POLICY INFORMATION PAPER

The Use of Animals in Research, Testing and Teaching

Users Guide to Part 6 of the Animal Welfare Act 1999

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Ministry of Agriculture and Forestry
Te Manatū Ahuwhenua, Ngāherehere

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Users guide to Part 6 of the Animal Welfare Act 1999

Abstract

The Animal Welfare Act 1999 came into force on 1 January 2000. The core philosophy of the Act is the prevention of ill-treatment and inadequate care. It does this through imposing obligations on those who own or are in charge of animals, to meet the animals' physical, health and behavioural needs and, where practicable, to provide treatment when animals are ill or injured that alleviates unreasonable or unnecessary pain and distress.

The purpose of this Guide is to assist organisations and individuals using animals in research, testing and teaching to understand the requirements in Part 6 of the Act. The Guide is divided into two main parts:

- Part I outlines the provisions of Part 6;
- Part II contains guidelines for the development of Codes of Ethical Conduct.

Part 6 is a self-contained set of provisions. When animals are manipulated as part of an approved research, testing or teaching project, the rest of the Act does not apply. This is because the nature of the research, testing or teaching may mean that the general obligations cannot be met. This recognises that compromised care and some pain or distress to a small number of animals may result in significant benefits to people, other animals or the environment. However, such use carries with it significant responsibilities and strict legislative obligations. Every proposed project is subject to scrutiny and approval by an Animal Ethics Committee (AEC).

The new provisions, although similar in many respects to the previous system, are more comprehensive and provide greater clarity as to process and procedure. New features include:

- Greater ethical guidance for decision makers including an express requirement for AECs, when considering project applications, to be satisfied that the benefits outweigh the harm and to promote the "three R's" (reduce the numbers of animals used to the minimum, refine techniques so the harm is minimised and benefits maximised, and replace animals where possible with non-living or non-sentient alternatives);
- Statutory provision for AECs, with a requirement for three members to be drawn from outside the organisation which is carrying out the research, testing or teaching;
- A stronger focus on monitoring of projects to ensure compliance with the conditions of project approval;
- A requirement for all codeholders to be subject to independent review every 5 years with an additional review two years after an organisation is first approved to undertake research, testing or teaching. Independent reviewers must be accredited by the Director-General of the Ministry of Agriculture and Forestry;
- A substantial increase in penalties for breach of the Act or regulations. Fines rise from a maximum of $5,000 to a maximum of $25,000 for an individual and a maximum of $125,000 for a body corporate. Imprisonment (which may be imposed on individuals in addition to, or instead of a fine) rises from a maximum of three months to a maximum of six months;
- Special provisions covering research, testing and teaching on non-human hominids.

Abbreviations used in this guide

AEC	Animal Ethics Committee
CEC	Code of ethical conduct
DG	Director-General of the Ministry of Agriculture and Forestry
MAF	Ministry of Agriculture and Forestry
NAEAC	National Animal Ethics Advisory Committee
NAWAC	National Animal Welfare Advisory Committee
RNZSPCA	Royal New Zealand Society for the Prevention of Cruelty to Animals
The Act	The Animal Welfare Act 1999

1. INTRODUCTION

1.1 Purpose of this guide

The Animal Welfare Act 1999 (the Act) came into force on 1 January 2000. Part 6 of the Act provides for the use of animals in research, testing and teaching. The purpose of this Guide is to assist individuals and organisations using animals in research, testing, and teaching understand the new legislative requirements. Included is information to assist the preparation of codes of ethical conduct (CECs). This information is not designed to give organisations the blueprint for their codes; it provides the starting point for organisations to develop their individual responses to the statutory requirements. Additional information on particular aspects covered by CECs will be covered in future guides to good practice produced by the National Animal Ethics Advisory Committee (NAEAC), an advisory committee to the Minister.

If you have any questions about the provisions in the Act or about this publication please contact:

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A general Guide to the Act is also available. Both Guides are available on the MAF web site (http: //www.maf.govt.nz/AnimalWelfare) or can be obtained from:

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1.2 Organisation of guide

The Guide is divided into two main parts:

- Part I outlines the provisions of Part 6 of the Act;
- Part II contains guidelines for the development of CECs

The Guide provides only a summary of each provision. Those undertaking research, testing or teaching are encouraged to read the provisions in the Act itself. The text of Part 6 and other provisions applying to research, testing and teaching are contained in Appendix II

References throughout the Guide to section numbers refer to sections in the Act unless otherwise specified.

1.3 Contributors to guide

The Guide was produced by the Ministry of Agriculture and Forestry (MAF) with input and assistance from NAEAC. This assistance is gratefully acknowledged.

Part I

2. KEY DIFFERENCES IN APPROACH BETWEEN THE ANIMAL WELFARE ACT 1999 AND THE ANIMALS PROTECTION ACT 1960 (INCLUDING THE ANIMALS PROTECTION (CODES OF ETHICAL CONDUCT) REGULATIONS 1987)

2.1 Definition of animal (section 2)

The definition of "animal" prescribes which animals are covered by the legislation. The definition in the Act addresses some of the inconsistencies in the Animals Protection Act 1960 (which, for example, covered vertebrates in captivity but few vertebrates in the wild). The Act also extends the definition to cover:

- Lower vertebrates (amphibians, fish);
- A small number of invertebrates (octopus, squid, crab, lobster, crayfish); and
- Mammalian fetuses, avian or reptilian pre-hatched young in the last half of gestation or development and marsupial pouch young. This acknowledges that fetuses and embryonated eggs may be sensitive to noxious stimuli.

2.2 Ethical direction

Part 6 provides greater ethical guidance to Animal Ethics Committees (AECs) and others making decisions under the Act than the previous legislation. In particular, the purposes section requires a harm/benefit analysis to be undertaken of every project application and for the "three Rs" (reduce, refine, replace) to be promoted. These are covered more fully in section 5 of this Guide.

2.3 Codes of ethical conduct and animal ethics committees

The Animals Protection (Codes of Ethical Conduct) Regulations 1987 provided that no person shall conduct any research, testing or teaching "involving the manipulation of any live animal ... unless that work or teaching is carried out in accordance with a code of ethical conduct relating to the welfare and humane treatment of the live animal involved."

In practice, it was not appropriate for CECs to contain detailed provisions relating to each species and type of research an organisation was involved in. Animal Ethics Committees (AECs) were established to consider project applications and set conditions relating to the nature of the care and the safeguards to be built into each research project. CECs became documents that provided general guidance on the membership and administration of AECs, and on the matters that each AEC should take into account when considering an application to use animals. This practice was largely successful.

A similar model has been used in the Act with the important difference that most of the matters previously included in CECs are now contained in the Act itself. This is consistent with modern drafting practice whereby significant obligations on animal users are contained in statute, allowing Parliamentary scrutiny that would not otherwise occur with regulations or other documents.

CECs now set out administrative matters (such as the appointment of the AEC chair, quorum for meetings, record keeping and complaint procedures), and general policy and procedures covering animal facilities and care. CECs are now approved for a fixed term of up to five years. This provides for periodic review. Under the previous Act, CECs were approved until such time as the holder ceased to use animals in research, testing and teaching.

2.4 Independent Reviews

A new feature is the requirement for code holders to periodically appoint an accredited reviewer to conduct a review. Accredited reviewers will be independent and impartial. They will assess the extent to which the code holder and the AEC are:

- implementing the policies, procedures, and requirements set out in the Act, in any regulations and in the CEC; and
- complying with the Act and any regulations and the CEC.

A satisfactory review report is a prerequisite to obtaining approval of a CEC for a second or subsequent period.

This feature builds on a voluntary review system initiated by the Australian and New Zealand Council for the Care of Animals in Research and Teaching shortly before the commencement of the Act. It will be an additional tool to assess compliance and will assist with building and maintaining public confidence in the legislative system.

3. WHEN IS THE USE OF ANIMALS IN RESEARCH, TESTING OR TEACHING SUBJECT TO THE ACT?

To assess whether a particular use of an animal is subject to Part 6 of the Act (thus requiring AEC approval), it is necessary to assess:

- whether the animal is covered by the Act i.e. whether it comes within the definition of "animal" covered in section 2.1 of this Guide;
- whether the use involves the "manipulation" of the animal as defined in section 3; and
- whether the manipulation of the animal is carried out as part of work that falls within the definition of "research, testing, and teaching" as defined in section 5.

3.1 The definition of "manipulation" (section 3)

"Manipulation" is a legal term defined as:

"... interfering with the normal physiological, behavioural, or anatomical integrity of the animal by deliberately-

(a) Subjecting it to a procedure which is unusual or abnormal when compared with that to which animals of that type would be subjected under normal management or practice and which involves –
  (i) Exposing the animal to any parasite, micro-organism, drug, chemical, biological product, radiation, electrical stimulation, or environmental condition; or
  (ii) Enforced activity, restraint, nutrition, or surgical intervention; or

(b) Depriving the animal of usual care; ..."

3.2 Exclusions

The following situations are excluded from the definition of manipulation and are thus not subject to the requirements of Part 6:

(i) Any therapy or prophylaxis necessary or desirable for the welfare of the animal (section 3(2)(a)).

This means that the administration of therapeutic drugs or vaccines or other medical treatment, carried out for the welfare of the animal as part of normal veterinary or owner practice, is not subject to the requirements in the Act.

(ii) The killing of an animal as the end point of research, testing or teaching or in order to undertake research, testing, or teaching on the dead animal, if the animal is killed in such a manner that the animal does not suffer unreasonable or unnecessary pain or distress (sections 3(2)(b) and (c)).

These exceptions are consistent with the philosophical approach taken throughout the Act. The rationale for this approach is set out in Appendix I to this Guide.

The practical effect of these exemptions for AECs are two-fold. Firstly, AECs when weighing the harm and benefits of a project that will require euthanasia, are not required by law to include the loss of animal life as part of the harm. The assessment of the harm should only cover the pain and suffering that the research, testing or teaching may cause the animals. Secondly, AEC approval is not legally required in order to carry out post-mortem research.

However, these exemptions do not mean that there are no controls over the killing of the animals in the research, testing and teaching situation. It must be emphasised that

all people and institutions are required to comply with section 12(c) of the Act. This provides that any person commits an offence who - being the owner, or person in charge of an animal, kills the animal in such a manner that the animal suffers unreasonable or unnecessary pain or distress. A future code of welfare under the Act will contain minimum standards and recommendations on best practice for killing for research purposes. Failure to meet such standards could result in a prosecution for an offence of ill-treatment under the Act.

Thus, every organisation thus needs to ensure that policies and procedures are in place relating to the methods of killing to be used and internal monitoring for compliance. It is up to an organisation to decide how this happens. Where an organisation has an AEC, it could request the AEC develop policies and carry out monitoring. However, this work would not be undertaken by the Committee to fulfill its functions under Part 6. It would be undertaken as part of a separate arrangement. Where an organisation does not have an AEC (for example, where it is involved in research, testing or teaching only on animal tissue), it needs to ensure that procedures are in place to comply with the Act.

It should be noted that any organisation can adopt additional standards to apply internally to its staff and operations that go beyond what is required by the law. Some organisations in New Zealand already have in place an internal requirement that any killing of animals for post-mortem research must be approved. If an organisation has an AEC, it can request it to consider such applications. However, to avoid confusion, it is recommended that any documents produced by the organisation (such as application forms for project approval) make it clear which aspects are subject to legal requirements and which are not.

(iii) The hunting or killing of any animal in a wild state by a method that is not an experimental method (section 3(2)(d)).

This provides that the hunting or killing of animals in a wild state (e.g. hunting or fishing for sport, commercial purposes or to assist management[1]) is not a manipulation except where an experimental method is being used. An example of an experimental method is the trialling of a new type of trap by a research institution. The development and trial is likely to require Animal Ethics Committee approval. If the trap was demonstrated to be effective and subsequently made available by the developers for sale or routine use, Animal Ethics Committee approval would no longer be required.

(iv) Any procedure that the Minister declares not to be a manipulation for the purposes of the Act (sections 3(2)(e) and 3(3)).

Section 3(3) provides for the Minister, after consideration of a number of specified matters and after consultation with NAEAC, to declare any procedure not to be a manipulation. Notification is by notice in the *Gazette* (a weekly Government

[1] For example, the use of electric fishing devices to monitor fish stocks and capture fish for relocation and the use of traps to test the efficacy of pest control operations.

publication). This recognises that some procedures, when first introduced, may fall within the definition of manipulation because they are novel or unusual but that this can change. Over time, they may eventually be used by a significant number of people and be regarded by the majority as standard practice. This mechanism enables such practices to be moved from being "manipulations" requiring AEC approval to being regarded as standard management practices that do not require such approval.

3.3 The definition of "research, testing, and teaching (section 5)

When an animal is manipulated its integrity is interfered with in some way. The types of interference subject to legislative intervention have been covered above. Section 5 covers the types of work involving manipulation that are subject to Part 6 of the Act.

"Research, testing, and teaching is defined as:

(a) Any work (being investigative work or experimental work or diagnostic work or toxicity testing work or potency testing work) that involves the manipulation of any animal; or

(b) Any work that –

(i) Is carried out for the purpose of producing antisera or other biological products; and

(ii) Involves the manipulation of any animal; or

(c) Any teaching that involves the manipulation of any animal.

The section contains two exemptions from the definition.

(i) Any manipulation of an animal in the immediate care of a veterinarian where the manipulation is either for clinical purposes (to diagnose disease or assess the effectiveness of a proposed treatment) or for assessing the characteristics of an animal with a view to maximising the productivity of the animal (for example the sporidesmin test for facial eczema susceptibility and the "Blockey" test for assessing the libido of bulls).

The term "in the immediate care of a veterinarian" covers normal veterinary practice where:

- the veterinarian has accepted responsibility from the owner or person in charge of the animal for the health and welfare of the animal; and
- is providing the animal with direct and continuing care.

The section contains a proviso that the veterinarian must believe on reasonable grounds that the manipulation will not cause the animal unreasonable or unnecessary pain or distress, or lasting harm.

(ii) *Routine manipulations that are undertaken by management agencies fulfilling responsibilities or functions under legislation administered by DOC and under the Fisheries Act 1996.*

Such manipulations are generally on animals in a wild state and are required as part of the day-to-day management or research responsibilities of these agencies. An example is the attachment of transmitters and bands to track animals and monitor distribution patterns. Well-trained staff carry out these manipulations in accordance with standard operating procedures. Note that this exemption does not apply to organisations, such as universities, that do not have statutory management responsibilities for the management of animals in a wild state.

3.4 The use of animals in schools for teaching purposes

MAF and NAEAC are frequently asked by schools whether their use of animals is subject to the research, testing and teaching provisions in the Act. Most classroom animal use in New Zealand involves family pets brought to school for simple observation and behaviour studies and for learning the responsibilities of humane care. Such use does not constitute a manipulation and thus does not require AEC approval.

A range of simple studies can be fun for children and do not require the administrative complications of AEC approval. These include:

- Observation of behaviour;
- Observation of body structure and function;
- Measurement of growth e.g. regular weighing to chart a growth curve;
- Identification of diet preferences, and food "treats";
- Observation of animal response to different cage equipment such as tubes, platforms and ramps;
- Breeding to teach reproduction and development; and
- Animal care and handling techniques.

Schools are referred to a 1999 publication from the Ministry of Education C*aring for Animals – a guide for teachers, early childhood educators and students.*

If activities are beyond the type described above, and constitute a manipulation as defined in the Act, then a school would need to comply with Part 6. If only a small amount of teaching is undertaken involving the manipulation of animals, AEC approval through a "piggy-backing" arrangement with another organisation may be the preferred approach (refer section 4.3 of this Guide).

4. THE REGULATORY FRAMEWORK

4.1 The central focus of the Act

The core philosophy of the Act is the prevention of ill-treatment and inadequate care of animals. Part 1 imposes two key obligations on every owner or person in charge of an animal to:

(i) Ensure that the physical, health and behavioural needs of the animal are met in a manner that is in accordance with both good practice and scientific knowledge; and

(ii) Where practicable, ensure that when the animal is ill or injured it receives treatment that alleviates any unreasonable or unnecessary pain or distress.

This contrasts with the previous legislation which was principally concerned with punishing acts of cruelty rather than prevention. A key feature of the Act is provision for the development of codes of welfare. These contain the detail of what constitutes appropriate care for particular animal species, animal uses and management situations (e.g. care of sheep, care of circus animals, transport of animals, killing of animals). Draft codes can be developed by any person or organisation within or outside Government.

The National Animal Welfare Advisory Committee (NAWAC), a statutory advisory committee to the Minister, is responsible for refining the provisions and recommending the final content of codes of welfare to the Minister. The process includes provision for public submissions to be made on the draft code and for NAWAC to directly consult submitters or others. Codes must be reviewed every 10 years or earlier if there is a need. This process helps to ensure that the standards of care are continually updated and remain consistent with the expectations of society.

4.2 The relationship of Part 6 with the rest of the Act

Part 6 of the Act stands separate from the rest of the Act. It provides a process that, in some circumstances, sanctions manipulations that cause suffering, distress, or compromised care. Provided the use of the animals has been approved in accordance with Part 6, those involved cannot be prosecuted for failure to meet the obligations in Part 1 or for ill-treatment under Part 2.

This recognises that the manipulation of a small number of animals may result in significant benefits to a wider group of people or animals, to society generally or to the environment. However, society has required that legislation include adequate safeguards governing such animal use. Any individual or organisation wanting to manipulate animals is subject to a comprehensive set of requirements.

4.3 Restrictions on who can manipulate animals (section 82)

There are two fundamental requirements on anyone wishing to use animals in research, testing or teaching:

(i) A person must hold an approved CEC or be employed by a person or organisation that holds an approved CEC; and

(ii) Each individual project must first be approved by an AEC appointed by the code holder.

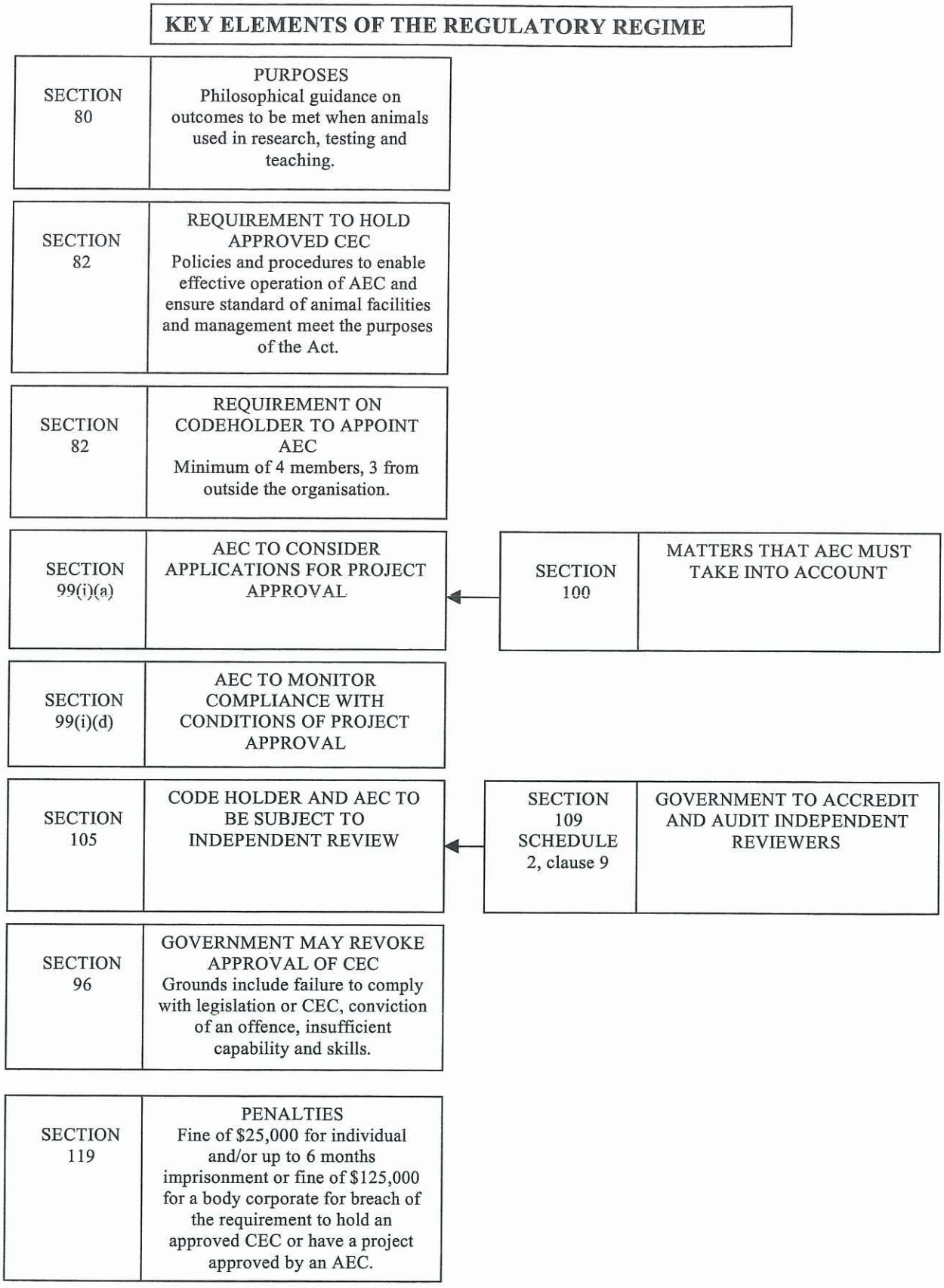
Section 84 of the Act provides an exception to the above whereby an organisation may obtain approval for each project from the AEC appointed by another organisation if:

- The policies and procedures relating to the arrangements are set out in the other organisation's CEC;
- The arrangements are agreed to by both organisations and the AEC;
- The code holder, before the research, testing and teaching commences, gives the DG written notice of the arrangements.

Such arrangements may be appropriate for small organisations or schools that may be carrying out research, testing or teaching infrequently. They are referred to as "piggy-backing" in this Guide. The table in section 13 of this Guide provides guidelines on the development of policies and procedures relating to the arrangements.

The following figure sets out the key elements of the regulatory regime. Further detail is provided in the following sections of this Guide.

Figure 1


KEY ELEMENTS OF THE REGULATORY REGIME
SECTION 80
PURPOSES
Philosophical guidance on outcomes to be met when animals used in research, testing and teaching.
SECTION 82
REQUIREMENT TO HOLD APPROVED CEC
Policies and procedures to enable effective operation of AEC and ensure standard of animal facilities and management meet the purposes of the Act.
SECTION 82
REQUIREMENT ON CODEHOLDER TO APPOINT AEC
Minimum of 4 members, 3 from outside the organisation.
SECTION 99(i)(a)
AEC TO CONSIDER APPLICATIONS FOR PROJECT APPROVAL
SECTION 100
MATTERS THAT AEC MUST TAKE INTO ACCOUNT
SECTION 99(i)(d)
AEC TO MONITOR COMPLIANCE WITH CONDITIONS OF PROJECT APPROVAL
SECTION 105
CODE HOLDER AND AEC TO BE SUBJECT TO INDEPENDENT REVIEW
SECTION 109 SCHEDULE 2, clause 9
GOVERNMENT TO ACCREDIT AND AUDIT INDEPENDENT REVIEWERS
SECTION 96
GOVERNMENT MAY REVOKE APPROVAL OF CEC
Grounds include failure to comply with legislation or CEC, conviction of an offence, insufficient capability and skills.
SECTION 119
PENALTIES
Fine of $25,000 for individual and/or up to 6 months imprisonment or fine of $125,000 for a body corporate for breach of the requirement to hold an approved CEC or have a project approved by an AEC.

5. THE PURPOSES OF PART 6 (section 80)

5.1 General approach

Section 80, which sets out the purposes of Part 6, should be read carefully by all those involved in the use of animals in research, testing and teaching. It is reproduced in Appendix I. The section provides guidance on the circumstances under which animals can be manipulated. Such guidance is particularly important for AECs (and the DG, in the case of non-human hominids), when they are considering project proposals. There are six components to the Purposes section. In essence, research, testing and teaching must be confined to cases where there must be good reason to believe that:

- The findings of the research, or testing or the results of the teaching will enhance understanding of humans, animals, or the natural or productive environment;
- The anticipated benefits of the research, testing, or teaching outweigh the likely harm to the animals;
- Any research, testing or teaching involving the use of a non-human hominid is in the best interests of the animal, or is in the interests of the species to which the animal belongs and the benefits outweigh the harm to the animal;

  and:

- All reasonable steps must be taken to meet the physical, health, and behavioural needs in accordance with both good practice and scientific knowledge, except where this is not possible because of the nature of the work, in which case any pain or distress must be reduced to the minimum possible in the circumstances;
- Where animals are ill or injured they must receive, where practicable, treatment to alleviate unreasonable or unnecessary pain and distress caused by illness and injury, except where this is not possible because of the nature of the work, in which case any pain or distress must be reduced to the minimum possible in the circumstances;
- Decision makers must promote efforts to reduce the numbers of animals used, refine techniques to minimise harm and maximise benefits, and replace animals with non-living or non-sentient alternatives where appropriate (the three Rs).

5.2 Harm / benefit analysis (section 80(1)(a) and (b))

A harm/benefit analysis must be undertaken for each project proposal. Of necessity, this analysis is a qualitative one. It requires a collective judgement to be made by the AEC members on whether the likely benefits of the project outweigh the likely harm. AECs are made up of a range of people from different backgrounds including members from outside the organisation. Different perspectives expressed in the analysis helps to ensure that the balance of benefit and harm is carefully considered.

In assessing any potential harm, a range of matters are relevant including, the status of the animals (diseased, pregnant, protected wildlife etc), the severity of the manipulation in terms of intensity and duration, and steps that can be taken to mitigate any stress or pain caused (such as use of anaesthetics or analgesics).

The potential harm is then assessed against the likely benefits, including enhanced understanding of humans beings, animals or ecosystems, the maintenance or protection of human or animal health or welfare and so on (the full list is in section 80(1)(a)).

The Act recognises that the benefits of research are often incremental; in other words, the direct benefits of the project may be less than if they are added to the results of other work. Accordingly, the assessment can include the likely benefits when combined with the findings of other related projects undertaken in the past, currently underway or planned for the future.

In cases where the potential benefits are extremely high, this does not, however, provide justification for the infliction of extreme levels of suffering. The requirement to carry out a harm/benefit analysis must be read together with additional purposes listed in section 80(2)(a)(iii), which provide that "any degree of pain or distress is reduced to the minimum possible in the circumstances". Section 100(d) provides further guidance on this issue for AECs. It provides that Committees must consider

"The harm to, or the distress felt by, the animals as a result of the manipulation, and the extent to which that harm or distress can be alleviated by any means (including, where the pain or distress cannot be held within reasonable levels, the abandonment of the manipulation or the humane destruction of animals)".

As noted in section 3.2 of this Guide, AECs should not include the moral aspects of killing animals as the endpoint of research, testing or teaching within their assessment of harm.

5.3 The use of non-human hominids (section 80 (1)(c))

"Non-human hominid is defined in section 2 to mean "any non-human member of the family Hominidae, being the gorilla, chimpanzee, bonobo, or orangutan." These animals are often referred to as the "great apes".

The specific reference in the Purposes section to non-human hominids reflects Parliament's view that these animals merit special consideration. This followed Parliament's assessment of research and information that shows that great apes share similar qualities with humans including "the ability to communicate symbolically, the ability to solve problems through reasoning, self awareness and emotional complexity."[2]

Like research on other animals, the benefits of research must not be outweighed by the harm to the animal. However, a significant difference is that the assessment of the benefits must be confined to whether it is in the best interests of the individual non-human hominid or is in the interest of the species to which the non-human hominid belongs. It is not possible to carry out research, such as on AIDS (Acquired Immuno - deficiency Syndrome), where the aim is to have a greater understanding of the disease in humans. The Primary Production Select Committee, in its report to Parliament,

[2] Commentary on the Animal Welfare Bill No.2 as reported from the Primary Production Committee No.209-2 pg xx.

cautioned that "These provisions are not intended to provide a back-door method of approving experiments on great apes for the benefit of humans."[3]

Applications to use non-human hominids in research, testing or teaching are subject to a different process to that for other animals. This process is covered in section 8 of this Guide.

5.4 The Three Rs (section 80(2)(b))

The last component of the Purposes section is the promotion of the "three Rs" This is a set of principles to guide decisions on the use of animals in research, testing and teaching that were first enunciated in 1957.[4] They are:

(i) "To reduce the number of animals used in research, testing, and teaching to the minimum necessary:

(ii) To refine techniques used in any research, testing, and teaching so that the harm caused to the animals is minimised and the benefits maximised:

(iii) To replace animals as subjects for research, and testing by substituting, where appropriate, non-sentient or non-living alternatives:

(iv) To replace the use of animals in teaching by substituting for animals, where appropriate, non-sentient or non-living alternatives or by imparting the information in another way."

AECs, when considering project applications must have regard to the Purposes of Part 6. This includes the need to promote efforts to 'reduce, refine and replace'. In the context of the New Zealand legislation, the requirement to reduce the number of animals used refers to live animals. It does not cover animals killed in order to carry out post-mortem research, observation, or study. However, many organisations choose to also apply the reduction principle to the killing of animals for post-mortem research.

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[3] Commentary on the Animal Welfare Bill No.2 as reported from the Primary Production Committee No.209-2 pg xxi.

[4] Russell, W.M.S. The Increase of Humanity in Experimentation: Replacement, Reduction and Refinement. Paper read at UFAW Symposium on Humane Technique in the Laboratory, May, 1957, London; Abstract in *Coll.Papers Lab. Animals Bur.*, 6, 79-81.

6. CODES OF ETHICAL CONDUCT (sections 87 – 97)

6.1 What is a CEC?

An approved CEC is essentially a licence to operate. A CEC sets out an organisation's policies and procedures to ensure that its AEC can operate effectively and that the organisation is able to meet its obligations under the Act. Applications for approval are made to the Director-General of MAF (DG). A draft CEC is submitted along with additional information to assist the DG assess whether the organisation is managed by people of honesty and good character, whether they and their staff have adequate skills and experience in managing animals of the type being used, and whether the organisation has a good past record (where a CEC is being renewed).

Part II of this Guide contains information to assist in the preparation of a CEC.

Codes of welfare under Part 5 of the Act and codes of ethical conduct under Part 6, although both referred to as "codes", are different in nature. Codes of welfare contain minimum standards and recommendations for good practice in the care of animals. A breach of a standard in a code can be used as evidence to support a prosecution for an offence under the Act. Codes of welfare apply to all owners of animals.

Codes of ethical conduct are written by and apply to an individual person or to a single organisation. They are principally administrative documents covering the operation of Animal Ethics Committees. While such codes also need to cover, in a general way, the animal management practices and facilities in place to meet the requirements of the Act, the standards of care for particular animals involved in particular projects will be tailored to those projects and covered in the conditions attached by an AEC to each project approval.

Should an organisation choose to adopt particular policies that go beyond what is required by the Act, this could be included in the code of ethical conduct but would lie outside of the matters that the DG would take into account when considering an application for approval. Such policies would also not be subject to independent review. Examples could be: internal procedures requiring that the killing of any animals for post-mortem research be approved; a corporate policy to *never* use great apes in research irrespective of potential benefits to the animal or species as a whole; or a corporate policy to never undertake research that would necessitate the euthanasia of animals. To avoid confusion, it is desirable that the wording of CECs clarify which aspects are subject to legal obligation and which are not.

6.2 Applications for CEC approval (section 89)

Any person who wishes to be engaged in research, testing or teaching must apply in writing to the DG for approval. "Person" is defined in section 2 to include "a corporation sole, and also a body or persons, whether corporate or un-incorporate". Applications can thus be made by an individual person or by an organisation. Consent needs to be obtained from the DG to transfer an approval to another person or organisation.

The application must contain:

- Information on the general nature and extent of the applicant's proposed or existing research, testing or teaching;
- The period for which approval is sought (a maximum of 5 years); and
- Information on any convictions against any of the Acts listed in section 89(1)(c). A conviction against any of these Acts does not immediately disqualify a person from having their CEC approved. A conviction is one of a number of matters that the DG takes into account. The DG would take particular account of the reason for the conviction and its degree of relevance to the carrying out of research using animals.

In addition to the above, every application must be accompanied by:

- The proposed CEC;
- Evidence (in the form of independent references and academic qualifications) that the applicant or employees have the relevant capability, skills and experience; and
- A satisfactory report by an accredited reviewer where the applicant is not a new entrant.

6.3 Consideration of an application (sections 90 – 92, and section 97))

When the DG receives an application, he or she refers it to NAEAC for comment. If NAEAC considers that the contents of a code should be changed, it must consult with the applicant before making its recommendation to the DG.

On receipt of an application, the DG has 40 working days to make a decision on whether to approve the code, decline to approve, approve with changes, or attach conditions. The time period includes consultation with NAEAC. An example of a condition might be that the applicant is only able to carry out research on small animals if the DG does not consider the applicant has the skills, experience or facilities to ensure the welfare of large animals.

The 40 day time limit is automatically extended to 80 days if the DG or NAEAC requires more information from the applicant or needs to consult the applicant.

If the DG refuses to approve a proposed CEC, he or she must advise the applicant in writing of the reasons for the refusal. The applicant then has the opportunity to have that decision reviewed. If the decision was made by a staff member under delegated authority of the DG, the decision will be reviewed by the DG. If the decision was made by the DG then the applicant is entitled to have the decision reviewed by the Minister.

Applicants will be notified in writing of the DG's decision. Notices of approval are published in the *Gazette*. Approval is normally given for 5 years but the Act provides for the period to be shorter.

At the time of writing, the approval of codes of ethical conduct is delegated to the Director, Animal Welfare. The power of delegation is in section 41 of the State Sector Act 1988.

6.4 Approval is personal to the code holder (section 93)

An approval of a CEC is personal to that code holder (which may be an individual or an organisation) and is not transferable, except with the consent of the DG. This is because the approval process takes into account the skills, experience and background of the applicant. It could not be guaranteed that the same attributes would be found in the transferee or that the policies and procedures set out in the CEC would be appropriate for, and complied with by, the transferee.

Section 93(3) provides that where a code holder remains as the legal principal of the business but has divested day-to-day control, by assigning the assets and goodwill of the business or transferring some of the share capital to another person, this has the effect of revoking the approval of a CEC unless the assignment or transfer has the DG's consent.

6.5 Suspension or revocation of a CEC (section 95 and 96)

The suspension or revocation of an approval of a CEC may be sought voluntarily by a code holder or may be initiated or made by the DG.

Voluntary requests for suspension or revocation may be sought in instances such as when a code holder goes out of business or if the code holder no longer has a need to manipulate animals. The request should be made in writing to the DG giving reasons for the suspension or revocation.

An approval may be suspended or revoked by the DG in the absence of a request from a code holder if the code holder:

- Is no longer carrying out research, testing or teaching; or
- Has been convicted of any offence against any of the Acts listed in section 96(2)(b); or
- No longer has the necessary capability or skills; or
- Has failed to comply in a material respect with the Act, any regulation or the CEC; or
- Provided information in the original application for CEC approval that was false in a material respect.

Prior to making such a decision the DG must give the code holder the opportunity to be heard and must consult with NAEAC. The code holder has the opportunity to have a decision reviewed in the same manner as a review of a refusal to approve a CEC (covered above). In all cases a suspension or revocation is notified in the *Gazette.*

6.6 Amendments to a CEC (sections 95 and 96)

Section 95 provides that amendments to the CEC of a minor nature may be made by the code holder without reference to the DG. These are amendments that would "not materially affect the purposes of the code". A judgement needs to be made by the code holder as to whether the change will have a material effect on how the AEC does its job or on how animals are managed. Should there be any doubt, a proposed amendment could be discussed with NAEAC. As soon as practicable after the end of December and not later than 31 March the next year, each code holder must advise the DG of any minor amendments made. This ensures that MAF holds an accurate copy of each CEC. Notification of minor changes can be sent to MAF at the same time organisations supply statistics on animal usage.

Where proposed amendments to a CEC are likely to have a significant effect on how a code holder or AEC operates, code holders must apply in writing to the DG for his or her approval. The application must state the reasons for the amendment. The DG then seeks comments from NAEAC. When reaching a decision the DG must consider:

- Whether the current provisions of the CEC are appropriate to the activities of the code holder;
- Whether scientific developments make it appropriate for the CEC to be amended; and
- The comments received from NAEAC.

6.7 Transitional arrangements (sections 192 and 193)

Where, at the commencement of the Act, a person or organisation held a CEC approved under the Animals Protection Act 1960, section 192 deems that code to have been approved under the new Act. The term of the approval depends on the length of time the approval under the previous Act had been in place. The Act provides a progressive process for the review of deemed codes as set out below:

Date CEC was approved under Animals Protection Act 1960	**Period CEC is deemed to be approved under the new Act**
Before 31 December 1990	For three years from Act commencement (until 31 December 2002)
1 January 1991 to 31 December 1994	For four years from Act commencement (until 31 December 2003).
After 31 December 1994	For five years from Act commencement (until 31 December 2004)

The ability to progressively review CECs over three years allows the workload to be spread in a manageable way. If code holders intend to apply for approval of a CEC for a further period when the deemed approval expires, they will be required to commission an independent review of their operations prior to the expiry of the deemed approval (refer section 9 of this Guide).

A number of matters covered in CECs under the previous legislation are now provided in the Act itself. For example, the "aims" section of most CECs under the old Act is now covered by the purposes section in the Act. Because it was desirable that the provisions in the Act prevail during the transition period, the Act provides that where any provision of a deemed code would be outside the scope of a code of ethical conduct approved under the Act, it does not have effect. The Act makes it clear that where an AEC was in existence immediately before the commencement of the Act, that committee may continue in existence for the whole of the transition period, even if its membership does not comply with section 91.

Where, before the commencement of the Act, a person or organisation had an arrangement to submit project proposals for consideration by another organisation's AEC (i.e. a "piggy-backing" arrangement covered in section 4.3 of this Guide), that arrangement can continue during the transition period.

A person holding a deemed approval under section 192 may also enter into new "piggy-backing" arrangements after the commencement of the Act provided:

- Each project is approved by the code holder's AEC;
- The arrangements in relation to the research, testing or teaching are agreed on by the code holder, its AEC and the person carrying out the research, testing or teaching; and
- The code holder forwards written notice of the arrangements to the DG before the research, testing or teaching commences.

7. ANIMAL ETHICS COMMITTEES

7.1 Obligation (section 98)

Every code holder must establish and maintain an AEC.

7.2 Membership (section 101)

Appointment of members of an AEC is by the code holder, where that is an individual, or by the chief executive or his or her nominee, where the code holder is an organisation. An organisation may have more than one AEC. Provision for the chief executive's nominee to make an appointment is particularly helpful for large organisations that are spread over several sites. Individual site managers or other senior staff will be more familiar with the policies and procedures and management issues for their site.

Each committee must have a minimum membership of 4 people made up of:

(i) The code holder or in the case of an organisation, a senior member of the organisation appointed by the chief executive. That person must be capable of evaluating:

- Each project proposal;
- The qualifications and skills of the project proposer; and
- The scientific value or teaching value of the project;

(ii) A veterinarian from outside the organisation nominated by the New Zealand Veterinary Association or similar such body;

(iii) A person nominated by an "approved organisation". An approved organisation is an animal welfare organisation, approved by the Minister to enforce the Act. At the time of writing the only approved organisation is the RNZSPCA. This person must not be employed or associated with the code holder or be involved in the use of animals for research, testing or teaching; and

(iv) A person nominated by a territorial authority or regional council. This person must not be employed by, or associated with, the code holder nor associated with the scientific community or an animal welfare agency. The intent is that this person should bring the perspective of a member of the public.

A code holder may appoint additional members to its AEC, either from within the organisation or outside, to provide the appropriate range and balance of skills and experience. If certain skills or experience are required infrequently, the secondment of a person with the appropriate expertise is an option.

This may result in the AEC having a majority of internal members on the Committee. In some overseas countries such decision-making bodies are required to have a majority of outside members to ensure that decision-makers are viewed as independent and representative of the community. This has not been favoured in New Zealand because our small population would often make it difficult to find the appropriate outside expertise.

However, the Act contains a number of safeguards to help protect against internal members having an undue influence over Committee affairs and decisions:

- CECs must set out policies and procedures to enable outside members to have an effective input into the working of the committee and to ensure that complaints by AEC members are dealt with fairly and promptly (section 88(2)(f));
- Any member of an AEC who believes that the AEC or the code holder is failing to comply in a material respect with the legislation or the CEC may make a report to the DG. Except in certain limited circumstances, the DG must not disclose the complainant's identity. This ensures that the possibility of being identified does not provide a barrier to reporting of non-compliance. This provision overrides the Official Information Act 1982 and the Privacy Act 1993 (section 103);
- At five-yearly intervals, an independent review must be carried out to assess compliance by the code holder and AEC with the legislation and the CEC (refer

section 9 of this Guide). If outside members have concerns that the style and method of Committee management prevents them from making effective input, they can advise the independent reviewer. If concerns arise between review periods, and the Minister considers an independent review is necessary; the Minister has the power to commission one at the Crown's expense (section 117); and

- The overall approach taken within Part 6 generally encourages good process. When the regulation of research, testing and teaching was first introduced, the option of having central government approve all projects was rejected in favour of decisions being made within organisations themselves (with appropriate outside input). This has fostered a sense of "ownership" of the process and to date, organisations have demonstrated a significant commitment to ethical practice.

Most of the mechanisms noted above are also available to internal members of the AEC to raise concerns. The requirement on the DG to not disclose a complainant's identity should alleviate any concerns of staff members that such action would jeopardise their employment. While section 103 does not apply to staff in general, staff who are not members of the AEC could convey any concerns to an AEC member if they did not wish to raise them directly with management.

7.3 Functions and powers (section 99)

The functions of an AEC are:

- To consider and make decisions on project applications. These may be applications from within the organisation, or they may be applications from another organisation that does not have its own AEC and has entered into a "piggy-backing" arrangement (refer section 4.3 of this Guide);
- To set, vary and revoke conditions of project approvals;
- To monitor compliance with conditions of project approvals;
- To monitor animal management practices and facilities to ensure compliance with the terms of the CEC;
- To consider and determine applications for the renewal of project approvals;
- To suspend and revoke, where necessary, project approvals; and
- To recommend to the code holder amendments to the CEC.

7.4 Matters to be considered by an AEC (section 100)

Section 100 of the Act sets out a list of criteria that an AEC must have regard to when considering:

- An application for the approval of a project, and setting the conditions of approval;
- An application to vary the conditions of a project approval; or
- Whether a project approval should be revoked.

An AEC is required to have regard to each of the criteria in the list as is relevant to the project under consideration and any other matters that it considers relevant. Section 183(1)(d) provides for regulations to be made prescribing additional matters to those listed in section 100. No regulations are in place at the time of writing. The full text of section 100 can be referred to in Appendix II.

7.5 What constitutes a project?

"Project" is defined in section 2 to mean:

(a) Any experiment, or series of related experiments, forming a discrete piece of research; or

(b) A protocol for the carrying out of routine manipulations within a specified period; or

(c) Any experiment or demonstration, or series of related experiments or demonstrations, undertaken for teaching purposes.

Where a number of experiments are required for a particular research project, AEC approval is required only once, at the beginning of the work. Similarly, when animals are manipulated routinely (for example, for production of hyper-immune sera), an approval is not required every time an animal is manipulated. Rather, a protocol covering the operational procedures and the relevant matters in section 100 must be submitted for the Committee's consideration. While such procedures may be carried out year after year, the protocol must be periodically reviewed. This enables fresh consideration to be given by those manipulating the animals and by members of the AEC to whether impacts on the animals can be reduced, whether the number of animals could be reduced or alternative methods, not requiring animals, used. The term of protocol approval is included as a condition of project approval by the AEC.

When work on a research project is being carried out in more than one organisation or spread over several sites of a single institution (e.g. on different campuses of a university), a decision should be made on which is the lead organisation/site and the approval of its AEC should be obtained.

Experiments or demonstrations may be repeated annually or more frequently for teaching purposes. The definition of "project" would suggest that teachers need approval each time. In practice, AECs could, on a single occasion, provide separate approvals covering a multiple year period if they were confident that the conditions of project approval would continue to be observed.

7.6 Committee procedure (section 102)

The Act provides that the procedure followed by an AEC must, except as provided in the Act or in regulations or in the CEC, be determined by the Committee. The principal means of setting out the Committee procedure is the CEC. Discussion of the contents of the CEC and guidelines on their development are contained in Part II of this Guide.

7.7 Protection of members of Animal Ethics Committees (section 104)

Section 104 provides that no member of an AEC is personally liable for any act done or omitted by the member or the committee, in good faith, in the course of the operation of the committee.

8. PROCESS FOR CONSIDERING APPLICATIONS TO USE NON-HUMAN HOMINIDS (section 85)

Applications to use non-human hominids in research, testing or teaching are not considered by AECs. Applications must be made to the DG, who makes a decision after consulting with NAEAC. Conditions may be imposed on any approval.

The DG is required to monitor the implementation of any project and may, after consultation with NAEAC, revoke any condition, revoke a condition and impose another in its place or amend any condition.

The DG may at any time, by notice in writing, revoke an approval if satisfied:

- The use of the non-human hominid is no longer in its best interests; or
- The use of the non-human hominid is no longer in the interests of the species to which the non-human hominid belongs; or
- The harm outweighs the likely benefits; or
- A condition of the approval is not being complied with; or
- The person is no longer carrying out research, testing, or teaching; or
- The person has been convicted of an offence against an Act listed in section 96(2)(b); or
- The person no longer has the capability and skills to carry out the research, testing and teaching; or
- The person has failed to comply in a material respect with the legislation or any CEC; or
- Information was included in a person's application that was false in a material respect.

Before revoking an approval, the DG must give the person an opportunity to be heard.

9. INDEPENDENT REVIEW OF CODE HOLDERS AND ANIMAL ETHICS COMMITTEES (sections 105 – 116)

9.1 Requirement to commission review

A new feature is the requirement for code holders to periodically appoint and pay an accredited reviewer to conduct a review. The purpose of the review is to assess the extent to which the code holder and the AEC are:

- Implementing the policies, procedures, and requirements set out in the Act, in any regulations and in the CEC; and
- Complying with the Act and any regulations and the CEC.

A satisfactory review report is a prerequisite to obtaining approval of a CEC for a second or subsequent period.

9.2 Timing of review (section 105)

Where a code holder holds an approved CEC for the first time, or where a person did not carry out research, testing or teaching in the 2 years prior to obtaining their current CEC approval, the first independent review must take place within 2 years. Subsequent reviews must be completed before the term of approval of the current CEC has expired. For example, where the CEC was approved for the maximum term of 5 years, an independent review must be carried out within the first 2 years and again 3 years later. After that, reviews take place every 5 years (provided the CEC is approved for 5 years each time).

9.3 Accredited reviewers (section 109)

Reviewers are accredited by the DG. Before granting accreditation, the DG must be satisfied that a person is a fit and proper person having regard to his or her:

- Competencies;
- Character or reputation; and
- Ability to maintain an appropriate degree of impartiality and independence when conducting reviews.

The DG may from time to time, after consultation with NAEAC, specify in the *Gazette,* the qualifications and experience or other requirements to be met by persons wishing to become accredited reviewers.

Detailed provisions covering the process for considering applications for accreditation, fees, grounds for withdrawal of accreditation, and audit by the DG of reviewers' performance are found in Schedule 2 of the Act.

9.4 The reviewer's report (sections 115 and 116)

After conducting a review, a reviewer is required to prepare a draft report setting out the preliminary conclusions reached and recommendations made. This is sent to the code holder who has at least 15 working days to comment. After considering any comments, the reviewer prepares a final report, which is sent to the code holder. A copy is also sent to the DG and to NAEAC, along with any comments made by the code holder on the draft report.

The DG must then inform the code holder in writing whether the review indicates that a satisfactory level of compliance has been achieved. If compliance is unsatisfactory, the DG must inform the code holder of the actions that must be taken in order to achieve a satisfactory level of compliance. If the code holder does not subsequently comply, or if the response is unsatisfactory, the DG can decline to approve a new CEC or can revoke the existing CEC.

10. POWER OF MINISTER TO APPROVE RESEARCH OR TESTING IN THE NATIONAL INTEREST (section 118)

The Minister may authorise any person or organisation to carry out research or testing without the approval of an AEC where the Minister is satisfied that approval is necessary in the national interest.

In considering whether the national interest test is met, the Minister must have regard to whether the research or testing:

- Is necessary to protect New Zealand's biosecurity interests;
- Relates to matters that affect or are likely to affect, New Zealand's international obligations; and
- Is necessary for the purpose of protecting human or animal health.

An example that could meet the second criteria above is food safety testing that may be specified in an international trading agreement (e.g. a requirement to use mice to test the safety of the water from which mussels are harvested before export). If an AEC considered that the use of the animals was not justified in terms of the Act this could prevent the export trade unless the Minister had the power to intervene.

The Minister must consult with NAEAC before exercising these powers.

11. ENFORCEMENT

As in most other areas of animal use, the Government relies on complaints about non-compliance with Part 6 being identified by members of the public or those closely associated with research, testing or teaching activity. The latter would include staff members in an organisation and AEC members.

Warranted inspectors under the Act have a range of powers to enter land, places, vehicles, aircraft, ships and premises and to take steps (or require the owner or person in charge to take steps) to prevent or mitigate suffering. In some cases a search-warrant is required. Such powers can be exercised where an inspector has reasonable grounds to believe that the animal has been willfully ill-treated, that its physical, health or behavioural needs are not being met or that it is suffering, or is likely to suffer, unreasonable or unnecessary pain or distress.

Part 6 contains three offence provisions. A person commits an offence who:

(i) Carries out research, testing or teaching while not holding an approved CEC or not working for a person who holds an approved CEC (section 82(2));

(ii) Carries out a project that has not been approved by an AEC or which is not carried out in accordance with conditions imposed by an AEC (section 83(2));

(iii) Carries out research, testing, or teaching involving the use of a non-human hominid that has not been approved by the DG, or which is not carried out in accordance with conditions imposed by the DG (section 85(7)).

A person who commits an offence against section 82(2) or section 83(2) or section 85(7) is liable on summary conviction:

- In the case of an individual, to imprisonment for a term not exceeding 6 months or to a fine not exceeding $25,000 or to both; and
- In the case of a body corporate, to a fine not exceeding $125,000.

12. ANIMAL WELFARE (RECORDS AND STATISTICS) REGULATIONS 1999

The provisions in the Animals Protection (Code of Ethical Conduct) regulations 1987 have largely been carried over into the Animal Welfare (Records and Statistics) Regulations 1999. The main differences are that the expanded definition of "animal" applies to all records and statistics and that the requirement for an annual return has been made explicit in the regulations. Returns are due by the end of January each year for the previous calendar year.

More comprehensive information can be found in MAF's publication "Animal Use Statistics", which is supplied to all code holders.

Part II

13. GUIDELINES FOR THE DEVELOPMENT OF CODES OF ETHICAL CONDUCT

13.1 The role of CECs within the regulatory framework

The system for regulating research, testing, and teaching broadly follows the conceptual model progressively being applied in other legislation e.g. the Animal Products Act 1999 and, to a limited extent, the Food Act 1981 (as amended in 1996). It has the following key components:

- Standards or required outcomes are set in legislation;
- The system and methods for meeting these standards are determined by an organisation and set out in a policy document developed by the organisation and approved by the Government;
- Monitoring for compliance is undertaken by an independent third party reviewer accredited by Government;
- The performance of reviewers is subject to Government audit;
- Non-compliance can lead to revocation of an organisation's approval to operate.

Under this model, the outcomes are set in law but each organisation determines the procedures to best meet the outcomes. The lack of prescription provides flexibility for each organisation to tailor its methods and procedures to fit its own situation. It also allows more rapid incorporation of new and innovative ideas.

Two types of outcomes are specified in the Animal Welfare Act 1999. The first is the purposes of Part 6 in section 80. The second relates to process. With respect to the latter, Parliament has required community representation on the decision-making bodies (the AECs) and prescribed some of the outcomes to be met with respect to Committee operation (e.g. prompt and fair hearing of members' complaints). This is because there is a significant value component to decision making and a need to ensure external community members have effective input.

Consistent with the above model, the Act does not prescribe the day-to-day management policies and procedures to enable an organisation and its AEC to meet these outcomes. This is the role of the CEC. The DG, when considering an application for the approval of a CEC, can not predetermine that certain matters need to be covered, or that they need to be covered in a certain way. However, the DG will make a judgement that, collectively, the provisions enable the prospective code holder to meet the outcomes in section 88 of the Act set out below.

13.2 Outcomes to be met by the CEC

Section 88 provides that a CEC must contain policies to be adopted and procedures to be followed by the code holder and AEC that will:

(a) "Enable the AEC to carry out its functions effectively; and

(b) Enable persons who are members of the Animal Ethics Committee but who are not employed by the code holder to have an effective input into the working of the committee; and

(c) Make provision for adequate monitoring of compliance with the conditions of project approvals to be carried out; and

(d) Make provision for the code holder to collect the information and to maintain the records required by regulations made under this Act; and

(e) Specify animal management practices and facilities that are such as to enable the purposes of this Part to be met adequately; and

(f) Be such as to ensure that where any member of the Animal Ethics Committee makes a complaint, that complaint may be dealt with fairly and promptly by the Animal Ethics Committee or the code holder; and

(g) Include, if necessary, the policies and procedures referred to in section 84(1)(b)".

It should be noted that section 101(10) provides that "The appointed members of each Animal Ethics Committee hold office for such terms and on such conditions as are specified in the code of ethical conduct." Accordingly, the terms and conditions of appointment are a matter that must be included in the CEC.

13.3 CEC development

The following table provides guidance on the matters organisations should consider including in their CEC to enable the above outcomes to be met. If organisations choose, they can fill out a form, which can be obtained from the Director-General, Ministry of Agriculture and Forestry, P O Box 2526, Wellington. Organisations that are not applying for CEC approval for the first time may find it helpful to involve their AECs in the development of their new CEC.

Outcome	Matters suggested for inclusion	Explanation / Issues for consideration
Provisions to enable the AEC to carry out its functions effectively.	Membership	The core members are prescribed in section 101. The Act does not provide an upper limit to the number of members. Desirable to ensure that the expertise of the members covers the range of manipulations and animal management situations encountered.

		Ideally this would include the person responsible for the procurement, production and maintenance of the animals and the institutional veterinarian, consultant veterinarian or animal welfare officer. If provision of the full range of expertise would make the size unwieldy, provision could be made for people with particular expertise to be seconded. Desirable to specify procedures for filling of vacancies, to provide confidence that outside vacancies will be promptly filled.
	Term of appointment	Need to strike a balance between ensuring continuity of experience and providing fresh input from time to time. Terms of appointment may be staggered so that terms do not all expire in the same year. Desirable to state the policy on eligibility for reappointment. Limiting the number of terms ensures 'new blood', but in some areas the number of outside people available for new appointments may be limited.
	Remuneration	This is a matter for negotiation with the nominee or with the organisation supplying a nomination. Remuneration, can cover: • Travel and other expenses; and/or • Daily fee for meetings and preparatory work.
	Other conditions of appointment	For example: • Confidentiality of commercially sensitive information; and • Expectations relating to attendance at meetings.

	Committee procedure	Note that section 102 provides that procedure must be determined by the committee if not provided in the CEC or legislation. Organisations must, therefore, decide whether committee procedure will be set out in the CEC or determined by the AEC or a mix of both. Desirable that where the AEC determines procedure, this is made explicit in the CEC. Can include policy and procedures relating to: • Quorum; • Appointment of chair and deputy; • Decision-making if consensus cannot be reached; • Meeting frequency; • Distribution of agendas; • Minute taking (person responsible, scope and detail etc); • Decision-making between meetings in cases of urgency or for projects of low ethical cost; • Establishment of subcommittees, delegated powers etc; • Disclosure of official information where organisations are subject to the Official Information Act 1987; • Protection of commercially sensitive information; • Public attendance at AEC meetings where AEC is subject to the Local Government Official Information and Meetings Act 1987; • Maintenance of AEC records (project approvals, rejections, inspections etc); • Annual or other reports to institution.
	Input by AEC to significant organisational decisions that may affect animal welfare	For example: • The building of, or modification of animal facilities; • Proposals relating to changes in staff numbers and training.

	Project applications and consideration by the AEC	For example: • Procedures for staff members to follow when submitting a project application to the AEC and the information that the application must cover. A standard form for completion by project leaders may be considered; • Policy on whether applicants can present proposals in person; • Procedures to ensure responses to applications occur without undue delay; • Provision for consideration by the AEC of amendments to accommodate unanticipated and legitimate changes
	Routine manipulations	Policy on review periods for protocols covering routine manipulations.
	Lines of communication and accountabilities	Open communication between AEC and management will generally be facilitated by the presence of the chief executive or a senior staff member on the AEC. Nevertheless desirable to set out: • The various people/positions in the organisation responsible and accountable for decisions affecting animal management and in particular to whom AECs should address recommendations of a general nature relating to animal care (i.e. outside of conditions on project approvals); • Procedures to be followed by the AEC when it considers that a project should be terminated because it is breaching the legislation or a condition of AEC approval; • Policy and procedures for organisational responses to recommendations made by the AEC; • Mechanisms to keep AEC members up-to-date with organisational developments/activities between meetings e.g. by sending copies of in-house newsletters.

Provisions to enable external members to have an effective input into the working of the committee.	Minimum number of external members involved in decision making.	In many cases AECs will have a majority of internal members. To ensure that project decisions are always made with outside scrutiny and input, it is desirable to specify the minimum number of external members that must be present when project proposals are considered.
	Induction of external members	External members new to an AEC will be able to contribute more effectively if they are familiar with the organisation, its work and procedures. A formal familiarisation process would be helpful.
Provision for adequate monitoring of compliance with the conditions of project approvals.	Monitoring within the organisation	For example: • Compliance monitoring included in the job descriptions of project managers and their supervisors; • System of formal reporting either to the AEC (see below) or to management; • Disciplinary procedures where staff have not complied with the conditions of project approval.
	Monitoring by the AEC	The CEC should indicate the arrangements in place to allow AEC members to independently check for compliance with conditions of project approvals. Access to projects and information should be granted to outside members at any time, with any necessary limitations to ensure the scientific validity or success of a project is not compromised. Consideration could be given to establishing a system of animal welfare reporting sheets. These would be filled in by staff and forwarded to the AEC. The AEC could then follow up any issues that arise.

	Record keeping systems and accountability	CECs should refer to the systems that are in place to ensure the information required by the Animal Welfare (Records and Statistics) Regulations 1999 is collected, held and reported to MAF by the specified date. Records should be in a form that enables AEC members to assess the cumulative effect of successive projects on animals' welfare (section 100(k)).
Specification of the animal management practices and facilities to enable the purposes of Part 6 to be met.	Animal management practices and facilities	This should be general in nature. The conditions on each project approval will specify the particular requirements for the animals used in that project.
	Staff training and supervision	High standards of animal care are dependent on well-trained and well-supervised staff. For small-animal facilities, animal acquisition, breeding and holding facilities should be supervised by people with appropriate veterinary or animal care qualifications or experience. For large-animal acquisition, breeding and holding facilities should be under the control of a farm manager or a person experienced in managing and handling large animals. Veterinary oversight is recommended. Other personnel working with the animals should be appropriately instructed in their care, how they may affect their well-being and how their actions may affect the outcome of experiments. Formal training in animal science or technology is desirable. New staff should be given appropriate training relating to their job and

		organisational policies.
Provision for complaints by AEC members to be dealt with fairly and promptly.		Consideration should be given to including: • The person/position that complaints should be addressed to; • The person or body responsible for considering complaints; • Mechanisms to ensure confidentiality where necessary; • Opportunity for complainant to be heard; • Timelines; • Notification of decision; • Opportunities for review of decisions.
Policies and procedures referred to in section 84(1)(b) ("piggy-backing" arrangements)		Where a code holder enters into an arrangement to allow its AEC to consider project applications from another organisation, that code holder is accountable for ensuring that the other organisation complies with the conditions on project approvals and with the legislation. Accordingly, there needs to be adequate arrangements put in place for supervision, inspection, and reporting. Consideration can be given to including policies in the CEC on: • The geographical area within which "piggy-backing" arrangements will be entered into (given that inspection will be difficult if distances are large); • Fees to be charged to cover expenses; • Monitoring arrangements.

Appendix I

RATIONALE FOR THE EXCLUSION OF KILLING FROM THE DEFINITION OF MANIPULATION (section 3(2)(b) and (c))

Animals are used in a variety of ways – for food and fibre, as companions and for sport. In some instances, this involves killing, including when animals are used for food or research, or when they cannot be re-homed by the Society for the Prevention of Cruelty to Animals (RNZSPCA). There is a range of views in the community on appropriate uses of animals. However, the Act does not take a position on whether the use of animals for some purposes is morally more or less acceptable than for other purposes. Indeed, it would be very difficult for legislation to provide guidance in this area. The focus of the Act is on ensuring that, whatever the use, animals:

- Are cared for properly;
- When ill or injured are, where practicable, given treatment to alleviate any unreasonable or unnecessary pain or distress; and
- Are killed in such a manner that the animals do not suffer unreasonable or unnecessary pain or distress.

Accordingly, where killing is the endpoint of a manipulation, provided it is done humanely, Part 6 does not require that any views on the morality of this should be taken into account by an AEC in its assessment of harm (refer to discussion on harm/benefit analysis in section 5.2 of this Guide). When assessing the harm that may result from a manipulation, AECs are required to look at this in terms of pain and distress only.

Nevertheless, AECs will have a significant influence on the number of animals that need to be killed to end the suffering caused by manipulations. A manipulation of this type would generally be at the upper end of the severity range. An AEC must, therefore, be satisfied that the likely benefits are sufficiently high to outweigh the harm. In addition, it must give consideration to whether the minimum number of animals are proposed, whether non-sentient or non-living alternatives are available, whether there are means of reducing the pain and suffering so that killing is not needed as the endpoint, and at what point the manipulation should be abandoned and the animals humanely destroyed, if pain or distress cannot be held within reasonable levels.

There is a view that if AECs are not required to approve the killing of animals, this may result in some organisations using inhumane methods. It must be emphasised that all people and institutions are required to comply with the Act. This includes the requirement in section 12(c) to kill any animal in such a manner that it does not suffer unreasonable or unnecessary pain or distress. A future code of welfare under the Act will contain minimum standards and recommendations on best practice for killing for research purposes. Failure to meet such standards could result in a prosecution for an offence of ill-treatment under the Act.

Thus, every organisation needs to ensure that policies and procedures are in place relating to the methods of killing to be used and internal monitoring for compliance. It is up to an organisation to decide how this happens. Where an organisation has an AEC, it could request the AEC to develop the policies and carry out monitoring. However, this work would not be undertaken by the Committee to fulfill its functions under Part 6. It would be undertaken as part of a separate arrangement with the organisation.

Even if AEC members are not officially involved, clearly members will be in a good position to make a complaint to an Animal Welfare Act inspector or MAF if they consider the institution is in breach of section 12(c). The enforcement of the Act in relation to other types of killing (such as in slaughter premises and in RNZSPCA shelters) also relies, in the main, on complaints being made by employees and the public.

While the scope of the Act is confined to dealing with animal welfare (preventing or alleviating pain or distress), this does not preclude individuals or organisations making their own judgements about when it is appropriate to kill animals and when it is not. Many people are committed vegetarians because of their opposition to taking the life of animals for the purpose of providing food. Many people oppose hunting and fishing because a humane death cannot always be achieved. In the research, testing and teaching context, many organisations take the view that there should be appropriate justification for the killing of any animal for post-mortem research. Accordingly they have instigated formal processes to scrutinize applications. This enables such organisations to exercise a case-by-case judgement as to whether proposals for post-mortem research are justified in terms of the ethical parameters set by the organisation.

Appendix II

PART 6 OF THE ANIMAL WELFARE ACT 1999

USE OF ANIMALS IN RESEARCH, TESTING, AND TEACHING

80. Purposes--

(1) The principal purpose of this Part is to ensure that the use of animals in research, testing, and teaching is confined to cases in which there is good reason to believe--

(a) That the findings of the research or testing or the results of the teaching will enhance--

(i) The understanding of human beings, animals, or ecosystems; or

(ii) The maintenance or protection of human or animal health or welfare; or

(iii) The management, protection, or control of ecosystems, plants, animals, or native fauna; or

(iv) The production and productivity of animals; or

(v) The achievement of educational objectives; and

(b) That the benefits derived from the use of animals in research, testing, and teaching (whether the direct benefits of a project or the likely benefits of that project when combined with the findings of other related projects that have been undertaken in the past or that are currently being undertaken or are planned for the future) are not outweighed by the likely harm to the animals; and

(c) That, where the research, testing, or teaching involves the use of a non-human hominid, that research, testing, or teaching may be carried out only where either--

(i) It is in the best interests of the non-human hominid; or

(ii) It is in the interest of the species to which the non-human hominid belongs and the benefits to be derived from the use of the non-human hominid in the research, testing, or teaching (being benefits of the kind described in paragraph (b)) are not outweighed by the likely harm to the non-human hominid.

(2) The other purposes of this Part are-

(a) To ensure that,--

(i) In relation to animals used in research, testing, and teaching, all reasonable steps are taken to ensure that the physical, health, and behavioural needs of those animals are met in accordance with both good practice and scientific knowledge; and

(ii) Where animals used in research, testing, and teaching are ill or injured, they receive, where practicable, treatment that alleviates any unreasonable or unnecessary pain or distress:

(iii) Where, because of the nature of the research, testing, or teaching, the needs referred to in subparagraph (i) cannot be fully met or the treatment referred to in subparagraph (ii) cannot be provided, any degree of pain or distress is reduced to the minimum possible in the circumstances:

(b) To promote efforts-

(i) To reduce the number of animals used in research, testing, and teaching to the minimum necessary:

(ii) To refine techniques used in any research, testing, and teaching so that the harm caused to the animals is minimised and the benefits are maximised:

(iii) To replace animals as subjects for research, and testing by substituting, where appropriate, non-sentient or non-living alternatives:

(iv) To replace the use of animals in teaching by substituting for animals, where appropriate, non-sentient or non-living alternatives or by imparting the information in another way.

81. Effect of this Part--

(1) Nothing in Parts 1 and 2 prevents animals being used in research, testing, or teaching in accordance with this Part.

(2) The limitation imposed by subsection (1) on the application of Parts 1 and 2 does not apply in any case where any animal is used in research, testing, or teaching other than in accordance with this Part or other than in accordance with the conditions of any project approval.

Restrictions

82. Restrictions on Research, Testing, and Teaching involving Use of Animals--

(1) No person may carry out research, testing, or teaching involving the use of animals unless--

(a) That person holds a code of ethical conduct approved under this Part; or

(b) That person is authorised or required by a contract of employment, or any other type of contract, entered into with a person of the kind described in paragraph (a) to carry out the research, testing, or teaching.

(2) A person commits an offence who contravenes subsection (1).

83. Restrictions on Carrying out of Projects--

(1) Notwithstanding section 82, no person may carry out any project unless it has first been approved by an Animal Ethics Committee appointed by the code holder and is carried out in accordance with any conditions imposed by that Animal Ethics Committee.

(2) A person commits an offence who contravenes subsection (1).

84. Power to Carry out Certain Projects--

(1) A person may carry out research, testing, or teaching without obtaining, under section 91, approval of a code of ethical conduct and without appointing an Animal Ethics Committee, if--

(a) Each project carried out by that person is approved by an Animal Ethics Committee established by a person who is a code holder; and

(b) The policies and procedures relating to the arrangements in relation to the research, testing, or teaching are set out in the code holder's code of ethical conduct; and

(c) The arrangements in relation to the research, testing, or teaching are agreed on by that person, the code holder, and the Animal Ethics Committee; and

(d) The code holder, before the research, testing, or teaching is commenced, gives to the Director-General written notice of the arrangements for the research, testing, or teaching.

(2) This section has effect despite anything in sections 82 and 83.

85. Restrictions on Use of Non-Human Hominids-

(1) No person may carry out any research, testing, or teaching involving the use of a non-human hominid unless such use has first been approved by the Director-General and the research, testing, or teaching is carried out in accordance with any conditions imposed by the Director-General.

(2) The Director-General may, in giving approval under subsection (1), impose, as conditions of that approval, such conditions as the Director-General thinks fit.

(3) The Director-General may from time to time, by notice in writing to any person holding an approval under subsection (1),--

(a) Revoke any condition of that approval:

(b) Revoke any condition of that approval, and impose another condition in its place:

(c) Amend any condition of that approval.

(4) The Director-General must consult with the National Animal Ethics Advisory Committee before exercising the powers conferred by subsection (1) or subsection (2) or subsection (3).

(5) The Director-General must not give approval under subsection (1) unless he or she is satisfied--

(a) That the use of the non-human hominid in the research, testing, or teaching is in the best interests of the nonhuman hominid; or

(b) That the use of the non-human hominid in the research, testing, or teaching is in the interests of the species to which the non-human hominid belongs and that the benefits to be derived from the use of the non-human hominid in the research, testing, or teaching are not outweighed by the likely harm to the non-human hominid.

(6) The Director-General must monitor the carrying out of any research, testing, or teaching to which an approval given under subsection (1) relates.

(7) A person commits an offence who contravenes subsection (1).

(8) Nothing in sections 82 to 84 applies in relation to research, testing, or teaching that involves the use of a nonhuman hominid.

86. Revocation of Approval--

(1) The Director-General may at any time, by notice in writing to the person to whom an approval under section 85 (1) was given, revoke that approval if the Director-General is satisfied,--

(a) Where the approval was given in accordance with section 85 (5) (a), that the use of the non-human hominid in the research, testing, or teaching is no longer in the best interests of the non-human hominid; or

(b) Where the approval was given in accordance with section 85 (5) (b), that the use of the non-human hominid in the research, testing, or teaching is no longer in the interests of the species to which the nonhuman hominid belongs; or

(c) Where the approval was given in accordance with section 85 (5) (b), that the benefits to be derived from the use of the non-human hominid in the research, testing, or teaching (being benefits of the kind described in section 80 (1) (b)) are outweighed by the likely harm to the non-human hominid; or

(d) That any condition of the approval is not being complied with; or

(e) That the person to whom the approval was granted--

(i) Is no longer carrying out research, testing, or teaching; or

(ii) Has been convicted of an offence against any Act specified in section 96 (2) (b); or

(iii) No longer has the capability and skills to carry out research, testing, or teaching; or

(iv) Has failed to comply in a material respect with this Act or any regulations made under this Act or any code of ethical conduct; or

(v) Has provided in that person's application for the approval information that was false in a material respect.

(2) The Director-General must, before revoking the approval, give the person to whom the approval was given, an opportunity to be heard.

Codes of Ethical Conduct

87. Codes of Ethical Conduct--

Any person who--

(a) Is engaged in, or wishes to be engaged in, research, testing, or teaching; and

(b) Wishes to use animals in that research, testing, or teaching,--

may apply to the Director-General for approval of a code of ethical conduct in relation to the use of animals.

88. Contents of code of Ethical Conduct--

(1) Each code of ethical conduct must contain provisions that set out, in relation to the carrying out of the research, testing, or teaching to which the code relates, the policies to be adopted and the procedures to be followed,--

(a) By the code holder; and

(b) By an Animal Ethics Committee appointed by the code holder.

(2) The policies and procedures must—

(a) Enable the Animal Ethics Committee to carry out its functions effectively; and

(b) Enable persons who are members of the Animal Ethics Committee but who are not employed by the code holder to have an effective input into the working of the committee; and

(c) Make provision for adequate monitoring of compliance with the conditions of project approvals to be carried out; and

(d) Make provision for the code holder to collect the information and to maintain the records required by regulations made under this Act; and

(e) Specify animal management practices and facilities that are such as to enable the purposes of this Part to be met adequately; and

(f) Be such as to ensure that where any member of the Animal Ethics Committee makes a complaint, that complaint may be dealt with fairly and promptly by the Animal Ethics Committee or the code holder; and

(g) Include, if necessary, the policies and procedures referred to in section 84 (1) (b).

(3) The provisions of each code of ethical conduct must--

(a) Be consistent with this Act and with any standards or policies prescribed by regulations made under this Act; and

(b) Be such as to enable any requirements specified in regulations made under this Act to be met.

89. Application for Approval--

(1) Every application under section 87 must be in writing and must contain--

(a) Information on the general nature and extent of the research, testing, or teaching in which the applicant is engaged or proposes to be engaged; and

(b) A statement of the period in respect of which the approval is sought; and

(c) Particulars of any convictions against--

(i) This Act; or

(ii) The Animals Protection Act 1960; or

(iii) The Agricultural Compounds and Veterinary Medicines Act 1997; or

(iv) The Biosecurity Act 1993; or

(v) The Companies Act 1993; or

(vi) The Crimes Act 1961; or

(vii) The Dog Control Act 1996; or

(viii) The Serious Fraud Office Act 1990; or

(ix) The Trade in Endangered Species Act 1989; or

(x) The Veterinarians Act 1994; or

(xi) Any Act that was replaced by any of the Acts specified in subparagraphs (ii) to (x); or

(xii) Any Act passed in substitution for any of the Acts specified in subparagraphs (iii) to (x).

(2) Every application under section 87 must be accompanied by--

(a) The proposed code of ethical conduct to which the application relates; and

(b) Evidence, in the form of independent references and appropriate academic qualifications, that the applicant, or the persons employed or engaged to do the work, have the capability, skills, and experience to carry out the type of research, testing, or teaching to which the application relates; and

(c) Where the application relates to a second or subsequent period of research, testing, or teaching, a report-

(i) Made by an accredited reviewer; and

(ii) Showing that the work carried out during the previous period of research, testing, or teaching was satisfactory in terms of section 106 (1).

(3) The Director-General must refer to the National Animal Ethics Advisory Committee for its comments every application made under section 87 and must consult with that Committee with regard to every such application.

(4) Where a person, who is deemed, by section 192 (b) (ii), to be a code holder for the purposes of section 105 (3), makes an application under section 87, that application is deemed for the purposes of this section to be an application relating to a second or subsequent period of research, testing, or teaching.

90. Changes to Proposed Code--

The Director-General may, before deciding whether to approve, or to refuse to approve, a proposed code of ethical conduct, change the contents of the code if the National Animal Ethics Advisory Committee so recommends after consultation with the applicant.

91. Approval of Code of Ethical Conduct--

(1) The Director-General must, in considering any application under section 87, have regard to the following matters:

(a) The contents of the proposed code of ethical conduct; and

(b) The evidence and other information and particulars supplied to the Director-General in accordance with section 89 (1) and paragraphs (b) and (c) of section 89 (2); and
(c) The consultation conducted under section 89 (3).

(2) On approving the proposed code of ethical conduct, the Director-General may impose such conditions as he or she considers appropriate.

(3) Where the Director-General approves a proposed code of ethical conduct, the Director-General must publish a notice of the approval in the Gazette.

(4) Where the Director-General refuses to approve a proposed code of ethical conduct, the Director-General must give the applicant written notice of--
(a) The refusal; and
(b) The reasons for the refusal.

92. Time Limits--

(1) Subject to subsection (3), the Director-General must, within 40 working days after receiving an application under section 87--
(a) Decide whether to approve the proposed code of ethical conduct, with or without changes, and, if it is to be approved, any conditions to be imposed; and
(b) Give or post to the applicant written notice of the decision on the application.

(2) If the period specified in subsection (1) expires without the Director-General having approved the proposed code of ethical conduct and without having given a notice under subsection (1) (b), the Director-General is deemed to have refused to approve the proposed code of ethical conduct.

(3) If, within the period specified in subsection (1), the Director-General notifies the applicant in accordance with subsection (1) (b) that either the Director-General or the National Animal Ethics Advisory Committee either--
(a) Requires more information from the applicant; or
(b) Needs to consult the applicant,--
the period specified in subsection (1) is deemed to be extended by a further 40 working days.

93. Approval to be Personal to Code Holder--

(1) An approval of a code of ethical conduct is personal to the code holder and, except with the consent of the Director-General, is not transferable.

(2) An approval of a code of ethical conduct does not vest by operation of law in any person other than the code holder.

(3) For the purposes of subsection (1), where-
(a) A code holder assigns the assets and goodwill of the code holder's business to another person; or
(b) A transfer of all or some of the share capital of the code holder has the effect of transferring control of the code holder's business to another person,--
every such assignment or transfer has the effect of revoking the approval of the code of ethical conduct held by the code holder unless that assignment or transfer is effected with the consent of the Director-General.

94. Duration of Approval--

(1) Every approval under section 91 of a code of ethical conduct has effect for such period, not exceeding the period of 5 years beginning with the date of the publication in the

Gazette of notice of the approval of that code, as the Director-General specifies in that notice.

(2) Subsection (1) is subject to sections 95 and 96.

95. Application for Amendment, Suspension, or Revocation of Code of Ethical Conduct-

(1) Every code holder may apply to the Director-General for his or her approval to the amendment, suspension, or revocation of the approval of the code of ethical conduct in respect of which the code holder holds the Director-General's approval.

(2) Every such application must be in writing and must state the reason why the code of ethical conduct should be amended, suspended, or revoked.

(3) The Director-General must refer to the National Animal Ethics Advisory Committee for its comments every application made under subsection (1) for his or her approval to the amendment of a code of ethical conduct and must consult with that committee with regard to every such application.

(4) Despite subsections (1) to (3), nothing in this section prevents a code holder from making minor amendments to a code of ethical conduct (being minor amendments that would not materially affect the purposes of the code) without the approval of the Director-General.

(5) Where, in any year ending with 31 December, a code holder makes minor amendments to a code of ethical conduct, that code holder must, as soon as practicable after the end of that year but not later than 31 March in the succeeding year, give to the Director-General in writing particulars of those minor amendments.

96. Amendment, Suspension, or Revocation--

(1) The Director-General must, in considering any application under section 95 for approval to the amendment to a code of ethical conduct, consider--

- (a) Whether the current provisions of the code of ethical conduct are appropriate to the activities of the code holder; and
- (b) Whether scientific developments make it appropriate for the code of ethical conduct to be amended; and
- (c) The consultation conducted under section 95 (3).

(2) The Director-General may, whether or not an application is made under section 95, suspend or revoke the approval of a code of ethical conduct if the Director-General believes, on reasonable grounds, that the code holder--

- (a) Is no longer carrying out research, testing, or teaching; or
- (b) Has been convicted of an offence against--
  - (i) This Act; or
  - (ii) The Animals Protection Act 1960; or
  - (iii) The Agricultural Compounds and Veterinary Medicines Act 1997; or
  - (iv) The Biosecurity Act 1993; or
  - (v) The Companies Act 1993; or
  - (vi) The Crimes Act 1961; or
  - (vii) The Dog Control Act 1996; or
  - (viii) The Serious Fraud Office Act 1990; or
  - (ix) The Trade in Endangered Species Act 1989; or
  - (x) The Veterinarians Act 1994; or
  - (xi) Any Act that was replaced by any of the Acts specified in subparagraphs (ii) to (x); or

(xii) Any Act passed in substitution for any of the Acts specified in subparagraphs (iii) to (x); or

(c) No longer has the capability and skills necessary to carry out research, testing, or teaching; or

(d) Has failed to comply in a material respect with this Act or any regulations made under this Act or the code of ethical conduct; or

(e) Has provided in or with the code holder's application under section 87 information that was false in a material respect.

(3) Except where a code holder applies under section 95 (1) for the suspension or revocation of the approval of a code of ethical conduct, the Director-General must, before revoking or suspending the approval of a code of ethical conduct, give the code holder an opportunity to be heard and must consult with the National Animal Ethics Advisory Committee with regard to the proposed revocation or suspension of the code of ethical conduct.

(4) Where the Director-General decides to approve the suspension or revocation of the approval of a code of ethical conduct, the Director-General must publish a notice of the decision in the Gazette.

(5) Where the Director-General refuses to approve an amendment to a code of ethical conduct, the Director-General must give the applicant written notice of--

(a) The refusal; and

(b) The reasons for the refusal.

97. Review of Decisions--

(1) Where a decision under section 85 or section 86 or section 91 or section 96 is made by a person acting under the delegated authority of the Director-General, the person seeking an approval or holding an approval under section 85 or the applicant or the code holder, as the case may be, are each entitled to have the decision reviewed by the Director-General.

(2) Where a decision under section 85 or section 86 or section 91 or section 96 is made by the Director-General, the person seeking an approval or holding an approval under section 85 or the applicant or the code holder, as the case may be, are each entitled to have the decision reviewed by the Minister.

Animal Ethics Committees

98. Establishment of Animal Ethics Committees--

Every code holder must establish and maintain an Animal Ethics Committee.

99. Functions and Powers--

(1) The functions of an Animal Ethics Committee are--

(a) To consider and determine on behalf of the code holder applications for the approval of projects:

(b) To consider and determine, under section 84 (1) (a), applications for the approval of projects:

(c) To set, vary, and revoke conditions of project approvals:

(d) To monitor compliance with conditions of project approvals:

(e) To monitor animal management practices and facilities to ensure compliance with the terms of the code of ethical conduct:

(f) To consider and determine applications for the renewal of project approvals:

(g) To suspend or revoke, where necessary, project approvals:
(h) To recommend to the code holder amendments to the code of ethical conduct.

(2) Each Animal Ethics Committee has such powers as are reasonably necessary to enable it to carry out its functions.

100. Criteria--

In considering any application for the approval of a project and in setting, varying, or revoking conditions of the approval of a project, every Animal Ethics Committee must have regard to such of the following matters as are relevant:

(a) The purposes of this Part; and
(b) Any matters that the Committee is required to consider by regulations made under this Act; and
(c) The scientific or educational objectives of the project; and
(d) The harm to, or the distress felt by, the animals as a result of the manipulation, and the extent to which that harm or distress can be alleviated by any means (including, where the pain or distress cannot be held within reasonable levels, the abandonment of the manipulation or the humane destruction of animals); and
(e) Whether the design of the experiment or demonstration is such that it is reasonable to expect that the objectives of the experiment or demonstration will be met; and
(f) The factors that have been taken into account in the choice of animal species; and
(g) Whether the number of animals to be used is the minimum necessary to ensure a meaningful interpretation of the findings and the statistical validity of the findings; and
(h) Whether adequate measures will be taken to ensure the general health and welfare of animals before, during, and after manipulation; and
(i) Whether suitably qualified persons will be engaged in supervising and undertaking the research, testing, or teaching; and
(j) Whether any duplication of an experiment is proposed and, if so, whether any such duplication will be undertaken only if the original experiment--
  (i) Is flawed in a way that was not able to be predicted; or
  (ii) Needs to be duplicated for the purpose of confirming a result that was unexpected or has far-reaching implications; and
(k) Whether the same animals are to be used repeatedly in successive projects, and, if so, the cumulative effect of the successive projects on the welfare of the animals; and
(l) Whether there is a commitment to ensuring that findings of any experiment will be adequately used, promoted, or published; and
(m) Any other matters that the Committee considers relevant.

101. Membership--

(1) Each Animal Ethics Committee is to consist of at least 4 members.
(2) If the code holder is an organisation, the members of the Animal Ethics Committee must be appointed by the chief executive of the organisation or his or her nominee.
(3) One member must be-
  (a) The code holder; or
  (b) If the code holder is an organisation, a senior member of the organisation appointed by the chief executive to be a member of the committee.
(4) Any senior member of an organisation who is appointed under subsection (3) (b) must be a person who is capable of evaluating--
  (a) Each proposal for a project; and
  (b) The qualifications and skills of the proposer of a project; and

(c) The scientific value or the teaching value, as the case may require, of a project.

(5) One member must be a veterinarian (not being a veterinarian who is an employee of, or is otherwise associated with, the code holder) appointed by the code holder on the nomination of the New Zealand Veterinary Association or a similar national body of veterinarians.

(6) One member must be a person appointed by the code holder on the nomination of an approved organisation.

(7) The person appointed under subsection (6) must not be-

(a) A person who is in the employ of, or is otherwise associated with, the code holder; or

(b) A person who is involved in the use of animals for research, testing, or teaching.

(8) One member must be a person appointed by the code holder on the nomination of a territorial authority or regional council.

(9) The person appointed under subsection (8) must not be-

(a) A person who is in the employ of, or is otherwise associated with, the code holder; or

(b) A person who is associated with the scientific community or an animal welfare agency.

(10) The appointed members of each Animal Ethics Committee hold office for such terms and on such conditions as are specified in the code of ethical conduct.

102. Procedure--

The procedure of an Animal Ethics Committee must, except as provided in this Act or in regulations made under this Act or in the code of ethical conduct, be determined by the committee.

103. Report of Non-Compliance--

(1) Any member of an Animal Ethics Committee who believes that the Committee or the code holder is failing to comply in a material respect with this Act or with any regulations made under this Act or with the code of ethical conduct, may report the non-compliance to the Director-General.

(2) A member of an Animal Ethics Committee who makes a report under subsection (1) in good faith is not to be liable to any civil or criminal proceedings or to any disciplinary proceedings by reason of having made that report.

(3) The Director-General must use his or her best endeavours not to disclose any information that might identify the person who made the report unless--

(a) The person consents to the disclosure of that information; or

(b) The Director-General reasonably believes that disclosure of the identifying information--

(i) Is essential to the investigation of the allegations made in the report; or

(ii) Is essential having regard to the principles of natural justice.

(4) Nothing in the Official Information Act 1982 or the Privacy Act 1993 requires the Director-General to disclose information that might identify the person who made the report.

104. Protection of Members of Animal Ethics Committees--

No member of an Animal Ethics Committee is personally liable for any act done or omitted by the member or the committee in good faith in the course of the operations of the committee.

105. Independent Reviews--

(1) An independent review of each code holder and of each Animal Ethics Committee established and maintained by the code holder must be undertaken in accordance with this section.

(2) Where the code holder in respect of a code of ethical conduct is--

(a) A person who, on the approval of that code, became a code holder for the first time; or

(b) A person who, on the approval of that code, was a person who had not, at any time in the period of 2 years immediately preceding the date of that approval, been a code holder,--

an independent review must take place within 2 years after the date on which notice of that approval was published in the Gazette.

(3) Where a code holder (including a code holder to whom subsection (2) applies) applies for the approval of a code of ethical conduct for a second or subsequent period, an independent review must have been completed before the period of the current approval has expired.

106. Purpose--

(1) The purpose of an independent review is to review compliance by a code holder, and by each Animal Ethics Committee appointed by the code holder, with the requirements and standards of this Act and of any regulations made under this Act and of the code of ethical conduct.

(2) The accredited reviewer is entitled, in relation to an Animal Ethics Committee, to review all aspects of the committee's decision-making process but is not entitled to pass judgment on the validity or appropriateness of the final decision except where failure to comply with the Act or poor process appears to have had a significant bearing on the decision.

107. Period to which Independent Review Relates--

The independent review is to relate,--

(a) In the case of an independent review to which section 105 (2) relates, to the period since the code of ethical conduct was approved; or

(b) In the case of an independent review to which section 105 (3) relates, to the period since the last independent review.

108. Conduct of Independent Review--

(1) Each independent review is to be conducted by an accredited reviewer appointed by the code holder.

(2) The code holder appointing the accredited reviewer must pay the accredited reviewer for the accredited reviewer's work in conducting the review.

(3) The remuneration paid for the work is to be such as is agreed on by the code holder and the accredited reviewer.

109. Accredited Reviewers--

(1) The Director-General may, on the application of any natural person, accredit that person to carry out independent reviews under section 105.

(2) Before granting accreditation, the Director-General must be satisfied that the person is a fit and proper person to conduct reviews under section 105, having regard to--

(a) The relevant competencies possessed by the person; and

(b) The person's character or reputation; and

(c) The person's ability to maintain an appropriate degree of impartiality and independence in conducting reviews under section 105.

(3) The Director-General may from time to time, after consultation with the National Animal Ethics Advisory Committee, specify, by notice in the Gazette, the qualifications, experience, or other requirements to be met by persons wishing to become accredited reviewers.

(4) For the purposes of this Act, the Director-General may, without application being made, grant accreditation to any officer or employee of the Ministry who is qualified to carry out reviews under section 105.

110. Performance of Duties--

Every accredited reviewer must--

(a) Maintain an appropriate degree of impartiality and independence in carrying out his or her duties; and

(b) Take all reasonable steps to ensure that his or her judgment is not impaired--

(i) By any relationship with, or interest in, the person or organisation subject to review; or

(ii) By any involvement in the development of, or the process for the approval of, a code of ethical conduct; and

(c) Use his or her best endeavours to comply with, and give effect to, any relevant performance standards or other requirements issued by the Director-General under section 112; and

(d) Keep full and readily accessible records of each independent review conducted by the accredited reviewer.

111. Applications for Accreditation--

(1) Every application for accreditation under section 109 must--

(a) Be made in writing to the Director-General; and

(b) Be made on a form provided by the Director-General and in a manner approved by the Director-General; and

(c) Be accompanied by the prescribed fee (if any).

(2) For the purpose of assessing the matters specified in section 109 (2), the Director-General may require an applicant to supply information additional to that contained in the application.

(3) If the applicant fails to supply the information within 3 months after the request, or within such further time as the Director-General may allow, the application lapses.

112. Performance Standards--

The Director-General may from time to time, by notice in the Gazette,--

(a) Issue performance standards in relation to the exercise or performance by accredited reviewers of their functions, powers, and duties under this Act:

(b) Amend or revoke any performance standards issued under paragraph (a).

113. Provisions Applying in Respect of Accreditation and Accredited Reviewers--

The provisions set out in Schedule 2 apply in respect of both accreditation under section 109 and accredited reviewers.

114. Review--

The accredited reviewer must, in conducting the independent review, assess the extent to which the code holder and the Animal Ethics Committee are--

(a) Implementing the policies, procedures, and requirements set out in this Act and in any regulations made under this Act and in the code of ethical conduct; and

(b) Complying with this Act and any regulations made under this Act and the code of ethical conduct.

115. Report--

The accredited reviewer must, after conducting a review,--

(a) Prepare a draft report setting out--

(i) The preliminary conclusions reached by the reviewer; and

(ii) The preliminary recommendations to be made by the accredited reviewer; and

(b) Send copies of the draft report to the code holder; and

(c) Allow the code holder at least 15 working days within which to respond to and comment on the contents of the draft report; and

(d) After complying with paragraphs (a) to (c) and considering any response and comments made by the code holder in relation to the draft report, prepare a final report setting out the accredited reviewer's conclusions and recommendations; and

(e) Send, to the code holder, a copy of the final report; and

(f) Send, to the Director-General and the National Animal Ethics Advisory Committee,--

(i) A copy of the final report; and

(ii) A copy of any response and comments made by the code holder in relation to the draft report.

116. Level of Compliance--

(1) The Director-General must, after receiving a copy of the final report, inform the code holder in writing whether, in the opinion of the Director-General, the report indicates either--

(a) That the code holder has achieved a satisfactory level of compliance; or

(b) That the code holder has not achieved a satisfactory level of compliance.

(2) Where the Director-General is of the opinion that the report shows that the code holder has not achieved a satisfactory level of compliance, the Director-General must inform the code holder in writing of the actions that the code holder is required to take in order to achieve a satisfactory level of compliance.

117. Power of Minister to Commission Review-

(1) Where the Minister has reasonable grounds to believe that a code holder or an Animal Ethics Committee may not be complying with this Act or any regulations made under this Act or the relevant code of ethical conduct, the Minister may, at the Crown's expense, appoint a person to make an independent review of that code holder or that Animal Ethics Committee or both.

(2) The Minister may determine the terms of reference for the review.

(3) This section has effect despite anything in sections 100 to 114.

(4) Sections 115 and 116 apply, with all necessary modifications, in relation to a person appointed under this section,--

(a) As if that person were an accredited reviewer to whom section 115 applies; and

(b) As if, for the expression "Director-General" wherever it appears in those sections, there were substituted in each case the word "Minister".

Power of Minister to Approve Research or Testing

118. Power of Minister to Approve Research or Testing--

(1) The Minister may authorise any person or organisation to carry out research or testing without the approval of an Animal Ethics Committee where the Minister is satisfied that such research or testing is necessary in the national interest.

(2) In considering whether the research or testing is necessary in the national interest, the Minister must have regard to the following matters:

(a) Whether the research or testing is necessary for the purpose of protecting New Zealand's biosecurity interests:

(b) Whether the research or testing relates to matters that affect or are likely to affect or are relevant to New Zealand's international obligations:

(c) Whether the research and testing is necessary for the purpose of protecting human or animal health.

(3) Subject to subsection (4), the Minister must consult with the National Animal Ethics Advisory Committee before exercising the powers conferred on the Minister by subsection (1).

(4) Subsection (3) does not apply in any case where the research or testing is necessary in relation to the exercise of emergency powers under other Acts.

(5) Nothing in section 82 or section 83 applies in relation to the carrying out of research or testing authorised by the Minister under subsection (1).

Penalties

119. Penalties--

A person who commits an offence against section 82 (2) or section 83 (2) or section 85 (7) is liable on summary conviction,--

(a) In the case of an individual, to imprisonment for a term not exceeding 6 months or to a fine not exceeding $25,000 or to both; and

(b) In the case of a body corporate, to a fine not exceeding $125,000.

RELEVANT DEFINITIONS

Section 2. Definitions of "animal" and "project"

"Animal" --

(a) Means any live member of the animal kingdom that is--
  (i) A mammal; or
  (ii) A bird; or
  (iii) A reptile; or
  (iv) An amphibian; or
  (v) A fish (bony or cartilaginous); or
  (vi) Any octopus, squid, crab, lobster, or crayfish (including freshwater crayfish); or
  (vii) Any other member of the animal kingdom which is declared from time to time by the Governor-General, by Order in Council, to be an animal for the purposes of this Act; and

(b) Includes any mammalian foetus, or any avian or reptilian pre-hatched young, that is in the last half of its period of gestation or development; and

(c) Includes any marsupial pouch young; but

(d) Does not include--
  (i) A human being; or
  (ii) Except as provided in paragraph (b) or paragraph (c) of this definition, any animal in the pre-natal, pre-hatched, larval, or other such developmental stage:

"Project" means--

(a) Any experiment, or series of related experiments, forming a discrete piece of research; or

(b) A protocol for the carrying out of routine manipulations within a specified period; or

(c) Any experiment or demonstration, or series of related experiments or demonstrations, undertaken for teaching purposes:

Section 3. Definition of "manipulation"—

(1) In this Act, unless the context otherwise requires, the term "manipulation", in relation to an animal, means, subject to subsections (2) and (3), interfering with the normal physiological, behavioural, or anatomical integrity of the animal by deliberately--
  (a) Subjecting it to a procedure which is unusual or abnormal when compared with that to which animals of that type would be subjected under normal management or practice and which involves--
    (i) Exposing the animal to any parasite, micro-organism, drug, chemical, biological product, radiation, electrical stimulation, or environmental condition; or
    (ii) Enforced activity, restraint, nutrition, or surgical intervention; or
  (b) Depriving the animal of usual care;--
  and "manipulating" has a corresponding meaning.

(2) The term defined by subsection (1) does not include--
  (a) Any therapy or prophylaxis necessary or desirable for the welfare of an animal; or

(b) The killing of an animal by the owner or person in charge as the end point of research, testing, or teaching if the animal is killed in such a manner that the animal does not suffer unreasonable or unnecessary pain or distress; or
(c) The killing of an animal in order to undertake research, testing, or teaching on the dead animal or on prenatal or developmental tissue of the animal if the animal is killed in such a manner that the animal does not suffer unreasonable or unnecessary pain or distress; or
(d) The hunting or killing of any animal in a wild state by a method that is not an experimental method; or
(e) Any procedure that the Minister declares, under subsection (3), not to be a manipulation for the purposes of this Act.

(3) The Minister may from time to time, after consultation with the National Animal Welfare Advisory Committee and the National Animal Ethics Advisory Committee, declare any procedure, by notice in the Gazette, not to be a manipulation for the purposes of this Act.

(4) The Minister must, in deciding whether to publish a notice under subsection (3) in relation to a procedure, have regard to the following matters:
(a) The nature of the procedure; and
(b) The effect that the performance of the procedure will or may have on an animal's welfare; and
(c) The purpose of the procedure; and
(d) The extent (if any) to which the procedure is established in New Zealand in relation to the production of animals or commercial products; and
(e) The likelihood of managing the procedure adequately by the use of codes of welfare or other instruments under this Act or any other Act; and
(f) The consultation conducted under subsection (3); and
(g) Any other matter considered relevant by the Minister.

Section 4. Definition of "physical, health, and behavioural needs"—

In this Act, unless the context otherwise requires, the term "physical, health, and behavioural needs", in relation to an animal, includes--
(a) Proper and sufficient food and water:
(b) Adequate shelter:
(c) Opportunity to display normal patterns of behaviour:
(d) Physical handling in a manner which minimises the likelihood of unreasonable or unnecessary pain or distress:
(e) Protection from, and rapid diagnosis of, any significant injury or disease,--
being a need which, in each case, is appropriate to the species, environment, and circumstances of the animal.

Section 5. Definition of "research, testing, and teaching"--

(1) In this Act, unless the context otherwise requires, the term "research, testing, and teaching" means, subject to subsections (2) to (4),--
(a) Any work (being investigative work or experimental work or diagnostic work or toxicity testing work or potency testing work) that involves the manipulation of any animal; or

(b) Any work that--
  (i) Is carried out for the purpose of producing antisera or other biological products; and
  (ii) Involves the manipulation of any animal; or
(c) Any teaching that involves the manipulation of any animal.

(2) **The term defined by subsection (1) does not include any manipulation that is carried out on any animal that is in the immediate care of a veterinarian, if--**
(a) The veterinarian believes on reasonable grounds that the manipulation will not cause the animal unreasonable or unnecessary pain or distress, or lasting harm; and
(b) The manipulation is--
  (i) For clinical purposes in order to diagnose any disease in the animal or any associated animal; or
  (ii) For clinical purposes in order to assess the effectiveness of a proposed treatment regime for the animal or any associated animal; or
  (iii) For the purposes of assessing the characteristics of the animal with a view to maximising the productivity of the animal or any associated animal.

(3) The term defined by subsection (1) does not include any manipulation of an animal--
(a) Which is carried out with the principal objective of--
  (i) Assisting the breeding, marking, capturing, translocation, or trapping of animals of that type; or
  (ii) Weighing or taking measurements from the animal; or
  (iii) Assessing the characteristics of animals of that type; and
(b) Which is a manipulation of an animal that--
  (i) Is carried out routinely; or
  (ii) Is a minor modification of a manipulation that is carried out routinely; and
(c) Which is used to fulfill responsibilities and functions under--
  (i) The Conservation Act 1987; or
  (ii) Any Act listed in the First Schedule of the Conservation Act 1987; or
  (iii) Any other Act or regulations under which the Minister of Conservation or the Director-General of Conservation or the Department of Conservation has responsibilities or functions; or
  (iv) The Fisheries Act 1996.

(4) For the purposes of this section, an animal is in the immediate care of a veterinarian if the veterinarian--
(a) Has accepted responsibility for the health and welfare of the animal; and
(b) Is providing the animal with direct and continuing care.

(5) In the other sections of this Act (except section 57 (a) (i)),--
(a) The term "research" means any research work that comes within the term defined by subsection (1); and
(b) The term "testing" means any testing work that comes within the term defined by subsection (1); and
(c) The term "teaching" means any teaching that comes within the term defined by subsection (1).