

# National Animal Ethics

## Advisory Committee



### Occasional Paper No 2

Regulation of animal use in research,  
testing and teaching in New Zealand  
– the black, the white and the grey

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# FOREWORD

This is the second paper in a series published from time to time by the Ministry of Agriculture and Forestry (MAF) under the auspices of the National Animal Ethics Advisory Committee (NAEAC). The objective is to disseminate to a wider audience articles about the use of animals in research, testing and teaching that appear in academic journals and in the proceedings of conferences and also material prepared for another purpose.

Linda Carsons' "Regulation of animal use in research, testing and teaching in New Zealand – the black, the white and the grey" provides a straightforward guide to the essentials of New Zealand's regulatory system under Part 6 of the Animal Welfare Act 1999. It takes the reader through the questions that must be asked when a project is being considered and provides useful practical examples. The article reflects Linda's long experience in the Animal Welfare Directorate and familiarity with the statute. It will, we believe, be of assistance to those associated with Animal Ethics Committees and to those in the wider community interested in animal welfare in research, testing and teaching. NAEAC is grateful to the Ministry of Agriculture and Forestry for permission to publish.

John Martin  
Chair, NAEAC

April 2009

## Regulation of animal use in research, testing and teaching in New Zealand – the black, the white and the grey

This article updates one that appeared in *Surveillance* in 1998.<sup>(1)</sup>

The law requires those who manipulate live animals for the purposes of research, testing or teaching to do so in accordance with an approved code of ethical conduct and with the approval of an animal ethics committee established under that code. Deciding which activities are encompassed by this requirement, and which are not, is not always straightforward.

### Historical background

In 1983 the Animals Protection Act 1960 was amended to remove the exemption from the provisions of the Act previously enjoyed by 'bona fide research workers'. The amendment provided for regulations to be made to control the use of live animals in research, experimental, diagnostic, toxicity or potency testing work and teaching. It was the result of submissions made by the Royal Society of New Zealand to the Minister of Science.<sup>(2)</sup> The regulations, the Animals Protection (Codes of Ethical Conduct) Regulations 1987, came into force in early 1987 and took effect from 1 September that year. The scope of the regulations was later extended to include work for the purposes of producing antisera or other biological agents (from 1 July 1988).

The 1983 amendment also required the Minister of Agriculture (the Minister responsible for administration of the Act), to establish a committee to advise the Minister on matters related to the use of animals in research, testing and teaching and in particular, the content of codes of ethical conduct. Thus, the National Animal Ethics Advisory Committee (NAEAC) was created.

This legislation was replaced, from 1 January 2000, by the Animal Welfare Act 1999. Part 6 of the Animal Welfare Act, although similar to the previous statutory and regulatory regime, is more comprehensive and provides greater clarity as to process and procedure. New features included:

- a statutory requirement for animal ethics committees to be established and to approve projects;
- greater ethical guidance for animal ethics committee members on the factors that they must take into account before deciding whether to approve a project, including the promotion of the Three Rs;
- a stronger focus on monitoring projects to ensure compliance;
- requirements for independent reviews of code holders and their animal ethics committee(s) by a MAF-accredited reviewer.<sup>(3)</sup>

### Issues

The Animal Welfare Act contains definitions of the terms 'animal', 'manipulation' and 'research, testing and teaching' (see appendix 1).

In trying to determine whether an activity needs animal ethics committee approval, it is useful to use a three step test:

1. Is the activity being performed on a live animal (as defined)?
2. Does the activity constitute a manipulation (as defined)?
3. Does the reason that the activity is being performed fall into the category of research, testing, or teaching (as defined)?

If the answers to all three questions are 'yes' then the activity must be performed in accordance with an approved code and with the approval of the animal ethics committee. If the answer to any of the questions is 'no' then animal ethics committee approval is not necessary.

A flowchart has been developed by NAEAC to assist in such deliberations (see appendix 2).

### **The black ...**

Some examples of activities which clearly require animal ethics committee approval are:

- basic biological, biomedical, veterinary and agricultural research using live animals;
- non-recovery surgery carried out by veterinary students as part of their training;
- testing animal vaccines on laboratory rodents.

Although it may not be the first legal issue which springs to mind when considering rabbit calicivirus disease (RCD), the spreading of the RCD virus by injecting caged rabbits with the virus mixture for the production of additional virus material and releasing them into the wild is also an activity which requires ethical approval. The decision-making process for this example is as follows:

- rabbits fall within the definition of animal;
- injecting them with a viral mixture is exposing them to a micro-organism, and is therefore a manipulation;
- the purpose of the activity is the production of biological products, which falls within the definition of research, testing and teaching.

Note, however, that harvesting dead rabbits for the same purpose does not require ethical approval.

### **... the white**

There are other activities which definitely do not require a code of ethical conduct. For example, keeping animals in kindergartens/classrooms as pets or for purely observational purposes does not involve a manipulation and thus does not require a code.

Dissections on carcass material do not require ethical approval either. The Act is specifically restricted to live animals. An exemption is provided for the killing of animals to in order to undertake research, testing or teaching on dead animals or 'prenatal or developmental' tissue provided the animal is killed humanely.

For the same reason, farming practices which involve surgical procedures (such as tailing or castration) when done in the context of routine farm management are not manipulations, because they are not being performed for the purposes of research, testing and teaching. However, it is worth noting that the same procedures do require ethical approval in some circumstances. One example would be where the procedures were being carried out as part of a research programme to compare different methods of castration.

There are other exemptions for veterinarians carrying out trials on animals in their immediate care for clinical diagnostic purposes, for clinical assessment of a proposed treatment regime or for productivity assessment. The veterinarian must believe 'on reasonable grounds' that the animals concerned will not suffer unreasonable or unnecessary pain or distress or lasting harm.

Similarly, certain activities such as assisting the breeding, translocation of animals and the like, carried out under conservation or fisheries legislation is also exempted from the need for approval by an animal ethics committee.

### ...and the grey

There are a number of activities which fall within a “grey” area i.e. where the answer to one or more of the questions in the three step test is not immediately clear or is a matter of judgement.

One issue that has arisen a number of times over the years is blood harvesting. Given that reference was made to the production ‘of antisera and other biological agents’, in the Animals Protection Act, blood harvesting was considered to fall within the range of activities requiring a code of ethical conduct. Under current legislation, careful consideration of the precise nature of the harvesting and of the legal definitions is required.

Given that the animals involved in commercial blood harvesting are usually livestock, then clearly they fall within the definition of animal. The purpose of the work is to produce blood, which is a ‘biological product’, so the activity falls within the definition of research, testing and teaching. However, while harvesting blood simply by insertion of a hypodermic needle into a vein may be insufficient to constitute ‘surgical intervention’, the restraint involved in the collection process is considered to meet the criteria specified in the definition of manipulation. Thus blood harvesting by this method requires ethical approval. Furthermore, the collection of blood by indwelling catheter would be regarded as a surgical intervention, and therefore need approval, and situations where substances (eg antigens) are administered to the animal prior to blood collection would also require ethical approval on the basis of exposure to drugs, chemicals, micro-organisms et cetera.

Another grey area relates to what might be termed “incidental” manipulations. Wild animals (eg possums) may be required for research projects so they are captured. In order to ensure that there are sufficient animals to meet any age or sex ratio requirements more animals are captured than are needed for the project. Some surplus animals are euthanased, others may die before being assigned to a specific research project. The question is, should these animals be regarded as having been manipulated? Capture and holding in captivity does not constitute a manipulation. Thus possums which are not actually used in a research project are not manipulated and numbers should not be included in statistical returns.

Prior to the Animal Welfare Act coming into force, the use of foetuses was considered a grey area as it was unclear at what point an animal became an animal. The Animal Welfare Act largely resolved this by specifying that the definition of animal includes marsupial pouch young, mammalian foetuses in the second half of gestation and pre-hatched birds or reptiles in the second half of development. Thus an inquiry regarding the need for ethical approval for a teaching project involving embryonic zebra fish elicited the response that ethical approval was not required because a zebra fish embryo does not fall within the definition of animal.

Debate arises regarding training courses. There are a number of courses at the senior secondary school, pre-employment or polytechnic level which teach animal handling/husbandry or veterinary nursing skills. The animals involved are generally livestock or companion animals. Two of the criteria are clearly met - the animals fall within the definition and the activity is for teaching purposes. The question to resolve is, is it a manipulation? Docking tails certainly interferes with the anatomical integrity of an animal. One may decide that teaching people to dock tails during a training course is a manipulation. The ramifications of this are possible perceptions of ‘bureaucracy gone mad’, not to mention an argument for saying that every farmer who teaches a new farmhand some animal handling skills needs a code of ethical conduct.

On the other hand, bringing the family pet into a veterinary nursing course so that students can practise injection techniques repeatedly may be an activity that more readily suggests the need for ethical approval.

The rule of thumb developed to cover these types of situations is that if the procedure that is performed in a teaching situation would be performed anyway (eg the trainees are learning how to drench sheep that were due to be drenched) then coverage by a code is not necessary. However, if the procedure is one which would not have been carried out at the time, or if the procedure is repeated a number of times, then careful consideration of the legal definition of ‘manipulation’ is necessary and a code of ethical conduct may be advisable.

## **Conclusion**

The requirement for codes of ethical conduct have now been in place for 20 years and some 30-odd organisations have a code of ethical conduct which has been approved by the Director-General of MAF. Over 70 additional organisations or individuals have a formal arrangement, in accordance with the relevant provisions of the Animal Welfare Act, to use another organisation’s approved code. Such codes ensure that the welfare and humane treatment of live animals used for research, testing and teaching is fully considered by an animal ethics committee (which includes at least three members from outside the organisation) prior to any manipulations being performed.

If anyone is unclear whether particular activities need approval by an animal ethics committee, the flowchart and legal definitions should be the first reference point. If further assistance is required they are advised to contact MAF Biosecurity New Zealand’s Animal Welfare Directorate.

## Appendix 1: Definitions from the Animal Welfare Act 1999

Excerpt from section 2(1)

“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:

### 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.

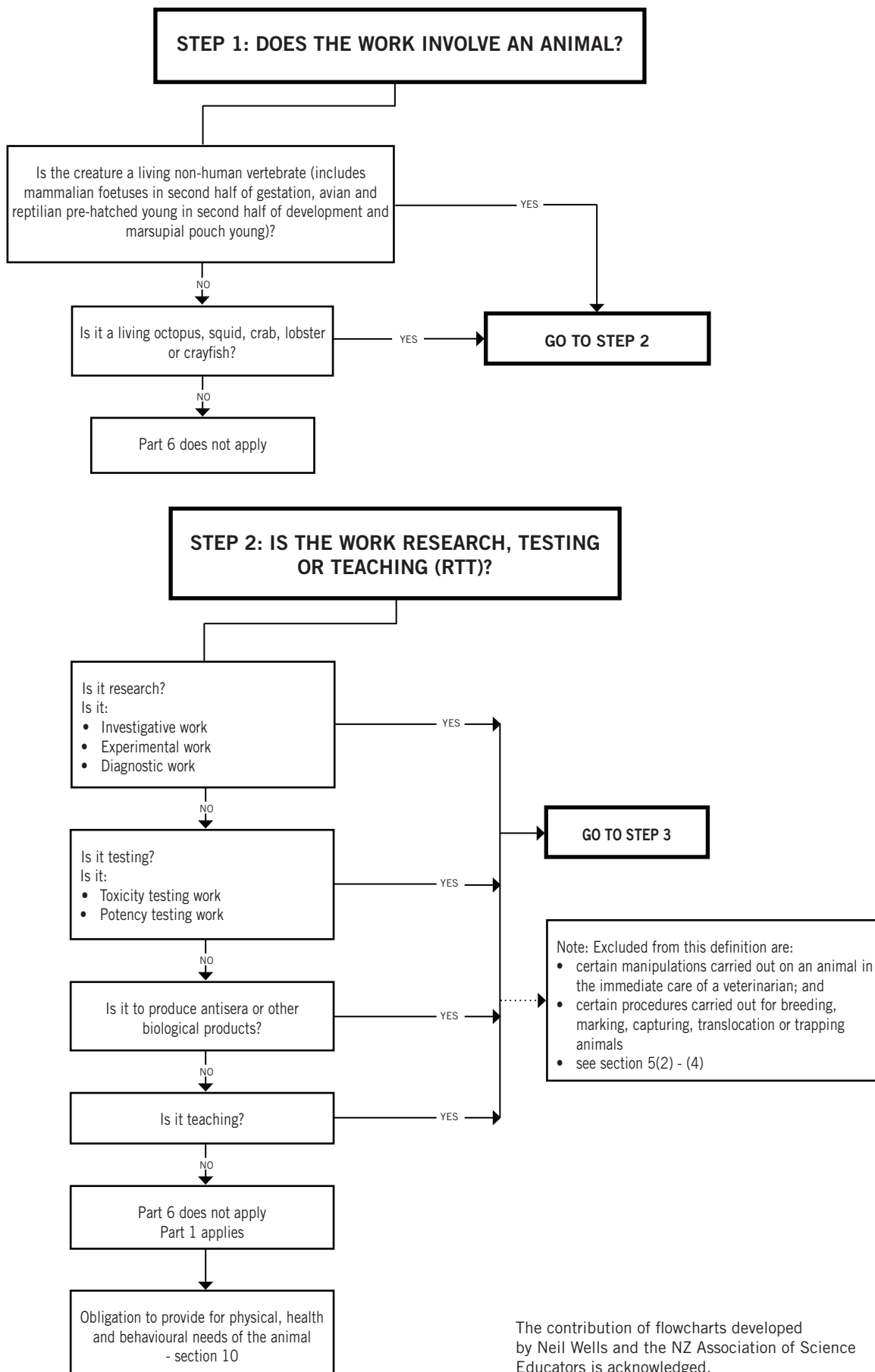
3. The term defined by subsection (1) does not include any manipulation of an animal-
  - a. Which is carried out with the principal objective of-
    - i. Assisting the breeding, marking, capturing, translocation, or trapping of animals of that type; or
    - ii. Weighing or taking measurements from 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).

### **3 Definition of “manipulation”-**

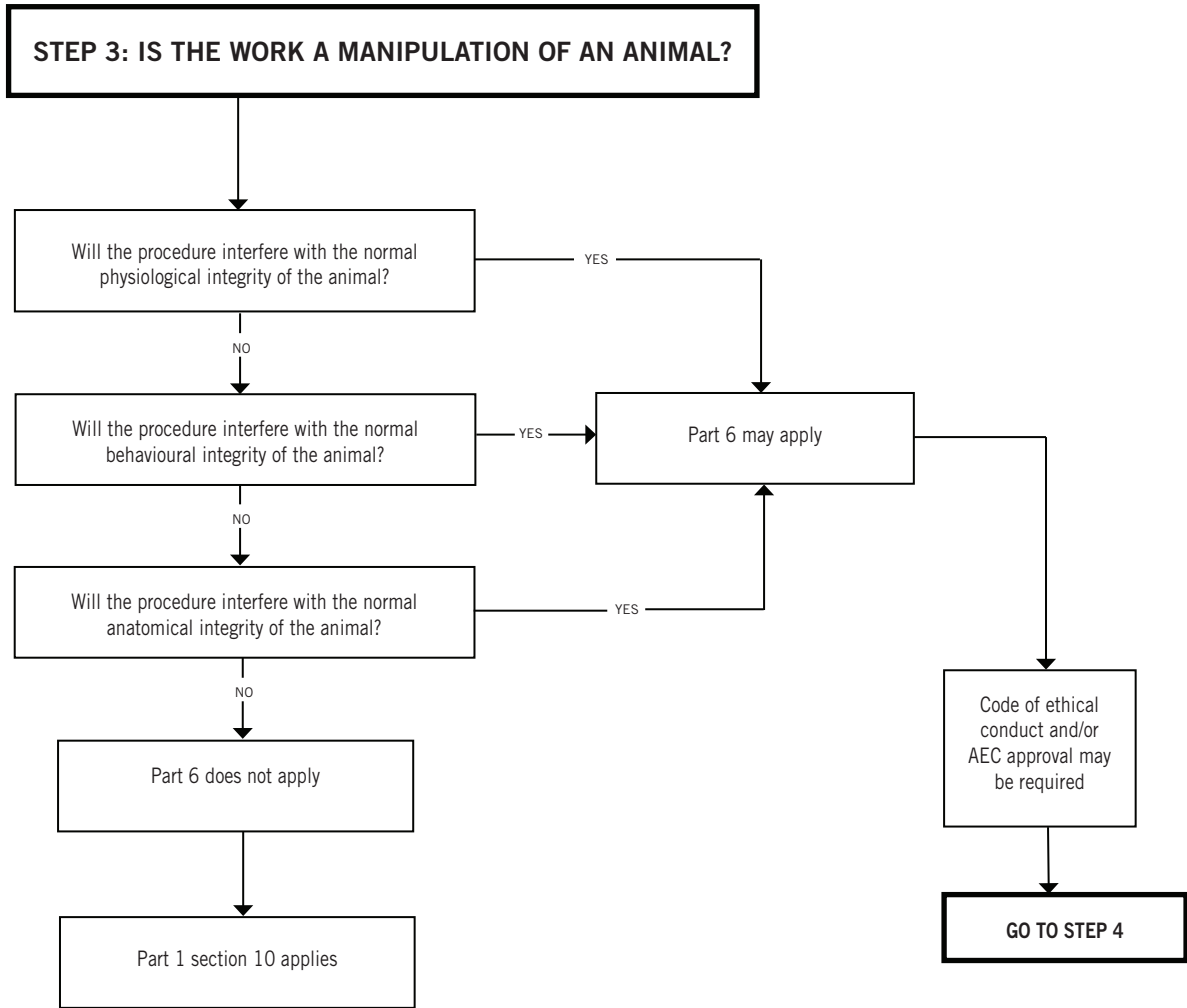
1. In this Act, unless the context otherwise requires, the term “manipulation”, in relation to an animal, means, subject to subsections (2) and (3), interfering with the normal physiological, behavioural, or anatomical integrity of the animal by deliberately--
  - a. Subjecting it to a procedure which 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

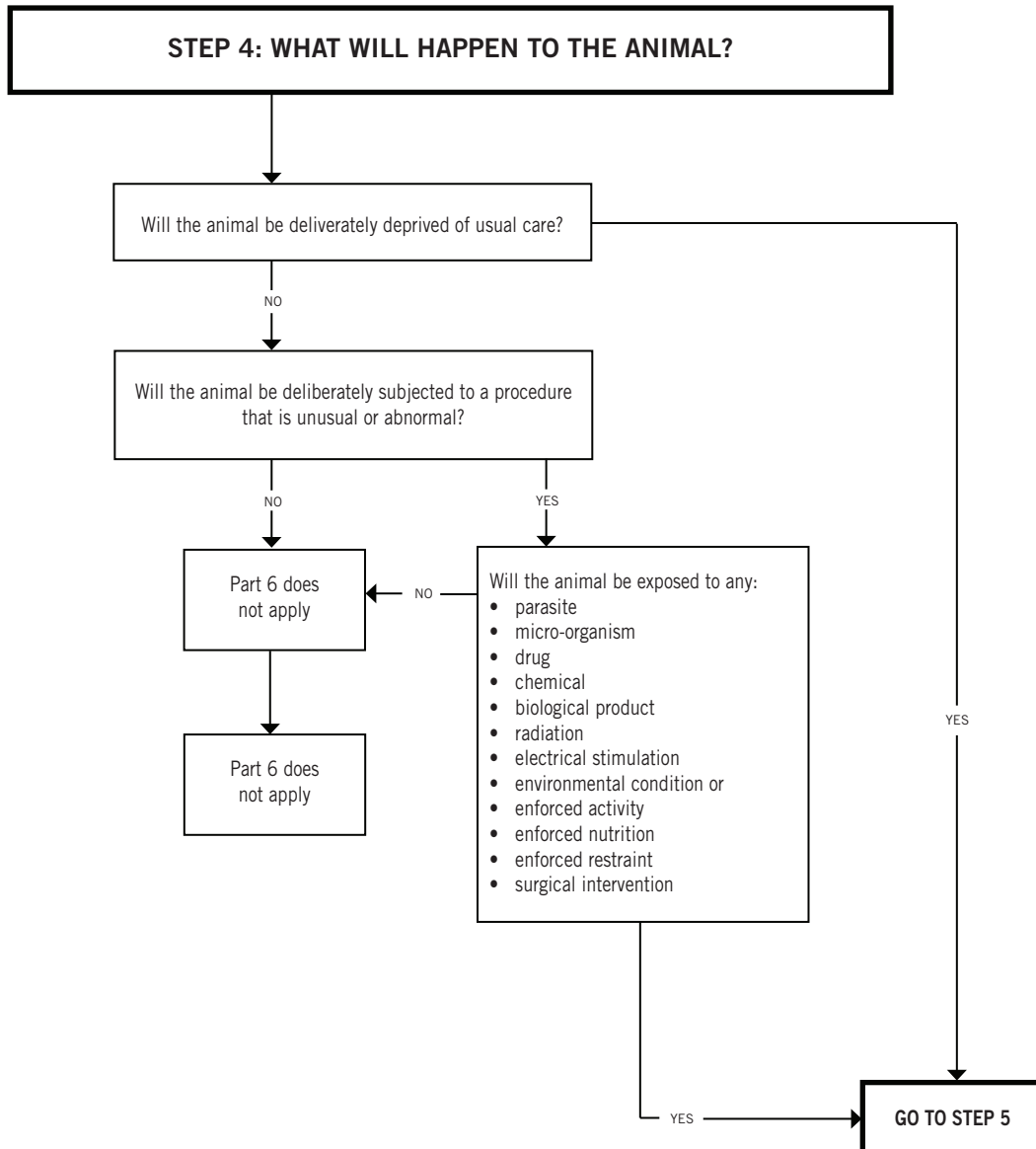
- b. The killing of an animal by the owner or person in charge as the end point of research, testing, or teaching if the animal is killed in such a manner that the animal does not suffer unreasonable or unnecessary pain or distress; or
  - c. The killing of an animal in order to undertake research, testing, 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.

# NEED FOR ETHICAL APPROVAL



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New Zealand Government