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# Severity assessment – The New Zealand experience and perspective

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**Abstract**
This paper outlines the New Zealand experience, with severity assessment over the period 1987 to 2007, from a policy, legislative and regulatory perspective and emphasises the invaluable interaction between academia, industry, animal welfare advocacy organisations and Government, including the independent New Zealand ministerial advisory committee, the National Animal Ethics Advisory Committee (NAEAC).

Information relating to the number and relative severity of live animal manipulations, undertaken for the purposes of research, testing or teaching, is extremely valuable in relation to the high degree of political and public interest in this sensitive public policy area. The information can also be used to directly target, as priorities for Three Rs research and development, those areas of animal usage which involve the greatest animal welfare compromise (e.g. shellfish biotoxin testing and efficacy and safety testing of human and animal biological products).

The communication of information on severity assessment, as part of a policy of openness and transparency, carries with it particular challenges in terms of responsible, informed and productive media coverage. Freedom of information legislation also presents additional challenges in terms of balancing the public's right to know with the security of institutions and the personal safety of individual researchers.

**Keywords:** severity assessment, New Zealand, national policy, transparency, freedom of information

## Introduction

New Zealand is one of a relatively small number of countries which has introduced, and continues to develop and refine, severity assessment policies and procedures relating to the use of live animals in research, testing and teaching. Severity assessment is important both as part of harm: benefit analysis, for justification of animal use, and in public reporting of outcomes.

Since the 1980s the use of live animals in research, testing and teaching has been addressed, as an important public policy issue, by the New Zealand Government in consultation with the National Animal Ethics Advisory Committee (NAEAC) and all key national stakeholders. The New Zealand regulatory system was introduced in 1987 and operated until the commencement of the Animal Welfare Act 1999 ('the Act'). It has been described by (Mellor (1999), (Bayvel (2000) and MAF (2000). The part of the Act dealing with animal use in research, testing and teaching is underpinned by a philosophical commitment to the Three Rs of Russell and Burch (1959).

In assessing the severity of manipulations, as defined in the Act, New Zealand uses a five point scale first devised by Mellor and Reid (1994) and further described by Mellor (2004) in relation to the concept of the five "domains of animal welfare compromise." At the request of Government, Williams, Mellor and Marbrook (2006) reviewed the operation and effectiveness of the scale, made comparisons with other scales used internationally and outlined proposed modifications for consideration by Government and NAEAC.

This paper outlines, from a policy and regulatory perspective, the New Zealand use of this severity scale in the annual reporting of animal use statistics. Particular consideration is given to the associated benefits, risks and safeguards, the challenge of effective communication with the general public and the implications of freedom of information legislation.

## Policy considerations

Severity assessment is an important input to the harm: benefit justification of animal use which is of direct interest to Animal Ethics Committees and

 

of general public and political interest. Information on severity also assists with the tracking of general research trends and the tracking specifically of Three Rs developments. The information can also be used to justify the need for support for Three Rs research. Public availability of severity information, unfortunately however, carries with it the risk that individual scientists and research institutions will be targeted by extremist groups prepared to undertake criminal activities and, thus, the New Zealand policy is to publish national sector totals only.

**Legislation on the recording and reporting of animal use**

Under the Animal Welfare (Records and Statistics) Regulations 1999 every organisation with the relevant approval to conduct research, testing or teaching must keep information in respect of the 'manipulation' of any animal during the year. 'Manipulation' essentially means subjecting it to treatment or a procedure that is unusual or abnormal. The information to be kept includes: the severity of that manipulation according to the following scale taking into account the effect of any anaesthetic, analgesic, euthanasia technique, or any 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:

a) a manipulation that causes no stress or pain or virtually no stress or pain ("no suffering or virtually no suffering");
b) a manipulation that causes stress or pain, of a minor intensity for a short duration ("little suffering");
c) 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");
d) 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"); and
e) 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").

**Freedom of information legislation**

The New Zealand Official Information Act 1982 is based on the principle of availability i.e. "the question whether any official information is to be made available, where that question arises under this Act, shall be determined, except where this Act otherwise expressly requires, in accordance with the purposes of this Act and the principle that the information shall be made available unless there is good reason for withholding it."

This Act includes detailed provisions regarding who can make requests, decisions on requests and response time frames, deletion of information from documents and refusal of requests. Grounds for refusal include "endangering the safety of any person" and circumstances where release would be "likely to unreasonably prejudice the commercial position of the person who supplied or who is the subject of the information." Person is defined in the Act to cover both individuals and organisations. Any refusal of information must be accompanied by the provision of information regarding the applicant's right, by way of complaint to an Ombudsman, to seek an investigation and review of the refusal.

The New Zealand experience is that this legislation is not used by the public at large but is frequently used by individuals ideologically opposed to the use of live animals in research, testing and teaching. Responding to these requests can be extremely resource intensive both in relation to the original request and responding to any subsequent complaints. Fortunately, the Act includes sufficient provisions to ensure the safety of both individuals and institutions and the protection of commercial interests.

**Reporting and communication**

The information on animal use statistics required by the Animal Welfare Act 1999 must be reported annually to Government. After collation and analysis, this information is then included in the NAEAC Annual Report (NAEAC, 2006) with appropriate commentary. In an attempt to ensure appropriate media coverage, Ministry of Agriculture and Forestry (MAF) and NAEAC issue press releases and, in 2004, made the report the subject of a ministerial press conference. In spite of these efforts, the media and animal rights activists inevitably focus on the statistics relating to severity grading and ignore the accompanying NAEAC commentary. The policy of providing national sector information is alleged to constitute a "veil of secrecy." This latter allegation is particularly frustrating, as New Zealand has one of the most transparent systems used internationally regarding the reporting of animal use statistics.

Examples of the information provided in relation to severity grading of manipulations are provided in Tables 1, 2 and 3. To assist with interpretation of these statistics, NAEAC provides the following commentary, "In considering the annual animal use statistics, it is important to emphasise that every manipulation having a high negative animal welfare impact must be supported by a strong cost benefit justification. The justification is individually assessed and approved by the appropriate institutional animal ethics committee (all of which contain three external members) before the work may proceed. The final approval of a research proposal is often the result of a significant iterative process and every animal ethics

Table 1 - Manipulation grading of animals used over the past five years

| Year | Total Animals Reported | Manipulation grade categories | | |
|---|---|---|---|---|
| | | "No" or "little" suffering | "Moderate" suffering | "Severe" or "very severe" suffering |
| **2002** | 263,684 | 206,416 | 41,451 | 15,817 |
| **2003** | 320,911 | 273,971 | 31,391 | 15,549 |
| **2004** | 246,122 | 201,087 | 32,592 | 12,443 |
| **2005** | 263,214 | 217,290 | 29,505 | 16,419 |
| **2006** | 318,489 | 277,048 | 25,228 | 16,213 |
| **2006(%)** | | 87.0% | 7.9% | 5.1% |

Table 2 - Manipulation grading of animals used in 2006

| 2006 summary | Total reported | Number in each manipulation grade | | | | |
|---|---|---|---|---|---|---|
| | | No suffering | Little suffering | Moderate suffering | Severe suffering | Very severe suffering |
| **Sheep and cattle** | 136,280 | 48,510 | 85,107 | 2,224 | 433 | 6 |
| **Rodents** | 80,185 | 3,088 | 42,054 | 20,822 | 2,819 | 11,402 |
| **Birds** | 59,404 | 45,534 | 13,297 | 385 | 188 | 0 |
| **Other[1]** | 12,821 | 1,120 | 10,810 | 601 | 290 | 0 |
| **Other domestic species** | 11,598 | 1,247 | 10,250 | 99 | 2 | 0 |
| **Aquatic species[2]** | 11,490 | 2,856 | 8,075 | 559 | 0 | 0 |
| **Possums and rabbits** | 6,711 | 1,003 | 4,097 | 538 | 1,072 | 1 |
| **Grade totals** | 318,489 | 103,358 | 173,690 | 25,228 | 4,804 | 11,409 |
| **Grade percentages** | | 32.5% | 54.5% | 7.9% | 1.5% | 3.6% |

1: reptiles, mustelids, hedgehogs, wallabies, alpaca, bats, chimpanzees and elephants.
2: amphibians, fish, marine mammals, cephalopods and crustaceans.

Table 3 - Animal Usage Report: summary of the species used (by manipulation grading)

| Species | No suffering | Little suffering | Moderate suffering | Severe suffering | Very severe suffering | Total |
|---|---|---|---|---|---|---|
| **Amphibians** | 509 | 459 | | | | 968 |
| **Birds** | 45,534 | 13,297 | 385 | 188 | | 59,404 |
| **Cats** | 254 | 441 | 60 | 2 | | 757 |
| **Cattle** | 7,386 | 33,419 | 577 | 360 | 6 | 41,748 |
| **Deer** | 447 | 7,609 | 6 | | | 8,062 |
| **Dogs** | 491 | 191 | | | | 682 |
| **Fish** | 1,234 | 7,493 | 77 | | | 8,804 |
| **Goats** | 5 | 877 | 18 | | | 900 |
| **Guinea pigs** | 38 | 698 | 8 | 1,379 | 918 | 3,041 |
| **Horses / donkeys** | 50 | 325 | 15 | | | 390 |
| **Marine mammals** | 125 | 31 | | | | 156 |
| **Mice** | 1,677 | 31,972 | 15,769 | 111 | 10,407 | 59,936 |
| **Pigs** | | 807 | | | | 807 |
| **Possums** | 974 | 2,444 | 518 | 1,072 | 1 | 5,009 |
| **Rabbits** | 29 | 1,653 | 20 | | | 1,702 |
| **Rats** | 1,373 | 9,384 | 5,045 | 1,329 | 77 | 17,208 |
| **Reptiles** | 982 | 10,532 | 601 | 3 | | 12,118 |
| **Sheep** | 41,124 | 51,688 | 1,647 | 73 | | 94,532 |
| **Misc. species** | 1,126 | 370 | 482 | 287 | | 2,265 |
| **TOTAL** | **103,358** | **173,690** | **25,228** | **4,804** | **11,409** | **318,489** |

committee benefits from the input and perspective of the three external independent members."

This narrative is complemented by the following comment designed to communicate NAEAC's ethical, operational and strategic commitment to humane animal-based science, "NAEAC will continue to promote the concepts of humane science and the Three Rs and to actively pursue specific initiatives that contribute to those strategic goals. These include:

- maintaining contacts with 'Alternatives Centres' in Europe and North America;
- actively participating in the triennial international Congress on Alternatives and the use of Animals in the Life Sciences;
- drawing attention to state of the art articles on alternatives and the Three Rs in NAEAC News;
- sponsoring conferences on humane science;

- sponsoring workshops on pain control and its amelioration;
- encouraging regulatory acceptance of alternative non-animal tests where and when applicable;
- encouraging the use of non-animal teaching programmes;
- distributing copies of RDS News to all animal ethics committees;
- secondment of New Zealand personnel to the Home Office to gain experience in the United Kingdom animal research regulatory system.

Although the New Zealand animal use statistics collection system is recognised as one of the most comprehensive in the world, NAEAC will continue to pursue refinements and improvements. In NAEAC's experience, in all projects associated with moderate, severe or very severe suffering, all possible steps are taken to reduce or ameliorate the negative animal welfare impact. Those steps include a high level of veterinary care, where practical, pre- and post-operative pain relief, where appropriate, and removal from the study or euthanasia immediately the research objective is achieved".

## Conclusion

The benefits of the New Zealand system of animal use reporting are seen to far outweigh the risks and the latter are adequately ameliorated by legislative safeguards. The system, and associated ongoing improvements, make a major contribution to public, political and media confidence in the regulatory system (Williams, 2006). The policy of not linking animal use data to specific institutions and the provisions of freedom of information legislation also ensure that security risks are minimised, and commercial risks prevented.

In New Zealand, the use of animals in regulatory testing for the safety and efficacy testing of veterinary vaccines and for public health reasons, is a major contributor to the severe and very severe categories of severity grading. The introduction of scientifically validated *in vitro* tests will require improvements in the current level of regulatory harmonisation internationally. New Zealand is, thus, working closely with the International Cooperation on Harmonisation of Technical Requirements for Veterinary Medicinal Products (VICH) and the World Organisation for Animal Health (OIE) to support greater priority being given to these harmonisation efforts.

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