

# Collecting statistics on the use of animals in research, testing and teaching

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The proposals in this paper are for consultation purposes and do not necessarily represent agreed Government policy.

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# 1 Summary

The purpose of this discussion paper is to seek feedback about the regularity with which statistics are collected on the use of animals in research, testing and teaching. We welcome your feedback on the issues raised in this discussion paper.

The use of animals in research, testing and teaching is tightly regulated through the Animal Welfare Act 1999. Every proposed project is subject to scrutiny and approval by an Animal Ethics Committee, and must be conducted by a person who holds an approved code of ethical conduct (code), works for a person who holds an approved code or is covered by another person's approved code.

This discussion paper explains the reporting requirements of the Animal Welfare (Records and Statistics) Regulations 1999, notes that current reporting practice differs from those requirements, and seeks feedback on two options for collecting statistics that relate to projects that span more than one calendar year in the future. As required by government guidelines, the substantive elements of regulatory impact analysis have been included in this paper.

The Regulations require that organisations and individuals that use animals in research, testing and teaching must submit to the Ministry of Agriculture and Forestry (MAF) annual returns of the animals they use each year.

Current practice is not in line with these requirements in one respect. Annual reporting as required by the regulations would result in an overstatement of the number of animals being used in research, testing and teaching. For example, animals used in projects that span two calendar years would be reported twice.

Because of this problem, it has been accepted since the 1990s that the number of animals used in long-term projects can be reported at the end of a project, or at the end of three years, rather than annually. However, a return is still required for each calendar year.

The objective of this discussion paper is to assist with decisions on how the Regulations and reporting practices should be aligned.

MAF invites submissions from organisations involved in research, testing and teaching and other interested parties on the two options outlined in this paper, and on any alternative options. The closing date for submissions is **Friday 7 November 2008**.

Questions are provided throughout the document to guide feedback.

## 2 Background

### 2.1 ANIMAL USE IN RESEARCH, TESTING AND TEACHING

Animals have been used in research, testing and teaching throughout the history of scientific research. In recent times, society has become more aware and concerned about animal use in research, testing and teaching. Society must balance up the benefits that arise from using animals in research, testing and teaching with the animal welfare implications of doing so.

### 2.2 THE ANIMAL WELFARE ACT 1999

MAF administers the Animal Welfare Act 1999 (the Act). The Act defines “research, testing and teaching” to include investigative, experimental, diagnostic, toxicity or potency testing or production of biological products or teaching work that involves the manipulation of any animal, with some exceptions.

Research, testing and teaching activities are not allowed unconditionally – the Act sets up a regulatory framework through which these activities are controlled. The Act requires that any person using animals in research, testing and teaching holds an approved code of ethical conduct (code), works for a person who holds an approved code or is covered by another person’s approved code. In addition, individual projects must be approved by an Animal Ethics Committee and carried out according to any conditions imposed.

The Act sets up the National Animal Ethics Advisory Committee (NAEAC), an independent advisory committee. One of NAEAC’s functions is to advise the Minister of Agriculture on ethical issues and animal welfare issues arising from research, testing and teaching.

### 2.3 THE ANIMAL WELFARE (RECORDS AND STATISTICS) REGULATIONS 1999

All organisations and people who use animals in research, testing and teaching are required to keep records as specified in the Animal Welfare (Records and Statistics) Regulations 1999. The records are required to include, amongst other things, information on the number of animals of each species manipulated during the year and the severity of the manipulation. An annual return of the number of animals used during the previous calendar year must be submitted to MAF by 31 January each year. The full text of the Regulations is provided in Appendix 2 of this paper.

NAEAC publishes aggregate information on animals used in research, testing and teaching in its annual report. In its latest report, NAEAC notes that 246,667 animals were manipulated in research, testing and teaching in 2007.

### 2.4 THE PROBLEM

Since the mid-1990s, on the advice of NAEAC and in accordance with international practice, the number of animals used in long-term projects has not been reported annually to MAF but every three years or at the end of the year in which the project is completed (if less than three years). This is to avoid problems with multiple-counting of animals used in long-term projects, and has been explained in NAEAC’s annual reports.

A drafting error in the Regulations overlooked this agreed practice and required reporting of all animals used at the end of each calendar year. There are concerns that the Regulations, if strictly applied, would result in the numbers of animals used in research, testing and teaching being overstated. This is because animals used in projects that span two calendar years would be reported twice. For example, if a project ran from November 2001 until February 2002, the

Regulations require that the animals used in this project be reported as part of both the 2001 and 2002 returns.

In December 2006, NAEAC wrote to the Minister of Agriculture to request that he progress an amendment to the Regulations to reflect the current practice of three yearly reporting.

### 3 Purpose of Collecting Statistics

Identifying the purpose of collecting the statistics is important to determine what type of collection system is needed.

The use of animals in research, testing and teaching is controlled through a number of regulatory mechanisms as discussed in section 2.2. The Animal Welfare (Records and Statistics) Regulations support these mechanisms by requiring information on the nature of manipulation of animals in research, testing and teaching to be recorded and disclosed to MAF. Information disclosure regulatory regimes are typically the least stringent form of regulation. They are primarily designed to encourage reasonable behaviour, without specifically requiring it.

MAF considers that the purpose of collecting statistics on the use of animals in research, testing and teaching is to:

- provide the public with timely information on the nature and scale of national animal use in research, testing and teaching;
- allow scientists and teachers to communicate with the public about their animal use in research, testing and teaching;
- allow monitoring of the use of animals in research, testing and teaching;
- allow comparison of current and historical usage of animals in research, testing and teaching with particular reference to severity assessment; and
- allow comparison with international usage of animals in research, testing and teaching.

- a) Do you agree with MAF's view of the purpose of collecting statistics on animal use in research, testing and teaching? If not, what do you believe the purpose to be?
- b) What do you use the information provided on animal use for? Is the information provided sufficiently accurate and timely?

### 4 Objective of this Review

The objective of this review is to amend the Regulations to ensure that information on animals used in research, testing and teaching is reported with sufficient frequency and accuracy that the purpose of the regulations outlined above is met. We also want to ensure that the right information is collected at the least cost.

The review will not cover any other aspect of the regulatory system around the use of animals in research, testing and teaching.

## 5 Options

MAF has identified two options for interested parties to consider. Two further options were considered and rejected. These are discussed briefly at the end of this section for completeness. Whichever method is used, accurately defining trends over time in animal use would require some form of time-averaging. The three-year rolling average is currently used as there are typically three-yearly cycles in the data.

### 5.1 OPTION 1: REPORTING AT THE END OF A PROJECT OR AT THE END OF THREE YEARS

This option would continue the current practice of code holders reporting the number of animals manipulated at the end of the year in which a project is completed or at the end of three years. NAEAC has recommended that the Regulations be amended to reflect this option.

#### 5.1.1 Multiple counting

The main advantage of this option is that there would be no multiple counting of animals for projects less than three years in length. An animal that is used in a project that spans two or three calendar years would only be counted at the end of the project rather than in each calendar year. Three yearly reporting is currently used because it is assumed that most research projects are less than three years in duration.

However, projects that run for longer than three years would be required to report on the animals used in year three and then again at the end of the project, thus counting them twice.

c) Is it valid to assume that most projects are less than three years in duration or do most research projects last more than three years?

#### 5.1.2 Timeliness and usefulness of information

This option may not meet the test of providing the public with timely information on the use of animals in research, testing and teaching, as some information may be up to three years out of date.

When the data is aggregated for NAEAC's annual report, its usefulness is compromised by the lack of a consistent time unit (data is aggregated for projects that began between one and three years ago). This problem was addressed, in part, by the introduction of a three year rolling average in 2007.

#### 5.1.3 Comparability with past data

This option would be fully comparable with data gathered since the current system was implemented in 1995.

#### 5.1.4 Compliance costs

As this option does not change the current system of collecting animal use statistics, it should mean that there is no change in compliance costs.

d) Is the cost of complying with the current requirements appropriate? Why or why not?

## 5.2 OPTION 2: REPORTING ANNUALLY WITH PREVIOUSLY REPORTED ANIMALS IDENTIFIED

This option would require code holders to report the number of animals manipulated in the previous calendar year. The code holders would be required to state how many animals were new to the project and how many had been counted in a previous year's return as part of the same project.

### 5.2.1 Multiple counting

This option would prevent all multiple counting of animals, as those that have been previously reported will be identified.

### 5.2.2 Timeliness and usefulness of information

The main advantage of this option is that the data collected would be accurate and timely, as it would fully reflect how many animals are manipulated in research, testing and teaching during the previous year, regardless of whether or not the project has finished.

This option would allow trends in animal use in research, testing and teaching to be tracked on an annual basis. However, there would be fluctuations of animal use between years as projects do not tend to use the same number of animals throughout the duration of the project.

### 5.2.3 Comparability with past data

Consistency in reporting requirements from year to year is important to ensure that the information is useful. Any change to current practice will mean that it is more difficult to ascertain trends with data collected before and after the change. However, this must be balanced with the current lack of a consistent time unit (as outlined in section 5.1.2).

Regardless, the data collected under this option could be compared with past data by manipulating the data to give the same information as collected under the current system.

### 5.2.4 Compliance costs

This option is likely to increase compliance costs for code holders as they will be required to provide additional information about those animals that are involved in projects that span more than one calendar year.

- e) What types of systems do code holders use to keep records currently, for example, are records of the animals used kept throughout a project, or is information recorded only at the end?
- f) Would compliance costs increase under Option 2? If so, by how much? Would these compliance costs be reasonable? Why or why not?
- g) Would submitting returns for projects that are not yet complete cause any problems? If so, please provide details of the problems.
- h) Are there other feasible options for collecting statistics that relate to projects that span more than one calendar year that have not been considered? If so, please provide details, including the potential impacts of the proposed option/s.

## 5.3 DISCARDED OPTIONS

### 5.3.1 Annual reporting

Annual reporting would require code holders to provide information to MAF annually, regardless of whether a project is completed or will continue into the next calendar year. It is a simple reporting method. Code holders would know that they must report the number of animals used every year and that all research conducted has a standard requirement to report the number of animals used.

However, annual reporting is seen as undesirable, as it overstates animal use numbers (as explained in section 2.4). In addition, code holders would be required to report more frequently than they are currently. This is likely to increase compliance costs.

### 5.3.2 Abolishing reporting

Abolishing the collection of animal use statistics would mean that code holders would not be required to report how many animals they use in research, testing and teaching. While this is the least costly option, it would not meet any of the purposes of collecting animal use statistics.

## 6 Notes for Submitters

We welcome submissions from all interested parties on any aspect of the analysis and proposed options presented in this document.

Submissions are public information and may be the subject of requests under the Official Information Act 1982. If you consider that any or all of the information in your submission should be treated as confidential or commercially sensitive, please state this clearly in your submission. Any decision to withhold information under the Official Information Act may be reviewed by the Ombudsman.

### 6.1 KEY ISSUES MAF SEEKS COMMENT ON

The key issues that MAF seeks comment on are:

- a) Do you agree with MAF's view of the purpose of collecting statistics on animal use in research, testing and teaching? If not, what do you believe the purpose to be?
- b) What do you use the information provided on animal use for? Is the information provided sufficiently accurate and timely?
- c) Is it valid to assume that most projects are less than three years in duration or do most research projects last more than three years?
- d) Is the cost of complying with the current requirements appropriate? Why or why not?
- e) What types of systems do code holders use to keep records currently, for example, are records of the animals used kept throughout a project, or is information recorded only at the end?
- f) Would compliance costs increase under Option 2? If so, by how much? Would these compliance costs be reasonable? Why or why not?
- g) Would submitting returns for projects that are not yet complete cause any problems? If so, please provide details of the problems.
- h) Are there other feasible options for collecting statistics that relate to projects that span more than one calendar year that have not been considered? If so, please provide details, including the potential impacts of the proposed option/s.

### 6.2 REQUIREMENTS FOR SUBMISSIONS

Submitters are asked to include the following information in their submissions:

- the title of this discussion paper;
- your name and title;
- your organisation's name (if applicable);
- your address and contact details (e.g. phone, fax and email); and
- the number(s) of the section/question you are commenting on.

### 6.3 CLOSING DATE FOR SUBMISSIONS

All submissions must be received by MAF Biosecurity New Zealand no later than **5pm** on **Friday 7 November 2008**. Please address submissions to:

Fleur Matthews  
Policy and Risk  
MAF Biosecurity New Zealand  
PO Box 2526  
WELLINGTON 6140

Email: [fleur.matthews@maf.govt.nz](mailto:fleur.matthews@maf.govt.nz)  
Facsimile: 04 894 0730

### 6.4 PROCESS FOLLOWING RECEIPT OF SUBMISSIONS

The next stage in the review will be to analyse all submissions and prepare a final proposal to submit to Government. A document summarising the submissions will be made public and distributed to each submitter.

It is intended that changes to the Animal Welfare (Records and Statistics) Regulations 1999 will be implemented by 1 July 2009. Any changes to the Regulations would not come into effect until the beginning of the following reporting year.

## References

Bayvel, A. C. D. (2004). Animal Use Statistics: The New Zealand and Australian Experience and Perspective. *ATLA 32 (Supplement 1)*, 297-292.

Carsons, L. A. (1998). Regulation of animal use in research, testing and teaching in New Zealand – the black, the white and the grey. *Surveillance 25*(1).

Marbrook, J (2000). *Animals and Statistics – A Review*. A report for the Ministry of Agriculture and Forestry.

National Animal Ethics Advisory Committee (2008). *2007 Annual Report*.

Ministry of Agriculture and Forestry (2000). *User's Guide to Part 6 of the Animal Welfare Act 1999*. MAF Policy Information Paper 33, May 2000.

## Appendix 1: Definitions

**Animal Ethics Committee (AEC)** – a committee established under the Animal Welfare Act to consider applications for approvals of projects and set and monitor compliance with conditions approval. Every code holder must establish an Animal Ethics Committee, made up of scientific, veterinary and community representatives.

**code holder** – defined in the Animal Welfare (Records and Statistics) Regulations as a person or organisation that has an approved code of ethical conduct, works for someone who has an approved code of ethical conduct or someone who is covered by another person or organisation’s code of ethical conduct.

**code of ethical conduct** – under the Animal Welfare Act, all organisations or individuals that manipulate live animals for the purposes of research, testing and teaching are required to do so in accordance with a code of ethical conduct. A code of ethical conduct sets out the policies to be adopted and the procedures to be followed by the code holder and its Animal Ethics Committee.

**Ministry of Agriculture and Forestry (MAF)** – the Government department responsible for administering the Animal Welfare Act and all Regulations made under that Act.

**manipulation** – defined in section 3 of the Animal Welfare Act as interference with the normal physiological, behavioural or anatomical integrity of an animal by deliberately 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. Manipulation involves exposing the animal to any parasite, micro-organism, drug, chemical, biological product, radiation, electrical stimulation, or environmental condition; or enforced activity, restraint, nutrition, or surgical intervention; or depriving the animal of usual care.

**National Animal Ethics Advisory Committee (NAEAC)** – the Committee established under the Animal Welfare Act to provide the Minister of Agriculture with advice and recommendations on ethical and welfare issues arising from the use of animals in research, testing and teaching.

**project** – defined in section 2 of the Animal Welfare Act as any experiment, or series of related experiments, forming a discrete piece of research; or a protocol for carrying out routine manipulations within a specified period; or any experiment or demonstration, or series of experiments or demonstrations, undertaken for teaching purposes.

**research, testing and teaching** – defined in section 5 of the Animal Welfare Act. It covers any research, testing or teaching that involves the ‘manipulation’ of any animal.

**Three Rs** – efforts to **reduce** the number of animals used to the minimum necessary, **refine** techniques so that the harm caused to the animals is minimised and the benefits are maximised, and where possible **replace** animals with non-sentient or non-living alternatives.

## Appendix 2: Animal Welfare (Records and Statistics) Regulations 1999

1. **Title** – These regulations may be cited as the Animal Welfare (Records and Statistics) Regulations 1999.
2. **Commencement** – These regulations come into force on 1 January 2000.
3. **Interpretation** – In these regulations, unless the context otherwise requires,—
  - “The Act” means the Animal Welfare Act 1999:
  - “Animal” has the meaning given to it by section 2(1) of the Act:
  - “Code holder”, in relation to a code of ethical conduct, means--
    - (a) The person who, by virtue of an application under section 87 of the Act, obtained the Director-General's approval of that code; or
    - (b) Where the approval of that code has, with the consent of the Director-General, been transferred under section 93(1) of the Act to any other person, that other person; or
    - (c) Any person carrying out research, testing, or teaching in accordance with section 84 or section 85 or section 118(1) or section 192(4) or section 192(5) of the Act:
  - “Director-General” means the chief executive of the Ministry:
  - “Inspector” means an inspector appointed under section 124(1) or section 124(2) of the Act; and includes every member of the police:
  - “Manipulation”, in relation to an animal, has the meaning given to it by section 3 of the Act:
  - “Minister” has the meaning given to it by section 2(1) of the Act:
  - “Ministry” has the meaning given to it by section 2(1) of the Act:
  - “Protected wildlife” has the meaning given to it by section 2(1) of the Conservation Act 1987:
  - “Research, testing, and teaching” has the meaning given to it by section 5 of the Act:
  - “Year” means a period of 12 months beginning on 1 January and ending with 31 December.
4. **Records** – (1) Every code holder must keep, in relation to the research, testing, and teaching carried out by the code holder, readily accessible records, in which must be entered, in relation to each year, the following information:
  - (a) The name of each species of animal manipulated during the year:
  - (b) The number of animals of each species manipulated during the year:
  - (c) The purpose for which each animal was manipulated:
  - (d) The source of supply of each animal manipulated during the year:
  - (e) The status of each animal manipulated during the year according to the following categories:
    - (i) Normal/conventional:
    - (ii) Specific pathogen free/germ free:
    - (iii) Diseased:
    - (iv) Transgenic/chimera:
    - (v) Protected wildlife:
    - (vi) Pregnant:

- (vii) Developmental stage (which category applies only in relation to an animal that comes within either paragraph (b) or paragraph (c) of the definition of the term animal (as set out in section 2(1) of the Act));
- (viii) Other:
- (f) The number of animals of each species manipulated during the year which --
  - (i) Have not been previously manipulated:
  - (ii) Have been previously manipulated --
 at any time before or during the year:
- (g) In respect of the manipulation of any animal during the year, the severity of that manipulation according to the following scale (taking into account the effect of any anaesthetic, analgesic, euthanasia technique, or other strategy or practice that is applied or used, or any other step taken, to avoid or alleviate the stress or pain caused to the animal):
  - (i) A manipulation that causes no stress or pain or virtually no stress or pain (“no suffering or virtually no suffering”):
  - (ii) A manipulation that causes stress or pain, of a minor intensity for a short duration (“little suffering”):
  - (iii) A manipulation that causes stress, or pain, of a minor intensity for a long duration or of a moderate intensity for a short duration (“moderate suffering”):
  - (iv) A manipulation that causes stress, or pain, of a moderate intensity for a long duration, or of a severe intensity for a short duration (“severe suffering”):
  - (v) A manipulation that causes stress, or pain, of a severe intensity for a long duration, or of a very severe intensity for any duration (“very severe suffering”):
- (h) The number of animals of each species that died or were destroyed during the year in the course of, or subsequent to, the manipulation of those animals (whether directly or indirectly as a result of their manipulation):
  - (i) The number of animals manipulated during the year which are still alive at the end of the year:
  - (j) In respect of the number of animals referred to in paragraph (i), the number of such animals--
    - (i) Released from captivity:
    - (ii) Retained by the code holder that manipulated the animals:
    - (iii) Delivered to a person other than the code holder that manipulated the animals:
  - (k) In respect of any person referred to in paragraph (j)(iii), the name and address of, and the number of animals delivered to, that person.
- (2) Every code holder must retain the records kept under subclause (1) for not less than the period of 5 years beginning with the expiry of the year in respect of which the records were kept.

**5. Annual returns** – (1) Every code holder must, in January of each year, make to the Director-General a return setting out for the immediately preceding year details of the records kept for that year in accordance with regulation 4(1).

(2) A return under subclause (1) must be made in writing.

- 6. Information to be supplied on request** – (1) The Director-General, or any Inspector, may from time to time, by notice to any code holder, require that--
- (a) A copy of any records kept by the code holder under regulation 4; or
  - (b) Such details as the Director-General or the Inspector may specify of the information required to be contained in any records kept under regulation 4,--
- be sent to the Director-General or the Inspector, as the case may be, at such address as may be specified in the notice.
- (2) Every code holder to whom a notice under subclause (1) is addressed must forward the copy or details within such time, being not less than 7 days after the receipt of the notice, as the Director-General or Inspector may specify in the notice.
  - (3) A notice under subclause (1), and any copy or details given in response to such a notice, must be given in writing.
- 7. Offences** – (1) Every person commits an offence who--
- (a) Wilfully fails to keep records in accordance with regulation 4(1):
  - (b) Wilfully fails to retain records in accordance with regulation 4(2):
  - (c) Without reasonable excuse, fails to make a return within the time prescribed by regulation 5:
  - (d) Makes a return under regulation 5 that to that person's knowledge is false or misleading in any material particular:
  - (e) Without reasonable excuse, fails to comply with a notice given to that person under regulation 6(1):
  - (f) Forwards, in response to a notice given to that person under regulation 6(1), a copy, or details, that to that person's knowledge is or are false or misleading in any material particular.
- (2) Every person who commits an offence against these regulations is liable on summary conviction to a fine not exceeding--
    - (a) In the case of an individual, \$5,000; or
    - (b) In the case of a body corporate, \$25,000.
- 8. Revocations** – The regulations specified in the Schedule are revoked.

#### SCHEDULE

#### REGULATIONS REVOKED

Title	Statutory Regulations Serial Number
Animals Protection (Codes of Ethical Conduct) Regulations 1987	1987/12
Animals Protection (Codes of Ethical Conduct) Regulations 1987, Amendment No 2	1987/389
Animals Protection (Codes of Ethical Conduct) Amendment Regulations 1997	1997/303