

18 July 2012

Update for AEC members from the Chair of NAEAC – July 2012

Animal Welfare Act Review

NAEAC has been liaising with Ministry for Primary Industries (MPI) Policy staff on the review of the Animal Welfare Act 1999. While it is planned that the proposed revisions will be put out for public consultation in August/September, NAEAC has already raised a number of issues with MPI, along with two other submissions sent directly to NAEAC. Raising them does not, however, mean they will be addressed within the revised legislation. The committee encourages AECs to make their own submissions during the public consultation phase. NAEAC's preliminary submission is attached for your interest.

New Technologies

NAEAC is aware that the science and technology around the use of animals in research, testing and teaching (RTT) is constantly evolving, sometimes in ways that might not have been anticipated within the current definitions and requirements of the Animal Welfare Act 1999. We would like to remind you that both NAEAC and the Ministry are available to give advice on whether applications involving new technologies fall within the ambit of Part 6 of the Act. To help keep NAEAC up-to-date, we would also ask that such new technologies, especially if they impact on animal welfare in either a positive or negative sense, be shared with the committee - and thence the wider AEC community if appropriate.

A Reminder

A fish being an "animal" under the welfare legislation, Part 6 of the Act applies to any research using fish. Section 97 of the Fisheries Act 1996 allows the chief executive to issue special fishing permits, which authorise the holder of the special permit to take fish for the purpose and on the conditions specified in the special permit. Nothing in section 97, however, provides that the permission to take fish under the special permit means that the person does not have to comply with other legislation. All that the special permit does is allow the permit holder to fish without having a normal fishing permit under Part 6 Fisheries Act. Compliance with both the Fisheries Act and the Animal Welfare Act is needed. This means that the permit holder would need both the special fishing permit (to allow them to carry out the fishing without a normal fishing permit) and AEC approval (to allow them to carry out RTT on the fish).

Guidelines for Reporting Research

There are a number of guidelines that set minimum expectations for the design of clinical trials as an aid to assessing the evidence for particular treatments provided in trial reports. The information in these guidelines can also be helpful in assessing proposed clinical trials and AEC members may find them useful:

- ARRIVE (Animal Research: Reporting *In Vivo* Experiments) Guidelines are intended to improve the reporting of animal experiments. <http://www.nc3rs.org.uk/page.asp?id=1357>
- REFLECT (Reporting Guidelines for Randomised Controlled Trials for Livestock and Food Safety) focus on clinical trials in food animals. <http://www.reflect-statement.org/statement/docs/reflectstatementchecklist.pdf>

- CONSORT (Consolidated Standards of Reporting Trials) were developed specifically for human clinical trials <http://www.consort-statement.org/consort-statement/overview0/#checklist>

The guidelines come with a caution that while they can help identify poorly conducted or reported studies on which little weight should be placed, they cannot confirm that a study is reliable.

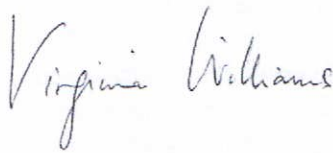
NAEAC Three Rs Award

A reminder that nominations for the 2012 NAEAC Three Rs Award close this Friday – 20 July! For information about this year's award visit: <http://www.biosecurity.govt.nz/regs/animal-welfare/research#three-rs-award>

AEC Workshop

NAEAC will be hosting a workshop for AEC members in Wellington on Friday 16 November 2012. The programme is currently being finalised and will be circulated to AECs in August.

Kind Regards



Virginia Williams
Chair

National Animal Ethics Advisory Committee (NAEAC) Submission on the Animal Welfare Act Review

15 May 2012

A. Current structure relating to the use of animals in research teaching and testing

The use of animals in research, testing and teaching (RTT) has a specific part of the Animal Welfare Act 1999 devoted to it, in part as an acknowledgement that because of the nature of the work, the general obligations imposed by the Act i.e. to provide treatment when animals are ill or injured so as to alleviate unreasonable or unnecessary pain and distress, may not be met. In some cases, potential benefits of the work are assessed as outweighing compromised care or some pain or distress. However, because of these potential harms, this use of animals is recognised as a particularly sensitive issue which has led to the current system of ethical oversight for all such work.

NAEAC members, many of whom have considerable experience as scientists, accredited reviewers and animal ethics committee (AEC) members as well as from their NAEAC role, are strongly of the opinion that New Zealand's regulatory system for the use of animals in RTT is, for the most part, working well. The basic structure, where decision-making is devolved to AECs operating under codes of ethical conduct with oversight and advice provided by a committee – NAEAC – whose independence from the government lends both credibility and transparency, is sound, and provides a measure of protection for both the Minister and the Ministry for Primary Industries (MPI).

However, the NAEAC membership considers that there are currently some gaps in the ethical oversight of animals used in RTT as well as a number of other concerns, and would submit the following issues for consideration in the review of the Animal Welfare Act 1999.

B. Issues relating to the production and use of genetically modified (GM) and selectively bred animals

1. Definition of 'animal'

- a. GM can negatively affect the welfare of the animal created – indeed it is often the expected consequence when testing gene function, creating models of human disease or creating 'super-producer' livestock or pharmaceutical 'biofactories'. This should be recognised as part of the ethical cost of the study, hence necessitating consideration by an AEC. However, because of the exclusion from the definition of an animal of fetuses in the first half of gestation or development, there is presently no requirement for researchers to declare, and AECs to consider, the welfare cost to GM animals. Since most such animals are initially created using embryos, then perpetuated by breeding, considerable welfare impact is likely to be overlooked under the Act as it stands.
- b. Further welfare impact may be presently overlooked where those animals that fail to manifest the desired characteristics, or are surplus to requirements, are euthanased. These animals may comprise the majority of those produced and may experience reduced quality of life before being euthanased (see 3 below).

- c. As most GM animals used in New Zealand are bred from founders produced by laboratories overseas, it would be impossible for NZ legislation to apply ethical oversight at the 'creation' stage. Rather, the ethical consideration should focus on the use of GM animals in studies proposed in NZ.
- d. Failure to recognise the creation and/or use of 'adverse phenotypes' may lead to a failure of the AEC to institute adequate monitoring

Possible alternative solutions –

- a. Revise the Act reference to specifically include GM animals after 2 (1) (b):
(c) includes, for animals listed in (a), animals created by GM or bred from such animals.

The term 'genetic modification' would need definition in section 2 of the Act.

- b. Revise the Act along the lines of the The UK Animals (Scientific Procedures) Act 1986¹ which states that protection is also provided when regulated procedures are applied at an earlier stage of development if:

(i) the animal is to be allowed to live beyond the stage of development set out in paragraph 2.7 above (i.e. mammals, birds and reptiles - from halfway through the gestation or incubation period; fish, amphibia and *Octopi vulgaris* - from the time at which they become capable of independent feeding); and

(ii) the procedure may result in pain, suffering, distress or lasting harm after the animal has reached that stage of development.

2. Definition of 'manipulation'

- a. As above (1a), production of GM animals is excluded due to the present exclusion of gametes and early stage fetuses from the definition of 'animal'.
- b. Selective-breeding, such as crossing inbred mouse lines, breeding from spontaneous mutant animals to produce disease models, or breeding outlier animals for other novel traits, may also have similar aims and animal welfare consequences as GM, and again, this may not presently receive consideration by an AEC. This is because breeding may be considered 'normal management' thus exempting it from the definition of 'manipulation'. Researchers would be expected to seek AEC approval for any manipulation of the selectively-bred animal, but the welfare impact of breeding for a specific trait may not necessarily be declared.
- c. Failure to recognise the creation of 'adverse phenotypes' may lead to a failure of the AEC to institute adequate monitoring
- d. Further welfare impact may be presently overlooked where those phenotypes that fail to manifest the desired characteristics, or are surplus to requirements, are euthanased. These animals may comprise the majority of those produced and may experience reduced quality of life before being euthanased (see 3 below).

Possible solution - Revise the Act reference to include after s 3 (2):

(3) Additionally, 'manipulation' occurs when negative or uncertain welfare consequences arise for animals produced by genetic modification or selective breeding.

¹ <http://tna.europarchive.org/20100413151426/http://www.archive.official-documents.co.uk/document/hoc/321/321-02.htm#gen45>

3. Definition of 'killing'

Euthanasing 'unsuccessful' GM or selectively-bred animals is presently not recognised as 'killing' despite the fact that these can be a high proportion of animals bred. NAEAC regards this as an ethical cost that is additional to the impact of GM or breeding on the animal's welfare up to the point of death.

Possible solution – see item B below.

4. Good practice in production and use of GM or selectively bred animals

Guidelines (or 'Regulations') should be developed to assist researchers, animal carers, and AECs in considering all ethical and welfare requirements in the production and use of GM or selectively-bred animals.

Possible solution - Regulations could be referred to in the Act, as is done in Australia:

<http://www.nhmrc.gov.au/files/nhmrc/file/publications/synopses/ea17.pdf>

These have been developed to be consistent with an overriding Act:

http://www.opbw.org/nat_imp/leg_reg/australia/GeneTechnology2000.pdf

A key part of the Australian Act is:

Function of the Gene Technology Ethics Committee

The function of the Ethics Committee is to provide advice, on the request of the Regulator or the Ministerial Council, on the following:

- (a) ethical issues relating to gene technology;
- (b) the need for, and content of, codes of practice in relation to ethics in respect of conducting dealings with GMOs;
- (c) the need for, and content of, policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons.

[Note that while New Zealand does have a Gene Technology Advisory Committee (GTAC), its terms of reference appears focused on scientific review of relevant clinical trials, with no mention of animal welfare and/or ethics.]

Similarly, it is desirable that the Act should refer to NAEAC as a source of advice on good practice in animal husbandry and animal-based experiments:

<http://www.biosecurity.govt.nz/files/reqs/animal-welfare/pubs/naeac/guide-for-animals-use.pdf>

C. Killing surplus animals or killing for tissues prior to manipulation

As the Act stands, animals used in, or specifically bred for, RTT work but which are killed prior to manipulation as currently defined do not fall under the umbrella of ethical oversight, nor are their numbers required to be recorded. The numbers published every year in the NAEAC Annual Report as "Animal Use Statistics" would therefore more accurately be described as "Animal Manipulation Statistics". This is because the numbers do not accurately reflect the number of animals used, because they do not include:

- those animals that are killed prior to manipulation – for example for their tissues;

- those that were bred for RTT purposes but found to be surplus to or unsuitable for requirements and are therefore killed;
- those included in section A3 above.

This means that these groups are neither required to be subject to ethical scrutiny (although many institutions require this despite it not being legally necessary), nor is there any monitoring of potential overproduction. NAEAC believes that the use of these animals should be under AEC scrutiny, whether that be by changing the definition of "manipulation" or other means, for the following reasons:

- The current definition has been defended on the grounds that New Zealand uses and kills animals for many reasons. However, the use of animals in RTT has been given a special status - and specific legislation in Part 6 of the Act - in recognition of the degree of societal concern about such use. As such, it has been placed apart from other uses - and reasons for killing - animals. NAEAC feels this justifies our belief that killing in relation to animal use in RTT should fall under ethical scrutiny.
- Without including such animals under ethical scrutiny, statistics released to the public are, at best, misleading.
- Maintaining the current situation without additional instruction leads to equivocal situations for researchers with respect to inclusion of control groups of animals in experiments in statistical records.
- The failure to include the killing of animals as requiring ethical oversight is objectionable to many AECs on ethical grounds, as has been established when opinions were canvassed.

Overseas jurisdictions:

EU and the UK - euthanasia by usual methods is not a procedure and animals killed as for tissue harvest are not counted.

Canada - animals that are killed specifically to collect tissues are counted.

USA - animals killed specifically for tissue harvest are counted. However, rats and mice are not legally animals so are excluded.

Australia - euthanasia is covered by a national code of practice but counting varies from state to state.

In addition, the UK Animals (Scientific Procedures) Act 1986 addresses overbreeding as follows:

Overbreeding should be minimised as far as reasonably possible. In addition to commercial pressures or cost recovery arrangements which act as incentives against overproduction, users should be encouraged to:

- plan projects carefully and with sufficient lead times to breed animals for specific requirements;
- apply proper experimental and statistical designs which minimise the number of animals needed;
- justify their requirements for particular characteristics and specifications (for example, sex, weight or age) within a properly designed study;

- collaborate with other users (in their own establishment and at other places), including those using tissues and organs outside the operation of the Act;
- question the need for small, in-house breeding colonies of common strains;
- share or cryopreserve "tick over" strains;
- keep records of the surplus produced and review the reasons for this.

The Australian code of practice for the care and use of animals for scientific purposes (7th edition 2004)² states that records of animals culled and the reasons for their cull should be maintained and reviewed to identify overproduction and implement steps to avoid this occurrence.

Possible Solution - NAEAC believes that one option to deal with this would be for the definition of manipulation in the Act to be amended as follows:

Section 3 (2) (b and c) should be deleted.

Section 3 (1) should have a further section (c) which would read "Killing of an animal by the owner or person in charge, as the endpoint of RTT or in order to undertake RTT on the dead animal, if the animal would not have been otherwise been killed at that time."

Further, NAEAC recommends that a specific impact grading would apply to those animals killed prior to manipulation. This would require consequential amendments to the relevant regulations.

D. Code Holders

As the Act stands, only an individual or an institution can hold a Code of Ethical Conduct (CEC) entitling them to use animals in research, testing and teaching and form an animal ethics committee (AEC). While in most cases this is appropriate, exceptions have arisen. For example, in the case of the CEC and AEC for schools, which should properly sit with the Ministry of Education, this has not been legally possible because the Ministry itself does not carry out research. The current code holder being the NZ Association of Science Educators.

Possible Solution – Change the legislation to allow statutory bodies to be code-holders.

E. Intersection with other legislation

Clarification is needed in the definition of "manipulation" to remove confusion around the intersection of the Animal Welfare Act and the Biosecurity Act, particularly in relation to routine surveillance for diseases such as avian influenza, where blood samples are taken. Advice from MAF Legal that indicated that if more blood had been taken they might regard this as a manipulation has not removed NAEAC's confusion on this matter.

Possible solution: NAEAC suggests that routine surveillance, such as the taking of blood samples, under the Biosecurity Act be added to 3(c) in section 5 (Definition of research, testing and teaching) as an exclusion to the definition of a manipulation.

² <http://www.nhmrc.gov.au/guidelines/publications/ea16>

F. Payment of the legislatively required external members of AECs

NAEAC would like to see payment of external AEC members made compulsory. There are still some AECs that don't pay, contrary to strong recommendations from NAEAC. This has been excused on the grounds that payment would compromise the independence of the external members. However, it is unrealistic to expect nominees to carry the cost, in both time and expenses, for the good of the company or institution involved.

Possible solution: Add a further clause under 101 Membership:

(11) External members shall be paid an honorarium and their expenses covered.

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