Summary of Submissions:

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

(MAF Biosecurity New Zealand Discussion Paper: 2008/05)

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Every effort has been made to ensure the information in this report is accurate.

The proposals in this paper do not necessarily represent agreed Government policy.

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1. Introduction

In September 2008 the Ministry of Agriculture and Forestry (MAF) released a discussion paper, *Collecting statistics on the use of animals in research, testing and teaching* (Discussion Paper No: 2008/05), and invited submissions on the paper. The paper presented options for the regularity with which statistics are collected on the use of animals in research, testing and teaching.

MAF placed the discussion paper on its website and directly notified all code holders and other interested parties.

Six weeks were allowed for feedback on the discussion paper, although submissions that were received up to one month after this time were also considered. This document provides a summary of the issues raised in submissions.

Submitters

MAF received 21 submissions on the discussion paper.

Advisory committees	3
Animal Ethics Committees	11
Consultancies	1
Individual researchers	1
Professional associations	1
Research organisations	4

2. Preferred option

Submission #	Option 1: Reporting at the end of a project or at the end of three years	Option 2: Reporting annually with previously reported animals identified
1	x	
2	x	
3	Did not state a preference	
4	x	
5	x	
6		x
7	x	
8	x	
9	Did not state a preference	
10	x	
11	x	
12		x
13	x	
14		x
15	Did not state a preference	
16	x	
17	x	
18		x
19		x
20	x	
21	x	

Table 1. Overall preference for options proposed in the Discussion Paper

Table 1 above shows that there is a clear preference from submitters for Option 1: Reporting at the end of a project or at the end of three years. 13 submitters preferred option 1, five submitters preferred option 2 and three submitters did not state a clear preference.

3. Issues raised in submissions

USE OF THE INFORMATION

The submissions from Animal Ethics Committees indicated that they tend to use the information as a form of audit of individual projects, by comparing the actual number of animals used with the number of animals approved for use.

Other organisations use the information to educate staff and/or students about the responsible use of animals in research, testing and teaching.

Almost all submitters considered that the statistics were sufficiently accurate and timely. However, some submitters commented that statistics collected on an annual basis would commonly be expected to reflect the number of animals used in the previous year, regardless of whether the particular project they are part of is complete or not.

CURRENT SYSTEMS TO COLLECT STATISTICS AND COMPLIANCE COSTS

There is a wide range of systems currently used to keep records of the numbers of animals used in research, testing and teaching. In some cases, individual users maintain their own records throughout the project and submit hard-copy returns to the Animal Ethics Committee for compilation. In other cases, animal use is recorded in real time and can be reported on at any time.

Submitters that had electronic systems in place to collect the statistics tended to consider that the current compliance costs were reasonable. One submitter said that current compliance costs were excessive.

Two submitters considered that introducing a standardised electronic recording system would reduce compliance costs significantly, as well as increase levels of compliance. One submitter attached an example spreadsheet system.

Four submitters considered that the deadline for submitting returns to MAF on 31 January was not practical, as many users of animals in research, testing and teaching are not available to submit their returns. One submitter suggested that statistics should be collected for the year 1 July – 30 June rather than the calendar year.

OTHER SUGGESTIONS FOR COLLECTING STATISTICS

Three submitters suggested other possibilities for collecting statistics. The following options were suggested.

1 *Collect statistics based on the number of animals sold to the user, and assume that each is manipulated.*
The submitter considered that this is an accurate enough method because:
- most users report the most invasive grade of manipulation without splitting into categories;
- the regime can never be completely accurate and a 5-10 percent error is acceptable;
- if an animal is manipulated more than once in a single study, it is only counted once; and
- it is easy to do.

2 *Collect statistics based on the numbers of animals approved for use and assume that each is manipulated.*
The submitter considered that this is an accurate enough method because:
- almost all animals are used as proposed;
- the error variation would be small; and
- it is easy to do.

3 *Count every animal each year that it is used.*
The submitter considered that this would provide the most accurate representation of animals used, and allows for the fact that a single animal may undergo several manipulations during a study. Note: this suggestion appears to be the same as Annual reporting as described in section 5.3.1 of the Discussion Paper.

4 *Collect statistics only at the end of the project* (even if the project is longer than three years).
The submitter considered that this seems to be the simplest solution and least costly to administer. The data should be exact with less chance of duplication and multiple-counting.

OTHER ISSUES RAISED

One submitter suggested that project managers should submit annual interim reports on their project to AEC members, particularly in regard to animal welfare. These reports could be passed on to MAF for information, but not included in the published statistics.

One submitter considered that animals killed prior to being manipulated should be included in the statistics to give greater accuracy of the real number of animals used in research, testing and teaching.

One submitter considered that the single category for dead animals is misleading, as it does not differentiate animals that are euthanised as part of the planned procedure, those euthanised because they were suffering, those whose death was caused by the manipulation and those who died for a reason unrelated to the manipulation.

One submitter expressed concern about inconsistency about the grading of animals. In some cases all animals in a study are allocated to the most severe grade of suffering that some animals experienced. This submitter considered that there should be a nation-wide policy for filling in returns that avoids this problem.

Appendix 1: Submissions received on *Collecting statistics on the use of animals in research, testing and teaching* (Discussion paper no: 2008/05)

	Option 1	Option 2	Justification	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?	What do you use the information provided on animal use for? Is the information provided sufficiently accurate and timely?	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?	Is the cost of complying with the current requirements appropriate? Why or why not?
1	x						
2	x			Yes	Information used to teach graduate students about responsible animal use in research, testing and teaching. Provides context of use from an international perspective. Is accurate and timely enough.	While projects may be longer than three years, AEC approval must be sought after three years. This means that three years is a suitable amount of time.	Current compliance costs are excessive. MAF should develop a streamlined electronic system for institutions to use to keep records of the animals used.
3	No preference stated.			Yes	Information is used only in a general way to monitor progress in improving methods.	Projects are often extended for a variety of reasons. However, terms of 3 to 5 years are reasonably relevant because these terms match the typical funding cycle of research projects.	The cost of permit holder reporting their data is minimal given electronic recording systems. Most of cost (which can be significant) is in compiling the data.
4	x		There is no point in annual reporting of animal use, as there is variability in the absolute numbers used from year to year. It is the overall trend that is important.	Animal use statistics should provide the public with an accurate indication of trends in animal use, rather than the absolute numbers.			
5	x		There is quite a lot of work involved with communicating with animal users and obtaining the required information.				
6		x	Option 1 is not preferred as it will not provide accurate numbers on the nature and scale of animal use and is not conducive to accurate statistical analysis over time. Irregular reporting is not preferred because it is harder to set up institutional reporting systems to ensure compliance. Option 2 would require annual reporting of animal numbers used, which would also encourage good record keeping procedures.	Yes	Keep a log of all animals used to monitor against the number approved for a specific project. Once the allocated number has been reached, a supplementary application has to be considered by the AEC.	It is not possible to make general assumptions about the length of most projects. AEC approval is given for a maximum period of three years. Extension can only be done by further AEC approval.	
7	x			Yes	Information is used to monitor variances between the number of animals approved under a protocol and the actual number used. The information is also used to monitor the severity of manipulations, especially where outcomes are unknown when the project begins. While the information is sufficiently accurate, the timeliness is questionable as the AEC does not know a discrepancy in the number of animals used has occurred until after the project is completed.	Protocols have a mandatory expiry of three years. Most trials are more than one year but less than three years.	Current compliance costs are appropriate. Requests are presently made at the end of each quarter for returns for protocols that have expired during that period.
8	x		The length of the project is not of main importance when we consider the overall proposal and the specific manipulations to the animals. What does matter is the severity of the manipulation, the overall worth and justification of the project and how many animals are used to achieve a significant result.	The statistics should indicate the actual number of animals which have been used to achieve the expected outcome of the research, testing or teaching.			
9	No preference stated.			Yes	Figures are used for internal audit against the numbers approved by the AEC.	It is not valid to assume the duration of any project. Approval is given for a maximum of three years. Many research groups work on projects for longer than three years, and apply for consecutive approvals.	The submitter accepts these costs as a legislative requirement.
10	x		The most transparent and efficient way to collect the statistical information required.	Yes		No, most of our approved protocols run for three years, with only two or three running for a shorter period of time. Any extensions are for a maximum of six months, and such requests must provide a detailed justification.	

	Option 1	Option 2	Justification	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?	What do you use the information provided on animal use for? Is the information provided sufficiently accurate and timely?	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?	Is the cost of complying with the current requirements appropriate? Why or why not?
11	x		Option 1 would enable data to continue to be fully comparable with that published over the years. It is fully understood by those involved in collecting statistics. There are no obvious gains to the public in 'accuracy or timeliness' that would justify the additional compliance costs and break with historical series that would be associated with option 2.	The over-riding purpose is to provide the public with timely information on the nature and scale on national animal use in research, testing and teaching.			
12		x	Providing numbers of animals used during a three year project in one year (as in option 1) is not representative of the actual numbers used in a given year. Although an explanation can be given, this makes the system cumbersome and reliant on the understanding of the general public with a somewhat complex concept.	One of the most important reasons for providing animal use statistics is for the public to be aware of the numbers and severity of animals used in research, testing and teaching each year.		Most of our projects are of three years duration. Projects lasting more than three years must be re-applied for to the AEC, and therefore regarded as new projects.	Cost of complying is reasonable. The time taken to produce the information is minimal and providing this information is regarded as very important.
13	x		Longer projects are generally of very low impact on the animals.	Yes	Use the statistics as part of staff training in the ethics of animal experimentation to provide context for the work of the organisation. The information is sufficiently timely and appropriate.	Yes, most projects are less than three years.	Yes.
14		x	Annual statistics would commonly be expected to reflect the animals used in a particular calendar year, regardless of whether they were also used in previous years.	The primary purpose is in providing publicly available information on the nature, scale and changing trends in animal use.			
15	No preference stated.			Yes	No use for the information.	Yes.	There is a cost in collecting the information, however this is understood and the systems are in place.
16	x			Yes	Uses information related to its own use of animals for internal purposes.		Compliance costs are minimised by managing the information through an electronic database.
17	x		The collation of statistics is a logistical issue for some institutions and any change would need to be carefully worked through with them. Retaining a 3-year reporting period is in keeping with the spirit or intent of the Animal Welfare Act. How many animals are actually used to achieve each of the expected outcomes (as well as the severity of the manipulation and the overall worth of the project) is the most important aspect, not the length of the project.	The primary purpose is in providing publicly available information on the nature, scale and changing trends in animal use.			
18		x	Statistics collated on an annual basis would commonly be expected to reflect the animals used in a particular calendar year, regardless of whether they were also used in previous years. While acknowledging there is a risk of over-reporting (as there might also be a perception of under-reporting), identifying such animals would highlight this. While there may be practical concerns with annual reporting, three-yearly reporting would need to be clearly justified in terms of aspects such as over-reporting, rather than simply making statistics easier to collate.	The primary purpose is in providing publicly available information on the nature, scale and changing trends in animal use. The use of animals in research, testing and teaching is contentious requiring any relevant facts to be publicly available.			
19		x	Data should be as accurate as possible - option 2 would seem to provide for the greatest accuracy.	Yes	Information used to keep members informed of the current use, and trends of use of animals for these purposes.	Most, but not all projects are less than three years. It does seem somewhat arbitrary to set a limit of three years after which the animals must be counted again.	
20	x						
21	x			Yes	Information from individual projects are used to monitor the completion of individual projects.	Yes. However, many of the submitter's projects exceed three years, meaning that animals in those projects are counted more than once.	Yes.

	Would compliance costs increase under Option 2? If so, by how much? Would these compliance costs be reasonable? Why or why not?	Would submitting returns for projects that are not yet complete cause any problems? If so, please provide details of the problems.	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.	Other issues
1				
2	Compliance costs would increase by at least 200% as 2 additional reports would be needed in a three year period.	Submitting returns for projects that are not yet complete would cause problems such as: - miscounting of animals due to confusion with determining when an animal is manipulated, when animals should be counted etc. - lack of buy-in to a change from users of animals in research, testing and teaching.	1. Collect statistics based on the number of animals sold to the user, and assume that each is manipulated. 2. Collect statistics based on the numbers of animals approved for use and assume that each is manipulated. 3. Count every animal each year that it is used.	Requiring reports by 31 January each year is a problem as the researchers have very high workloads at the end of the year and then the University shuts down over the summer holidays. It would be more reasonable if reports were due at the end of June.
3	For permit holders the costs of option two would probably not be high. However, the cost to the Chairperson trying to get colleagues to return data would be high.	There could be some problems as the outcome of the handling might not be known for some time, so the annual nature of the return might not be sensible. It would also involve duplication for those compiling the data.	Collect statistics once - at the end of the project.	Staff are generally involved in the field work which includes handling animals at the same time the statistics are required.
4	Yes, as an individual researcher, would need to spend extra time and effort on collecting and reporting the data.			
5	Requesting numbers every year would add great confusion to the reports and add to the work of the Committee following up and collating the information.			Support the annual reporting of animals used in teaching.
6		No problems are foreseen.		A standardised, well-structured reporting system should be implemented, including training to ensure all organisations are using it correctly. Submitter attached an example spreadsheet system.
7	Compliance costs would greatly increase under Option 2. Asking for more frequent reports on current projects and identifying previously reported animals would create unreasonable pressure and complexity in recordkeeping.	There would be significant problems with meeting the end-January MAF deadline for returning statistics. There is likely to be confusion around which animals have previously been reported unless records are accurate, clear and accessible. However, academics feel that their research and teaching is far more important than any associated paperwork, so this is unlikely to be the case. There is also likely to be people who claim that they are unaware of the new requirements.		Researchers take the bulk of their annual leave in January/February, causing problems with getting the statistics returned.
8				Internal interim reports on animal use should be submitted to AEC members, particularly in regard to animal welfare. These could be passed on to MAF for information, but not inclusion in the published statistics.
9	The submitter essentially collates the information required for both option 1 and option 2. Enquiries under the Official Information Act may require further explanation if the data is not directly comparable with previous years, increasing compliance costs.	There would be no problems with annual returns. There are potential problems with double counting of animals in the NAEAC annual report as it does not currently discriminate between those with or without prior use.	No.	
10	Compliance costs would increase considerably under Option 2, tripling the workload for each current protocol. It would also compress the reporting time frame to the last couple of weeks of each year.	A change to option 2 would be administratively difficult to manage, requiring an intensive period of collection at the worst time of year. Increasing the complexity of reporting would increase the likelihood of errors in reporting.		
11	Introducing further complexity to the collection of statistics carries with it the presumption that there will be additional compliance costs.			
12	Only marginally in terms of the amount of time spent on creating a report in our database. This cost would not be significant.	Use of animals in any given project can fluctuate within a three year period, therefore if data is extrapolated it may appear that animal use will be higher than it turns out to be.	No.	
13	Costs would not be altered significantly. Animals used across multiple years are already recorded. A report would need to be submitted each year rather than waiting until the final year of a multi-year trial.Changes to the AEC database would be needed however, creating additional costs.	This would not be a problem.		

	Would compliance costs increase under Option 2? If so, by how much? Would these compliance costs be reasonable? Why or why not?	Would submitting returns for projects that are not yet complete cause any problems? If so, please provide details of the problems.	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.	Other issues
14	The cost of getting teachers holding three year approvals to provide annual returns is minimal compared with the probability of accidental omissions that could occur when individuals are only required to keep records to be provided every three years.			
15	Yes. Changing the system would be onerous, as the current systems are embedded in our approved documentation systems.	Yes, as reporting would be required before outcomes were clear (and therefore assessing against the severity scale would be difficult).	No.	
16	Yes, by at least double. Accurate record keeping would become very cumbersome.		No.	
17				
18				
19				The submitter considers that animals that are killed prior to being manipulated need to be included in the statistics to give greater accuracy of the real number of animals used in research, testing and teaching.
20				
21	Option 2 would be burdensome and time-consuming. It is impossible to quantify the additional cost, but it is likely to be unreasonable.		Reporting at the end of project is more feasible than the current practice.	Researchers take the bulk of their annual leave in January/February, causing problems with getting the statistics returned. The single category for dead animals is misleading, as it does not differentiate animals euthanised as part of the planned procedure, those euthanised because they were suffering, those whose death was caused by the manipulation and those who died for a reason unrelated to the manipulation. There is inconsistency about the grading of animals. In some cases all animals in a study are allocated to the most severe grade of suffering that some animals experienced. There should be a nation-wide policy for filling in returns that avoids this problem.