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The Project Officer – *Australian code of practice for the care and use of animals for scientific purposes*

Health & Research Ethics Section
Research Translation Group
National Health and Medical Research Council
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via email: ethics@nhmrc.gov.au

Dear Sir/Madam

Australian code of practice for the care and use of animals for scientific purposes

The Society's Animal Law Committee has considered the proposed revisions to the above Code and accordingly the Society's response is being submitted electronically via the website.

A hard copy of the submission is attached.

Yours sincerely

Ralph Böning
PRESIDENT



Submission in relation to proposed revisions to the

**Australian code of practice for the care and
use of animals for scientific purposes**

The Animal Law Committee is a committee of the Law Society of South Australia to represent the interests of the Society and the profession in the legal regulation of the relationship between animals and people and other entities or organisations (“The ALC”). The ALC promotes debate on animal law issues, law reform in animal law and development of animal law. The ALC also assists organisations and individuals to understand animal law issues and assists in the processes of review of animal law legislation by providing legal analysis and submissions.

In accordance with the ALC’s terms of reference, it responds to the request for comment on the following issues identified in the technical Discussion Paper :-

1. Does the document clearly and concisely set out the governing principles?
2. Does the document clearly and concisely set out, and correctly attribute, responsibilities of all parties involved?
3. Does the document provide all relevant parties with sufficient practical guidance on the application of principles of the Code of Practice in terms of their responsibilities?
4. Are the terms ‘should’ and ‘must’ used appropriately in the document?
5. Is there a clear connection between the Code of Practice and the NHRMC *Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals* (2008) (Wellbeing Guidelines)?
6. Is there sufficient balance between principles and detailed guidance?
7. Is ‘animal’ appropriately defined?
8. Not within ALC terms of reference.
9. Not within ALC terms of reference.

10. Not within ALC terms of reference.

11. Not within ALC terms of reference.

This submission also identifies other issues upon which the ALC considers it appropriate to comment, namely: -

1. The adequacy of the content and terms of *Section 5: Complaints and non-compliance*
2. The adequacy of the content and terms of *Section 6: External review of the operation of institutions and their animal ethics committees*

Structure of the submission

This submission works through the Draft Code in sequence identifying sections in respect of which the ALC recommends amendment. Each clause (or part thereof) is set out and the proposed amendment underlined. An explanation is then provided in *italics* setting out the rationale for the proposed amendment. As some of the proposed amendments are common to a number of sections, the explanation is not repeated but reference is made to the first clause in which it appears. In structuring the submission in this way, the issues identified in topics 1 -7 above have been addressed. For clarity, each relevant amendment is footnoted with the issue(s) to which it relates.

Introduction

The public guide to the technical Discussion Paper endorsed by NHRMC Council states that “[t]he humane and ethical care and use of animals for scientific purposes has been a primary consideration in the development of the consultation draft. The Code of practice aims to ensure this level of care. It is intended that the principle of respect for animals is the key governing principle that underpins the Code of Practice.”¹

The preamble to *Section 1: Principles for the care and use of animals for scientific purposes* of the draft Code, states that the foundations of the Code are, *inter alia*, that the use of animals for scientific purposes must have scientific and/or educational merit, must be conducted with integrity and purports to recognise the inherent imperative to respect animals

¹ “Public Guide to the technical discussion paper endorsed by the NHRMC Council”, p. 1.

and promote their wellbeing and minimise harm, including pain and/or distress.² There must be adequate justification for the use of animals for scientific purposes and this use must be subject to ethical review.

In light of these stated aims and objects, the ALC has examined the draft Code and recommends a number of amendments to the Code designed to ensure the consistent application and implementation of the key governing principle. Many of the recommended amendments involve the replacement of the word *'should'* with *'must'* where a mandatory obligation is required to give effect to the key governing principle and/or otherwise avoid inconsistency in the application of requirements.

'Definitions' section

Animal³

'Animal' is currently defined in the Code as:

“any live non-human vertebrate, that is, fish, amphibians, reptiles, birds and mammals, encompassing domestic animals, purpose-bred animals, livestock, wildlife, and also cephalopods such as octopus and squid.”⁴

The only material change to the proposed definition is to remove the word *'cephalopods'*. No explanation has been provided as to why it is proposed to constrict the definition in this way. We have been unable to find any research since the last version of the Code was adopted that suggests that cephalopods are not capable of feeling pain or are not worthy of any form of protection.

Rather, the ALC notes that in 2007, a research paper was published by a number of scientists from all over the world (including five from Australia) that sought to provide guidance to those using cephalopods for scientific procedures.⁵ Further, the paper referred to the well-developed nervous system of cephalopods and the presence of free nerve endings in the skin,

² Page 5 of the draft Code.

³ Issue number 7 – is 'animal' appropriately defined?

⁴ National Health and Medical Research Council, *Australian code of practice for the care and use of animals for scientific purposes*, 7th ed, 2004, p. 3.

⁵ N. A. Moltshaniwskyj & Ors, 'Ethical and welfare considerations when using cephalopods as experimental animals' (2007) 17 *Rev Fish Viol Fisheries* 455.

suggesting that perception of pain is possible and behavioural responses suggesting that many cephalopods do respond to pain.⁶ A number of papers have come to similar conclusions.⁷

In Canada, cephalopods are included in the definition of ‘*animal*’ for the purposes of scientific procedures.⁸

The ALC notes that in the United Kingdom, only one species of cephalopods, *octopus vulgaris*, is included in the definition of ‘*animal*’ in the *Animals (Scientific Procedures) Act 1986*.⁹ However, this will have to be revisited as a result of a recent European Union Directive, which the UK will have to incorporate into its legislation by January 2013.¹⁰

The EU Directive defines animals as:

- (3) (a) *Live non-human vertebrate animals, including:*
 - (i) *independently feeding larval forms; and*
 - (ii) *foetal forms of mammals as from the last third of their normal development;*
- (b) *live cephalopods.*

The ALC recommends that the definition of ‘*animal*’ should retain its current form, which includes all cephalopods, and not the proposed definition, which restricts the definition to octopus and squid.

Further, the ALC notes that in the draft Code, the definition of ‘*animal*’ includes an added explanation as to the definition of ‘*animal*’. The explanation states:

“As a guide, when embryos, fetuses and larval forms have progressed beyond half the gestation or incubation period of the relevant species, or they become capable of

⁶ *Ibid* at 457.

⁷ J. A. Mather & R. C. Anderson, ‘Ethics and invertebrates: a cephalopod perspective’ (2007) 75 *Diseases of Aquatic Organisms* 119; D. J. Oestmann & Ors, ‘Special Considerations for Keeping Cephalopods in Laboratory Facilities (1997) 36(2) *Contemporary Topics* 89; M. D. Kreger (ed.) *Information Resources on the Care and Use of Invertebrates* (2000) AWIC Resource Series No. 8.

⁸ Canadian Council on Animal Care, *Categories of Invasiveness in animal experiments*, CCAC Policy Statement, February 1991.

⁹ s 1(1) of the *Animal (Scientific Procedures) Act 1986* (UK).

¹⁰ Directive 2010/63/EU, *Directive on the protection of animals used for scientific purposes*.

independent feeding, the potential for the experience of pain or distress should be taken into account.”¹¹

The ALC is of the view that such an explanation placed under the definition of ‘*animal*’ is likely to cause confusion and may result in different and inconsistent interpretations. For those reasons, the ALC recommends that the reference to ‘*embryos, fetuses and larval forms*’ be incorporated into the definition of ‘*animal*’ in the Code.

We note that a similar incorporation is used in the *Animals (Scientific Procedures) Act 1986* (UK) as follows:

“(2) Any such vertebrate in its foetal, larval or embryonic form is a protected animal only from the stage of its development when—

(a) in the case of a mammal, bird or reptile, half the gestation or incubation period for the relevant species has elapsed; and

(b) in any other case, it becomes capable of independent feeding.”¹²

For the avoidance of doubt, it is respectfully recommended that the definition of ‘*animal*’ incorporate the proposed explanation as part of its definition rather than as a form of guidance.

Evidence¹³

The ALC recommends that the following definition of ‘*evidence*’ be inserted in the definition section:

Evidence: available body of empirical facts or data such as is applicable to the particular field of inquiry and is properly documented in accordance with a method of inquiry based on gathering empirical and measurable evidence subject to specific principles of reasoning.

The term ‘evidence’ is used in a number of sections within the Code.¹⁴ Unless this term is defined, then those to whom the Code applies will have no guidance regarding the type and

¹¹ Page 1 of the draft Code.

¹² *Animals (Scientific Purposes) Act 1986* (UK) s 2.

¹³ Issue number 3 – does the document provide all relevant parties with sufficient practical guidance on the application of principles of the Code of Practice in terms of their responsibilities?

content of information that is required to be provided in order for relevant decisions, recommendations or other action to be determined. The definition of ‘evidence’ should accord with scientific principles of the gathering of information and facts in a measurable way.

Section 1: Principles for the care and use of animals for scientific purposes –

Governing Principles¹⁵

Using animals only when justified

1.6 Evidence to support the case to use animals must demonstrate that:

(i) the activity has scientific or educational merit and the predicted outcomes will further the scientific or educational purpose of the activity to an extent that outweighs any negative impact or harm likely to be caused to the animal(s) used.

1.7 Scientific or educational activities must only be undertaken:

(i) to obtain and establish significant information relevant to the understanding of the physiology, behaviour, health or welfare of humans and/or animals that is not otherwise available without the use of animals in the proposed activity

(iii) for the improvement of animal management or production provided those improvements are not detrimental to the wellbeing of the animals whose management or production is being examined or considered

(v) for the achievement of educational objectives provided that those educational objectives cannot be achieved via means that do not involve the use of animals for educational purposes.

The amendments to clause 1.6 and 1.7 are designed to reflect the underpinning principle of respect for, and the humane and ethical care of, animals used for scientific purposes. Accordingly, a balance must be struck between the use of animals for scientific purposes and the effect of that use upon those animals. Therefore, it is recommended that the beneficial effect or merit of the activity be weighed against the likely negative impact upon the

¹⁴ The following clauses use the word evidence: 1.4, 1.6, 1.8, 1.18, 1.32, 2.19, 2.2.43, 2.3.3, 2.4.11, 2.4.12, 2.4.17, 2.4.29, 2.5.4, 3.1.6, 3.2.6, 3.3.2, 3.4.3, 3.5.7, 3.6.5, 3.7.12, 3.7.32, 3.7.35, 3.7.57 and 6.2.2.

¹⁵ Issue 1 – Does the document clearly and concisely set out the guiding principles?

animal(s) concerned. To reflect adequately the primacy of the principle of respect, humane and ethical care it is necessary for the anticipated merit of the activity to outweigh any expected or likely harm. Accordingly, the test posed is one that will avoid the use of animals for scientific or educational purposes where alternatives exist or where that use does not enhance or increase the existing body of knowledge, research or education. This test is consistent with the NHRMC Guidelines to Promote the Wellbeing of Animals Used for Scientific Purposes.¹⁶

Accepting Responsibilities

Institutions

1.15 Institutions must implement policies and procedures to:

- (i) promote and ensure compliance with the Code, reflecting in particular the principles in Clause 1.1 and the application of the 3Rs

The inclusion of the words ‘and ensure’ is consistent with the requirements in clause 2.3 that the institution, through the AEC, ensure that all care and use of animals is conducted in compliance with the Code.¹⁷

Replacement

Application of “Replacement” includes the following:

- 1.21 ...Replacement techniques that ~~should~~ must be considered include the use of epidemiological data, physical and chemical analysis, computer and mathematical models, in vitro systems or non-sentient organisms.
- 1.22 Persons involved with the care and use of animals ~~should~~ must ensure they are aware of emerging alternatives to replace animals in their field of expertise.

¹⁶ “Investigators must weigh up whether the potential benefits of the scientific knowledge gained will outweigh harm to the animal. If animals are required for the research, the information in this section must be considered before submitting a proposal to the animals ethics committee (AEC).” Part 4.1, page 17.

¹⁷ Issue 2 and 3.

1.23 Opportunities to replace the use of animals ~~should~~ must be kept under review during the life-time of a project and, where ~~relevant~~ the opportunity to utilise a replacement method arises that does not compromise the purposes of the project and its implementation does not affect the wellbeing of the animal(s) being used, that method must be adopted for the balance of the duration of the project and the animal(s) involved in the project must then be dealt with in accordance with clause 3.9. Where a review results in the identification of an opportunity to replace the animals, the outcome of the review must be taken into account in planning future activities.

As “Replacement” is one of the fundamental matters required to be considered by any person involved with any aspect of the care and use of animals for scientific purposes, the ALC recommends the use of the term ‘must’ rather than ‘should’ to maintain consistency and give proper effect to this governing principle. The ALC recommends that where the opportunity to implement replacement of animals with other techniques, systems or organisms is identified during the life-time of a project, its implementation, where practicable and with no adverse effect on wellbeing, should not be deferred.¹⁸

Refinement

Application of “Refinement” includes the following:

1.31 In making decisions about the impact of circumstances on the wellbeing of animals, it must be recognised that animals have the capacity to experience pain and distress. Evidence from sources other than the proposed activity must be gathered that has been used to predict whether animals may experience pain and/or distress and to inform procedures to monitor and manage such circumstances.

The inclusion of the words ‘from sources other than the proposed activity’ ensures that decisions regarding the likelihood of negative impact upon animals used in the project or activity are made prior to the activity or project commencing and based upon existing available evidence. That is, the impact of circumstances on the wellbeing of animals is not to be assessed during the course of the activity.¹⁹

¹⁸ Issues 1-4.

¹⁹ Issues 1-3.

1.32 Practices and procedures must be based on recognised standards of good practice, that take into consideration relevant aspects of species-specific biology, physiology and behaviour, are based on evidence of the potential negative impact of conditions and procedures on the wellbeing of the animals and include strategies to minimise such impacts. Special consideration is required where these conditions are precluded by the requirements of a project and ~~must be approved by the AEC~~ thus affect compliance with clauses 1.1-1.12.

The ALC considers that the term 'recognised standards' should be made referable to the applicable standards in the relevant NHRMC Codes. Further, there should be a definition of 'special consideration' in relation to approval of activities that will involve non-compliance with the governing principles. It is not within the ALC's area of expertise to determine what may constitute special consideration, but examples such as research into vaccines or cures for new strains of disease or virus may fall within the rubric of exceptional circumstances.²⁰

1.34 Investigators and animal carers must:

(v) so far as is reasonably practicable take ~~prompt~~ immediate action to treat animals with signs of pain and/or distress not anticipated or authorised in applications to the AEC.

In order to give proper effect to the governing principle underpinning the Code, it is recommended that the mandate of immediate, rather than prompt, action be adopted. Although the legal and dictionary definitions equate prompt with immediate, the ALC suggests that the word immediate will convey, without ambiguity, the necessary connotation.²¹ Macquarie Dictionary defines 'prompt' as 'done, performed, delivered etc, at once or without delay'.²² Butterworths Encyclopaedic Australian Legal Dictionary describes 'prompt' as analogous to 'immediate' and 'without delay'.²³ 'Promptly' or 'immediately' have been described as stronger words than the expression 'within a reasonable time'.²⁴ 'As soon as possible' has been described as analogous to 'as quickly as the task at hand is capable of being done in the circumstances'.²⁵

²⁰ Issues 1-3, 5.

²¹ Issues 2-3.

²² S. Bulter (ed), *Macquarie Dictionary* (2009), 5th ed., p. 1328.

²³ *Butterworth's Encyclopaedic Australian Legal Dictionary* I 'Immediately'.

²⁴ *Dorsman v Nichol* (1978) 20 ALR 231.

²⁵ See also *Linder v Wright* (1976) 14 ALR 105.

1.35 In addition to above clauses (1.30-1.34):

(iii) animals must not be taken from natural habitats unless animals bred in captivity are not ~~available or are not~~ suitable for the specific scientific purpose.

The Code recognises the additional risks involved in projects involving the use of wildlife or vertebrate pest animals taken from natural habitats (see Part F: additional investigator responsibilities for specific activities; 2.4.40; Section 3: Animal Wellbeing; 3.3.6; 3.8.1-3.9.6). Accordingly, the ALC recommends that the taking of animals from their natural habitats be restricted to those activities where other animals (domesticated, bred in captivity, privately owned etc) are not suitable for the specific scientific purpose. This will avoid the use of wild animals simply because, at the time of the particular project, there are no alternative animal sources available. In light of the recognised risks involved in the use of wild animals, mere unavailability of an alternative should not be sufficient justification for their use.²⁶

(vi) using ‘Death as an end-point’ (see definition) must be avoided, ~~where possible.~~ ~~Where~~ unless death as an end-point is accepted as essential for the purpose of the project in which case investigators must consider, and implement ~~where possible,~~ the means to prevent or minimise pain and/or distress at all stages of the activity.

The Code requires persons involved with any aspect of the care and use of animals for scientific purposes to take steps at all times to promote the wellbeing of the animals involved and to prevent, alleviate or minimise known or potential causes of pain, distress or lasting harm to the animals (1.30). Consistent with this mandate, death as an end-point should be seen as the option of last resort. The ALC therefore recommends that this clause be amended to emphasise the necessity to avoid death as an end-point unless that is accepted as essential for the purpose of the project and a corresponding requirement that measures to prevent or minimise pain be implemented at all stages of the activity. The words ‘where possible’ have been removed as surplusage.²⁷

²⁶ Issues 1-3.

²⁷ Issues 1-3.

Section 2: Responsibilities Reporting by institutions

2.1.11 Institutions ~~should consider~~ must make publicly available:

- (i) an annual report of compliance with the Code
- (ii) a summary of the external review report (see 2.1.12, Section 6).

To a large extent the Code embodies a system of self-regulation by which each institution must put in place processes to ensure compliance with the Code. The AEC is a key component of this system of self-regulation (Section 6). In order to promote effective self-regulation and ensure transparency and accountability, the ALC recommends that the annual report of compliance with the Code and a summary of the relevant external review report be made publicly available.²⁸

External Review

2.1.12 Institutions must ensure they conduct an external review which enables assessment of its compliance with the Code, identifies matters that should be addressed and informs future planning. The external review must be undertaken every ~~three year and must be undertaken at least every four years~~ unless the external review results in a variation of this requirement to a period of two years (see section 6, External review of the operation of institutions and their animal ethics committees).

The ALC notes that clause 2.2.50 requires the AEC to submit a written report on its operations at least annually. Consistent with that requirement, it is recommended that the external review be conducted annually. The written report prepared pursuant to clause 2.2.50 can be utilised for the purposes of an external review. However, the ALC recognises the additional burden that an external review may have upon the operation and resources of an institution and therefore recommends an incentive system whereby, demonstrated compliance to the satisfaction of the external review team, may lead to a variation of the annual external review requirement.²⁹

²⁸ Issues 1-3.

²⁹ Issues 1-3.

Projects involving more than one institution and/or AEC

2.1.13 For projects to be conducted at more than one institution, procedures must be in place to ensure that:

(iii) respective AEC's ~~are~~ must be permitted to visit and inspect the phases of the project conducted at other institutions and should be provided with copies of the terms of the approval granted by the AEC of the other institution(s) prior to the commencement of the project and, where evidence of non-compliance with the terms of approval or the Code exists, the AEC associated with the site of the non-compliant activity must institute an inquiry in accordance with Section 5

The ALC recommends that each AEC involved in an activity conducted at different sites by different institutions be provided with the terms of approval of each AEC involved and be permitted to visit the site of the any relevant phase of activity. This ensures that any difference of opinion regarding the employment of techniques, methodology and manner of compliance with the Code will inform the decision making process of each AEC in respect of the grant or continuance of approval for the relevant part of the project.

(v) the respective AECs ~~are aware~~ have considered the relevant approvals granted by each AEC of a site involved in a phase of the project when considering the application of the cumulative effect on the animals of the proposed procedures.

Consistent with the amendments proposed to clause 2.1.13, the ALC recommends that the AEC of each site consider the relevant approvals granted by each AEC in determining the cumulative effect on the animals of the proposed procedures. Unless the terms of approval are sighted, the ability to make this assessment may be compromised.³⁰

Projects conducted by Australian investigators and institutions in other countries

2.1.18 In the case of an Australian institution operating facilities that use animals for scientific purposes in another country, projects conducted at those facilities must comply with the Code as a minimum, provided such compliance does not conflict with relevant local legislation. Where minimum compliance conflicts with local

³⁰ Issues 1-3, 6.

legislation in circumstances which will result in non-compliance with mandatory obligations under the Code, the AEC of the institution should not provide, or should withdraw, approval for the project.

The ALC recommends this amendment to ensure that a conflict between the Code and local legislation does not result in dispensation with the obligations imposed by the Code. As currently worded, the clause is ambiguous and does not set out the consequences of a conflict. Further, as currently worded, the clause leaves open the possibility of the use of overseas facilities as a means by which the obligations imposed under the Code can be avoided.³¹

Section 2.2 Responsibilities of Institutions for the governance of an Animal Ethics Committee

AEC Membership

2.2.15 The institution must establish and maintain an AEC that has a membership that will allow it to fulfil its terms of reference (see 2.2.7).....

(i) Category A – A person with qualifications in veterinary science who is that are recognised for registration as a veterinary surgeon in Australia and who is registered to practice within the State or Territory in which the AEC operates and with experience relevant to the activities of the institution. Veterinarians who are not familiar whose experience is not current or who lack this experience must familiarise themselves with the biology and clinical characteristics of the species of animal used must familiarise themselves in that regard.

The ALC recommends this amendment in order to ensure that the requisite experience and capacity to treat animals is a matter governed and determined by the relevant statutory body of the particular State or Territory in which the category A member is situated. Requiring current registration as a condition of membership will provide a ready mechanism by which eligibility can be determined. Current registration will ensure the necessary currency of

³¹ Issues 2-3.

*experience and the corresponding requirement to familiarise will ensure the member is aware of the particular characteristics of the animal(s) to be used.*³²

Section 2.3 Responsibilities of Animal Ethics Committees

Decisions of the AEC

2.3.4 The AEC must base decisions on the information it receives from the applicant in the documentation (see 2.2.41-49), and any direct discussions with the applicant. The AEC may use relevant evidence in addition to that obtained from the applicant in making decisions.

*The ALC recommends the use of the word ‘evidence’ consistent with the proposed definition of ‘evidence’. If ‘evidence’ is used rather than ‘information’ the opportunities for decisions being made on unreliable or unverified information will be reduced.*³³

Monitoring of animal care and use

2.3.11 The AEC ~~should~~ must ensure that activities likely to cause pain and/or distress are subject to early monitoring by the AEC (for example, the study of pain, responses to stressors, certain animal models of human diseases, and attempts to change behaviour by physical or chemical means). To effectively monitor these activities and ensure compliance with the Code, members of the AEC are permitted to carry out regular inspections of the site of these activities without prior warning. This requirement must be a condition of approval for the activity.

*Consistent with the governing principle underpinning the Code, the obligation to ensure monitoring of activities likely to cause pain and/or distress should be mandatory rather than recommended.*³⁴ *The ALC also recommends a power of random and regular inspections as a means by which effective monitoring can occur and facilitate detection of non-compliance.*³⁵

³² Issues 2-3, 6.

³³ Issues 2-3, 6.

³⁴ Issues 1-4.

³⁵ See for example: Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes [36].

2.3.12 Members of the AEC must inspect all animal housing and laboratory areas at least annually. A Category C or D member of the AEC who is external to the institution ~~should~~ must participate in animal facility inspections.

The ALC recommends a mandatory requirement for the participation of a Category C or D member of the AEC external to the institution. In light of the potential negative impact of non-compliance upon the well-being of animals, the ALC considers that a requirement for annual inspection does not give proper effect to the key governing principle of ensuring the humane and ethical care of animals used for scientific purposes.³⁶

2.4 Responsibilities of investigators

Part B. Planning projects

2.4.11 From the outset, when planning projects, investigators must not consider using animals unless they are satisfied that there is evidence to ~~support the case~~ demonstrate that ~~the project has scientific or educational merit~~ the criteria in clause 1.6 and 1.7 have been met and the goals cannot be achieved without the use of animals.

In light of the proposed amendments to clauses 1.6-1.7 it is no longer necessary to include (i) or the final paragraph.

2.4.12 When planning projects, investigators must take into account the need to demonstrate to the satisfaction of the AEC ~~that the principles of the 3Rs~~ compliance with clause 1.6 - 1.7 and 1.20-35, notably that:....

The ALC recommends reference be made to clauses 1.6 and 1.7 in addition to 1.20-135 to emphasise the importance of compliance with the principles governing the circumstances in which use of animals for scientific or educational activities is justified.³⁷

Part C. Application to the AEC

2.4.17 Investigators must provide the following information:

³⁶ Issues 1-3

³⁷ Issues 2-3.

(viii) assessment of the potential negative impact on animal wellbeing for the duration of the project including

(a) a step-by-step description of what will happen to each animal at each stage of the activity, including provisions for the animal at the conclusion of their use.

(xii) for teaching projects, details as outlined in ~~(see 4.5.1)~~ *[removal of brackets-typo]*

The ALC recommends a reference to each stage of the activity to ensure the comprehensive assessment of any potential negative impact throughout the life of the project.³⁸

Part D. Conduct of projects

2.4.19 Investigators must:

(v) provide ~~prompt~~ immediate notification of any unexpected adverse events (see definitions) that may have a negative impact on the wellbeing of an animal in their care (see 1.34 (vii))

The ALC recommends the use of the word ‘immediate’ instead of prompt for the reasons referred to in its recommendations regarding 1.34 above.

Detecting and minimising pain and distress

2.4.25 Investigators must

(vi) take ~~prompt~~ immediate action to treat animals with signs of pain and/or distress not authorised or anticipated in applications to the AEC...

The ALC recommends the use of the word ‘immediate’ instead of prompt for the reasons referred to in its recommendations regarding 1.34 above.

³⁸ Issues 2-3.

Specific procedures

2.4.29 Investigators must ensure that practices and procedures involving animals ~~are based on recognised standards of good practice~~ as a minimum comply with *NHMRC Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals*. Further, ~~these standards~~ the practices and procedures must take into consideration relevant aspects of species-specific biology, physiology and behaviour, be informed by evidence of the potential adverse impact on the wellbeing of the animals and include strategies to minimise such impacts.

The ALC recommends that specific reference is made to the NHRMC Guidelines which govern the promotion of the wellbeing of animals used for scientific purposes rather than a generic reference to ‘recognised standards of good practice’. The latter term is ambiguous and fails to identify the relevant standards upon which the practices and procedures involving animals are based. The ALC notes that Section 3: Animal Wellbeing refers to the NHRMC Wellbeing Guidelines but also refers to other sources of ‘information’ such as ‘other NHRMC guidelines and policies and ‘best-practice guidelines’. The ALC recommends that reference is made to the specific guidelines with which the practices and procedures must comply, if those practices and procedures are not already spelt out in Section 3. This will avoid reliance upon standards which may fall short of, or conflict with, the standards set out in Section 3: Animal Wellbeing.³⁹

Wildlife studies

2.4.40 For projects involving the use of wildlife or vertebrate pest animals, investigators must:

- (i) avoid taking animals from natural habitats unless animals bred in captivity are ~~unavailable or~~ unsuitable for the scientific purpose

The ALC recommends the deletion of the words ‘unavailable or’ for the reasons set out in its recommendations regarding 1.35 above.

³⁹ Issues 2-3, 5.

(ii) ensure that risks to animal wellbeing in both target and non-target species and populations are identified, assessed, and avoided or minimised, and managed. Risks may arise from:

(b) indirect effects from disturbance to the habitat including the potential negative impact caused by disruption of social structure and on dependent young.

To ensure consistency with the requirements set out in 3.8.8, 3.8.12 (ii) and 3.8.22 (ii), the ALC recommends the inclusion of a reference to the risk of disruption to social structure and dependent young.⁴⁰

Issues requiring special consideration

2.4.47 During the planning of projects, investigators must give particular consideration to....

(i) unrelieved pain and/or distress, including where the planned end-points will allow severe adverse effects to occur

(b) Investigators must ~~promptly~~ immediately treat or humanely kill without delay animals that develop signs of pain and/or distress not anticipated or authorised in the application to the AEC...

The ALC recommends the use of the word ‘immediate’ instead of prompt for the reasons referred to in its recommendations regarding 1.34 above.⁴¹

(iv) Prolonged restraint or confinement...If any negative impact is detected, investigators must immediately release the animal, or modify the method of restraint to minimise the impact.

The ALC recommends the use of the word ‘immediate’ instead of prompt for the reasons referred to in its recommendations regarding 1.34 above.⁴²

⁴⁰ Issues 2-3.

⁴¹ Issues 2-3.

⁴² Issues 2-3.

Section 3: Animal wellbeing

The ALC recommends that an explanation be given regarding the relevance of the sources of additional information referred to in the preamble to Section 3. The current wording does not make sufficiently clear the connection between the Code of Practice and the Wellbeing (and other unspecified) Guidelines. The ALC notes that the Public guide to the technical discussion paper suggests that detailed guidance on the topics such as the conduct of specific procedures and techniques is now provided via reference to appropriate guidelines. However, if it is intended that the NHRMC Guidelines and other guidelines inform the manner in which practices and procedures are conducted, then the Code must either incorporate those guidelines by inserting them as sections or provisions within the Code or otherwise refer to the relevant guidelines or parts thereof and make compliance with those guidelines a requirement of the Code.

Strategies to minimise and manage the negative impact on wellbeing

3.2.7 The strategy developed to minimise and manage the adverse impact on wellbeing ~~should~~ must be:

As the promotion of the wellbeing of animals is one of the fundamental matters required to be considered by any person involved with any aspect of the care and use of animals for scientific purposes, the ALC recommends the use of the term ‘must’ rather than ‘should’ to maintain consistency and give proper effect to this governing principle.

Setting intervention points and humane end-points

3.2.9 Criteria for minimising pain and/or distress ~~should~~ must be used to identify:

The ALC repeats the recommendations in regards to 3.2.7 above.

3.2.11 If uncertain as to the validity and efficacy of criteria for intervention, investigators ~~should~~ must undertake a pilot study. The pilot study must be approved by the AEC and must comply with the requirements of this Code and the *NHMRC Guidelines to promote the wellbeing of animals used for scientific purposes.*

*The ALC considers that a pilot study should be subject to the same approval requirements as the project itself, given the likelihood that a pilot study will involve the use of animals, albeit a smaller number on a smaller scale. Pilot study is defined in clause 4.6.1 of the NHRMC Guidelines to promote the wellbeing of animals used for scientific purposes but no reference is made to approval by the AEC. If clause 3.2.11 is amended in the terms set out above, it will be necessary for a similar amendment to be made to clause 4.6.1 of the Wellbeing Guidelines.*⁴³

Acquisition and breeding

3.3.5 When animals are obtained from outside an institution:

- (i) they ~~should~~ must be acquired from sources including dedicated breeding and supply facilities that maintain conditions consistent with the Code or relevant species-specific codes

*The ALC considers that the acquisition of animals from sources external to the institution be restricted to Code compliant institutions. If such a requirement is inserted this will prevent the requirements of the Code being circumvented and deter non-compliant institutions by reducing the market for animals bred or supplied by them.*⁴⁴

3.3.6 Wildlife animals are particularly susceptible to stress in captivity and ~~should~~ must not be removed from their natural habitat unless animals bred in captivity are ~~unavailable~~ ~~or~~ unsuitable for the scientific purpose.

*The ALC recommends the deletion of the words ‘unavailable or’ for the reasons set out in its recommendations regarding 1.35 above. The ALC notes that the word ‘must’ has been used in 1.3.5 and, to ensure consistency of application and consistency with the governing principles of the Code, it should be substituted for ‘should’ in 3.3.6.*⁴⁵

⁴³ Issues 2-3.

⁴⁴ Issues 2-3.

⁴⁵ Issues 2-3

Transport of animals

3.3.9 Containers must be secure and escape proof. They ~~should~~ must contain adequate nesting or bedding material and provision for refuge if appropriate for the species...

*The ALC repeats the recommendations in regards to 3.2.7 above.*⁴⁶

3.3.13 Personnel responsible for monitoring animals during transport ~~should~~ must be able to recognise signs of pain and/or distress in the species under their care.

*The ALC repeats the recommendations in regards to 3.2.7 above.*⁴⁷

Admission of new animals to facilities

3.3.14 New animals admitted to holding areas should be held separately and their health and wellbeing assessed by a ~~qualified~~ suitably qualified person.

*The ALC considers that the current description ‘qualified person’ is ambiguous and does not adequately define the suitability of a person to make health and wellbeing assessments of a newly admitted animal. The ALC recommends that the term ‘suitably qualified person’ be appropriately defined in the definition section. As the promotion of the wellbeing of animals is one of the fundamental matters required to be considered by any person involved with any aspect of the care and use of animals for scientific purposes, the ALC recommends that a veterinarian be required to make these assessments.*⁴⁸

3.3.16 The suitability of the animals for their intended scientific purpose ~~should~~ must be assessed by a suitably qualified person, including, as appropriate, confirmation of genetic constitution, health status and clinical history.

*The ALC repeats the recommendations in regards to 3.2.7 above. In addition, to ensure consistency with clause 3.3.14 and ensure the assessment is conducted by a suitably qualified person, the ALC recommends the inclusion of a reference to a suitably qualified person.*⁴⁹

⁴⁶ Issue 4.

⁴⁷ Issue 4.

⁴⁸ Issue 2-3, 6.

⁴⁹ Issues 2-4.

3.3.17 Animals ~~should~~ must be acclimatised to the facility and personnel before they are used. Those that do not adapt satisfactorily, for example by exhibiting signs of distress or deviations from normal behaviour, ~~should~~ must be returned promptly to normal husbandry conditions of their natural habitat ~~if appropriate and permitted where possible~~ or, ~~if necessary~~, if there is no other alternative, humanely killed.

The ALC repeats the recommendations in regards to 3.2.7 above. In addition, to maintain consistency with clause 1.34 (iv), the ALC recommends reference be made to animals exhibiting signs of distress or deviations from normal behaviour as an example of unsatisfactory adaptation requiring return to normal husbandry conditions or the wild. Finally, the ALC considers that the alternative of humane killing should only be considered where no other viable alternative exists. This should remove killing based upon considerations of expediency.⁵⁰

Housing and care

3.3.19 The Facility Manager ~~should~~ must consult the AEC and investigators in advance of planned changes to the housing conditions of animals, which can affect both the welfare of animals and results of the scientific and teaching activities

The ALC repeats the recommendations in regards to 3.2.7 above.⁵¹

Indoor facilities

3.3.26 Air exchange, temperature, humidity, light and noise ~~should~~ must be maintained within limits compatible with animal wellbeing and good health.

The ALC repeats the recommendations in regards to 3.2.7 above.⁵²

⁵⁰ Issues 2-4.

⁵¹ Issues 2-4.

⁵² Issues 2-4.

Pens, cages and containers

3.3.33 The number of animals in, and placement of, cages, pens or containers ~~should~~ must enable maintenance of social and environmental conditions for the species.

The ALC repeats the recommendations in regards to 3.2.7 above.⁵³

Food and water

3.3.37 Clean, fresh drinking water ~~should~~ must be available at all times as suitable for species.

The ALC repeats the recommendations in regards to 3.2.7 above.⁵⁴

3.4 Handling and restraint of animals during experiments

3.4.3 Electroimmobilisation ~~should~~ must not be used for restraint unless evidence shows that it causes less distress than traditional methods (see 3.7.11)

The ALC repeats the recommendations in regards to 3.2.7 above.⁵⁵

3.5 Humane killing

3.5.7 If there is reason to believe, but no supportive evidence that a method of killing will influence data and the proposed method has a higher risk of negative impact on the animal's wellbeing, a pilot study ~~should~~ must be undertaken to validate the use of the proposed method and investigate opportunities to refine techniques. The pilot study must be approved by the AEC and must comply with the requirements of this Code and the *NHMRC Guidelines to promote the wellbeing of animals used for scientific purposes.*

⁵³ Issues 2-4.

⁵⁴ Issues 2-4.

⁵⁵ Issues 2-4.

The ALC repeats the recommendations in regards to 3.2.7 above. The ALC also recommends that the same criteria for the approval of a project or activity be applied to a pilot study undertaken in order to validate and/or refine the method and techniques to be used in the substantive project. Such a requirement is important given the likelihood that a pilot study will involve the use of animals, albeit a smaller number on a smaller scale.⁵⁶

3.5.8 Animals with dependent offspring or foetuses or embryos must not be used in death as the endpoint projects unless it is necessary for the purposes of the project to use such animals. Where such animals are used, appropriate provision must be made for the care of the dependent offspring of animals to be killed. Alternatively, If there is no other viable alternative, the dependent offspring must be humanely killed using methods appropriate for their stage of development.

The ALC considers that the use of animals with dependent offspring, foetuses or embryos in death as endpoint projects conflicts with the Reduction and Refinement principles. The aim of those principles is to ensure animal wellbeing, avoid, alleviate or minimise pain and/or distress or lasting harm to animals by, inter alia, using no more than the minimum number of animals necessary to achieve the scientific or educational aims. Using animals with dependent offspring, foetuses or embryos in death as endpoint projects contemplates the possibility if not probability that those offspring/foetuses/embryos may themselves suffer distress, lasting harm or require humane killing. For this reason, the ALC recommends that animals with dependent offspring or foetuses or embryos not be used in such projects unless animals of that type are essential for the purposes of the project. In addition, where the use of such animals is essential to achieve the aims of the project the ALC considers that the humane killing of offspring should only occur whether there is no other viable alternative.⁵⁷

3.6 Conduct of Projects – General Considerations

Acclimatisation and conditioning

3.6.1 If there is any change in the conditions of housing, husbandry and/or care at the time an animal is allocated to a project, animals ~~should~~ must be allowed time to acclimatise before the study commences.

⁵⁶ Issues 2-4.

⁵⁷ Issues 2-3.

*The ALC repeats the recommendations in regards to 3.2.7 above.*⁵⁸

3.6.2 To minimise any negative impact on animal wellbeing, the persons who will conduct the activity ~~should~~ must, before commencing an activity, condition the animals to handling and particular experimental conditions such as restraint devices or procedures and testing equipment.

*The ALC repeats the recommendations in regards to 3.2.7 above.*⁵⁹

3.6.3 An animal that appears not to have acclimatised to the conditions of the study ~~should~~ must not be used.

*The ALC repeats the recommendations in regards to 3.2.7 above.*⁶⁰

Animal housing and care requirements

3.6.4 If the proposed conditions of housing and care for a project differ from recognised standards of good practice, the application to the AEC ~~should~~ must describe those differences, explain why they are necessary, identify any potential negative impact on wellbeing and describe how such an impact will be managed and minimised.

*The ALC repeats the recommendations in regards to 3.2.7 above.*⁶¹

3.6.5 If alterations to housing and care involve the following circumstances, evidence of an appropriate level and frequency of monitoring ~~should~~ must be provided:

*The ALC repeats the recommendations in regards to 3.2.7 above.*⁶²

3.6.6. When changes to an animal's living conditions are proposed, consideration ~~should~~ must be given to:

*The ALC repeats the recommendations in regards to 3.2.7 above.*⁶³

⁵⁸ Issues 2-4.

⁵⁹ Issues 2-4.

⁶⁰ Issues 2-4.

⁶¹ Issues 2-4.

⁶² Issues 2-4.

⁶³ Issues 2-4.

Injections, blood sampling and non-surgical procedures

3.7.12 Procedures ~~should~~ must be performed using ~~recognised standards of good practice~~ *[insert reference to specific guidelines/practices]* relevant to the species ~~and based on~~ ~~guidelines~~ that are informed by evidence of the potential negative impact on the wellbeing of the animals and include strategies to minimise such effects.

*The ALC repeats the recommendations in regards to 3.2.7 above. In addition, the ALC recommends that reference is made to the specific guidelines with which the procedures must comply: see comments on Section 3: Animal Wellbeing, page [to be inserted when document finalised]. This will avoid reliance upon standards which may fall short of, or conflict with, the standards set out in Section 3: Animal Wellbeing.*⁶⁴

3.7.13 The least invasive method compatible with the aims of the investigation ~~should~~ must be used.

*The ALC repeats the recommendations in regards to 3.2.7 above.*⁶⁵

3.7.14 The methods used ~~should~~ must be those that minimise the risk of an animal experiencing pain and/or distress and developing complications.

*The ALC repeats the recommendations in regards to 3.2.7 above.*⁶⁶

Surgical procedures

3.7.21 The impact of a surgical procedure on an animal's wellbeing ~~should~~ must be minimised by prior identification...Similarly strategies ~~should~~ must be developed to prevent or minimise post-operative complications such as infection, delayed wound healing or impaired function.

*The ALC repeats the recommendations in regards to 3.2.7 above.*⁶⁷

⁶⁴ Issues 2-3.

⁶⁵ Issues 2-4.

⁶⁶ Issues 2-4

⁶⁷ Issues 2-4.

3.7.24 If an animal will undergo more than one surgical procedure, the time between each procedure must allow recovery to good general health unless otherwise justified specifically or generally approved by the AEC.

*The ALC considers the wording of the current exception to the rule that an animal must be allowed to recover to good general health before undergoing another surgical procedure is ambiguous. The words “unless otherwise justified” do not identify the criteria to be applied or the person to whom this decision is entrusted. The ALC recommends that an animal that has not recovered to good general health should not be subjected to another surgical procedure unless approval has been granted by the AEC. Such a requirement will ensure that the provisions of the Code are complied with in any assessment of the appropriateness of such a procedure.*⁶⁸

Post-procedure care

3.7.32 If an animal must be housed in isolation or separated from a group following a procedure, the duration of such housing conditions ~~should~~ must be minimal. The animals ~~should~~ must receive visual, auditory and olfactory contact with animals of the same species unless there is evidence that such contact will interfere with data collection and interpretation.

*The ALC repeats the recommendations in regards to 3.2.7 above.*⁶⁹

3.7.33 ...As part of the specific plan to manage pain and/or distress, the animals ~~should~~ must be given analgesics and sedatives appropriate to their species, and antibiotics as appropriate to prevent or manage post-operative infection.

*The ALC repeats the recommendations in regards to 3.2.7 above.*⁷⁰

3.7.37 If the procedure for the implantation of a recording or sampling device requires an animal to be isolated or restrained for a prolonged period, the animal ~~should~~ must be conditioned to such circumstances before the procedure is undertaken.

*The ALC repeats the recommendations in regards to 3.2.7 above.*⁷¹

⁶⁸ Issues 1-3.

⁶⁹ Issues 2-4.

⁷⁰ Issues 2-4.

Induction of tumours

3.7.41 Animals ~~should~~ must be humanely killed as soon as tumours have reached the minimum size necessary to obtain valid results.

The ALC repeats the recommendations in regards to 3.2.7 above.⁷²

3.7.42 To minimise the adverse impact of a tumour on wellbeing, imaging techniques ~~should~~ must, if reasonably practicable, be used to measure tumour growth and determine early end-points.

The ALC repeats the recommendations in regards to 3.2.7 above.⁷³

Genetic modification of animals

The preamble to these provisions refers to the Guidelines for the generation, breeding, care and use of genetically modified and cloned animals for scientific purposes. If it is intended that any or all of the guidelines are to be adopted as part of the Code, the ALC recommends that the preamble be amended to provide as follows⁷⁴: -

The Guidelines for the generation, breeding, care and use of genetically modified and cloned animals for scientific purposes must be complied with.

Alternatively, if only specific parts of those guidelines are relevant, they should be identified specifically by amending the preamble to read:

Clauses [insert relevant clauses] of the Guidelines for the generation, breeding, care and use of genetically modified and cloned animals for scientific purposes must be complied with.

3.7.44 The nature and extent of potential impacts due to genetic modification and the difficulty in predicting them ~~should~~ must, if reasonably practicable, be considered in the development of strategies to minimise the negative impact of genetic modification on the wellbeing of the animals involved.

⁷¹ Issues 2-4.

⁷² Issues 2-4.

⁷³ Issues 2-4.

⁷⁴ Issues 2-3.

*The ALC repeats the recommendations in regards to 3.2.7 above.*⁷⁵

3.7.45 New animal lines ~~should~~ must not be generated by the techniques of genetic modification if a similar, suitable animal model is available.

*The ALC repeats the recommendations in regards to 3.2.7 above.*⁷⁶

3.7.46 The methods used to generate a new animal line by genetic modification ~~should~~ must be consistent with the following international benchmarks [insert relevant guidelines/practices/benchmarks]

*The ALC repeats the recommendations in regards to 3.2.7 above. Further, if international benchmarks are to be used as the framework for methods to generate a new animal line, specific reference should be made to the applicable benchmarks to avoid confusion and inconsistent application of standards.*⁷⁷

3.7.47 For genotyping, the least invasive technique that yields sufficient tissue ~~should~~ must be used.

*The ALC repeats the recommendations in regards to 3.2.7 above.*⁷⁸

3.7.51 The investigator ~~should~~ must provide regular reports to the AEC on the monitoring of new lines created through genetic modification at a frequency determined by the AEC (see 2.4.38).

*The ALC repeats the recommendations in regards to 3.2.7 above.*⁷⁹

Modification of behaviour and neurological function

3.7.56 Positive reinforcement ~~should~~ must be used to motivate an animal to modify its behaviour or perform specific tasks.

*The ALC repeats the recommendations in regards to 3.2.7 above.*⁸⁰

⁷⁵ Issues 2-4.

⁷⁶ Issues 2-4.

⁷⁷ Issues 2-4.

⁷⁸ Issues 2-4.

⁷⁹ Issues 2-4.

⁸⁰ Issues 2-4

3.7.58 ~~Severe~~ Deprivation of water, food, social interaction or sensory stimuli to an extent that negatively impacts upon an animal's wellbeing must not be used to induce an animal to modify behaviour...

The ALC recommends the removal of the word 'severe' from this clause and the inclusion of the requirement that any deprivation of water, food, social interaction or sensory stimuli be limited to that which does not negatively impact upon wellbeing. The term 'severe' requires a subjective judgment to be made regarding the nature and extent of the effect of deprivation which may be a value judgment based upon considerations that are not necessarily connected to wellbeing. For example, 'severe' may be construed as of a particular duration or ongoing in circumstances where 'moderate' or even mild deprivation may nevertheless produce a negative impact upon wellbeing. For this reason, the ALC recommends a test which recognises that the same period of deprivation of water, food, social interaction or sensory stimuli may have different effects upon different animals and therefore differing effects upon wellbeing. In such variable circumstances, the optimal test, and one which promotes the wellbeing of animals, is one which prohibits deprivation resulting in a negative impact on wellbeing. Such a test is consistent with the requirements of 3.7.60.⁸¹

3.7.59 Painful or noxious stimuli ~~should~~ must, if reasonably practicable, be avoided. If unavoidable use occurs the level and duration of the stimulus must be minimised and provision must be made for the animal to be able to escape the stimulus.

The ALC repeats the recommendations in regards to 3.2.7 above. The ALC recommends a specific reference to approval being granted by the AEC for the use of painful or noxious stimuli to ensure that any such technique has been ratified by the AEC rather than by the individual performing the test.⁸²

3.7.60 Projects involving the withholding or restriction of food or water must be designed such that the animal experiences no continuing or permanent detrimental effect.

The ALC recommends the inclusion of the word 'permanent' to ensure that potential permanent effects which may not manifest themselves at the time of the project are taken into account in devising appropriate techniques for food or water restriction.⁸³

⁸¹ Issues 2-3.

⁸² Issues 2-3.

⁸³ Issues 2-3.

3.8 Wildlife and field techniques

General considerations

3.8.1 Free living wildlife and vertebrate pest animals (see definition), must not be taken from their natural habitats or otherwise disturbed unless it is essential for the work proposed and no alternative source of animals or data is ~~available~~ suitable.

The Code recognises the additional risks involved in projects involving the use of wildlife or vertebrate pest animals taken from natural habitats (see Part F: additional investigator responsibilities for specific activities; 2.4.40; Section 3: Animal Wellbeing; 3.3.6; 3.8.2-3.9.6). Accordingly, the ALC recommends that the taking of animals from their natural habitat be restricted to those activities where other animals (domesticated, bred in captivity, privately owned etc) are not suitable for the specific scientific purpose. This will avoid the use of wild animals simply because, at the time of the particular project, there are no alternative animal sources available. In light of the recognised risks involved in the use of wild animals, mere unavailability of an alternative should not be sufficient justification for their use.⁸⁴

Studies in the natural habitat

3.8.8 Steps ~~should~~ must be taken when designing field studies to minimise changes to the landscape, noises, and smells that the animal normally detects in its habitat as such disturbances can adversely affect the resources available to both target and non-target species and have a negative impact on the wellbeing of the animals.

The ALC repeats the recommendations in regards to 3.2.7 above.⁸⁵

Use of traps

3.8.12 If trapping is to be used for capture, the application to the AEC must cover issues such as:

⁸⁴ Issues 2-4.

⁸⁵ Issues 2-4

(iii)⁸⁶ ways of ~~minimising~~ avoiding the potential negative impact caused by disruption of social structure and on dependent young, for example by avoiding trapping in breeding season if possible

*In light of the recognised risks involved in trapping, the ALC recommends that the consequential negative effects of trapping must be avoided rather than minimised. Avoidance rather than minimisation gives proper effect to the key principle of the promotion of the well being of animals.*⁸⁷

3.8.13 All trapping activities must be monitored in a way that takes into account...:

(ii)...If wet pitfall traps are used for the capture of invertebrates, they ~~should~~ must be managed and monitored to minimise the inadvertent capture of vertebrates, including by locating the trap where vertebrate entry is unlikely and using the smallest possible trap diameter.

*In light of the recognised risks involved in trapping the ALC recommends that the consequential negative effects of trapping must be avoided rather than minimised. The ALC repeats the recommendations in regards to 3.2.7 above.*⁸⁸

Transport, holding and release

3.8.15 If animals are to be held in captivity, the time of holding must be minimal and consistent with the achievement of scientific or educational objectives. If animals are to be released, all possible steps must be taken to avoid their becoming habituated to human activity. Where an animal has become habituated to human activity to an extent that its ability to return to the wild without adverse effects is compromised, alternatives such as re-homing or placement with a zoological institution must be considered.

In light of the recognised possibility of habituation of a captured wild animal, the ALC considers it necessary to make provision for the situation where an animal has become habituated to an extent that its wellbeing is compromised if it is returned to the wild. The

⁸⁶ Incorrect numbering.

⁸⁷ Issues 2-4.

⁸⁸ Issues 2-4.

*provision is silent as to what should occur in such a situation. The recommended amendments ensure that alternatives which will promote the wellbeing of the animal are considered.*⁸⁹

3.9 Future of animals at the completion of their use

3.9.2 Decisions regarding the future of an animal ~~should~~ must take into account the potential impact on its wellbeing and future management.

*The ALC repeats the recommendations in regards to 3.2.7 above .*⁹⁰

Re-housing (re-homing)

3.9.3 Opportunities to re-home animals ~~should~~ must be considered, especially when in the course of an activity the impact on their wellbeing has been minimal and their physiological condition and behavioural attributes indicate that they can be introduced to a new environment with minimal, transient impact on their wellbeing.

*The ALC repeats the recommendations in regards to 3.2.7 above .*⁹¹

Section 5: Complaints and non-compliance

The ALC strongly recommends that guidelines for the investigation of complaints and suspected breaches be developed by NHRMC. Those guidelines should then be incorporated into the Code by a specific provision requiring compliance with the Guidelines in the conduct of any relevant investigation. The obligation to comply with promulgated Guidelines will ensure uniformity of approach to complaint resolution and the investigation of non-compliance and any disciplinary consequences. As it currently stands, clauses 5.6-5.7 leave it to the AEC of the relevant institution to determine the nature and extent of the investigation with little guidance regarding the manner in which information is gathered, evidence taken

⁸⁹ Issues 2-3

⁹⁰ Issues 2-4.

⁹¹ Issues 2-4.

*or assessed and findings made. The lack of any comprehensive framework puts at risk the proper, efficient and effective investigation and remediation of non-compliance.*⁹²

In the alternative, the ALC recommends that the Code contain a requirement that the written procedures promulgated by the institution pursuant to Section 5 be provided to the NHMRC for approval. This will ensure that any procedures developed by the institution comply with the Code and facilitate the discharge of the obligations of the institution to address complaints and non-compliance.

In the event that neither of these recommendations is adopted, the ALC has further recommendations in respect of the current provisions in Section 5.

5.1 The institution must have written procedures for addressing complaints and non-compliance related to the care and use of animals for scientific purposes (see 2.1.69 (ix), 2.2.38-39), including: ...

*The ALC recommends that written procedures be stipulated. Written procedures can be disseminated, reviewed and made available to an external review team. It is undesirable to have procedures for addressing important issues such as complaints and non-compliance in any other form.*⁹³

5.5 Any person who has a ~~reasonable~~ belief on reasonable grounds/reasonable cause to suspect that a breach of the Code has occurred ~~should~~ must report the matter to the AEC.

*The ALC recommends a test based on a ‘belief on reasonable grounds’ or ‘reasonable cause to suspect’. Those phrases are commonly used in penal statutes⁹⁴ and have been consistently interpreted by the courts as importing a subjective and objective test. That is, a person must genuinely (subjective) believe that a breach has been committed and there must be (objectively viewed) reasonable grounds for that belief. The use of this terminology will assist in ensuring that the obligation to report a suspected breach arises in circumstances where there is, objectively viewed, a reasonable basis for the belief that a breach has occurred.*⁹⁵

⁹² Issues 1-3, 6.

⁹³ Issues 1-3, 6.

⁹⁴ See for example, Summary Offences Act (SA) 1953, ss 67-71, Road Traffic Act 1961 (SA) s 47E.

⁹⁵ Issues 1-3, 6.

5.6 The AEC ~~should~~ must ensure that an investigation into complaints and non-compliance is conducted by appropriately skilled persons following the written procedures required pursuant to 5.1.-5.2.

Investigations into complaints and non-compliance is an important aspect of ensuring that effect is given to the governing principle of the promotion of the wellbeing of animals by all persons involved with any aspect of the care and use of animals for scientific purposes governing principle. Accordingly, the ALC recommends the use of the term ‘must’ rather than ‘should’ to maintain consistency and give proper effect to this governing principle.⁹⁶

5.9 The institution ~~should~~ must maintain a register of breaches of the Code which is publicly available. Persons found guilty of breaches resulting in negative impacts upon an animal or animals’ wellbeing should not be permitted to occupy the role of an investigator or be involved in any stage of an AEC approved project involving the care or use of animals without the permission of the external review team appointed pursuant to clause 6.3.

The ALC considers that the maintenance of a register of breaches be a mandatory obligation. Further, to promote transparency and accountability, such a register should be publicly available. In addition, where breaches have been proved to the requisite degree, consideration must be given to ensuring that the breaches do not recur. One mechanism to achieve this is to prohibit the person found responsible for the breach (where that breach results in a negative impact upon wellbeing rather than a breach of a technical or administrative nature) from occupying a position where he or she might repeat the breaching behaviour. In order to ensure that a person found guilty of a breach is accorded procedural fairness, it is recommended that the external review team be charged with the responsibility of determining that person’s fitness to return to duties involving the care or use of animals for scientific purposes.⁹⁷

⁹⁶ Issues 2-4.

⁹⁷ Issues 2-3, 6.

Section 6: External review of the operation of institutions and their animal ethics committees

6.1.1 Institutions must ensure the conduct of an external review (see 2.1.12) which enables assessment of its compliance with the Code, identifies matters that should be addressed and informs future planning (see 2.1.7 (iii)). Such an external review ~~should~~ must be undertaken every ~~three years and must be undertaken at least every four years~~ unless the external review team appointed pursuant to clause 6.3 has approved reviews on a two yearly basis in accordance with the criteria in 6.3.9.

The ALC recommends annual external reviews. This recommendation takes into account the requirement of the AEC to prepare an annual report in 2.1.11. In light of the governing principles of the Code, the ALC considers that limiting the opportunity for independent and external review to identify deficiencies or non-compliance with the Code to a minimum period of 4 years is unsatisfactory. However, the ALC recognises the burden that such reviews may place upon an institution and suggests a system whereby compliance is rewarded by a relaxation of the stricture of an annual external review. Such an opportunity will provide additional incentive to an institution to ensure compliance and thereby dispense with the obligation of an annual external review.⁹⁸

Scope and outcomes of the external review

6.2.2 The primary focus of the external review ~~should~~ must include establishing evidence that all scientific and teaching activities involving the use of animals are adequately justified, that the welfare of those animals used is given proper and due consideration and that the AEC is effective, taking into account its terms of reference as set out in the Code.

The ALC considers the external review process to be an important mechanism in ensuring and enforcing compliance. Accordingly, the assessment by external review of compliance with the Code should be mandatory rather than simply strongly recommended.⁹⁹

⁹⁸ Issues 2-3, 6.

⁹⁹ Issue 4.

6.2.3 The external review ~~should~~ must enable the institution to evaluate and, if necessary, modify processes to ensure it meets its responsibilities under the Code. To this end, the report of an external review ~~should~~ must, where appropriate, contain recommendations for improvement.

*The ALC considers the external review process to be an important mechanism in ensuring and enforcing compliance. In order to be effective, the review process must impart relevant information, advice, directives to the institution in order to ensure compliance with the Code.*¹⁰⁰

Conduct of the external review

6.3.2 Members of the review team must be external to the institution and the AEC under review and must declare any position or office which may result in a conflict of interest. The review team ~~may~~ must include persons who have relevant and appropriate qualifications or experience such as knowledge of animal welfare matters pertaining to research and teaching institutions, a demonstrated interest in animal welfare or experience in the administration of animal welfare and animal ethics, a background in veterinary science or experience in animal care appropriate to the institution.

*The ALC considers the external review process to be an important mechanism in ensuring and enforcing compliance. Conflict of interest is defined in the definition section. It is fundamental to the review process that those conducting an external review discharge their obligations with impartiality. Accordingly, the ALC recommends that each member of the review team be required to consider whether any conflict of interest arises by virtue of any office or position held. For example, a member of the review team may be a director of a company that supplies the institution with pharmaceuticals for use in scientific testing. Although external to the institution and AEC, that person will nevertheless have an actual or perceived conflict of interest which should disentitle him or her from participating in the review process.*¹⁰¹

¹⁰⁰ Issue 4.

¹⁰¹ Issues 2-3, 6.

6.3.3 The ways in which the review team accesses information and conducts its enquiries will vary but ~~should~~ must include review of documentation, observation of activities and procedures, random inspections and discussions with involved parties, including those who may wish to speak with the review team in confidence. Elements of the external review ~~should~~ must include:..

In order to ensure effective external review, the ALC recommends random inspections¹⁰² and a mandatory obligation upon the AEC/institution to provide the review team with all relevant documents and opportunities to observe activities and procedures.¹⁰³

6.3.7 The institution ~~should~~ must publish ~~a summary of the~~ external review report in an institutional annual report publicly available or a publicly accessible web site and ~~consider~~ make the report available to the relevant regulatory authority and funding bodies of the institution (see 2.1.11).

The ALC refers to its comments regarding 5.9 above. The publication of the external review report together with the annual report will ensure transparency and accountability and investigation, where appropriate, by regulatory authorities required to investigate and/or prosecute breaches of legislation into which the Code has been incorporated.¹⁰⁴

¹⁰² “To effectively monitor compliance a proportion of inspections should be carried out without prior warning which would better ensure public confidence and transparency: Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, OJ L 276/33, 36.

¹⁰³ Issue 4.

¹⁰⁴ Issues 2-4, 6.