



6 November 2008

POCTA Regulation Review
Bureau of Animal Welfare
475 Mickleham Rd
Attwood
VIC 3049

Dear Sir/Madam,

Thank you for the opportunity to comment on the Prevention of Cruelty to Animals Regulations Exposure Draft.

As AAHR is an organisation that challenges the use of animals in research and teaching and promotes the use of more humane and scientifically-valid non-animal alternatives, we herewith provide our comments on Part 4 – Scientific Procedures - only.

We also wish to emphasize that being an abolitionist organisation, any comments provided by AAHR are not to be considered an endorsement of the regulations in any way.

"Animal welfare" (as defined on your website) means how an animal is coping with the conditions in which it lives. An animal is in a good state of welfare if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, able to express innate behaviour, and if it is not suffering from unpleasant states such as pain, fear, and distress. Good animal welfare requires disease prevention and veterinary treatment, appropriate shelter, management, nutrition, humane handling and humane slaughter/killing. Animal welfare refers to the state of the animal; the treatment that an animal receives is covered by other terms such as animal care, animal husbandry, and humane treatment. [*OIE May 2008 - International Office of Animal Health*]

It must be acknowledged that the use of animals in research and teaching disqualifies them from the above definition as in many cases 'subject' animals are exposed to a wide variety of procedures and inflicted with disease and debilitating conditions that would constitute a distinct lack of welfare, and, if not exempted by the codes of practice, would clearly be considered cruelty.

Compliance with codes of practice/Use of pound animals

Throughout your draft document [initially 87 (2)] it is stated that scientific procedures must comply with codes of practice, including the Pound Dogs Code of Practice.

Section 15 however – ‘Sources of animals used under the license’ - specifies what types of premises animals must be obtained from. Under these specifications the use of both pound dogs and donated animals should be prohibited.

Section 21c also states that records must be kept of the place where each animal was bred. Again, this is not possible in the case of pound animals as their history is unknown.

AAHR is very much opposed to the use of pound animals in research and teaching and urges the Victorian government to prohibit the practice – as has been done in New South Wales. Our opposition is based on the following grounds:

Betrayal of Trust

Abandoned animals in pounds and shelters have already suffered the fear and distress of losing their carers and familiar territory. Their use in research and teaching is the ultimate betrayal which, as a caring society, we should never condone.

Pet overpopulation

The number of healthy animals euthanased each day due to a lack of suitable homes is a tragedy, but using pound animals is actually creating a dependence on the problem rather than helping to solve it.

Whilst these animals are regarded as a resource, there is a conflict of interest and there will not be sufficient emphasis by councils to addressing the core of the problem nor satisfactory efforts made to rehabilitate and rehome them. Researchers and veterinary schools that use pound dogs are therefore benefiting from the human irresponsibility and cruelty necessitating pounds and shelters.

Similar concerns have been raised by US group Physicians Committee for Responsible Medicine, who have suggested “People bringing animals into a shelter expect that animals will either be adopted or humanely euthanased. When people know that pound seizure is routine, they tend to leave the animals on the street. Studies in New Mexico and Washington DC showed that pound release practices measurably erode public confidence in animal control facilities.”

Nomination and membership of Animal Ethics Committees

According to the draft regulations, the license holder must nominate one or more Animal Ethics Committees. Such a committee however, should be independent as they are currently heavily weighted in favour of the research rather than the animals.

The draft also suggests that if an AEC does not carry out its functions under the licence in accordance with the Australian Code of Practice, the licence holder must nominate another AC to take its place.

Animal Ethics Committees carry an enormous moral responsibility. A failure to adhere to the code of practice should involve more than simply being replaced, and harsher penalties should therefore apply for non-compliance.

Functions of Animal Ethics Committee

A core responsibility of these committees, and one that is often given little emphasis, is to consider the *ethics* of the protocol. They must take measures to ensure that all

avenues have been explored relating to the replacement of animals with alternative methods of research.

In the absence of alternatives, the committee must further determine whether the protocol is justified at all.

According to William Russell, who co-authored of The 3R's in 1959, "*Refinement is never enough, and we should always seek further reduction and, if possible, replacement... Replacement is always a satisfactory answer.*"¹

It's absolutely essential that we ask the question, "Can the aims of the research be achieved in ways that do not involve animals?" And "Will the scientific outcome of this research justify the lives it will take and the suffering it will cause?" In many cases it will not.

The House of Lords Select Committee 2002 has said: "*We are not, however, persuaded that enough effort is always made to avoid the use of animals. We are similarly not persuaded that where this is possible, sufficient effort is always made to minimize the number of animals used, and to minimize the pain and suffering inflicted on each animal.*"²

Animal care and welfare

(19) *A person must not carry out a scientific procedure unde the license involving the eye of any animal to determine irritancy of a chemical or biological agent unless the procedure is carried out under terminal anaesthesia.*

The Draize eye test is one of the most controversial testing procedures conducted on animals and has long been abandoned by many companies. There are now several non-animal methods of determining the irritancy of a chemical. These methods, including Eyetex, human corneal cell lines, Microphysiometer and computer modelling have proven to be more effective than the use of an animal's eye due to there being no 'species differences' to consider. It would therefore be logical to prohibit the use of the eye irritancy test altogether.

(20cii) specifies that death as an end point cannot be carried out unless the procedure is related to..."*research in connection with cancer in animals or human beings.*"

It is unclear why cancer research is highlighted here as this type of research is covered by (i) "potentially lifesaving treatment for animals or human beings."

Completion of annual returns

The return should also specify the names of those people serving on the Animal Ethics Committee that approved the protocol. It is essential that these people accept ownership of their decisions.

Each return should include a declaration, signed by the ethics committee, that the 3R's principle has been adhered to.

¹ Quoted in *ATLA* 34, 271-272, 2006.

² House of Lords Select Committee 2002 *Animals in Scientific Procedures* (Norwich:TSO), quoted in *The ethics of research involving animals, Nuffield Council on Bioethics, 2005, p.206*

COMMENTS PERTAINING TO THE REGULATORY IMPACT STATEMENT:

There are several statements throughout the Regulatory Impact Statement which suggest that the document is biased and has little regard for the 3R's principle, nor for acknowledging the importance of the need to replace animal-based research with more reliable, scientifically-valid and species-specific research.

8.1 While **“approximately 40% of animals were subjected to procedures with minimal or no impact, being merely observed”** it is important to acknowledge that what might be considered “minimal impact” may still have severe and often life-threatening consequences for the animals.

Even studied in their natural environment, animals are sometimes trapped and restrained to be fitted with electronic tagging devices and again to have them removed at the end of the experiment. The trapping and anaesthetizing of the animals may leave them vulnerable to predators, particularly if they are still disorientated or relocated to unfamiliar territory. In some cases the tagging devices cannot be retrieved and they can remain on the animal throughout the remainder of their life. This can cause problems when the animal grows, for example collars can restrict breathing or small antennae may catch on foliage and cause an animal to be trapped.

“Victoria does not currently have any scientific procedures licenses issued to cosmetic companies.” (p.88)

Cosmetic testing is one of the most unjustified uses of animals. This has been acknowledged by the European Union whose *“7th Amendment to the Cosmetics Directive”* will ban the use of animals in cosmetic testing throughout Europe and the import of any cosmetics tested on animals – regardless of their country of origin.

Considering Victoria has no licenses issued to cosmetic companies, this is an opportune time to make a strong ethical statement by prohibiting cosmetic testing altogether.

“The purpose of an Animal Ethics Committee is to ensure there is a group of persons from a wide range of backgrounds to provide ongoing insight and control over an animal that is being used, or being held for future use, for research or teaching.” (p.88)

One of the major concerns about Animal Ethics Committees is that they are heavily weighted in favour of the researchers. Consider for example, the following quotes:

“...those who oppose the use of animals in research may also argue that animal ethics committees are stacked against the animals and in favour of the research. They may argue that a Category C person is unlikely to effectively make their voice heard for three reasons. First, they are often outnumbered; secondly, they may not be confident to speak up when in conference with doctors and professors, and finally, they are unlikely to have the scientific ability to understand

the detail of the protocol before them and come up with an effective counter argument. ” - Siobhan O’Sullivan³

“I and the other animal welfare representative have never succeeded alone in stopping an experiment. Recently, for example, we challenged on ethical grounds, the provision by our institution of transgenic pigs for research into organ transplantation. We did this on the grounds that the NH&MRC has placed a five-year moratorium on animal to human organ transplantation. The remainder of the committee opposed us and the experiments went ahead.” – (Category C member, name withheld.)

Another major concern is lack of expertise. AEC members are able to insist on more bedding, more appropriate food and cage sizes. Those with a greater understanding may also insist on higher dosage of analgesic, but do they have the scientific knowledge to challenge the legitimacy of the actual protocol itself?

“I certainly don't understand all the protocols. The scientists who develop the experiments are often specialists and have advanced knowledge in specific fields. Sometimes all members of the committee, even the scientists, admit that they don't fully grasp what the experiment is about. I tend to concentrate on specific areas such as animal housing, monitoring and pain relief..... I am certain that my lack of knowledge prevents me fully comprehending what the animals involved in experiments are going through.” – (Category C member, name withheld.)

Are AEC members:

- Capable of being able to question the design of the protocol?
- Able to critically evaluate the number of animals used in order to reduce that number, but to ensure that a sufficient number is used in order to statistically justify the research and not cause it to be repeated?
- Assured that the right species has been chosen to validate the work? This is particularly important because different species can produce vastly different outcomes.
- Over-relying on researchers to have sought alternatives?

“In a broader context, scientific research and teaching involving animals is important because it has led to some of the most significant medical advances and scientific discoveries over the last century.” (p.89)

AAHR strongly disputes this statement.

Researchers often cite a number of examples of which they consider the use of animals to be integral. However they do not provide any measure of how the perceived ‘successes’ compare with the number of delays and disasters animal use has caused throughout history. For example:

- 85% of drugs that reach clinical trial fail to attain general distribution (which certainly questions the efficacy of animal tests).⁴
- the development of the Polio vaccine, often cited by researchers as an example of the necessity of animal experiments, was long delayed due to misleading results from primate experiments. This was stated under oath by Dr Sabin (pioneer of the

³ *“Introduction to the Politics of Animal Protection”*, anzccart news, Volume 18, Number 1, 2005.

⁴Dr Robert Coleman of Pharmagene PLC, giving evidence at the House of Lords Select Committee on Animals in Scientific Procedures (April 2002) UK.

- polio vaccine)⁵
- Penicillin was delayed for 50 years and blood transfusions for more than a century.

Blood transfusions, Digitalis and Iron Sorbitol were also delayed for many years due to the misleading conclusions from animal-based research.

The following drugs were ‘successfully’ tested on animals:

Drug	Purpose	Result
Thalidomide	A sedative and to treat morning sickness in pregnant women.	Found to cause damage to the human foetus, resulting in 10,000 children born crippled and deformed with missing limbs.
Opren	Arthritis drug.	Found to be highly toxic in humans, with 3,500 reports of harmful effects including 61 British deaths, mainly through liver damage in the elderly.
Clioquinol	Ingredient in anti-diarrhoea drugs	At least 10,000 people, and possibly up to 30,000, fell victim to SMON (subacute myelo-optic neuropathy), a disease that causes numbness, weakness in the legs, paralysis, eye problems including blindness, all due to nerve damage.
Diethylstilbestrol (DES)	A synthetic estrogen prescribed to pregnant women to prevent miscarriage	Increased spontaneous abortions, premature births and neonatal deaths. Increased risk of vaginal cancer in daughters and granddaughters of users.
Vioxx	Painkiller for rheumatoid and osteoarthritis	Increased risk of cardiovascular events.
Ritalin and Dexamphetamine	Treatment of ADHD, especially in children.	Children as young as 5 suffered strokes, heart attacks, hallucinations and convulsions, shortness of breath, heart palpitations, hair loss, muscle spasms, severe abdominal pain, tremors, insomnia, severe weight loss, depression and paranoia.
TGN1412	Treatment of inflammatory conditions (especially rheumatism) and leukemia	Volunteers in a clinical trial suffered poor breathing, heavy swelling of neck and head, organ failure

Another thing worth considering is the number of drugs and treatments that were abandoned because they ***didn't*** work in animals. We may easily have inadvertently discarded a potential cure for cancer or AIDS!

Many researchers acknowledge the arguments against animal experiments, but they insist that using animals HAS made some advances. However these could have been made through other means. Additionally, many discoveries were made by non-animal methods, and later experiments on animals only further verified these breakthroughs as being correct.

Ovarian function, for example, was demonstrated by physician Dr. Robert.T. Morris in 1895 in surgical procedures on women, yet history credits the discovery to Emil Knauer who one year later reproduced the procedure in rabbits in 1896.⁶

⁵ Dr Ray Greek MD, Proof of Evidence supplied to University of Cambridge in response to their planning appeal for a proposed primate research facility.

⁶ Greek R. and Swingle Greek, Jean (2002) Sacred Cows and Golden Geese.

Banting and Best are often cited as having discovered insulin through animal experiments in 1922. However the connection between diabetic symptoms and the pancreas dates back to 1788 when an English physician, Thomas Cawley, performed an autopsy on a diabetic. Unfortunately subsequent research on animals delayed the acceptance of his hypothesis. Despite the existence of this knowledge, it was evidence obtained from Banting and Best's dog experiments that was the convincing factor for scientists.

*"Historically, vivisection has been much like a slot machine. If researchers pull the experimentation lever often enough, eventually some benefits will result by pure chance."*⁷

Such logic however, does NOT constitute good science.

"By fulfilling this responsibility [of regulation] and by keeping the public informed of the extent and nature of animal experimentation, public disquiet should be kept to a minimum." (p.90)

In our experience, the public has very little knowledge of the extent of animal experimentation in Australia. Furthermore, the intention that "public disquiet should be kept to a minimum" illustrates the lack of transparency within the research community which disables open public debate on the topic.

"This RIS identified two types of impacts associated with the proposed Regulations, which involve trade-offs between scientific research/advances in knowledge and animal welfare" and "...a complete ban on using animals for scientific procedures would maximise animal welfare outcomes but would significantly constrain branches of scientific research..." (p.100)

We do not consider that a complete ban on using animals for scientific procedures would significantly constrain branches of scientific research. Rather, it would create a significant reduction in wasted resources by promoting research that is species-specific and more likely lead to real medical progress.

In 2006, the British NHS (National Health Scheme) funded six studies to quantify the relevance to humans of testing treatments on animals. The studies compared systematic reviews of human clinical trials with corresponding animal experiments and found that in four out of six interventions, the animal studies did not clearly predict the human outcome.⁸

The report showed that:

- Animal researchers don't talk to hospital doctors about their work
- Clinical trials with human patients get underway even before the animal research is completed
- Drugs that fail in animals are used in humans anyway

⁷ Dr John McArdle, Animals Agenda, March 1988.

⁸ Animal Aid media release 7/6/06

- A drug that increased overall mortality in animals was, nonetheless, used in people
- Most of the animal research that was analysed was poorly conducted and gave conflicting results.

The study by Peral et al, which was titled “Comparison of treatment effects between animal experiments and clinical trials: systematic review” concluded that animal experiments often fail to predict outcomes in humans.⁹

“By requiring Animal Ethics Committees to assess all scientific procedures it ensures that no procedures are approved unless they are deemed by such a group of persons to be justifiable and that the potential benefits/objectives are substantial enough to outweigh the potential costs.” (p.105)

There has been a number of studies conducted overseas that address the problems that occur within animal ethics committees.

A Study by Catharine A. Schuppli and David Fraser, University of British Columbia, Vancouver was titled “Improving the Effectiveness of Research Ethics Committees” and was presented at the 5th World Congress for Alternatives in Berlin 2005.

The authors identified the following concerns:

1. Committee composition creates bias towards institutional/research interests versus interests of animals.
 - Institutional members make up the largest proportion
 - Chairpersons were often scientists
 - Community members reported they had limited power as they were outnumbered.
2. Committee dynamics prevent full participation of members.
 - Community members felt intimidated by scientists
 - They had insufficient expertise
 - They were ‘outsiders’
3. Recruitment strategies create bias towards institutional/research interests versus interests of animals.
 - Community members were recruited as friends, relatives or neighbours of AEC.
 - Word-of-mouth recruitment runs the risk of recruiting members who are perceived to ‘fit in’
4. Motivation for joining is to pursue agendas other than committee mandate.
 - Some scientists joined the AEC to promote their own or their department’s agenda, in some cases to limit the committee’s actions.
 - Concern about recruiting animal right advocates
5. Excessive workload or inadequate participation for adequate review.

Further comments:

In summary, AAHR considers it essential that measures are put in place by the Victorian government to demonstrate their commitment to the 3R’s principle. This could be done in a number of ways:

⁹ BMJ, 15/12/06, bmj.com

A reduction in animal usage must be achieved every year. This could be accomplished by putting a cap on the number of animals used and licenses issued, thereby enabling only those protocols that are deemed most justified. This would further result in a reduction of wasted resources – time and funding spent on futile experiments that are unlikely to be of any real benefit.

Increased funding for alternatives research.

According to our enquiries, the Victorian Government is the only state government that offers a financial incentive through the “DPI Minister’s Prize for Application of the 3R’s.” While this is encouraging, there does need to be more incentive for researchers to find alternatives and not just adhere to the 3R’s principle.

Other nations forge ahead in the area of alternatives research, but instead of committing to actively seek alternatives to animals, Australia focuses on ensuring that our laboratory animals are handled correctly, have comfortable bedding and toys to play with. While such environmental enrichment may clearly improve the lives of individual animals doomed to exist as mere laboratory tools, it does not address the fact that these animals should not be there at all. Instead, it reinforces the justification for using animals and detracts from the importance of finding alternatives.

The Australian government urgently needs to address this huge void and allocate a meaningful percentage of funding to fostering new methodologies in medical research which do not involve animals, and utilising to a greater extent existing non-animal methodologies.

Considering the public interest in preventing cruelty to animals, the likelihood of non-animal alternatives providing more beneficial outcomes for public health and the legislation itself requiring adherence to the 3R’s, it is essential that our governments allocate meaningful financial support to the development of non-animal models.

Yours sincerely,

Helen Rosser
Chief Executive Officer