act 1999, s 2(b) and (c).
[93] National Animal Ethics Advisory Committee *NAEAC Annual Report 2013* (2013) at 34; National Animal Ethics Advisory Committee *NAEAC Annual Report 2000* (2000) at 16.
[94] European Commission *Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union in the year 2011* (SWD(2013)467, 2013) at 7.

population uses around three times the number of animals (0.06 animals *per annum*) than the European Union (0.02 animals *per annum*).[95]

280,000 animals is probably a slight underestimation of the average number of animals subject to 'manipulations'. This is because manipulations that are necessary for animal welfare or for assessing productivity, and performed under the direct care of a veterinarian are excluded from the definition of RTT.[96] Manipulations involved in routine procedures under the Conservation Act 1987 or Fisheries Acts 1996 are also exempt from RTT,[97] provided these are necessary for:

- assistance in the breeding, marking, capturing, translocation, or trapping of an animal;
- the weighing or measuring of an animal;
- assessing an animals characteristics.[98]

New Zealand also has a uniquely high portion of production animals (cattle, sheep, deer, goats and pigs) used in RTT. Particularly a lot of cattle are used, representing 23% of total animals in 2013, with another 20% of the total made up by sheep.[99] This reflects New Zealand's large agricultural sector, which includes 48,000,000 cattle and sheep,[100] and generates around 4% of GDP,[101] with dairy and meat constituting 20.2% of total exports in 2014.[102]

Potentially as animals have such an important economic role in New Zealand, the commercial sector has dominated total animal use for over a decade,[103] and used 46%

[95] Own calculation, using 2011 European Census data extracted from Eurostat, ("European Commission | Eurostat Census Data" <http://ec.europa.eu/eurostat/web/population-and-housing-census/overview>.) accessed 22/7/2015; and 2013 NZ Population Estimate from Statistics New Zealand ("New Zealand National Population Estimates: At 30 June 2013" <http://www.stats.govt.nz/browse_for_stats/population/estimates_and_projections/NationalPopulationEstimates_HOTPAt30Jun13.aspx>.) accessed 22/7/2015.
[96] Animal Welfare Act 1999, s 5(4) and 5(2)(b).
[97] Animal Welfare Act 1999, s 5(3)(c).
[98] Animal Welfare Act 1999, s 5(3)(a)(i), 5(3)(a)(ii).
[99] National Animal Ethics Advisory Committee, above n 93, at 33.
[100] "Livestock statistics | MPI - Ministry for Primary Industries A New Zealand Government Department" accessed 22/7/2015 <http://www.mpi.govt.nz/news-and-resources/statistics-and-forecasting/agriculture/livestock-statistics/>.
[101] The Treasury *New Zealand Economic and Financial Overview 2013* (2013).
[102] Statistics New Zealand *Global New Zealand - International trade, investment, and travel profile: Year ended December 2014* (2015) at 13.
[103] National Animal Ethics Advisory Committee, above n 93.

of the total animals in RTT activities in 2013.[104] Commercial users mainly undertake testing, veterinary research, and biological agent production.[105] A further 24% of animals are used in Universities and 23% in Crown Research Institutes.[106]

C: The National Animal Ethics Advisory Committee

NAEAC is formally established under s 62 of the AWA, primarily serving as an expert advisory panel to MPI. NAEAC is directly responsible for both advising the Minister of Primary Industries on ethical issues arising from RTT,[107] and making recommendations about approving a specific RTT activity without AEC approval under s 118(3) of the AWA.[108] NAEAC also recommends setting standards and policies for CECs to the Minister, providing advice on their development and review, and recommends the approval, amendment, suspension or revocation of a code.[109] Independent reviews of code holders and AECs are also considered by NAEAC, as are appointments of the accredited reviewers themselves,[110] Finally they can recommend a manipulation be excluded from the definition of RTT under s 3(3).[111]

Membership is determined by MPI with reference to s 64 of the AWA. Appointments must strike a balance between members currently involved in RTT activities, and members somewhat removed.[112] Limited to only ten members, NAEAC must incorporate expertise across the following disciplines:

- veterinary sciences;
- biological and health sciences;
- the commercial use of RTT;
- ethical standards and conduct in respect to animals;
- the use of RTT in schools;

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[104] National Animal Ethics Advisory Committee, above n 93, at 39.
[105] At 39.
[106] At 39.
[107] Animal Welfare Act 1999, s 63(a).
[108] Animal Welfare Act 1999, s 63(j).
[109] Animal Welfare Act 1999, s 63(f), (d), (e).
[110] Animal Welfare Act 1999, s 63(h).
[111] Animal Welfare Act 1999, s 63(b); Summary of functions published in National Animal Ethics Advisory Committee *NAEAC Annual Report 2011* (2011) at 13.
[112] Animal Welfare Act 1999, s 64(c).

- environmental and conservation management; and
- animal welfare advocacy.[113]

NAEAC also publish annual reports,[114] which include animal use statistics, and details of code holders, AECs, and membership.[115]

In advising AECs, NAEAC issues regular reports, guidelines, and policies regarding RTT issues and problems commonly encountered by AECs. These reports offer in-depth information for lay-members of committees,[116] examples of manipulation best practice,[117] and clarification of definitions under the AWA.[118] To date, NAEAC has issued seven guidelines for AEC's, covering topics from teleconferencing;[119] to emergency protocol.[120]

Seven policy statements have also been issued, relating to AEC decision-making and clarifying ambiguities in the law. For example, the NAEAC Policy Statement on the Production of Generically-Modified Animals clarifies the definition of 'animal' in regards to the last half of its period of gestation or development.[121] Finally, as part of promoting best practice throughout RTT activities, NAEAC award the 'Three R's' prize to the person who has best promoted these principles in the last year. [122]

D: Ethical Codes of Conduct

CECs approve holders to use animals in RTT; and outline mandatory procedures and policies in relation to RTT for the code holder and their appointed AEC.[123] In 2013,

[113] Animal Welfare Act 1999, s 64(b)(i)-(ix).
[114] Animal Welfare Act 1999, s 66.
[115] For example; National Animal Ethics Advisory Committee, above n 93.
[116] Ministry of Agriculture and Forestry, above n 57; National Animal Ethics Advisory Committee *A Guide for Lay Members of Animal Ethics Committees* (2007).
[117] National Animal Ethics Advisory Committee *Occasional Paper 10: How to improve housing conditions of labratory animals: The possibilities of environmental refinement* (2014).
[118] National Animal Ethics Advisory Committee, above n 89; National Animal Ethics Advisory Committee *NAEAC Policy on Commercial Cloning* (2003).
[119] "NAEAC Guidelines on AEC's use of Teleconferencing to Assess Protocols" (November 2012) NAEAC 92/12 *NAEAC Guidelines*.
[120] "NAEAC Guidelines on Emergency Management of Animals used in Research, Testing and Teaching (RTT)" (May 2014) *NAEAC Guidelines*.
[121] Animal Welfare Act 1999, s 2(c).
[122] National Animal Ethics Advisory Committee, above n 93, at 13.
[123] Subsection 88(1).

113 organisations or individuals held CECs.[124] This has increased from around 60 in 1993, to over 95 in 2003,[125] and has plateaued at around 110 since 2006.[126] Importantly, CECs define the operation of the organisation's AEC. A CEC must allow the AEC to effectively complete its functions,[127] with effective input from non-employee members sitting on the AEC.[128] CECs must also establish adequate compliance monitoring, data recording, and complaints processes for the AEC, and specify animal management practices and facilities which achieve the purpose of Part 6 of the Act.[129] NAEAC will not issue a CEC unless the organisation complies with regulations and policies promulgated under the AWA.[130]

NAEAC will only recommend the approval of a CEC after it is consulted on both the code and the code holder.[131] The latter must demonstrate the necessary skills and experience to carry out the proposed RTT activities.[132] The Director-General of MPI, currently Martyn Dunne, has powers to impose conditions as he sees fit when approving a code,[133] and the power to change the code upon recommendation from NAEAC.[134] Each code is valid for five years,[135] and requires Ministerial consent to be transferred, even through the sale of the code holder.[136] During the CECs five-year duration, only minor amendments, those which do not materially affect the code's purpose, may be made by the code holder without approval from MPI.[137] Any material amendment must be approved by MPI upon consultation with NAEAC.[138] However, both types of amendment are rare, with only eight amendments having been made since 2009, and only three requiring approval.[139]

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[124] National Animal Ethics Advisory Committee, above n 93, at 17.
[125] See graph: National Animal Ethics Advisory Committee *NAEAC Annual Report 2003* (2003) at 13.
[126] National Animal Ethics Advisory Committee, above n 93, at 16 - 17.
[127] Animal Welfare Act 1999, s88(2)(a). For discussion of AEC functions, see below, page 24.
[128] For discussion of AEC membership, see below, page 26.
[129] Animal Welfare Act 1999, s 88(2)(b),(c),(d),(f) and (e).
[130] Animal Welfare Act 1999, s 88(3).
[131] Animal Welfare Act 1999, s 89(3).
[132] Animal Welfare Act 1999, s 89(2).
[133] Animal Welfare Act 1999, s 91(2).
[134] Animal Welfare Act 1999, s 90.
[135] Animal Welfare Act 1999, s 94.
[136] Animal Welfare Act 1999, s 93.
[137] Animal Welfare Act 1999, s 95(4).
[138] Animal Welfare Act 199995(1) and (3).
[139] National Animal Ethics Advisory Committee, above n 111, at 15; National Animal Ethics Advisory Committee, above n 93, at 15.

MPI may revoke CECs prior to their expiry, whether by application from the code holder,[140] or for a reason detailed in s 96 of the AWA. Reasons for revocation are the code holder no longer wishing to carry out RTT activities,[141] conviction under various Acts of Parliament, including the AWA,[142] failure to comply with regulations under the AWA or the code itself,[143] or if the code holder loses the capacity or skills to carry out the RTT activity.[144] Consultation with NAEAC is a prerequisite for a decision made by MPI under s 96 of the AWA. Between 2010 and 2013, only two were revoked,[145] but unfortunately no details about the reasons for revocation could be found. NAEAC Reports refer to *Welfare Pulse* published by MPI, which does not differentiate between CECs that were revoked and those which lapsed or were voluntarily terminated.[146] However, as external reviews do not appear to have triggered any revocations during this time, it can be inferred these CECs are likely to have been surrendered voluntarily.[147]

E: The Animal Ethics Committee

i) Decision Makers

AECs are the arbiters of the balancing act. Section 90 defines their scope and role as considering, determining, and revoking applications to undertake RTT activities, setting conditions or variations on projects, and monitoring compliance with the AWA. AEC powers are simply those "as reasonably necessary to carry out their functions", and AECs can be shared by organisations if their CEC's allow so;[148] in 2013 there were only 32 AECs for 113 code holders.[149]

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[140] Animal Welfare Act 1999, s 95.
[141] Animal Welfare Act 1999, s 96(2)(a).
[142] Animal Welfare Act 1999, s 96(2)(b).
[143] Animal Welfare Act 1999, s 96(2)(d).
[144] Animal Welfare Act 1999, s 96(2)(c).
[145] National Animal Ethics Advisory Committee, above n 111, at 15; National Animal Ethics Advisory Committee, above n 93, at 15.
[146] Linda Carsons "Codes of ethical conduct - approvals, notifications and terminations since issue 15" [2013] (16) Welfare Pulse at 7.
[147] VM Williams and LA Carsons "Reviewing the Reviews: An Analysis of the Process of Ensuring Regulatory Compliance in the Use of Animals in Science in New Zealand" (2010) 27 ALTEX 203; for discussion of the papers findings, see below, page discussion below, page 36.
[148] Animal Welfare Act 1999, s 90(2).
[149] National Animal Ethics Advisory Committee, above n 93, at 17.

Section 100 mandates the AEC consider the following statutory criteria:

- the purposes of Part 6 of the AWA;
- the scientific or educational objectives of the project;
- the harm and distress caused to the animals and the extent to which this can be alleviated, and how to abandon the manipulation or 'humanely destruct' the animals if their pain or distress cannot be held within reasonable levels;
- whether the study design is reasonable for the objectives of the study and if the number of animals used in the study will maintain statistical validity;
- the choice of animal;
- whether adequate measures are taken to ensure the general health and welfare of animals before and after the manipulation;
- and whether the RTT activity duplicates an old activity and if so, whether this is justified.

The AEC retains a power to determine its own decision-making procedure, however this is subject to limitations within their CEC, or any regulations made under the AWA,[150] however no regulations appear to have been issued.

The Amendment Act adds two criteria to s 100. From 1 January 2018, AECs considering applications for the killing of animals in order to use their tissues in RTT activity will have one consideration; approval will simply require that the animals will not suffer unreasonable or unnecessary pain or distress when killed.[151] Of wider ramification, s 100(1)(fa) requires AECs to consider whether replacing the animals with non-sentient or non-living alternatives has been assessed by the applicants. This explicitly includes replacement as a consideration under the RTT approval process. Arguably, this consideration was already obligatory under purposes of Part 6, which include the promotion of replacement,[152] and replacement is also relevant when examining animal choice.[153] Nevertheless, replacement is the best and arguably only way to completely remove animal suffering in RTT activity, so an unambiguous and unavoidable consideration for AECs can only reinforce its importance.

[150] Animal Welfare Act 1999, s 102.
[151] Animal Welfare Amendment Act (No 2) 2015, s 41(1) and (2).
[152] Animal Welfare Act 1999, s 80.
[153] Animal Welfare Act 1999, s 100(1)(f).

An AEC must have at least four members.[154] One member must be the code holder, or if the code is held by an organisation, must be a senior member of that organisation with the ability to evaluate the scientific or teaching value of projects.[155] Three independent members are mandatory: an independent veterinarian nominated by the New Zealand Veterinary Association;[156] a nominee of an approved animal welfare organisation (currently the RNZSPCA[157] or AWINZ[158]) who is not involved in RTT activities;[159] and an independent nominee from a territorial authority or regional council, who must be removed from the scientific community altogether.[160] Above this minimum, additional members can be appointed by the code holder, provided their CEC allows it. Any AEC member may report non-compliance with the AWA or the authorising CEC. This member then becomes immune from any disciplinary action the AEC faces, and usually remains anonymous unless it is necessary for MPI to identify them to properly investigate the complaint.[161]

ii) Compliance

Internal compliance with project approvals is a responsibility given to AECs.[162] The compliance monitoring process is created by the CEC, and NAEAC produces guidelines for its implementation. These guidelines recommend measures to be adopted "as appropriate to the scope and nature of RTT carried out" under an AEC's authorisation.[163] These range from scheduled and non-scheduled observation of manipulations, to self reporting and post-activity presentations to the AEC, and exist alongside recommended establishment of reporting avenues for whistleblowing.[164]

Independent reviewers are appointed by the AEC, and monitor compliance of the code holder and the AEC with the AWA and the organisations CEC.[165] However, this

[154] Animal Welfare Act 1999, s 101(1).
[155] Animal Welfare Act 1999, s 101(4).
[156] Animal Welfare Act 1999, s 101(5).
[157] Royal New Zealand Society for the Prevention of Cruelty to Animals
[158] Animal Welfare Institute of New Zealand
[159] Animal Welfare Act 1999, s 101(6) and (7).
[160] Animal Welfare Act 1999, s (7) and (8).
[161] Animal Welfare Act 1999, s 103.
[162] Animal Welfare Act 1999, s 99(1)(d),(e).
[163] Ministry of Primary Industries *NAEAC Guidelines for Animal Ethics Committees on Adequate Monitoring*.
[164] At 6.
[165] Animal Welfare Act 1999, s 105; 106(1).

review is limited to the AEC's process, and does not extend to any substantive decisions the AEC makes.[166] The reviewer is paid for their time by the code holder upon prior negotiation,[167] and can be appointed from within the code holding organisation so long as the Director-General of MPI is satisfied they will be able to maintain impartiality. Section 110 implies the reviewer can be someone who helped develop and implement the code being reviewed.[168]

The reviewer creates a report, which is given to the code holder to comment upon, and then presented to MPI.[169] The Director-General then decides whether performance is satisfactory and if not, must inform the code holder what corrective action they must take to become satisfactory.[170]

F: The Psychoactive Substances and Cosmetic Testing Bans

The PSAA did not directly interface with the AWA, but it heavily disincentivised the testing of psychoactive substances on animals in New Zealand. The Psychoactive Substances Act 2013 permits psychoactive substances to be sold if deemed as low risk.[171] However, the PSAA added s 12:[172]

> " Section 12: Advisory committee not to have regard to results of trials involving animals.
>
> (1) In performing the [determination of risk] the advisory committee must not have regard to the results of a trial that involves the use of an animal.
>
> (2) However, the advisory committee may have regard to the results of a trial undertaken overseas that involves the use of an animal if the advisory committee considers that the trial shows that the psychoactive product would pose more than a low risk of harm to individuals using the product"

[166] Animal Welfare Act 1999, s 106(2).
[167] Animal Welfare Act 1999, s 108.
[168] Animal Welfare Act 1999, s 109.
[169] Animal Welfare Act 1999, s 115.
[170] Animal Welfare Act 1999, s 116.
[171] Psychoactive Substances Act 2013, s 11(2).
[172] Animal Welfare Amendment Act (No 2) 2015, s 37 (emphaisis added).

This renders results from an animal trial on psychoactive substances inapplicable by New Zealand regulators, presumably hoping to discourage domestic animal testing of psychotropics. However animal trial data will be accepted in proving a drug is more-than-low risk. Currently, the calculation of a drugs risk without using animal trials is seen as impossible by the Psychoactive Substances Expert Advisory Committee, who assess drug safety under the Psychoactive Substances Act,[173] essentially banning psychoactive substances from sale in New Zealand for the near future.[174]

It has been suggested this amendment was adopted to ban psychoactive substances rather than prevent animal testing,[175] as the amendment merely imposes a disincentive for testing, and still allows psychoactive substances to be tested in New Zealand. This is a weaker restriction than the prohibition on cosmetic testing, examined below. Nonetheless, this amendment has conceivably prevented animal testing occurring, and provides the first example of legislation circumventing the existing system to restrict RTT activity.

The Amendment Act prohibits any RTT activity involving cosmetics or ingredients which are exclusive to cosmetics.[176] This represents the first time RTT activity has been prohibited on the basis of an explicit end product. Currently, this is the only activity where the balancing act is ignored, so regardless of the potential benefit of the RTT proposal, an AEC cannot approve it. Some exceptions are provided, allowing RTT on ingredients if the purpose is unrelated to their use in cosmetics, and allowing non-cosmetic uses of current cosmetic-only ingredients to be explored.[177] The Amendment Act also carefully defines "cosmetic" to exclude anything with a remotely medical use, and regulations promulgated under s 183 can exclude a captured cosmetic from the definition.[178]. This effectively codifies 'cosmetic use' as an improper benefit for AECs to consider in the balancing act. It also provides a

[173] Rychert M and Wilkins C, 2015. "Is the recent ban on animal testing of legal high products a fatal blow to the development of a legal market for 'low-risk' psychoactive products in New Zealand?" Addiction 110(4), p 714 - 715 at [4].
[174] Paul Hutchinson, (06 May 2014) 698 NZPD 17513; Kevin Hague (06 May 2014) 698 NZPD 17531.
[175] Hutchinson, above n 174; Hague, above n 174.
[176] Animal Welfare Amendment Act (No 2) 2015, s 84A.
[177] Animal Welfare Amendment Act (No 2) 2015, s 84(2).
[178] Animal Welfare Act 1999 s 2.

second recent example of the AEC approval system being overruled to bar certain RTT projects being undertaken.

G: Summary

The AWA has created a compartmentalised, in-house AEC system, responsible for undertaking the balancing act and approving RTT applications. AECs are bound by considerations that aim to ensure RTT involving animals occurs only where no alternative exists, and the balancing test is satisfied. NAEAC oversees this system, advising MPI on issuing and revoking CECs, and aid AECs through more complex and controversial areas of RTT activity. Inspectors, paid by code holders, review AEC monitoring of internal compliance with both the AWA, and conditions placed on RTT by AECs themselves. However, recent amendments skirt around the current regulatory system by banning certain practices, either through economic incentives or through statutory prohibition, rather than trusting the present system to prevent actions widely seen as non-beneficial. This begs the question of whether New Zealand's current system can properly undertake the balancing act, or if change is required.

Chapter 3: Critical Review of The Current Legislative Regime

At face value, the framework created by Part 6 of the AWA provides all the necessary components to properly regulate RTT activity,[179] reflected in its ranking as the best in the world.[180] It is centres around the balancing act and the Three R's, providing flexibility and accounting for a wide range of opinions by using an AEC system. However, recent statutory sidesteps of this system suggest serious problems are present within the current framework. When closely comparing the current system to an ideal regulatory regime, inadequacies appear across the frameworks information systems; consistency; flexibility; compliance monitoring; and transparency; and impartiality.

A: Information Systems

Up-to-date information about the animals involved, the experiment, potential alternatives, and lay opinions are all required to determine the costs and benefits of a given RTT activity, and in turn, the balance of moral acceptability. Alongside broad membership, AECs are granted wide powers,[181] and can request more information on proposals from applicants, reflected in 91% of AEC members stating adequate avenues existed for obtaining relevant information needed to make good decisions.[182] This appears to create a decision-making body combining cutting edge scientific knowledge with lay opinions on morality, and independent opinions on animal welfare.[183]

[179] For discussion of a regulatory framework's desired functions see above, page 11.
[180] "Ground-breaking Animal Protection Index assesses animal welfare around the world", above n 3. Accessed 21/8/2015.
[181] Animal Welfare Act 1999, s 99(2); see above, page 25.
[182] Ali Cullum "Training and support for Animal Ethics Committee members" (paper presented to ANZCCART Conference: Mixing it up - ethics, science and adventure tourism, Queenstown, July 2014) at 4.
[183] For discussion of membership see above, page 26.

i) Structural Issues

However beneath this appearance, the AECs have several structural difficulties. New Zealand AECs have been criticised for lacking hard 'ethical' deliberation, and in 2005, ANZCCART [184] recommended that New Zealand require ethicists or philosophers to sit on AECs, adding expertise in ethical reasoning to AECs current skillset.[185] While Human Ethics Committees in Universities around New Zealand include such expertise,[186] their inclusion in AECs is not mandatory. Their presence would lead to better analysis of the available information, and to more ethically robust balancing of the harms and benefits of RTT applications.[187]

A more fundamental issue is whether the structure of AECs affords them the ability to actually determine benefit. They lack both resources, expertise, and time to address the difficult problem of whether a RTT activity will have a large enough benefit to outweigh the given harm, particularly in situations where this harm is serious. While the amendment to the Psychoactive Substances Act 2013 may have been a 'vote grab' of the upcoming election,[188] and arguably cosmetic testing was never going to be allowed in New Zealand regardless of the recent ban;[189] these were both triggered by public distrust of the balancing act and animal testing. Such distrust may be justified by examining the subjectivity and inherent uncertainty involved in calculation of benefit, as opposed to harm.

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[184] The Australian and New Zealand Council for the Care of Animals in Research and Teaching.
[185] Anon "Conference Recommendations" (paper presented to ANZCCART Conference: Animal Ethics Committees and animal use in a monitored environment: is the ethics real, imagined or necessary?, Wellington, June 2005); Dare T, 1997. "Challenges to applied ethics", p 22-28 in: Ruth F Chadwick and Doris Schroeder *Applied Ethics* (Taylor & Francis, 2002) at 27.
[186] For University of Auckland's Human Participants Ethics Committee membership policy and a discussion of structural differences to AECs, see: Tim Dare "Animal Ethics Committees: ethics committees or compliance bodies?" (paper presented to ANZCCART Conference: Animal Ethics Committees and animal use in a monitored environment: is the ethics real, imagined or necessary?, Wellington, June 2005) at 36;
For University of Otago's membership policy see: "Human Ethics Committee, University of Otago Council, University of Otago, New Zealand"
<http://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html#composition >, accessed 22/8/2015;
For membership requirements of the Health Research Council's Ethics Committee, see the Health Research Council Act 1990 s 27.
[187] Chadwick and Schroeder, above n 185, at 27.
[188] Alex D Wodak "New psychoactive substances: reducing the harm caused by untested drugs and an unregulated market" (2014) 201 Med J Aust at 1.
[189] Nathan Guy (30 April 2015) 704 NZPD 3125.

Psychotropics provide a good example. Proponents of the Psychoactive Substances Bill argued in Parliament that animal testing is an initial step in creating a regulated market for safe psychoactive substances.[190] People who get 'high' could do so safely and legally, and addiction could be approached as a medical, rather than a criminal problem.[191] Therefore, this research will lead to maintenance and protection of human health, a consideration for AECs under s 100 (a).[192] Others argue that testing drugs with no therapeutic value will not help promote human health, and that causing animal suffering to test psychoactive substances is morally abhorrent.[193] While knowledgeable, AECs clearly lack the expertise, time, and resources to undertake such complex balancing, especially as this process was a world first, rendering any benefit hypothetical.

The balancing act is still essential in allowing the ethical development of biological science, and the societal benefit flowing from this.[194] However, the calculation of benefit is often too subjective and complex for small, unsupported AECs to achieve, and a large structural change is required to create a considered and coherent approach to benefit which can ensure RTT activity is ethical.

ii) Methodology

Section 102 allows AECs to create whatever decision-making procedure they see fit, so long as they remain within the bounds of the AWA and their empowering CEC. This can be problematic where decision-making becomes majority based. Every CEC must ensure that outside members have "effective input",[195] into the AEC's decisions, yet no membership limitations exist outside the minimum requirements.[196] This creates potential for the external members to become outnumbered by code holder employees or members, raising serious concerns about conflicts of interest, discussed below. NAEAC has responded to this concern by issuing guidelines for laypersons on

[190] Iain Lees-Galloway (11 July 2013) 692 NZPD 12001; Peter Dunne (11 July 2013) 692 NZPD 12000.
[191] Clare Curran (11 July 2013) 692 NZPD 12043.
[192] Animal Welfare Act 1999 s 80(1)(ii).
[193] Eugeinie Sage (2 July 2013) 693 NZPD 11575; Trevor Mallard (2 July 2013) 693 NZPD 11572.
[194] For discussion of the benefits of animal testing, see above, page 8.
[195] Animal Welfare Act 1999, s 88(2)(b).
[196] See above, page 26.

AECs and exemplar CECs.[197] These require RTT applications to be approved by a quorum of at least three, at least two of whom must be external members, and use majority decision-making including at least two outsiders.[198] However, the report also recognises that each code holder operates in different contexts and clearly states this recommended decision-process is non-binding.[199]

In 2000, the Ministry of Agriculture and Forestry (whose functions are now included under MPI) acknowledged that New Zealand was an international outlier in allowing internal members of an AEC to form a majority, and justified this because of concerns over locating relevant expertise within our small industry.[200] While the sincerity of members is widely established from internal and external reports,[201] allowing internal members to form a majority leads to both potential financial and nonfinancial conflicts of interest, which have been shown to have serious implications throughout academia.[202]

iii) Conflicts of Interest

Commercial organisations have a clear financial conflict of interest between undertaking profitable RTT activity, and precluding it on ethical grounds. Financial conflicts of interest have been heavily studied over the last 20 years. Systematic literature reviews found studies with pharmaceutical industry funding more likely to have poor study design, and lead to pro-industry conclusions.[203] For example, in a

[197] National Animal Ethics Advisory Committee, above n 116.
[198] National Animal Ethics Advisory Committee *Guide to the Preparation of Codes of Ethical Conduct* (2012) at 12.
[199] National Animal Ethics Advisory Committee, above n 198 at 7.
[200] Ministry of Agriculture and Forestry, above n 57, at 25.
[201] Mandy Paterson "Reflections on an Animal Ethics Committee" (paper presented to ANZCCART Conference: Science with feeling: animals and people, Auckland, June 2011); Tim Mather "Animal Ethics Committees: a veterinary practitioner's point of view" (paper presented to ANZCCART Conference: Science with feeling: animals and people, Auckland, June 2011); John Schofield "Animal Ethics Committees: a help or hindrance?" (paper presented to ANZCCART Conference: Animal Ethics Committees and animal use in a monitored environment: is the ethics real, imagined or necessary?, Wellington, June 2005); Nita Harding "Reviewing Animal Ethics Committees - The New Zealand Experience" (paper presented to ANZCCART Conference: Getting it Right, Melbourne, July 2007).
[202] Bekelman JE, Li Y and Gross CP "Scope and impact of financial conflicts of interest in biomedical research: A systematic review" (2003) 289 JAMA 454.
[203] GM Swaen and JM Meijers "Influence of design characteristics on the outcome of retrospective cohort studies" (1988) 45 Br J Ind Med 624; Bekelman JE, Li Y and Gross CP, above n 202 at 458; Maira Bes-Rastrollo and others "Financial conflicts of interest and reporting bias regarding the association between sugar-sweetened beverages and weight gain: a systematic review of systematic reviews" (2013) 10 PLoS Med e1001578; dicsussion e1001578.

study of author positions on the safety of a class of drugs known as calcium-channel blockers, 51% of industry-sponsored authors were found to reach supportive conclusions, compared to 0% of independent authors ($p<0.001$).[204] Similar effects are present in systematic literature reviews funded by the pharmaceutical industry.[205] Some AEC members clearly have financial conflicts of interest, and if such conflicts lead to widespread bias in medical studies, they likely cause a bias towards RTT approval in AECs. Even if this conflict is restricted to commercial RTT organisations, they will still be present in decision-making for over half of New Zealand's RTT activity. [206]

The scientific community is also deeply concerned by nonfinancial conflicts of interest, which generally stem from the publish-or-perish state of academia.[207] Researchers have justifiable interests in their own academic careers, so conduct research which aims to provide strong, publishable results and conclusions. If an unethical RTT application is lodged, this interest in pursuing research and the interest in preventing unethical research come into direct conflict. This same conflict can be perceived to be present throughout an RTT organisation, regardless of the presence of the applicant on its AEC. Such conflicts of interest have been recognised in the medical institutional review boards that oversee human trials in the United States of America, which like AECs operate in-house.[208] If human trials suffer from these problems, RTT activity involving animals is likely to be in a worse position as animal experiments are generally viewed as more acceptable and receive less oversight.[209]

iv) Summary

Inspection of the AEC system reveals three key problems. Structurally, altering membership requirements is necessary to create more a robust determination of the benefits of an RTT activity, and the ethical balancing of those benefits and animal

[204] Henry Thomas Stelfox and others "Conflict of Interest in the Debate over Calcium-Channel Antagonists" (1998) 338 New England Journal of Medicine 101.
[205] Anders W Jørgensen, Jørgen Hilden and Peter C Gøtzsche "Cochrane reviews compared with industry supported meta-analyses and other meta-analyses of the same drugs: systematic review" (2006) 333 BMJ 782.
[206] National Animal Ethics Advisory Committee, above n 93, at 39.
[207] Norman G Levinsky "Nonfinancial conflicts of interest in research" (2002) 347 N Engl J Med 759.
[208] Ralph S Freedman and Ross McKinney "Is conflict of interest becoming a challenge for institution-based institutional review boards?" (2013) 19 Clin Cancer Res 4034; Levinsky, above n 207.
[209] Williams, Dacre and Elliott, above n 51.

harm. This may demand an overhaul of the entire AEC system to allow more complex decisions about subjective benefits to be made. AEC decision-making methods need constraining to prevent important outside opinions from being overwhelmed; and the presently widespread conflict of interest in the current AEC system needs to be removed.

B: Consistency

Consistency in this regulatory system is required at two levels, within a single AEC ('internal consistency'), and between all AECs ('external consistency'). Logically, the presence of internal and external consistency will represent an entire regulatory system approving or denying like cases. Unfortunately, directly reviewing internal consistency in New Zealand is near impossible, as substantive outcomes are not reviewed.[210]

Overseas, external consistency has been doubted. In the United States of America research proposals from one group of committees were forwarded to a second group, and 79% of the latter committees responses disagreed with the former.[211] This is despite finding individuals tended to agree on the level of pain that the animals in the proposals would suffer.[212] This enormous discrepancy appears to stem from discrepancies in institutional processes and individual opinions about where the correct balance between harm and suffering lies.[213] In New Zealand, each AEC determines its own processes, so variation between AECs is to be expected, which raises strong doubts about external consistency.[214]

A recent survey of external s 105 reviews indicates AECs adopt a variety of internal approaches.[215] Out of 60 reviews, 12 had procedural "key issues",[216] and 14 were

[210] Animal Welfare Act 1999, s 106(2). For what is included in an external review see above, page 27.
[211] Scott Plous and Harold Herzog "Reliability of Protocol Reviews for Animal Research" (2001) 293 Science 608 at 608.
[212] R Dresser "Developing standards in animal research review" (1989) 194 J Am Vet Med Assoc 1184; Plous and Herzog, above n 211, at 608–609.
[213] Plous and Herzog, above n 211, at 609.
[214] See above, page 23.
[215] Williams and Carsons, above n 147.

criticised for lacking documentation of AEC procedures,[217] whereas other code holders received commendations for excellent AEC recording.[218] This reveals differing approaches to procedure, placing external consistency in doubt, while poor recording of AEC decisions raises doubts about internal consistency.

Without external consistency, the New Zealand system cannot treat like cases alike, and administrative justice is not achieved. AECs are currently afforded too much power to vary their internal procedures under the current CECs, which will lead to AECs approving RTT applications that others would decline. In order to prevent such highly variable approaches to the balancing act, a more universal procedure is necessary.

C: Compliance

New Zealand relies on internal and external compliance monitoring. Internal compliance monitoring is necessary to minimise harm occurring to animals, both from breach of restrictions imposed by AECs on certain RTT activity, and from incorrect manipulation procedure. External reviews supplement internal monitoring by identifying improvements that AECs adopt, and by creating a threat of CEC revocation for the code holder, incentivising good internal processes.

i) Internal Compliance Monitoring

Internal reviews are recommended by the AWA, however the CEC details the most appropriate measures, as not all monitoring procedures are seen as appropriate for all AECs.[219] Instead, NAEAC guidelines suggest for a number of different approaches to be selected from a range of possibilities. This pragmatic approach is sensible, because the variety of procedures falling under the definition of manipulation is so broad.[220] In 2013, 75.2% of animals were subject to manipulations which had "little – virtually no

[216] At 205. Procedural "key issues" for AECs include: AEC not appointed according to the code; lack of documented procedures and approvals; RTT projects occurring without AEC approval; stated standards for quorum, frequency, and recording of AEC meetings.
[217] At 205.
[218] At 205.
[219] Ministry of Primary Industries, above n 163, at 1.
[220] Animal Welfare Act 1999, s 3.

impact"; and since 2000, this averages at 81.1%.[221] These manipulations impose significantly less suffering than "high or very high impact" manipulations which 7% of animals were subjected to in 2013,[222] and manipulations causing large amounts of suffering deserve more intensive oversight.

NAEAC provides a number of methods to select from:[223]

- Scheduled observations of manipulations, possibly by a subcommittee within the AEC to ensure they are being carried out correctly;
- Detailed reviews of completed projects compared to approved protocol, giving more complete overviews of animal suffering than a proposal. These provide valuable insights for future proposals and highlight unanticipated deviations which occasionally occur during research.[224]
- Reports and presentations submitted to the AEC after completion of the RTT activity. These are particularly useful if manipulations occurred off-site and inspection could not be resourced; or where manipulations were low risk and direct oversight was less necessary.

Unscheduled observations are also suggested, but NAEAC warn these "may engender a defensive attitude amongst the RTT community [which] may obstruct the real intent of animal welfare legislation".[225] Reconciling this statement with the AWA is difficult, as a purpose of Part 6 is to ensure that "all reasonable steps are taken to ensure...the physical, health, and behavioural needs of [manipulated] animals are met…".[226] Counter to NAEAC's warning, this suggests AECs should adopt the best possible monitoring methods for ensuring animal welfare, these are undoubtedly unscheduled observations.[227]

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[221] National Animal Ethics Advisory Committee, above n 93, at 43; for details of "little - virtually no impact" manipulations, see Ministry of Primary Industries *Guide to Animal Welfare Statisitics* (2013) at 7.
[222] National Animal Ethics Advisory Committee, above n 93, at 44; Ministry of Primary Industries, above n 221, at 8.
[223] Ministry of Primary Industries, above n 163.
[224] For example, a moderate impact assessment for a study of cow recovery from calving was upgraded to high impact after an unexpected mastitis infection, see: AgResearch Corporate Office, above n 24, at 2.
[225] Ministry of Primary Industries, above n 111; Ministry of Primary Industries, above n 163, at 2.
[226] Animal Welfare Act 1999, s 80(2)(a)(i).
[227] Ministry of Primary Industries, above n 163, at 2.

NAEAC also encourage indirect compliance monitoring, to be undertaken by RTT practitioners. Methods include:

- Researcher-completed animal welfare monitoring systems; which are usually forms, filled out periodically to ensure constant monitoring of animal welfare during manipulations; and
- Establishing whistle-blowing protocol to encourage staff to report non-compliance of colleagues.[228]

However, NAEAC does not provide templates or other standardised methods of implementation to help AECs create these systems.

Evidence suggests NAEAC's recommendations are not leading to stringent internal oversight. Approximately 85% of AEC members inspected RTT projects as a committee, but 65% of those members have only inspected one RTT project.[229] This suggests observations, both announced and unannounced, are rare in New Zealand. Approximately five per cent of members inspected more than six projects a year, but whether a particularly stringent committee was responsible, or whether one member was delegated responsibility for monitoring is unknown.

A summary of external reviews also suggests that internal compliance monitoring is poor. A quarter of monitoring processes were inadequate, meaning either no formal monitoring procedure existed, or that external members never visited a manipulation.[230] However, no follow-up inspections were ordered by the Director-General of MPI unless monitoring procedure was completely absent.[231] This poor monitoring process is reflected in the poor quality of some animal care facilities, which AECs are directly responsible for supervising.[232] "Key issues" identified by external reviews which concerned animal facilities included inadequate ventilation, and poor temperature control which left animals in unacceptably high temperatures.[233] Five reviews also identified inappropriate cages and poor hygiene.[234]

[228] Ministry of Primary Industries, above n 163, at 3.
[229] Unfortunately the results are not more specific; see: Cullum, above n 182, at 93.
[230] Williams and Carsons, above n 147, at 205.
[231] Williams and Carsons, above n 147.
[232] Animal Welfare Act 1999 s 99(e).
[233] Williams and Carsons, above n 147, at 205.
[234] Williams and Carsons, above n 147, at 205.

Moreover, when poor internal compliance is present, internal procedures will miss the majority of RTT protocol breaches. For example, no record of a manipulation going wrong has been reported in over sixty reviews.[235]. This undermines the external review, making it impossible to determine whether a code holder is complying with their CEC or the AWA.

This analysis has revealed a large variety of problems within the internal monitoring process. External reviews highlight deficiencies in implementation and reporting, which suggests AECs lack either the resources or willpower to internally monitor RTT activities. Change is required to remove front-line compliance monitoring from AECs, and re-allocate it to an external body with the proper resources.

ii) External Reviews

The external review process suffers from poor timing, and an underlying conflict of interest. Initiated by the code holder,[236] reviews are required once every five years for established code holders, or after two years if the code holder is new.[237] NAEACs current chairperson calls these "expiry reviews", which summarise the code holder's five year CEC approval. This renders the issues raised in the review irrelevant unless the organisation wishes to continue RTT activity under a renewed CEC. Breaches of compliance with RTT protocol, a CEC or the AWA which emerge early in a code holders approval period may continue for years before they are corrected. If these issues are causing harm to animals, this will lead to large amounts of unnecessary suffering which will go unnoticed and probably unrecorded. This is not only undesirable for the suffering animals, but also for the code holder and the AEC members who may be ignorantly causing harm. Unless this timing issue is rectified, RTT activities are likely to remain poorly supervised and animals will be subject to excess harm.[238]

Of the six current MPI-accredited reviewers, one is chosen by code holder to undertake the external review. If this reviewer is employed by the code holder, the

[235] Williams and Carsons, above n 147.
[236] For description of external review system, see above, page 27.
[237] Williams and Carsons, above n 147, at 205.
[238] Williams and Carsons, above n 147, at 205.

Director-General of MPI can only allow the review if they are confident in the reviewers ability to remain independent.[239] In addition to selecting the reviewer, the code holder also pays them a negotiable rate for the review.[240] This creates a direct conflict of interest – the reviewer has an interest in being paid, and receives a negotiable rate from the code holder with an interest in getting a positive review. No data can be found on how much reviewers are paid for their work, nor whether this correlates to a better review result, so explicit analysis is unfortunately impossible. Nevertheless, a near identical conflict was present between health researchers and the tobacco industry in the 1990s when tobacco-companies wanted results suggesting second-hand smoke was safe. This led to 94% of industry-sponsored studies finding no ill-effects of second-hand smoke, compared to only 13% of independent studies (P >.001).[241]

In the New Zealand reviewers, this potential conflict is exacerbated by having only a few active reviewers – three inspectors carried out 73% of reviews between 2000 and 2010,[242] leaving the reviewers and code holders open to accusations of bias and collusion. Moreover, having such a diminutive group of reviewers is concerning as it limits the variety of expertise for inspection across an extremely broad area of compliance. This weakens the review system by recording a small number of individual opinions on compliance, and increasing the likelihood of poor external reviews.

D: Transparency

A lack of transparency underpins the current regulatory system, creating difficulties in detecting the extent and location of problems.[243] By preventing detailed external review of the system, opacity may lead to a suspicious and adversarial culture.[244] If outsiders could effectively analyse the system, more accurate identification of

[239] Animal Welfare Act 1999, s 109(2)(c).
[240] Animal Welfare Act 1999, s 108(3).
[241] DE Barnes and LA Bero "Why review articles on the health effects of passive smoking reach different conclusions" (1998) 279 JAMA 1566 at 1568.
[242] Williams and Carsons, above n 147, at 206.
[243] For areas of particular concern, see above, pages 32, 35, and 40.
[244] Jane Johnson "Some challenges with Animal Ethics Committees - Can greater transparency help?" (paper presented to ANZCCART Conference: Can we do better?, July 2013).

structural and procedural failings will ensue, helping to improve the system so it better serves the needs of animals and RTT practitioners.[245] Conversely, if the system is well crafted and creates positive outcomes, this can be promoted by independent observers and lead to wider trust in the regulatory system.

Researchers and scientific journals are pursuing this trust by promoting greater transparency to demonstrate their procedures and ethical controls when undertaking experiments.[246] The benefits are twofold – transparency is seen as a counter to the loud media campaigns of animal research opponents, and also increases study quality.[247] This is because results become more reproducible and robust as more precise details of manipulations are released, alongside information about experimental methods, including animal housing and transport conditions.[248]

Research led transparency will assist indirect assessments of New Zealand's ethical decision-making, however much RTT activity does not end in publication. For example, a response to an Official Information Act 1982 request from AgReseach; a Crown Research Institute; revealed that of the nine experiments graded as 'high impact' undertaken over the last two years, only two have led to published papers. [249] Moreover, publication bias will cause an over-estimation of benefits from published research, as papers with important results are far more likely to be published. These factors make it extremely difficult to determine from publications whether an appropriate balancing of benefits and harms is occurring. Further, publications cannot help reveal if the review process is properly catching code holder breaches. In order for these to be to occur there needs to be stronger oversight and an opportunity to assess the outcomes of RTT applications at an AEC level.

[245] Johnson, above n 244.
[246] John C McGrath, Elspeth M McLachlan and Rolf Zeller "Transparency in Research involving Animals: The Basel Declaration and new principles for reporting research in BJP manuscripts" (2015) 172 Br J Pharmacol 2427.
[247] Story C Landis and others "A call for transparent reporting to optimize the predictive value of preclinical research" (2012) 490 Nature 187; Kilkenny and others, above n 35, at 39.
[248] Landis and others, above n 247; Kilkenny and others, above n 35, at 40.
[249] AgResearch Corporate Office, above n 24.

E: Summary

The current structure of RTT regulation in New Zealand suffers from widely embedded conflicts of interest across AECs and the external review system. AECs form the central hub of this system, and to an extent they determine their own process, apply this process, and police the results. These functions must to be separated, to create a more uniform system that avoids these conflicts and creates consistent decision-making across the RTT sector. Currently, compliance monitoring is reduced to self-regulation, and is also subject to a flawed external review occurring at the end of a code holder's approval period. Compounding these issues is a pervasive lack of transparency, which makes any accurate assessment of the system extremely difficult. These issues all require addressing if New Zealand is to adopt robust and trustworthy regulatory regime to supervise RTT activity.

Chapter 4: Fixing the Regulatory Framework

Establishing consistent, transparent, and independent control of RTT activities requires re-engineering of the regulatory system. The criticisms above are deeply embedded in the system itself, stemming from the AWA, which creates supervised self-regulation, rather than independent oversight of RTT. Many problems require individual attention, but removing the pervasive conflicts of interest and opaqueness of the current regime requires an approach which focuses on separating AECs from their parent code holder, and more stringent oversight of the entire process.

Any proposed alternative must also integrate smoothly into New Zealand's particular RTT sector. An alternative system that leads to delays in approval could be ill-received by researchers, particularly if they view ethics as a bureaucratic hurdle.[250] Implementation of an inefficient system would therefore become challenging, even if it solved many current drawbacks. In the medical context, lengthy regulatory processes have serious adverse consequences. Delays in collaborative cancer treatment trials in Australia led to an estimated 60 cancer deaths a year, due to long approval times and burdensome bureaucracy and paperwork, which limited the number of trials research centres could achieve. [251]

The complex, multi-levelled approach of overseas regulatory systems has also been criticised by research doctors and ethicists as inefficient and burdensome. [252] Responding to this fragmentation, the United Kingdom in particular has campaigned for greater centralisation and standardisation of ethical applications and approvals, through centres such as the Health Research Authority, run by the National Health Service. Reflecting this forward thinking approach, the proposal below avoids piecemeal reforms which would add complexity and cause delays. Rather, systemic overhaul of the framework is envisaged, overcoming current weaknesses by

[250] Paterson, above n 201, at 2.
[251] DRH Christie, GS Gabriel and K Dear "Adverse effects of a multicentre system for ethics approval on the progress of a prospective multicentre trial of cancer treatment: how many patients die waiting?" (2007) 37 Intern Med J 680.
[252] Rustam Al-Shahi Salman and others "Increasing value and reducing waste in biomedical research regulation and management" (2014) 383 Lancet 176.

redesigning key processes and roles within the current system. As a result, this chapter details a centralised and simple, but technologically advanced framework.

A: The Proposed RTT Approval System

The proposed system will instate three large changes:[253]

1. Creation of the New Zealand Animal Ethics Committee ('NZAEC') (I). This independent ethics committee will determine all RTT applications classified as 'moderate', 'high', or 'very high' impact on MPI's five-point classification scale.[254] This partly centralises the approval process, but approval of lower impact manipulations is left with existing in-house AECs.

2. Standardisation of the system. Universal CECs will homogenise AECs to reduce conflicts of interest and balance harms and benefits more effectively. Further, RTT applications and some internal compliance will be completed on standardised forms.

3. Replacing the external review system with a larger and independent inspectorate (II) to review code holders and monitor RTT activity, particularly focussing on higher impact manipulations.

Two lesser changes will also be introduced:

1. A mandatory central register of RTT activity will be created (III).
2. NAEAC's capability to ensure RTT activity in New Zealand is ethical will increase; implanting binding official guidelines which AECs and the NZAEC must consider.

[253] See Figure 2; below page 45.
[254] Ministry of Primary Industries, above n 221, at 7–9.

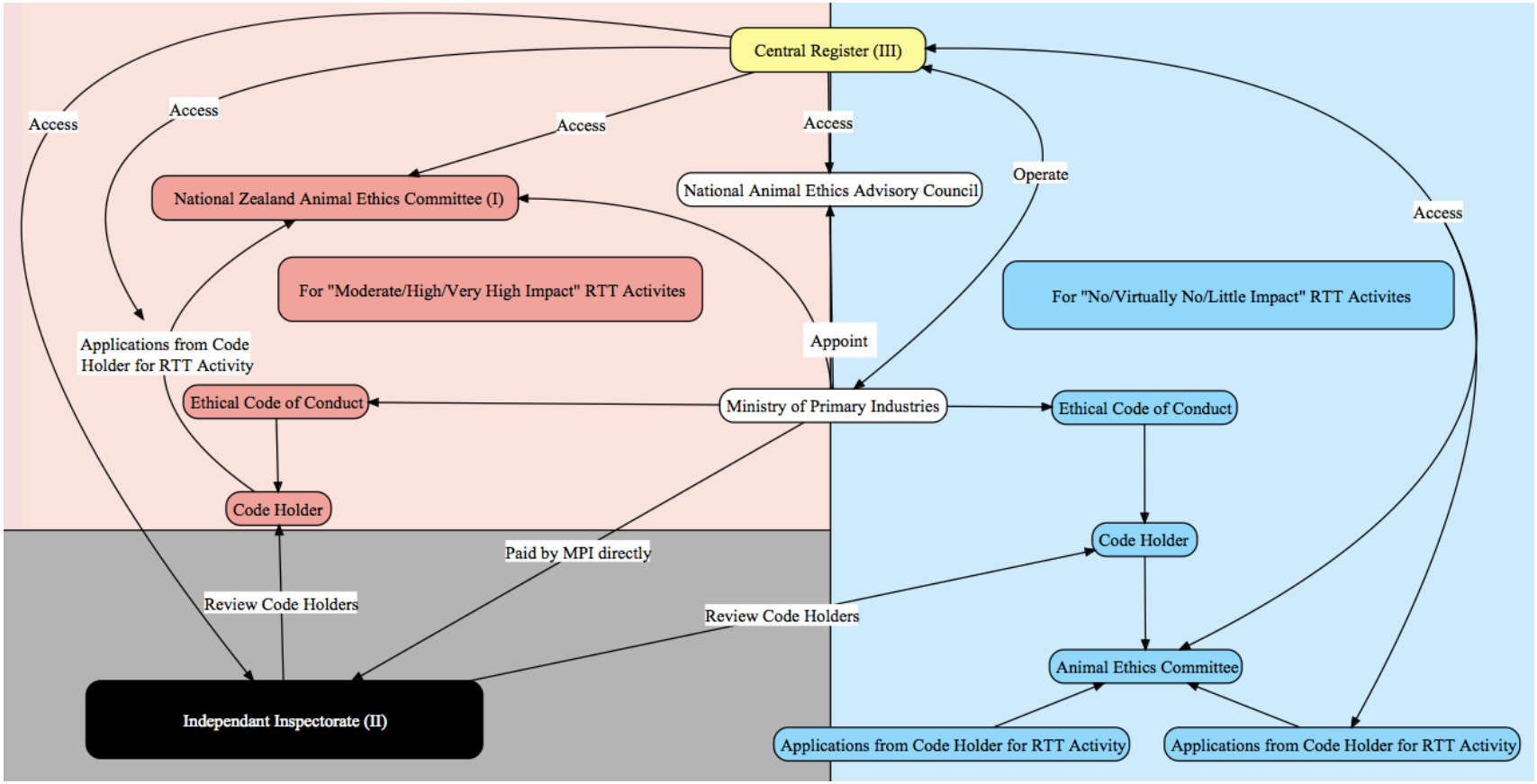

Figure 2: Simplified diagram of new, proposed regulatory system

B: The New Zealand Animal Ethics Committee

The NZAEC will determine all RTT applications rated 'moderate' or above on MPI's five point scale, ensuring all applications with serious implications for an animal's welfare are considered consistently and without the conflict of interest in the current AEC system.[255] The benefits of partially centralising AEC functions are explained below, and solutions are provided for the two largest problems which emerge from centralisation; membership and intellectual property,

i) Partial Centralisation

Dividing RTT applications into higher and lower impacts is an essential step in increasing the quality of the balancing act in more harmful manipulations, while maintaining the efficiency of the current system. Primarily, the split is pragmatic. New Zealand has used approximately 286,000 animals *per annum* over the last nine years, more *per capita* than Europe.[256] Expecting a new body to determine all the applications submitted for this RTT activity is probably unfeasible. By only considering 'moderate' impact to 'very-high' impact RTT applications, the number of animals NZAEC will take responsibility over decreases by 81%, [257] placing approximately 54,300 animals *per annum* under NZAEC's responsibility. This separation makes NZAEC responsible for only six times the number of animals currently overseen by the average AEC.[258] With proper resourcing, NZAEC will be able to easily complete this workload and respond to applications efficiently. Focussing on a smaller but important section of RTT activity will also allow NZAEC to be responsive to the needs of animals and RTT practitioners undertaking more harmful manipulations.

NZAECs threshold is set to 'moderate' impact because this impact grade is where potentially serious harm to animals arises. Below 'moderate' impact, manipulations

[255] At 7–9.
[256] National Animal Ethics Advisory Committee, above n 93, at 34.
[257] 81% is the average number of animals *per annum* subject to 'no or virtually no' impact of 'little' impact. Average calculated since 2001, see National Animal Ethics Advisory Committee, above n 93 at 43.
[258] Own calculation, where 32 AECs oversaw a mean of 8,940 animals each. Based on 2013 statistics, see National Animal Ethics Advisory Committee, above n 93, at 17 and 43;

only induce minor impact for a short duration.[259] A minor impact must be easily tolerated by the animal and not cause any long-term negative effects, and includes manipulations undertaken on animals under complete anaesthetic that will never regain consciousness.[260] 'Moderate' impact activities are either long lasting minor impacts, or involve more severe manipulations, such as:[261]

- exposure to severe cold or hot temperatures for short periods of time (where prolonged exposure will cause collapse);
- induction of clinical parasitism; and
- creating reversible stereotypies due to long-term restraint.

Incorrectly performed, these 'moderate' activities can cause long-lasting damage or death, a risk which is not present in lower impact RTT activities.

Subsequently, balancing the harm in low impact manipulations will require only small benefits.[262] As manipulation severity increases, strong and tangible benefits will be necessary. As explored above, inherent conflicts of interest and the current structure of AECs casts doubt on their capability to determine benefit and properly balance this against animal harm.[263] As an independent and well resourced body, NZAEC can determine applications without inherent bias, ensuring any seriously harm stemming from RTT activity is properly justified.

ii) Consistency and Removing Conflicts of Interest

NZAEC's two major strengths are its centralised position and independence from code holders. By having one large committee review all RTT applications across New Zealand, it will be able to develop a consistent approach and can compare decisions across applicants to maintain this consistency. Independence removes potentially deadly manipulations from AECs with embedded conflicts of interest, allowing their determinations to be undertaken without bias. Having a centralised NZAEC also improves the system beyond solving current issues. Collaborative research can be

[259] Ministry of Primary Industries, above n 221, at 7.
[260] At 7.
[261] At 8.
[262] For "no or virtually no impact" manipulations, no potential benefit will normally be required as the animal will not measurably suffer. See Ministry of Primary Industries, above n 215, at 6.
[263] For discussion of flaws in information systems, AEC structure, and conflicts of interest, see above, page 30.

difficult to initiate due to complex ethical approvals,[264] but in a centralised model collaborative research only requires one application for ethical approval. NZAEC can also improve statistical reporting, being able to record numbers of RTT applications and their approval status, which would help commentators analyse the regulatory system more effectively.

iii) Solutions to Potential Problems

NZAEC members must process a large number of proposals across a very wide variety of scientific disciplines. Many severe tests also use smaller sample sizes for ethical reasons, so NZAEC will be considering large numbers of applications.[265] However, the approval process is easily streamlined, and NZAEC can create sub-committees with specific expertise to determine applications requiring specialist knowledge. Attracting this expertise might be difficult, as most experts with the necessary knowledge are likely to be full-time scientists, but this is an inherent problem with any AEC, which New Zealand has experience in solving.[266] Health and safety regulation often requires periodic animal testing, such as testing shellfish toxicity and live vaccine-testing, and a fast-track process for these applications should be able to reduce the workload for NZAEC.[267]

In-house AECs can easily review commercially sensitive information or intellectual property in applications from their parent organisation. However, protecting commercially and intellectually sensitive ideas becomes a major issue for NZAEC as it is an external body. In a centralised system, this information, along with proposed avenues of research are presented in RTT applications, and will be open for theft by competitors if they sit on NZAEC. Conflicts of interest also arise where a member of the NZAEC stands to benefit by denying an application. These issues can be overcome by requiring NZAEC members to declare any perceived conflicts of interest across financial, commercial, and research related associations. If these will be engaged by an application the member will have to recuse themselves before details

[264] Christie, Gabriel and Dear, above n 251.
[265] For a comparison in animal numbers to current AECs, see above, page 47.
[266] Ministry of Agriculture and Forestry, above n 57.
[267] A Bayvel, LA Carsons and K Littin "Severity assessment - The New Zealand experience and perspective" (2007) 14 AATEX 711 at 713.

are released, preventing idea theft and bias. Combined with strong non-disclosure agreements, most worries about intellectual property theft and bias will be calmed.

C: Standardisation

New Zealand has adopted a very inconsistent approach to RTT applications, monitoring, and decision-making. Establishing NZAEC will reduce variation in high impact RTT approvals, but widely implemented standardisation is essential to secure consistency across the regulatory system. This will reduce internal inconsistency, and create a more homogeneous approach to RTT applications by both AECs and applicants.[268]

i) Standard CECs

Under the proposed model, MPI will only approve a CEC selected from pre-existing options. As code holders can widely vary and some flexibility is required in the system, a number of CECs tailored for large or small organisations; and research or teaching or testing activity will be designed, adapting a standard approach to suit interested organisations. Prospective code holders will have to select the CEC which they find most appropriate for their organisation.

NAEAC has already issued a CEC template, but this acts as a guide for code holders to help their CECs to remain within the statutory criteria.[269] The standard CECs will go further, comprehensively setting out AEC procedure to minimise conflicts of interest, and AECs will be forced to adopt this procedure under section 102 of the AWA.[270] The CECs will prevent members with conflicts of interest from approving RTT applications without support from external members. NAEACs template AEC process provides a useful exemplar,[271] requiring majority support from the entire AEC and a two-thirds majority from the three external members; the veterinarian, the

[268] See Plous and Herzog, above n 211, at 609; for discussion of consistency, see above page 35.
[269] Animal Welfare Act 1999, s 88.
[270] This allows AECs to determine their procedure except as provided by their CEC; see Animal Welfare Act 1999, s 102.
[271] National Animal Ethics Advisory Committee, above n 198, at 12.

interested animal welfare representative; and the non-scientific layman.[272] By sharing the same process, decisions between AECs are likely to be more similar, and external consistency will increase throughout the system.

Implementing these standard CECs is potentially achievable by an Order in Council under s 183 of the AWA. This section gives the Governor-General the power to issue regulations that prescribe standards and policies which must be included in every CEC. However, as discussed above, a flexible group of standard CECs is preferable, but would require more complex implementation. The Director-General of MPI has a discretion to approve codes under s 91 of the AWA, and this section needs be amended to restrict the Director-General so they can only issue CECs which are standard templates. Without the amendment, NAEAC could recommend the Director-General does not issue any non-standard CECs, but if the Director-General declines to issue CECs which meet the s 89 criteria, the possibility of judicial review proceedings is created, rendering a statutory amendment preferable.

ii) Standard Application Forms

Standard application forms will increase the internal and external consistency of AEC decision-making. Reviews have repeatedly found standardised application and monitoring documents were missing, causing applicants to suffer from a lack of guidance and AECs to potentially examine the wrong type of information. Making AECs create their own application forms also exacerbates poor documentation of AEC activities.[273]

Universal, simple, and well-designed forms will ensure RTT applications contain the necessary information concerning the benefits and harms of the activity. This will ensure AEC decisions are well informed, and save code holders time and money by reducing the time by applicants and AECs spend on ethical approval. Standard forms will also include the AEC's recommendations for proposals, helping applicants get clear feedback. This consistent information gathering will help increase internal

[272] Animal Welfare Act 1999, s 101.
[273] See discussion above, p 32; Williams and Carsons, above n 147, at 205.

consistency, creating a more predictive and clear system for AECs and applicants.[274] Further, by having to provide comprehensive details in RTT proposals, ethical reproducibility will increase and help internalise ethical processes into scientific research, rather than those processes being seen as impediments.[275]

External consistency will also be improved with standardised forms, unifying the information AECs receive, increasing AEC homogeneity. [276] Cross-AEC standardisation will also help smooth the transition for applicants who change organisations, and simplify collaboration over multiple organisations as one set of documents could be sent to all the relevant AECs.

Moreover, standardised forms will be invaluable tools for entrenching best-practice in research and testing.[277] Biological sciences have pushed for proper calculation of sample sizes for over a decade,[278] but little improvement has occurred in study design or reporting.[279] To ensure experimental effects are properly detected, and that a statistically significant result reflects a true effect, sample sizes must be large enough to generate the necessary level of statistical power.[280]

Application forms will require a calculation of statistical power, alongside comprehensive details about the strains of animal used, their sex, and other factors for controlling experiments. This is especially important in high impact RTT to ensure animal numbers are accurately reduced to an ethically acceptable level.[281] Proper calculation of sample size will avoid underestimation of animal numbers, a

[274] James A Anderson, Marleen Eijkholt and Judy Illes "Ethical reproducibility: towards transparent reporting in biomedical research" (2013) 10 Nat Meth 843 at 844.
[275] At 844.
[276] Plous and Herzog, above n 211, at 609.
[277] Kilkenny and others, above n 35.
[278] Festing and Altman, above n 35.
[279] Saurav Ghimire and others "Oncology trial abstracts showed suboptimal improvement in reporting: a comparative before-and-after evaluation using CONSORT for Abstract guidelines" (2014) 67 Journal of Clinical Epidemiology 658 at 5; David Baker and others "Two Years Later: Journals Are Not Yet Enforcing the ARRIVE Guidelines on Reporting Standards for Pre-Clinical Animal Studies" (2014) 12 PLoS Biol e1001756 at 3; Katherine S Button and others "Power failure: why small sample size undermines the reliability of neuroscience" (2013) 14 Nat Rev Neurosci 365 at 369.
[280] For expansion on the problems of poor study size and statistical power see: van der Worp and others, above n 35; For guidelines for calculation of sample sizes and study design, alongside other recommendations for robust biological studies see: Macleod and others, above n 35; Kilkenny and others, above n 35; Kenneth F Schulz and others above n 35, at 3–4.
[281] Festing and Altman, above n 35, at 245.

widespread problem throughout biological science, and prevent misidentification of effects and subsequent repetition of experiments.[282],

Standardisation of both CECs, and application forms will increase internal and external consistency across AECs. If properly drafted, these proposed forms will also lead to better consideration of the harms and benefits of given experiments, and lead to better biological scientific research and testing emerging from New Zealand. This will be a world-leading way to ensure scientific best-practice across a nation.

D: An Independent Inspectorate

The compliance and review system is currently ineffective. The small pool of accredited reviewers are perceived to have large conflicts of interest, and compliance checking is left to AECs, leading to poor monitoring which in turn weakens external reviews.[283] Rectification requires an expanded, independent inspectorate; external oversight of internal compliance processes and an expansion of external monitoring beyond the current review system; and increasing the efficacy of the external review system.

i) Independent Inspectors

Accredited reviewers will be replaced with a number of full time inspectors who are directly employed by MPI. These inspectors will become responsible for supervising internal monitoring by AECs, directly observing higher impact manipulations, and completing external reviews. Part 6 of the AWA will need widely amending to achieve this, but this proposal is essential to remove the perceived conflicts of interest from the review system.[284]

[282] At 244.
[283] See discussion of review system, beginning above, page 36.
[284] See discussion of external reviews above, page 39.

ii) Compliance Monitoring

AECs will still be responsible for all indirect monitoring, including detailed post-RTT activity reviews, and researcher completed animal observation or welfare records.[285] Standard CECs will help enforce direct monitoring methods by including a required number of observations of RTT manipulations *per annum*. This number will increase in proportion to the number and impact rating of RTT projects the code holder undertakes. [286] This means all RTT is subject to similar monitoring regardless of code holder.

Additionally, all activities requiring NZAEC approval will be subject to unscheduled observations by relevantly trained inspectors. These unscheduled observations are the best method of ensuring compliance with NZAEC protocol, so form an integral part of the new inspection regime. [287] Moreover, electronic monitoring of RTT activities by video-link will be possible in the near future, and may revolutionise inspection of high impact manipulations and RTT activities.[288] The redrafted review sections of Part 6 of the AWA must allow these and other innovative methods of observation to be introduced, which will lead to more comprehensive and efficient compliance monitoring.

iii) External Reviews

External reviews are essential to oversee AEC and code holder compliance, but need to become unannounced and randomised within the current five year window, rather than "expiry reviews".[289] By becoming unannounced, inspectors will gain a more representative view of the organisation's procedure, and randomisation will allow problems to be identified earlier in a code holder's approval period, rather than upon expiry, after the problem has potentially persisted for five years.

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[285] Ministry of Primary Industries, above n 163, at 3.
[286] Higher impact ratings will require more observations, as they are more harmful and errors in manipulation can lead to extreme adverse consequences for animals welfare, see above, page 46.
[287] Ministry of Primary Industries, above n 163, at 2.
[288] Electronic monitoring is already being implemented to monitor New Zealand's fishing industry, and in seen as the future of fisheries observation. See J Ruiz and others "Electronic monitoring trials on in the tropical tuna purse-seine fishery" (2015) 72 ICES J Mar Sci 1201; H McElderry and others *Electronic monitoring in the New Zealand inshore trawl fishery: a pilot study* (9 2011).
[289] Williams and Carsons, above n 147, at 205; for detailed issues with 'expiry reviews' see above, page 39.

E: A Central RTT Register

An electronic central register of RTT activity will increase the regulatory systems consistency, efficiency, and monitoring capability. All the documents associated with RTT applications will be stored, and differing levels of accessibility can be given to applicants, AECs, NAEAC, independent inspectors, and outside observers, allowing them to access relevant applications and information.

When electronically lodged, an RTT application will automatically be forwarded for approval depending on their impact level, to either the corresponding internal AEC, or the new NZAEC. In order to protect intellectual property, applicants and code holders will be able to highlight sensitive information to be redacted unless the user has explicit permission to access it. This ensures such information is restricted to those who have rights to it, or those that require access to carry out statutory functions, like AECs or inspectors. If approved, RTT application files will eventually include records of internal and external monitoring, their completion status, and their final review. Data which currently goes unreported will be collected, such as how many RTT applications are made, rejected, altered, and their average approval time, providing information for outside commentators, and for monitoring the systems internal efficiency.

This database has uses at every level of the regulatory system. Applicants will be able to monitor their applications, and easily check which monitoring procedures need to be followed. They could also search for similar applications by animal or manipulation type to investigate whether an application is likely to be approved. AECs and NZAEC will have an archive of their own decisions to maintain consistency. NAEAC will be able to access decision summaries to help promulgate new guidelines and recommendations. All relevant monitoring records will be uploaded to the application file, which will be accessible by inspectors, who will have to notify AECs when compliance is unsatisfactory.

The central register will also allow outsider observers to access basic summaries of RTT activity across the system. As with Official Information Act 1982 requests, sensitive information will be redacted, but experiment aims and manipulation details could be acceptable for release.[290] Significant statutory amendment will be required to allow this information to be released without legal impediment, and agreeing to such release will have to be a condition of CEC approval. This invasion of privacy is justified as accessing this information for all of New Zealand's RTT activity will greatly increase transparency and improve the quality of outsider commentary.

F: A Stronger NAEAC

Currently NAEAC promotes humane science by encouraging the 3Rs, running best practice workshops, lobbying for endorsement of alternatives where appropriate, and distributing newsletters to AECs.[291] However, a number of changes to a more heavily resourced and active NAEAC are proposed. It will adopt a role creating binding guidelines for balancing harms and benefits when assessing RTT applications. NAEAC can also currently advise the Minister of Primary Industries to remove a procedure from the definition of manipulation, and a converse ability to advise on new procedures to be included in the definition of manipulation is suggested. NAEAC will also assume the same oversight of NZAEC which it has for AECs.

i) Guidelines for the Balancing Act

NAEAC will gather the necessary expertise and examine manipulations which are particularly controversial. These investigations will lead to a new type of official guideline covering a defined manipulation, providing examples of what is and is not an appropriate balance of harms and benefits, and advising whether replacement techniques should be adopted instead of using animals. The Minister of Primary Industries, on their advice, will be able to issue these official guidelines under a newly created statutory power. Section 106(2) of the AWA will need amending so inspectors can review the appropriateness of a determination, based on a comparison of the

[290] AgResearch Corporate Office, above n 24.
[291] Bayvel, Carsons and Littin, above n 267, at 713.

decision with the relevant official guideline promulgated through the Ministers new statutory power.

Assessment will be based whether the AECs decision is within what a reasonable AEC would decide when having regard to the relevant official guidelines, and any review can be appealed to NAEAC. If a decision is found to breach this standard, there would be no official sanction for AEC members, so membership is not discouraged, but the code holder would become liable for a fine added to the AWA.[292] Breaches of this standard will also become another factor the Director-General must consider when contemplating code revocation.[293] The NZAEC will be held to the same standard, and notified if NAEAC or the inspectorate considers they have fallen outside the reasonable standard for an AEC.

This will help the regulatory system to make better decisions about RTT activity, by incorporating the objective determination of experts who are given adequate time to fully consider the balance of harms and benefits. By providing detailed and binding guidance to AECs, the decision-making system will better balance harms against benefits which are somewhat subjective or hypothetical, addressing deficiencies present within AECs determination of benefit.[294]

It also adds flexibility as NAEAC will be able to effectively ban a manipulation outright by recommending restrictive official guidelines are issued. For example, these guidelines could have been utilised to determine whether animal tests of psychoactive substances or cosmetics were ethically acceptable, rather than relying on statutory amendments.[295] Guidelines including examples of appropriate replacement techniques will help maintain the RTT systems relevance, by enforcing adoption of replacement techniques. Finally, the new guidelines will also help generate consistency throughout the regulatory system by providing clear and reasoned exemplar determinations for specific manipulations.

[292] Animal Welfare Act 1999, s 119.
[293] Animal Welfare Act 1999, s 96(2).
[294] For current problems AECs face when calculating benefit, see above, page 31.
[295] Animal Welfare Amendment Act (No 2) 2015, s 10; Psychoactive Substances Amendment Act 2014 2014, s 12.

ii) Adding to the Definition of 'manipulation'

The variety of manipulations animals are subject to in RTT activity is extremely broad, and is only expanding. The propagation of genetic techniques is rapidly accelerating, and new techniques are likely to fit poorly into the AWAs definition of manipulation.[296] Fifteen years after the AWA was first passed, the Amendment Act expanded the definition to include two new procedures,[297] and for New Zealand's regulatory system to stay relevant, an ability to include new activities within RTT is necessary. Statutory amendments will be required to give the Minister a second new power; adding new activities to the definition of 'manipulation'. This will operate in a similar manner to the Misuse of Drugs Act 1975, which adds drugs to different schedules by Orders in Council issued by the Governor-General, on the Minister of Health's advice.[298] Adopting this model, a schedule of procedures that are added to the definition of 'manipulation' under the AWA will be created. The Minister of Primary Industries will advise the Governor-General when to add new procedures, and NAEAC will adopt a role advising the Minister of Primary Industries of when a procedure should be added. This power is unlikely to be exercised often, but it incorporates another layer of flexibility to prevent regulatory disconnection and ensure use of animals in New Zealand retains ethical oversight.

Proposals for a stronger NAEAC will increase flexibility and determinacy in the current regulatory system. These benefits will help the system stay relevant, allowing it to address complex and controversial balancing acts in a more robust manner, and prevent regulatory disconnection.

G: Reforming the Animal Ethics Committee

Ignoring embedded conflicts of interest and potentially weak information processing,[299] the underlying AEC system provides a useful method for information gathering and incorporating a range of views when determining RTT applications.

[296] Asude Alpman Durmaz and others "Evolution of Genetic Techniques: Past, Present, and Beyond, Evolution of Genetic Techniques: Past, Present, and Beyond" (2015) 2015, 2015 BioMed Research International, BioMed Research International e461524 at 5.
[297] Animal Welfare Amendment Act (No 2) 2015, s 6.
[298] Misuse of Drugs Act 1975, s 4.
[299] For issues with the information process within AECs, see above, page 30.

Standardised CECs will minimise the conflicts of interest, but further changes to their personnel are proposed to improve their ethical decision-making.

Firstly, AECs will recieve wider expertise in the form of two additional external members. Section 101 of the AWA already requires three external members, a layman appointed by the territorial authority, a member of an animal interest group, and an independent veterinarian. The new roles, a statistician and an ethicist, require s 101 to have two additional subsections. A statistician will be required to comment upon the statistical validity of a proposed RTT activity, and additionally provide a non-biological scientific perspective on animal use. An ethicist or philosopher will also be necessary to create stronger ethical deliberation and better arbitration of the balancing act,[300] as well as bringing New Zealand AECs in line with Australia and endorsing ANZCCART's 2005 recommendation.[301]

Secondly, the majority of AEC members need to be external so the conflicts of interest arising from internal members is minimised. Section 101 will need further amendment, mandating the external members always remain in the majority. Therefore, if a code holder wants five internal members, an additional external member with no financial ties to the organisation will be need to be added. This balance must be maintained *ad infinitum*. A final statutory amendment to s 103 of the AWA is also required to make reporting non-compliance by AEC members mandatory, rather than simply allowing it.

As earlier proposed, AECs will be improved with the introduction of standardised CECs and forms. When coupled with expanded expertise and minimised conflicts of interest, AECs will become well placed to determine RTT applications and perform robust ethical deliberation.

[300] Dare, above n 185, at 27.
[301] Anon, above n 185.

H: Summary

This proposal focuses on systemic overhaul of New Zealand's regulatory framework, and requires wide changes to Part 6 of the AWA. By implementing the NZAEC and an independent inspectorate, perceived conflicts of interest are removed or minimised from both the review and decision-making processes, creating a system with less perceived bias. NAEAC will become a more powerful supervisory committee, able to constrain AEC and NZAEC decisions in ways currently impossible, and receive an ability to prevent regulatory disconnection as science and research progresses. Standardisation will help increase the consistency and efficiency of the system, and partial centralisation of RTT approvals under NZAEC will make ethical deliberation over dangerous animal uses more robust and independent.

Conclusions

Prima facie, New Zealand's RTT framework appears to fulfil the aims of effective regulation. Chapter 2 revealed AEC decision-making that is correctly based upon the balancing act, and incorporates a variety of information when considering applications. An external review system exists to hold AECs accountable, and NAEAC releases clear animal use statistics.

However, Chapter 3 finds cause strong for concern. AECs, to draw a final analogy, are the legislators, judges, and police of their own jurisdiction. By itself, this is worrisome, but this issue is compounded by the stark conflict of interest which incentivises AECs to allow RTT for intellectual or financial purposes; and disincentives the preclusion of RTT on ethical grounds. A similar financial conflict of interest is present in the weak external review system, which heavily relies upon AECs internal monitoring to prevent excess harm to animals. Such conflicts in other areas of scientific research have devastating effects for impartiality and reliability of both scientific publications and decision-making. Transparency consists of releasing the total number of animals used each year making, commentary difficult, and the potential variation among AECs renders consistency highly unlikely. In short, upon closer analysis, current framework does not achieve the aims identified in Chapter 1 of this paper.

However, Chapter 4 proposes reform which creates an efficient RTT framework that successfully accomplishes the targets from Chapter 1, while also increasing the efficiency of applying for, deciding upon and monitoring RTT activities. While conflicts of interest within AECs can be minimised by adding external members, removing bias in higher impact RTT calls for partially centralising decision-making and establishing a new NZAEC. Supervised by a bolstered NAEAC, the NZAEC will be able to achieve an unbiased balance between animal harm and accepted types of benefit. Under the proposal, NAEAC will also help create consistent decision-making across AECs and introduces a flexible way of providing binding guidance to the AEC system. Standardisation of AEC structure and paperwork will improve consistency, and also create more efficient application processes and lead to better biological

scientific research coming from New Zealand experiments. By constructing a framework that allows unbiased regulation to evolve to meet new scientific procedures and changes, this proposal does not simply achieve the essential aims of regulation in animal research, but it exceeds them.

Glossary

‘AWA’ – Animal Welfare Act 1999

‘PSAA’ – Psychoactive Substances Amendment Act 2014

‘MPI’ – Ministry of Primary Industries

‘RTT’ – Research, testing and teaching

‘NAEAC’ – National Animal Ethics Advisory Committee

‘CEC’ – Code of ethical conduct

‘AEC’ – Animal ethics committee

‘NZAEC’ – New Zealand Animal Ethics Committee

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