

**Submission
No 104**

**INQUIRY INTO ANIMAL WELFARE POLICY IN NEW
SOUTH WALES**

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Submission to Standing Committee on State Development,
NSW Legislative Council

Re: Draft Animal Welfare Bill 2022

This submission addresses the impact of the *Draft Animal Welfare Bill 2022 (Draft Bill)* on the welfare of animals involved in research activities in New South Wales.

It is notable and of concern that the *Draft Bill* removes the level of animal welfare protection mandated under the *Animal Research Act 1985*; one of the three Acts incorporated into the *Draft Bill*.

Under the *Animal Research Act 1985*, any research activity involving animals in NSW must be authorised based on review and approval by an Animal Ethics Committee (*the Committee*) and conducted in accordance with *the Code (Australian Code for the Care and Use of Animals for Scientific Purposes)*. This establishes a legislative framework that identifies the responsibilities of those who decide if an activity is justified (*the Committee*), those responsible for the conduct of an authorised activity (researcher/teacher) and the criteria by which such activities are assessed, authorised and conducted (*the Code*). Notably, this legislation mandates independent community involvement through membership of *the Committee*.

Within this framework, *the Committee* must decide if any proposed use of animals for research purposes is ethically justified taking into consideration evidence of the potential benefits of a proposal and the predicted impact on the welfare of the animals involved. This involves consideration of the scientific basis of a proposal and predicted benefits as well as justification for the use of animals and an assessment of the experiences and needs of the individual animals including the impact of procedures throughout an animal's lifetime and strategies to minimise this. *The Code* sets out the criteria by which these specific aspects of a research activity are evaluated on a case-by-case basis. Of note, a detailed assessment of the specific impact of a research activity is guided by the Principles of '*replacement, reduction and refinement*' and thus, as set out in *the Code*, these Principles are key enablers to a decision. Never the less, evidence of social and scientific benefit is essential to satisfy ethical justification. Thus through *the Committee* process and the criteria detailed in *the Code* this legislation seeks to protect the welfare of the individual animals involved within the context of justification to undertake animal research.

Under the *Draft Bill* the conduct of animal research is exempt from prosecution under the provisions of animal cruelty offences provided the person(s) responsible for conducting animal research or the supply of animals is(are) the holder of a licence. This is a broad, generic exemption for animal research activities. The legislative framework of the *Animal Research Act 1985* that establishes responsibilities for and criteria by which the welfare of animals involved in specific research activities is protected has been omitted; there is no legislative requirement in the *Draft Bill* for the review, approval and on-going oversight of these activities by an Animal Ethics Committee. This shift in the legislative framework and scope of oversight in the *Draft Bill* is significant with major consequences for the level of legislative protection provided for individual animals involved in research activities.

Although it is stated in the *Draft Bill* that, with regard to animal research, the objectives of the Act will be achieved by providing "*a licensing framework to regulate and oversee the conduct of such activities consistent with the principles of replacement, reduction and refinement*", no details as to how this will be achieved are provided. To be effective in protecting the welfare of animals involved in research, these Principles must be applied on a specific, case by case basis as required

under the *Animal Research Act 1985*. It should be noted, as outlined above and explicitly stated in *the Code*, ethical justification requires both evidence of the application of these Principles as well as evidence of benefit and scientific justification. Further, the proposal to establish an Animal Ethics Committee as a condition of licensing, as foreshadowed in *NSW Animal Welfare Consultation Outcomes 2022*, merely establishes a possible mechanism not a specific outcome by which to benchmark protection of the welfare of the animals involved.

It is strongly recommended that the key provisions of the *Animal Research Act 1985* are incorporated into the *Draft Bill* whereby, as a minimum,

- 1) institutions and individuals are licensed to conduct animal research under the condition that any activity is approved and monitored by an Animal Ethics Committee and conducted in accordance with the *Australian Code for the Care and Use of Animals for Scientific Purposes*;
- 2) the provision of the Act whereby Ministerial approval is required for lethality testing is reinstated and
- 3) community membership is a core requirement for Animal Ethics Committees.

As background to this submission the following comments outline the key components of the Draft Animal Welfare Bill 2022 in relation to animal research, discuss briefly key differences with the Animal Research Act 1985 and provide comment on issues raised in NSW DPI briefing documents.

1) Draft Animal Welfare Bill 2022

The primary objectives of the *Draft Bill* are (1) to promote the welfare of animals, and (2) to prevent cruelty to animals. The *Draft Bill* seeks to achieve these goals by

- ensuring animals are provided with an acceptable standard of care (minimum care requirements)
- protecting animals from cruelty and harm by prohibiting certain actions and activities and
- restricting by whom certain activities that may cause harm may be performed.

Concerning the use of animals for research purposes the *Draft Bill* provides for a licensing framework to regulate and oversee these activities including animal supply and provides an exemption from prosecution to those persons holding such a license. Those who hold such licenses are designated as a '*responsible person*' under the *Draft Bill* but without further detail concerning the licensing framework the scope of individual responsibilities is not known. The *Draft Bill* includes penalties for those who conduct animal research without a license or contrary to the conditions of a license.

The *Draft Bill* includes administrative and regulatory arrangements for the provision of licenses but no detail as to the condition of licenses or criteria by which "*the conduct of such activities consistent with the principles of replacement, reduction and refinement*" will be assessed. The Animal Research Review Panel (ARRP) is retained in the *Draft Bill* with responsibilities similar to those in the *Animal Research Act 1985* in terms of advice re licensing but without designated responsibility for providing advice to the Minister. The relationship between the Animal Welfare Advisory Council and the ARRP is unclear especially in relation to advice and determinations as to the welfare of animals used for research purposes.

A primary aim of the *Draft Bill* is to ensure a minimum standard of care however, there are no details as to how this will be applied in relation to the care, use and supply of animals for research although, as outlined below, these are matters that are addressed in principle in the Code and the subject of species-specific guidelines published by the ARRP.

The definition of 'animal research' in the *Draft Bill* is similar to that in the *Animal Research Act 1985* but whereas in the Act this is qualified as being linked to a defined research purpose in the *Draft Bill* '*a recognised research purpose*' is not defined but rather included in the 'Dictionary'.

In general, the scope and requirements of the *Draft Bill* are closely aligned with the legislative framework of the *Prevention of Cruelty Act 1979* but there are significant changes to the scope and impact of that legislation in terms of establishing minimum standards of animal care, and expanding the scope and definition of offences that will provide more certainty as grounds for successful prosecution and hence animal protection.

2) Animal Research Act 1985

"The object of this Act is to protect the welfare of animals used in connection with research by requiring persons or organisations carrying out animal research or supplying animals for research to be authorised under this Act and by regulating the carrying out of animal research and the supply of animals for research by those persons or organisations."

Under this legislation animal research is authorised conditional upon being in accordance with the approval and directions of an animal care and ethics committee (referenced as an Animal Ethics Committee) and being conducted in accordance with the Code for a recognised research purpose. It is an offence under this legislation to conduct animal research without such an authority, or otherwise than as approved or in accordance with the directions of the Animal Ethics Committee.

Under this legislation Animal Ethics Committees make recommendations concerning granting animal research authorities and supervise the conduct of authorised activities. In addition, the legislation provides for the inclusion of any additional requirements under the Code. Since implementation, it has been a requirement under the *Animal Research Act 1985* that at least one member of the Committee is not involved in animal research and independent of the institution(s) for which a Committee has responsibilities. Subsequent changes to the Code have expanded the number and role of such independent members.

The incorporation of the *Australian Code for the Care and Use of Animals for Scientific Purposes* in this legislation has been essential to provide a benchmark for relevant animal welfare standards. Revisions of the Code during the lifetime of the *Animal Research Act (1985)*, have ensured that the ethical framework aligns with community expectations and international standards and advances in animal welfare science, including the recognition and management of pain and distress, inform and underpin best practice.

These achievements can be seen with the changes to the definition of ‘animal welfare’ in the 2013 edition of the Code as “*an animal’s quality of life and encompasses the diverse ways an animal may perceive and respond to its circumstances from a positive state of wellbeing to a negative state of distress.*” Together with the emphasis on supporting and safeguarding wellbeing these changes in the Code align with current concepts of animal welfare taking into account broader consideration of an animal’s quality of life and not limited to experiences of pain and distress; concepts that only recently have been considered when discussing the welfare of animals in research. It is notable that the incorporation of these concepts into the 2013 edition of *the Code* and the accompanying *NHMRC Guideline on Animal Wellbeing* have been widely acknowledged as significant developments.

A second example is how detailed criteria for standards of the care and management of animals have been incorporated into *the Code*. In response, the ARRP produced comprehensive, evidence-based guidelines for the care and housing of rabbits(2003), guinea pigs(2006), rats(2007), sheep(2010) and mice(2012), that are comparable to international guidelines published in Europe (2010), Canada (2020) and North America (2011).

Comment:

Although the aims of both the *Draft Animal Welfare Bill 2020* and the *Animal Research Act 1985* are to protect the welfare of animals there are significant differences in how this is achieved and the standards of animal welfare taken into account.

Under the *Draft Animal Welfare Bill 2022* animals are protected by establishing minimum animal welfare standards and prohibiting or restricting certain activities as a threshold for prosecution; animal research is a restricted activity under license. In contrast, the *Animal Research Act 1985* requires all animal research activities to be individually reviewed, approved and monitored by an Animal Ethics Committee consistent with contemporary animal welfare

standards as detailed in the *Australian Code for the Care and Use of Animals for Scientific Purposes* (as reviewed from time to time); failure to meet these requirements is an offence

3) Issues identified in Background Documents

In July 2021, NSW Department of Primary Industries issued an *Animal Welfare Discussion Paper* that outlined proposed changes to animal welfare legislation in this state. This paper had been developed based on responses to a 2020 Issues Paper and proposed to amalgamate existing legislation, namely the *Prevention of Cruelty to Animals Act 1979*, the *Animal Research Act 1985* and the *Exhibited Animals Protection Act 1986*, into a single Act that would enhance existing legislation to reflect best practice consistent with the Five Freedoms and Five Domains models of animal welfare. The Discussion Paper advised that.....

“Where elements of the existing laws are effective, the intent of those provisions is proposed to continue under the new laws. As a result, these provisions have not been specifically covered by this Discussion Paper.”

The significant changes in the legislative protection afforded to animals involved in research identified in this submission were not foreshadowed in the Discussion Paper. Furthermore, animal welfare standards consistent with the Five Freedoms and the Five Domain models are integral to the requirements of the *Australian Code for the Care and Use of Animals for Scientific Purposes* and have been so for many years.

No explanation for these changes has been provided and seems contrary to assurances given in both the Discussion Paper and advice in the Consultation Outcomes document that accompanied the release of the Draft Bill that this Bill *“carries across existing practices from the three Acts”* and *“does not reduce existing animal protection.”*

The only justification for changes to the *Animal Research Act 1985* would seem to be the response in the Consultation Outcomes document that cited differences with legislation in other states. Whether these are differences of substance in relation to animal welfare or administrative was not identified and it should be noted that the legislative requirements under states legislation do differ.

It is important to note that the legislative framework of the *Animal Research Act 1985* is consistent with the model recommended in the *1989 Senate Select Committee Report on Animal Experimentation*. In the late 1970's Australia was one of the first countries to adopt a process for ethical review of animal research; a model that was strongly supported in the 1989 Senate Committee Report as the cornerstone in protecting animal welfare. Comparable arrangements have gradually been introduced in many countries so that today ethical review of animal research is widely adopted and incorporated into legislation in many countries (*CIOMS/ICLAS International Guiding Principles for Biomedical Research Involving Animals*, 2012); the introduction of EU Directive 2010/63 (*European Commission Directive of the European Parliament and of the Council of 22 September 2010 On the protection of animals used for scientific purposes*) being a significant milestone in this development. Prior to these developments for many years the RSPCA (UK) had advocated the legislative requirement for ethical review of animal research and, since these developments in the EU, has actively supported implementation.

If the legislative framework of the *Animal Research Act 1985* is considered against contemporary international standards not only does it meet those standards but foreshadowed developments in many countries. Given that today research activities often involve international partnerships, contemporary international standards should be taken into

consideration in the framing of legislation to protect of welfare of animals used for research purposes.

Authorship: *This submission was prepared by Margaret Rose AM, B.V.Sc., Ph.D. who has been involvement in the development of public policy in relation to the welfare of animals used for scientific purposes. Although this has informed her responses the opinions expressed in this submission are hers alone and in no way represent those of organisations with which she was involved (listed below) and she has not been associated with these organisations for some time.*

- *NSW Animal Welfare Advisory Council, member, 1981-2008*
- *NSW Animal Research Review Panel, member and chair, 1986-2010*
- *NHMRC Code Writing Group, member, 1986-2013*
- *CIOMS/ICLAS Committee, Australian representative, 2010-2012.*