

Reviewing the reviews: an update on the analysis of the process of ensuring regulatory compliance in the use of animals in science in New Zealand

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Abstract

New Zealand's Animal Welfare Act (1999) requires that organisations using animals in research, testing and teaching be audited at least every 5 years for compliance with both the Act and the organisations' individually approved codes of ethical conduct. This review process, during which time most of the organisations have been reviewed at least twice, indicates that the majority of institutions were complying, the remainder rectifying the issues identified.

Introduction

In New Zealand, the use of animals in research, testing and teaching is governed by a self-contained set of provisions contained within Part 6 of the Animal Welfare Act 1999 (the Act). While the central focus of the Act imposes obligations on owners or those in charge of animals to ensure that the physical, health and behavioural needs of the animal are met and, where practicable, ensure that when the animal is ill or injured it receives treatment that alleviates any unreasonable or unnecessary pain or distress,

Part 6 stands separate from the rest of the Act, because it provides a process that, in some circumstances, sanctions manipulations that have the potential to cause suffering, distress, or compromised care. 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 the legislation include adequate safeguards governing such animal use. Any individual or organisation wanting to manipulate animals is subject to a comprehensive set of requirements. Firstly, they must hold a Code of Ethical Conduct (Code) approved by the Director-General of Agriculture or be employed by a person or organisation that holds an approved Code, or be employed by a person or organisation that has an approved arrangement to use another organisation's animal ethics committee (AEC); and secondly, each individual project must first be approved by an AEC appointed by the code holder.

Currently, there are 30 code holders in New Zealand, two of which each have three AECs, giving a total of 34 such committees. An additional 85 organisations do not have their own code or AEC but are "parented" by a code-holding organisation. The types of organisations holding Codes are given in Table 1.

The review process

As a further layer of scrutiny of the animal ethics system in New Zealand, code holders and their AECs must undergo periodic reviews by independently accredited reviewers, with the aim of assessing

Table I Number of AECs at New Zealand institutions.

Institution type	Number	Number of AECs
Crown Research Institutes (CRIs)	4	6
Universities	7	9
Commercial organisations	10	10
Institutes of Technology	6	6
Government departments	1	1
Schools	1	1
Other	1	1

the extent to which the code holder and the AEC are both complying with the Act and the Code as well as implementing the policies, procedures, and requirements set out in the Act and the Code. A satisfactory review report is a prerequisite to obtaining approval of a Code for a second or subsequent period.

Where a code holder holds an approved Code for the first time, or where a person did not carry out research, testing and teaching in the 2 years before obtaining their current Code approval, the first independent review must take place within 2 years. Subsequent reviews must be completed before the term of approval of the current Code has expired.

Reviewers are accredited by the Director-General of the Ministry of Agriculture and Forestry, with due regard to their competency, their character or reputation, and their ability to maintain an appropriate degree of impartiality and independence when conducting reviews. There are currently six reviewers, although there have been up to eight. All are veterinarians except one.

The reviewer's draft report is initially sent to the code holder for comment, with the final report, along with any code holder comments, going back to the code holder, to the Director-General and to the National Animal Ethics Advisory Committee (NAEAC), an advisory committee to the Minister of Agriculture on matters relating to the use of animals in research, testing and teaching.

The report may notify a critical situation, key issues, key topics and/or recommendations. A critical situation is any situation which, in the judgement of the reviewer, places the code holder's, the AEC's or the Director-General's credibility at risk. If a critical situation is identified during a review, this must be

immediately notified to the Director-General, and could potentially lead to the suspension or revocation of the approval of a code of ethical conduct.

The Director-General, having received the final report, 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 Director-General 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 Director-General can decline approval of a new Code or can revoke the existing Code.

This analysis is based on and updates Williams and Carsons (2010) given at the 7th *World Congress of Alternatives and Animal Use in the Life Sciences* held in Rome in 2009.

Review results

Seventy-three reviews of 35 AECs were undertaken since the introduction of the Act at the beginning of 2000 until mid 2011. Of these, 56 were expiry reviews carried out at the end of the 5 year lifespan of each code, including 26 second-term expiry reviews. Seven reviews were undertaken of institutions with new Codes and AECs, and ten follow-up reviews were required as the result of unsatisfactory levels of compliance.

The compliance of 22 out of 30 institutions (73%) was judged satisfactory at their first expiry review, and of 22 out of 26 (85%) at their second expiry review. Six out of seven institutions (86%) with new codes of ethical conduct had satisfactory reviews, while all reviews that were required following identification of areas of non-compliance were satisfactory.

During the period surveyed, there were 11 institutions whose level of compliance was found to be unsatisfactory, one of these on two occasions. Of these, three institutions were not required to undergo re-review, one because it was amalgamating with another institution, one because it chose not to renew its Code but to be parented by another organisation, and the third because the key issue, although serious enough to warrant mention, had already been resolved by the time of the review. One institution was required to be reviewed annually for 3 years. Two

institutions that were found satisfactory on their first expiry review were found unsatisfactory for different reasons on their second expiry review.

Issues raised

Critical situations identified

A critical situation is defined as any situation which, in the judgement of the reviewer places the code holder's, the AEC's or the Director-General's credibility at risk. There were no critical situations identified during the survey period.

Key issues identified

A key issue is defined as a non-compliance that, in the opinion of the reviewer, demonstrates a major non-compliance of the institution's procedures and policies with the Act, its regulations or the Code. It may be a specific non-compliance or a system with multiple non-compliances having a cumulative effect. Key issues may be created by escalation of outstanding issues from previous reviews. Any key issues found will be discussed during the review, and will appear in the review report. The Director-General will require these to be resolved within an agreed timeframe. The effectiveness of corrective actions will be measured in subsequent reviews.

Key issues were identified in 15 reviews and fell into three main groups – AEC procedures, monitoring and animal facilities.

1. AEC procedures
 - a. AEC not appointed in accordance with the code
 - b. Lack of documented AEC procedures and approvals
 - c. Lack of adherence to maximum approval periods
 - d. Projects proceeding without AEC approval
 - e. Lack of compliance with Code and the Act in criteria for approval
 - f. Lack of compliance for stated standards for meeting frequency, quorum, minute taking
2. Monitoring of compliance
 - a. Failure to monitor compliance with approved protocols
3. Facilities
 - a. Inadequate ventilation
 - b. Temperature controls inadequate resulting in higher than acceptable temperatures.

Key topics identified

A key topic is defined as a point of interest, which is discussed in the report. It may include positive and negative findings and may give rise to key issues or recommendations.

Fifty-seven reviews identified key topics. In 30 reviews, positive key topics were identified. In nine cases, only positive topics were raised. Examples of positive key topics include:

- Commendation of animal care and enrichment;
- Commendation of the focus on animal welfare;
- Commendation of excellent recording and quality control systems;
- Commendation for inclusion of a biometrician on the AEC.

Negative key topics fell into seven categories:

1. AEC processes complying with some but not all Code requirements (noted in 26 reviews). Examples:
 - a. Procedures for dealing with complaints not included;
 - b. Endpoints not well defined.
2. Lack of documentation of AEC processes (noted in 14 reviews). Examples:
 - a. No formal detailing of AEC processes;
 - b. No clear process for managing records.
3. Inadequacy of the monitoring process (noted in 15 reviews). Examples:
 - a. Lack of a formal monitoring process;
 - b. Lack of visits to view procedures by external members.
4. Inadequate documentation of monitoring by the AEC (noted in three reviews). Examples:
 - a. Applicants not required to report back at the end of their study;
 - b. Monitoring reports not written or filed.
5. Inadequate facilities (noted in five reviews). Examples:
 - a. Rodent cages inappropriate;
 - b. Lack of hygiene on panels round ventilation vents;
 - c. Inadequate cage washer resulting in an unacceptable hygiene risk.
6. A lack of facility and animal care documentation in the form of standard operating procedures (noted in four reviews).

7. 11 Miscellaneous issues (noted in 11 reviews).
Examples:
- a. A lack of staff familiarity with the Code;
 - b. Inadequate attendance at AEC meetings of some members.

Recommendations

A recommendation is a suggestion aimed at improving the procedures and policies. As recommendations are non-binding, they tend to be suggestions from the reviewer for increasing quality and efficiency in the AEC process. Examples include:

1. The animal programme manager should be a member of the AEC;
2. Acclimatisation of sheep to indoor environments is recommended;
3. A review of meeting frequency is recommended;
4. An internal audit process is suggested;
5. The formalisation of monitoring procedures as a Standard Operating Procedure (SOP) is suggested;
6. An improvement in the clarity of the application form is suggested.

Re-reviews

The Terms of Reference for follow-up reviews are set by the MAF Director Animal Welfare and vary depending on the initial review result. Outstanding issues are required to be remedied within a given timeframe, with time limits set for follow-up reviews. Follow-up reviews are required to be performed by the same reviewer who did the initial non-compliant review. In all but one case, only a single follow-up review was required within at most a year of the unsatisfactory review, with the focus being on those areas of non-compliance. In one case, three follow-up reviews were required at yearly intervals. The first and third of these were focused only on identified non-compliant areas, while the second was a full review.

Reviewers

Although there are currently only six reviewers, reviews were carried out by eight reviewers during the sample period, with one review being conducted jointly by two of the eight.

The majority of reviews were performed by three reviewers who undertook 28 (44% of total), 12 (19%)

and 10 (16%) of the reviews respectively. Four of the eight reviewers had no unsatisfactory reviews.

With a small number of reviewers, some of whom have performed very few reviews, an emphasis is placed on ensuring consistency of the review process. Procedures to improve consistency include:

- Provision of performance standards for reviews;
- Provision of a template for a checklist based on information provided to code holders in two documents: the *Guide to the Preparation of Codes of Ethical Conduct* and the *Good Practice Guide for the Use of Animals in Research, Testing and Teaching* (NAEAC 2006);
- An annual teleconference where reviewers “meet” with MAF staff and members of the National Animal Ethics Advisory Committee to discuss the previous year’s reviews including any new issues raised as a result of those reviews;
- Regular update of reviewer documents as a result of the annual meetings as well as any other issues that have arisen;
- Three-yearly audit of the performance of the reviewers themselves by MAF.

In conclusion, the analysis of reviews between 2002 and 2011 shows that in the majority of cases (83%) a satisfactory level of compliance with the Act and Code was achieved. For those where compliance was adjudged unsatisfactory, subsequent follow-up reviews showed that a satisfactory level of compliance had been achieved. Given these results, the review system would appear to be working well and should add confidence to the overall regulatory system for the use of animals in research, testing and teaching in New Zealand.

References

- NAEAC 2006: Guide to the Preparation of Codes of Ethical Conduct. <http://www.biosecurity.govt.nz/animal-welfare/naeac/papers/naeaccec.htm>
- NAEAC 2010: Good Practice Guide for the Use of Animals in Research, Testing and Teaching. <http://www.biosecurity.govt.nz/regs/animal-welfare/pubs/animals-used-in-research>
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