

Environment Protection and Biodiversity Conservation Amendment (Prohibition of Live Imports of Primates for Research) Bill 2015

1.1 On 15 October 2015, the Senate, on the recommendation of the Selection of Bills Committee, referred the Environment Protection and Biodiversity Conservation Amendment (Prohibition of Live Imports of Primates for Research) Bill 2015 (the bill) to the Environment and Communications Legislation Committee for inquiry and report by 1 March 2016.¹

1.2 The bill is a private senator's bill introduced by Senator Lee Rhiannon on 17 September 2015. The bill proposes to prohibit the importation of live non-human primates (hereafter referred to as primates) for the purposes of research.

1.3 Senator Rhiannon had previously introduced a bill to prohibit the importation of live primates for the purposes of research. The Environment Protection and Biodiversity Conservation Amendment (Prohibition of Live Imports of Primates for Research) Bill 2012 was introduced on 22 November 2012 and lapsed at the end of the 43rd Parliament.

Conduct of the Inquiry

1.4 In accordance with its usual practice, the committee advertised the inquiry on its website and wrote to relevant individuals and organisations inviting submissions by 18 January 2016.

1.5 The committee received 93 submissions. A form letter supporting the continued importation of non-human primates for research purposes was received from 12 academics and researchers, including many from overseas research institutes. The committee also received correspondence in support of the bill from 34 individuals. The list of submissions and list of those who provided the form letter is at Appendix 1. Submissions and the form letter may be accessed through the committee's website: www.aph.gov.au/senate_ec.

1.6 The committee held a public hearing on 5 February 2016 in Canberra. A list of witnesses who appeared at the hearing may be found at Appendix 2.

Scope of the inquiry

1.7 The committee acknowledges the broader debate regarding the use of animals in scientific research and notes the correspondence and submissions received on this issue. However, the purpose of this inquiry is to examine the provisions and effects of the bill on scientific research, rather than the broader issue of research using animals.

1 *Journals of Senate*, 2013–15, No. 122, p. 3261.

1.8 The committee thanks all the organisations and individuals who assisted the committee with the inquiry.

Consideration by other committees

1.9 When examining a bill or draft bill, the committee takes into account any relevant comments published by the Senate Standing Committee for the Scrutiny of Bills. The Scrutiny of Bills Committee assesses legislative proposals against a set of accountability standards that focus on individual rights, liberties and obligations, and on parliamentary propriety.

1.10 The bill was considered by the Scrutiny of Bills Committee in its *Alert Digest No. 11 of 2015*. The committee had no comment on the bill.²

Overview of the bill

1.11 The bill proposes to amend Part 13A of the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act) which regulates the international movement of wildlife, including the importation of primates into Australia. The amendments would make it unlawful to import into Australia primates for the purpose of research.

1.12 Proposed subsection 303CG(5A) would prohibit the Minister from issuing a Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) import permit if the specimen is a live primate; and the proposed import would be for the purposes of research or for purposes that include research.

1.13 Proposed subsection 303EN(3A) would prohibit the Minister from issuing an import permit for a 'regulated live specimen' if the specimen is a live primate and the purpose is research, or for purposes that include research.

1.14 Proposed subsection 303GB(1AA) would prohibit the Minister from issuing an 'exceptional circumstances permit' authorising the import of live primates for research; or authorising the import of regulated live specimens that are primates, for research.

1.15 Proposed subsection 303GC(5A) would prohibit the Minister from issuing a permit authorising the Secretary to import a specimen, if the specimen is a live primate; and the proposed import would be for the purposes of research or for purposes that include research.

2 Senate Standing Committee for the Scrutiny of Bills, *Alert Digest No. 11 of 2015*, 14 October 2015, p. 10. The Scrutiny of Bills Committee noted that it considered an identical bill introduced into the Senate on 22 November 2012. The committee made no comment on this bill. See *Alert Digest No. 1 of 2013*, 6 February 2013, p. 49.

1.16 Senator Rhiannon, in her second reading speech, stated that:

This Bill, if passed, would confirm in law that Australia does not support the cruel and inhumane primate trade for experimentation and that Australia will not participate in practices leading to the extinction of primates in the wild.

This is a small but important step on the long road to ceasing the cruel practices of experimentation on animals.³

The importation and use of primates for research in Australia

1.15 The importation of primates for research (and for zoos) must be undertaken in accordance with CITES, the EPBC Act and transport regulations. The use of primates for research is regulated by the National Health and Medical Research Council (NHMRC).

Convention on International Trade in Endangered Species of Wild Fauna and Flora

1.17 CITES is designed to ensure that the trade in wildlife and wildlife products is both legal and sustainable. CITES lists the species covered in three Appendices according to the degree of protection required.⁴ All primates are listed under CITES, with those commonly used in scientific research listed under Appendix II. This Appendix includes species which are 'not necessarily threatened with extinction, but for which trade must be controlled to avoid utilisation that is incompatible with their survival'.⁵

1.18 The export permit system, which is the 'foundation on which the whole of the CITES system is based'⁶, requires the CITES Management Authority in the country of export to certify that:

...the export will not be detrimental to the survival of that species in the wild; the specimen was not obtained in contravention of the laws of that State for the protection of fauna and flora; and any living specimen will be prepared and shipped to minimise the risk of injury, damage to health or cruel treatment.⁷

1.19 In addition, permits for the import and export of species listed under CITES may only be issued for scientific purposes 'where the object of the research is to better

3 Senator Lee Rhiannon, *Senate Hansard*, 17 September 2015, p. 7123.

4 Department of the Environment, *Submission 7*, p. 2.

5 Department of the Environment, *Submission 7*, p. 2.

6 Mr Stephen Oxley, Department of the Environment, *Proof Committee Hansard*, 5 February 2016, p. 33.

7 Department of the Environment, *Submission 7*, p. 3.

understand or increase knowledge of the species, conserve biodiversity, or maintain and/or improve human health'.⁸

Environment Protection and Biodiversity Conservation Act 1999

1.20 The Australian Government implements CITES under the EPBC Act.⁹ Live primates may not be imported to Australia without a CITES import permit issued under the EPBC Act and an export permit issued by the CITES management authority of the exporting country. The EPBC Act permits the import of live CITES-listed animals for a restricted number of purposes and live primates may only be imported for eligible non-commercial purposes such as exhibition, education, research or conservation breeding.

1.21 The animal welfare and transport requirements are given effect under the EPBC Act and EPBC Regulations. The Department of the Environment commented that:

The EPBC Regulations include welfare requirements for live mammals, birds, reptiles and amphibians. The receiving facility must be suitably equipped to manage, confine and care for the animal, including meeting the behavioural and biological needs of the animal. To this end, an assessment is conducted on the facility, husbandry plans, diet and staff experience of the recipient.¹⁰

1.22 In making a decision to allow the import of a live animal, the decision-maker must be satisfied that:

- animal welfare requirements are met in regard to how the animal will be transported and the facility where the animal or animals will be confined, managed and cared for;
- the applicant has demonstrated that the researcher is suitably qualified;
- the relevant animal ethics authorities have approved the research and, where possible, the primate has been sourced from a captive-breeding facility; and
- the application must include a valid CITES export permit from the exporting country.¹¹

8 Department of the Environment, *Submission 7*, p. 2.

9 *Environment Protection and Biodiversity Conservation Act 1999*, Part 13A—International movement of wildlife specimens.

10 Department of the Environment, *Submission 7*, p. 3.

11 Mr Stephen Oxley, Department of the Environment, *Proof Committee Hansard*, 5 February 2016, p. 33.

1.23 Between 2000 and 2015, the Department of the Environment issued a number of CITES import permits for live captive-bred primates for research purposes. This included:

- 255 pigtail macaques from Indonesia;
- 46 owl monkeys from the United States of America;
- 59 common marmosets from Switzerland and France (one from Switzerland and 36 from France in 2014, and 22 from France in 2015); and
- ten long-tailed macaques from France.¹²

Use of primates in research in Australia

1.24 Australia has two primate breeding facilities currently funded by the NHMRC—the National Non-Human Primate Breeding and Research Facility, which includes a macaque colony and a marmoset colony, and the National Baboon Colony. These facilities were established to 'centralise breeding, provide a consistently high standard of animal care and management, and to allow access to non-human primates for research'.¹³ In addition, there is an owl monkey breeding facility in Queensland. This facility is not funded by the NHMRC.¹⁴

1.25 The NHMRC funds the use of macaques, marmosets and baboons in health and medical research through its competitive grants funding schemes. NHMRC funded research must comply with the *Australian code for the care and use of animals for scientific purposes* (the Code) and the *Policy on the care and use of non-human primates for scientific purposes* (NHP Policy).¹⁵

1.26 The Code has been incorporated into state and territory animal welfare legislation, and controls the operation of non-human primate facilities. It also regulates animal welfare requirements in these facilities.¹⁶

1.27 The NHP Policy requires researchers to 'ensure that documentation of the source of each non-human primate and assessment of its behaviour, clinical history and health status, accompany the animal and are kept current'. The NHP Policy also requires that, wherever possible, researchers must source primates from one of the three nationally funded breeding colonies. However, if animals are to be imported for NHMRC funded research they must be obtained from captive-bred populations and

12 Department of the Environment, *Submission 7*, p. 3; see also Department of the Environment, Answers to questions on notice, p. 2 and Attachment B.

13 National Health and Medical Research Council, *Submission 59*, p. 2.

14 National Health and Medical Research Council, Answers to questions on notice, p. 1.

15 National Health and Medical Research Council, *Submission 59*, pp. 1–2.

16 Professor Anne Kelso, National Health and Medical Research Council, *Proof Committee Hansard*, 5 February 2016, p. 19.

must be accompanied by documentation to certify their status. In addition, the Animal Welfare Committee of the NHMRC must be notified prior to importation.¹⁷

1.28 The NHMRC funds the use of primates in health and medical research, however the research must also have been approved by an institutional animal ethics committee (AEC). AECs are established by individual research institutions, based on the Code and controlled by the animal welfare legislation of the relevant state or territory.¹⁸

1.29 Under the Code, AECs must include people from four different categories with specified qualifications and experience including veterinary science, use of animals for scientific purposes relevant to the institution and the business of the committee and experience in furthering animal welfare. A person with no research or connection to the institution who should 'be viewed by the wider community as bringing a completely independent view to the committee and must not fit the requirements of any other category' is also to be appointed to an AEC.¹⁹

1.30 When assessing research proposals, AECs must be satisfied that the research complies with the 3R principles. These principles are Replacement (there is no alternative to the use of primates available), Reduction (researchers use a minimum number of primates), and Refinement (adverse impacts on the animals are minimised). If the importation of primates is proposed, the AEC must also be satisfied that it is essential.²⁰

Issues raised in relation to the bill

1.31 Submitters who supported the bill acknowledged that the bill would only prohibit the importation of primates for research rather than banning the use of primates for research purposes. However, it was seen as an important first step in ending animal experimentation. These submitters based their support of the bill on a range of issues including:

- concerns regarding the origins of imported primates;
- concerns with the transport of primates;
- concerns with institutional animal ethics committees;
- the failure rate of application of successful primate research to human application; and

17 Professor Anne Kelso, National Health and Medical Research Council, *Proof Committee Hansard*, 5 February 2016, p. 19.

18 Professor Anne Kelso, National Health and Medical Research Council, *Proof Committee Hansard*, 5 February 2016, p. 19.

19 Professor Anne Kelso, National Health and Medical Research Council, *Proof Committee Hansard*, 5 February 2016, pp. 19–20.

20 National Health and Medical Research Council, *Submission 59*, p. 2.

- the availability of alternative technologies and research techniques.

1.32 The committee received evidence from organisations and researchers which raised concerns about the effect of any ban on imports of primates on the long-term viability and genetic diversity of the primate colonies at Australia's breeding facilities. Submitters who did not support the bill also provided evidence in relation to the benefits of, and continued need for, the use of primates in research. Submitters also responded to evidence about the use of alternative technologies and research techniques. Finally, the committee received evidence on the effect on Australian research capacity should the bill be passed.

1.33 The following discussion canvasses the evidence received in relation to these issues.

Origin of imported primates

1.34 Submitters commented on concerns with the origins of primates imported for research. While it was noted that CITES and the NHP Policy restricted imports of animals to those from captive-bred populations, it was submitted that this requirement has not precluded the import of wild-caught primates.

1.35 Submitters pointed to the export of primates from Indonesia and argued that, while being exported as captive-bred, they were in actual fact wild-caught.²¹ Many primates are exported from so-called primate 'breeding islands' with Tinjil Island the most well-known. According to Cruelty Free International, between 1988 and 1994, 520 long-tailed macaques were released on Tinjil Island, and by 2002, the population was an estimated 2000 primates. By 2002, 1150 offspring had been trapped and transported for use in research. Tinjil Island and other primate breeding islands provide primates for a number of primate-supply companies in Indonesia.²²

1.36 According to RSPCA Australia, the Indonesian government authorises the capture of several thousand macaques each year to replenish breeding stock in these island facilities, although it noted that it is difficult to verify which animals are wild-caught or captive-bred when exported.²³ In addition, a large number of primates exported for research from these facilities are classified as 'first-generation' which indicates that animals captured from the wild are relied upon for breeding, and that such facilities are not self-sustaining.²⁴

1.37 Cruelty Free International also stated that it did not consider that 'island breeding' could legitimately be classified as 'captive breeding' as the animals live

21 Explanatory Memorandum, p. 1.

22 Cruelty Free International, *Submission 48*, Attachment 3, p. 1; see also Animal Liberation NSW, *Submission 9*, p. 3.

23 RSPCA Australia, *Submission 10*, p. 8.

24 RSPCA Australia, *Submission 10*, p. 8.

freely, interact with other wildlife, and are part of the islands' ecosystems.²⁵ In addition, breeding occurs naturally and there is no control of genetic lineage.²⁶

1.38 Ms Helen Marston, Chief Executive Officer of Humane Research Australia (HRA), told the committee that:

...we believe that the ban on wild-caught animals is a sham...mainly because the macaques that we have received for our research have been obtained from Tinjil Island in Indonesia, and they are classified as captive-bred because the island is contained, but they are actually free-living animals in a natural environment that are caught and then have been transported. There is also no ban on the capture of wild animals to replenish stocks.²⁷

1.39 The committee received evidence responding to concerns about the importation of wild-caught primates. Associate Professor James Bourne, medical researcher and Chair of the Nonhuman Primate Breeding and Research Facility Board operated by the Monash University, stated that:

None of the recently imported primates were taken from wild populations...Their breeding and health history was fully documented. All animals were either bred in the primatology centre or have continuously been held there for over two years.²⁸

1.40 Associate Professor Bourne went on to further assure the committee that:

None of the animals that have been imported since 2012 have been from an island such as Tinjil Island...They have been from European facilities which are accredited by AAALAC, which is an independent body that looks at animal welfare and care...They are also ISO 9001 accredited.²⁹

1.41 In addition, the committee received evidence from researchers who supported the ban on the use of wild-caught primates for research.³⁰

25 CITES Resolution Conference 10.16 (Rev) *Specimens of animal species bred in captivity*, requires that both 'first generation offspring' and offspring 'bred in captivity' must be produced in a 'controlled environment' which is defined as 'an environment that is manipulated for the purpose of producing animals of a particular species, that has boundaries designed to prevent animals, eggs or gametes of the species from entering or leaving the controlled environment, and the general characteristics of which may include but are not limited to: artificial housing; waste removal; health care; protection from predators; and artificially supplied food'.

26 Cruelty Free International, *Submission 48*, Attachment 3, pp. 1–2.

27 Ms Helen Marston, Humane Research Australia, *Proof Committee Hansard*, 5 February 2016, p. 9.

28 Associate Professor James Bourne, *Proof Committee Hansard*, 5 February 2016, p. 27; see also Monash University, *Submission 89*, p. 2.

29 Associate Professor James Bourne, *Proof Committee Hansard*, 5 February 2016, p. 31.

30 Professor Trichur Vidyasagar, *Submission 58*, p. 2; Dr John Capitanio, *Submission 71*, p. 1.

1.42 The committee sought evidence from the Department of the Environment as to whether there was a possibility that Australia could have imported wild caught animals via a third country. Dr Ilse Kiessling, Assistant Secretary, Wildlife Trade and Biosecurity Branch in the Department of the Environment told the committee that:

...CITES permits that are provided from exporting countries show the original origin of the animal. There are no permits that have come to us that have shown that the species are from wild caught.³¹

1.43 Mr Stephen Oxley, First Assistant Secretary, Wildlife, Heritage and Marine Division in the Department of the Environment, added that the non-human primates that have been exported to Australia from Europe have come with the certification of the CITES management authority of the exporting country which have very rigorous processes in place.³² In addition, Mr Oxley noted that the import permits required by Australia are 'stricter domestic measures', that is, they are a requirement over and above the obligations under CITES.³³

Transport of primates

1.44 A number of submissions raised concerns regarding the transport of live primates on international flights. For example, People for the Ethical Treatment of Animals (PETA) Australia stated that primates are:

...transported inside the dark cargo holds of long-haul flights — which in some cases can last up to three days and can involve turbulence, extreme fluctuations in temperature, multiple loadings and unloadings and a lack of food, water and veterinary care.³⁴

1.45 PETA Australia commented that researchers from the University of Oxford found that air transport causes stress in primates which can compromise their welfare and lead to changes in their behaviour. Chronic stress in captive animals can lead to self-harming behaviour such as slapping and biting themselves, hair pulling, rocking, circling and pacing.³⁵

1.46 Similarly, the joint submission from the Barristers Animal Welfare Panel and Sentient stated there is evidence that primates suffer weight loss after being subjected to long distance transportation. This is especially the case in juvenile primates where

31 Dr Ilse Kiessling, Department of the Environment, *Proof Committee Hansard*, 5 February 2016, p. 35.

32 Mr Stephen Oxley, Department of the Environment, *Proof Committee Hansard*, 5 February 2016, p. 35.

33 Mr Stephen Oxley, Department of the Environment, *Proof Committee Hansard*, 5 February 2016, p. 33.

34 People for the Ethical Treatment of Animals, *Submission 2*, p. 2.

35 People for the Ethical Treatment of Animals, *Submission 2*, p. 2.

the stress of 'unfamiliar handling and changes to diet and feeding schedules' compromises the animal's ability to recovery.³⁶

1.47 However, the Department of the Environment stated that the international transport of live animals by commercial airlines is regulated by the International Air Transport Association Live Animal Regulations (IATA Regulations). These worldwide standards are intended to ensure that all animals are transported by air safely and humanely. All CITES signatory countries agree to comply with the IATA Regulations when transporting live specimens.³⁷

1.48 Mr Oxley also noted that the EPBC Act and EPBC Regulations require that the transport of live animals be done in a humane way. In addition, the decision maker, in assessing an application to import a primate, must be satisfied that animal welfare requirements are met during transportation.³⁸

Concerns with institutional animal ethics committees

1.49 As noted above, the NHMRC requires the establishment of animal ethics committees. Ms Helen Marston raised concern with the composition of AECs and stated:

Many of the people on ethics committees are not scientifically expert to challenge the validity of the research using animals and to be aware of the alternatives that are available...³⁹

1.50 The RSPCA also voiced concern with AECs. It noted that AECs alone have the responsibility of 'balancing whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits to humans, animals or the environment in order to decide whether or not the project should be approved'. The RSPCA called for the NHMRC to investigate new mechanisms for the oversight of the use of primates in research.⁴⁰

1.51 In response to these matters, Professor Anne Kelso, Chief Executive Officer of the NHMRC, commented that 'while any one member of an ethics committee cannot have deep expertise in every area of research, they will have broad expertise relevant to the work of the committee'. Professor Kelso went on to note that all research approved for funding by the NHMRC has gone through a rigorous peer

36 Barristers Animal Welfare Panel and Sentient, *Submission 56*, p. 2.

37 Department of the Environment, *Submission 7*, p. 3; see also Associate Professor James Bourne, *Proof Committee Hansard*, p. 29.

38 Mr Stephen Oxley, Department of the Environment, *Proof Committee Hansard*, 5 February 2016, p. 37.

39 Ms Helen Marston, Humane Research Australia, *Proof Committee Hansard*, p. 8.

40 RSPCA, *Submission 10*, pp 6–7.

review process 'as to its quality and the relevance and appropriateness of any animal models, if they are proposed, in the research project'.⁴¹

1.52 All NHMRC funded research must comply with both the Code and the NHP Policy and the committee received evidence that both the Code and the NHP Policy ensure that all research carried out using primates is conducted to the highest standard of ethical care. This standard is considered to be higher than those in a number of other countries. For example, Dr Nicholas Price stated that:

...the NHMRC Policy on Non-Human Primates was recently reviewed and is world-leading; husbandry and housing policies are more strict, and ensure better welfare for animals than similar policies in USA, Japan, Europe and UK. The facilities are regularly inspected by members of an Animal Ethics Committee, as per NHMRC regulations.⁴²

1.53 Another submitter noted that the research codes mean that 'any NHP related work is performed to the highest standard of ethical care'.⁴³ The Australasian Neuroscience Society similarly added that the 'bar is set very high for support of primate research by academic institutions and funding agencies'.⁴⁴

1.54 Associate Professor Bourne provided evidence in relation to the care of primates and commented that research is conducted under the 'strictest scrutiny and followed the principles of reduction, refinement and [replacement]—the three Rs' and 'researchers are continuously looking for alternative models that can replicate the vast complexity of disorders and diseases'. He added that while undertaking research, 'the care and welfare of animals is of paramount concern'.⁴⁵ In relation to the care of primates in breeding facilities, Associate Professor Bourne stated that the facilities are managed by experts including geneticists. The facilities are inspected by animal ethics committees, state animal welfare agencies and the Department of the Environment.⁴⁶

Appropriateness of primate models for medical research

1.55 The committee received evidence which argued against the use of primates in medical research on the grounds that primates are not an appropriate model for medical research and that there are alternative research methods and technologies available. While this issue is not related directly to the bill, the following discussion is included to provide a complete picture of the arguments put forward by the submitters and witnesses supporting the bill.

41 Professor Anne Kelso, National Health and Medical Research Council, *Proof Committee Hansard*, 5 February 2016, pp 21–22.

42 Dr Nicholas Price, *Submission 70*, p. 2.

43 Name Withheld, *Submission 12*, p. 2; see also Dr Tim Kuchel, *Submission 75*, p. 1.

44 Australasian Neuroscience Society Inc, *Submission 63*, p. 1.

45 Associate Professor James Bourne, *Proof Committee Hansard*, 5 February 2016, p. 26.

46 Associate Professor James Bourne, *Proof Committee Hansard*, 5 February 2016, p. 29.

1.56 In relation to the appropriateness of the use of primate research, submitters pointed to instances where success in the use of drugs and vaccines on primates had not been transferred to humans. For example, HRA noted that data from the US Food and Drug Administration had shown that 95 per cent of drugs successfully tested on animals fail when translated to humans.⁴⁷

1.57 Cruelty Free International also pointed to some 100 HIV vaccines which have been tested in monkeys with positive results, 'yet none have provided protection or therapeutic benefit in humans'. Cruelty Free International went on to argue that primates are no better at predicting the safety of new drugs than other species. It also asserted that 'data from developmental toxicity tests in primates correlate with human data just 50 per cent of the time' which is less than species such as rats, hamsters and ferrets.⁴⁸

1.58 While pointing to recent cases where drugs successfully tested on monkeys had led to near fatal outcomes for volunteers, Dr Andre Menache commented that 'animal models are actually giving us a false sense of security and if we did not have the animals, we would be a lot more careful'.⁴⁹

1.59 HRA concluded that research on primates could not be 'accurately credited for any medical "breakthrough"' as:

The genetic, anatomic and metabolic differences between humans and other animals mean that any data obtained from animal tests cannot be translated to humans with sufficient accuracy. Even when genetically modified, there is no single animal model that can accurately mimic the complex human situation. There are far too many unknown variables that cannot all be accounted for.⁵⁰

1.60 The committee also received evidence which pointed to the emergence of new methods and technologies which, it was argued, called into question the continued use of primates in medical research. For example, Australians for Animals stated that the range of non-animal methods continues to grow and concluded that while it is claimed by some researchers that alternative methods are not yet sophisticated enough to replace animal tests, these methods are more dependable and produce more accurate results than tests on primates.⁵¹ HRA similarly argued that Australian researchers

47 Humane Research Australia, *Supplementary Submission 1*, p. 3; see also Dr Andre Menache, *Proof Committee Hansard*, 5 February 2016, p. 2.

48 Cruelty Free International, *Submission 48*, p. 5.

49 Dr Andre Menache, *Proof Committee Hansard*, 5 February 2016, p. 5.

50 Humane Research Australia, *Supplementary Submission 1*, p. 2; see also Animal Defenders Office, *Submission 3*, p. 2; Animal Liberation Queensland, *Submission 5*, p. 3; Animals Australia, *Submission 8*, p. 1.

51 Australians for Animals, *Submission 8*, p. 1.

should be using non-animal methodologies that are far more relevant to studying human disease.⁵²

1.61 Associate Professor Brett Lidbury and Dr Menache provided the committee with examples of research methods which they commented were viable alternatives to primate research. Dr Menache pointed to the use of toxicogenomics and Associate Professor Lidbury to the 'human-on-a-chip' technology.⁵³ In addition, Associate Professor Lidbury noted the use of the Ames test and the development, by the European Centre for Validation of Alternative Methods, of approximately 50 animal replacement alternatives for toxicology testing.⁵⁴

1.62 Dr Menache concluded that:

No-one is suggesting that we can replace an animal experiment with a bunch of cells or with a computer. What we are saying is that we want to replace animal experiments because they are not effective or efficient and they are not able to predict what will happen in people.⁵⁵

1.63 In response to these arguments, submitters who did not support the bill provided evidence of the benefits of, and continued need for, the use of primates in research. In addition, it was noted that the numbers of primates used for research purposes are small.

1.64 The European Animal Research Association noted that primates account for less than 0.05 per cent of all animals used in Europe 'yet their role has been central in many important medical advances'.⁵⁶ These include the development of the polio vaccine, anti-retroviral therapies, life support systems for premature babies and deep brain stimulation for Parkinson's disease.⁵⁷

52 Humane Research Australia, *Submission 1*, p. 4.

53 Dr Andre Menache, *Proof Committee Hansard*, 5 February 2016, p. 2; Associate Professor Brett Lidbury, *Proof Committee Hansard*, 5 February 2016, p. 13.

54 Associate Professor Brett Lidbury, *Submission 50*, p. 2; see also Associate Professor Brett Lidbury, *Proof Committee Hansard*, 5 February 2016, pp 16, 18.

55 Dr Andre Menache, *Proof Committee Hansard*, 5 February 2016, p. 2.

56 European Animal Research Association, *Submission 57*, p. 1; see also Associate Professor James Bourne, *Proof Committee Hansard*, 5 February 2016, p. 26.

57 Association of Primate Veterinarians, *Submission 62*, p. 2; Expert Group for Non-Human Primate Neuroscience Research in the UK, *Submission 73*, p. 1; Society for Neuroscience, *Submission 78*, p. 1.

1.65 Evidence pointed to the continued need for research on primates. Currently, primates are used in research on infectious diseases, brain function, neurodegenerative diseases, and reproduction, fertility and foetal research. Professor James McClusky, Deputy Vice Chancellor (Research) and Dr Mark Hargraves, Dean, The University of Melbourne, commented:

The areas of enquiry underway are not amendable to experiments in lower mammals, in vitro test tube approaches or virtual computer modelling or simulation. Animal models are used because it is the only way currently to understand a process in vivo i.e. in a living system, where it is possible to tease out a cascade of consequences with a given intervention. Living systems are highly complex, are relatively simple methods of investigation (e.g. cell culture or computer modelling) cannot effectively simulate such a complex environment.⁵⁸

1.66 It was also argued that research on primates allowed Australia to respond to emerging public health issues.⁵⁹ In this regard, submitters pointed to the development of novel vaccines which often require research using primates. An example provided was that of the novel dengue virus vaccine which is currently being tested in African green monkeys. The Zika virus was also mentioned by Associate Professor Bourne who commented that the development of a vaccine is likely to involve rhesus monkeys.⁶⁰ Professor Kelso also noted the development of a vaccine for Ebola where safety and efficacy of the vaccine was demonstrated in macaques.⁶¹

1.67 In response to arguments about alternatives to the use of primates in research, Professor Kelso indicated that there are some areas of research where use of primates is not appropriate either because they are not the best model or they are too expensive for the scale of work.⁶² However, while there are alternatives available these may have limited application. For example, Associate Professor Bourne stated that tests, genetics, proteomics and genomics are used but there are some areas of research, such as understanding brain disease, which require the use of primates.⁶³ Similarly, in relation to the use of rodents, it was submitted that while important research is undertaken on rodents, there are limits to the applicability of this research to humans. For example, it was stated that:

58 Professor James McClusky, Deputy Vice Chancellor (Research) and Dr Mark Hargraves, Dean, The University of Melbourne, *Submission 84*, p. 2.

59 Expert Group for Non-Human Primate Neuroscience Research in the UK, *Submission 73*, p. 1.

60 Associate Professor James Bourne, *Proof Committee Hansard*, 5 February 2016, p. 28.

61 Professor Anne Kelso, National Health and Medical Research Council, *Proof Committee Hansard*, 5 February 2016, p. 22.

62 Professor Anne Kelso, National Health and Medical Research Council, *Proof Committee Hansard*, 5 February 2016, p. 22.

63 Associate Professor James Bourne, *Proof Committee Hansard*, 5 February 2016, p. 28.

...diseases such as autism, schizophrenia and Alzheimers' disease cannot be completely modelled in lower order species such as rodents due to their rudimentary cognitive abilities, impeding the search for therapies for such diseases. This leads the way for more translatable primate-based research models, which have more comparable cognitive and behavioural abilities to humans to account for this short fall.⁶⁴

1.68 Associate Professor Bourne went further and commented that it was false to claim that knowledge gained from primate research is not applicable to humans. He went on to state:

Anyone who claims that insights gained from animals are meaningless when it comes to the understanding of normal and pathogenic processes in human bodies is either badly informed or knowingly untruthful. Primates share approximately 95 per cent of human genes and a number of anatomical and physiological similarities. For this reason primates are critical to biomedical research targeting the cause, progression, prevention and treatment of a wide variety of diseases.⁶⁵

1.69 Professor Kelso also commented on the need for continued research using primates:

...a critical effect on the development of new drugs and vaccines for the treatment of human conditions. That will particularly apply—again, from a research point of view rather than a regulatory point of view—to those conditions where non-human primates provide the best model—the best approximation—to human disease.⁶⁶

1.70 In addition, it was noted that many drugs validated in rodents have had poor translation into therapeutics for humans due to the differences between species. The Australasian Neuroscience Society commented that there have been occurrences where clinical trials have moved rapidly from rodents to human investigations resulting in harm of participants because additional experiments were not conducted in primates.⁶⁷

Long-term viability of primate colonies

1.71 Submitters who opposed the bill expressed concern that, without continued importation of primates when required, the long-term viability of primate colonies will be undermined and ultimately the welfare of animals in Australia's primate colonies

64 Name Withheld, *Submission 12*, p. 2.

65 Associate Professor James Bourne, *Proof Committee Hansard*, 5 February 2016, p. 26.

66 Professor Anne Kelso, National Health and Medical Research Council, *Proof Committee Hansard*, 5 February 2016, p. 22.

67 Australasian Neuroscience Society Inc, *Submission 63*, p. 2; see also Professor Anne Kelso, National Health and Medical Research Council, *Proof Committee Hansard*, 5 February 2016, p. 20.

would be adversely affected. It was argued that, without primate imports from colonies around the world, inbreeding would result in an increased chance of congenital defects, mortality and low fertility and thus the colonies usefulness in providing a reliable animal model.⁶⁸

1.72 The department indicated that 37 marmosets were imported in 2014 with another 22 imported in 2015 along with 10 macaques in that year.⁶⁹ Dr Price commented on the need for the importation of primates undertaken recently:

...separate groups of marmoset and macaque monkeys were imported to diversify the genetic pool of the existing Australian breeding colonies. This was necessary to limit the risks associated with in-breeding; without this importation, the breeding colony would have been: (1) unable to supply the number of animals required for research purposes; (2) suffered a steady decline in health due to in-breeding.⁷⁰

1.73 While supporting the continued importation of primates to ensure the viability of Australia's breeding colony, the need for those primates to be sourced from reputable breeders was endorsed.⁷¹

The need for continued genetic diversity of primate colonies

1.74 A number of submissions argued that the bill, in its current form, would have long-term negative consequences for the future of Australian biomedical research. In particular, a decline in the genetic diversity of primate colonies and/or a decrease in numbers of primates through disease and attrition would limit research opportunities.⁷²

1.75 Submitters commented on the importance of genetic diversity of primates used in research. It was noted that a captive primate population 'outbred' is important when primates are used in researching human diseases as they best reflect the human populace.⁷³ Associate Professor Bourne explained that:

68 Name Withheld, *Submission 12*, p. 3. See also Professor Marcello Rosa, *Submission 29*, p. 1; Association of Primate Veterinarians, *Submission 62*, p. 1; Australasian Neuroscience Society, *Submission 63*; Oregon National Primate Research Centre, *Submission 65*; Yerkes National Primate Research Centre, *Submission 66*; Society for Neuroscience, *Submission 78*, p. 1; Japan Neuroscience Society, *Submission 79*, p. 1; Associate Professor James Bourne, *Proof Committee Hansard*, 5 February 2016, p. 26.

69 Department of the Environment, Answers to questions on notice, Attachment B.

70 Dr Nicholas Price, *Submission 70*, p. 1.

71 Australasian Neuroscience Society Inc, *Submission 63*, p. 1; Expert Group for Non-Human Primate Neuroscience Research in the UK, *Submission 73*, p. 1; Associate Professor James Bourne, *Proof Committee Hansard*, 5 February 2016, p. 27.

72 Professor Trichur Vidyasagar, *Submission 58*, p. 1.

73 Associate Professor James Bourne, *Proof Committee Hansard*, 5 February 2016, pp. 26–27.

The health of these colonies and an ability for them to continue to represent a heterogeneous human population depends on outbreeding to maintain genetic diversity.⁷⁴

1.76 The Association of Primate Veterinarians also commented on the consequences of a reduction in genetic diversity over time are 'expected to be severe' and added:

In the short term, reduced genetic diversity can change the means and variability of important biomedical traits and will complicate or invalidate the interpretation of experimental findings in NHPs to human disease. Over the longer term, this loss of genetic diversity will result in fewer viable offspring, increased morbidity and mortality in the colony, and spiralling costs for veterinary care, as genetic variation that prevents disease is lost permanently from the colony. Ultimately, the colony will become unsustainable, and will collapse under this burden.⁷⁵

1.77 HRA responded to this issue and argued that a lack of genetic diversity would only be an issue if Australian researchers were looking at 'using large numbers in the future'.⁷⁶ Ms Marston also commented that a commitment to the 3Rs principle would mean that 'there should be no reason to improve that genetic diversity when we should be looking at replacing them altogether'.⁷⁷

1.78 However, Associate Professor Bourne explained that:

...we have enough in the colony for a period of time, but that aligns with a stable usage. In these colonies we do not keep animals for years on end or have a large colony; we keep a stable number that allows for the research of the day. There may be a need for some condition that we need to ramp up the size of the colony, and that may require an additional import.⁷⁸

1.79 Similarly, the Expert Group for Non-Human Primate Neuroscience Research in the UK commented that the 'Australian NHP breeding colonies are probably too small to maintain a diverse genetic background. The currently contemplated ban on the importation of lab-bred NHPs would prevent any new monkeys being imported to maintain the colony'.⁷⁹

74 Associate Professor James Bourne, *Proof Committee Hansard*, 5 February 2016, p. 26.

75 Association of Primate Veterinarians, *Submission 62*, p. 1.

76 Ms Helen Marston, Humane Research Australia, *Proof Committee Hansard*, 5 February 2016, p. 7.

77 Ms Helen Marston, Humane Research Australia, *Proof Committee Hansard*, 5 February 2016, p. 7.

78 Associate Professor James Bourne, *Proof Committee Hansard*, 5 February 2016, p. 28.

79 Expert Group for Non-Human Primate Neuroscience Research in the UK, *Submission 73*, p. 1.

The effect on Australian research capacity

1.80 A further matter raised with the committee by submitters opposing the bill was the effect on Australia's research capacity, particularly the ability of Australian scientists to respond to public health issues or new areas of biomedical research.⁸⁰ The International Basel Declaration Society, for example, commented on the standing of Australian research and the use of primates in that research:

Traditionally, Australian scientists have made a disproportionate contribution to biomedical research internationally. Current Australian research with non-human primates covers an impressive breadth, including endocrinology, immunology, and neuroscience, all areas in which progress has recently accelerated, mainly due to the introduction of novel approaches, particularly in gene-based technologies and imaging. Thus, many novel approaches to treatment for medical disorders, such as gene therapy and stem cell transplants, could not be developed and tested without research in non-human primates.⁸¹

1.81 It was also noted that many other countries undertake primate-based research programs. This primate research is 'an important factor for Australia to maintain a competitive edge in medical research globally'.⁸² In addition, a ban on the importation of live primates may force Australian researchers to move overseas to continue their work. Associate Professor Bourne told the committee that without access to primates he would 'have to ultimately leave Australia and enter into a country...[in] Europe or the United States' to continue his research.⁸³ It was also stated in another submission that should researchers move to other jurisdictions because of the lack of suitable primates for research, there is the possibility that they may go to other countries which do not have such a high ethical standards.⁸⁴

1.82 The European Animal Research Association concluded:

If an artificial limit is placed on the importation into Australia of NHPs for research, it will limit the progress that can be made in both fundamental research and innovative medicine development.⁸⁵

Committee view

1.83 The committee commends the Government for its commitment to implementing the Convention on International Trade in Endangered Species of Wild

80 Association of Primate Veterinarians, *Submission 62*, p. 1; *Submission 77*, p. 1.

81 International Basel Declaration Society, *Submission 76*, p. 1.

82 Name Withheld, *Submission 12*, p. 2.

83 Associate Professor James Bourne, *Proof Committee Hansard*, 5 February 2016, p. 28.

84 Name Withheld, *Submission 12*, p. 2.

85 European Animal Research Association, *Submission 57*, p. 2.

Fauna and Flora through the *Environment Protection and Biodiversity Conservation Act 1999*.

1.84 The committee notes that the bill is a response to concerns about the international trade in wild-caught primates and seeks to ensure that Australia does not participate in this trade. In addition, as stated in the second reading speech, the bill is a first step in stopping the use of primates in research.

1.85 The committee has considered the evidence received and believes that it does not point to a need for a ban on the import of primates for research. Moreover, the evidence indicates that there will be significant effects on biomedical research in Australia should a ban on imports be implemented.

1.86 While acknowledging concerns about the trade in wild-caught primates, the committee notes that there is no evidence that primates recently imported to Australia are wild-caught. In addition, the committee draws attention to submissions from researchers which point to support for bans on the use of wild-caught primates in research.

1.87 In relation to concerns about the welfare of primates used in research in Australia, the committee acknowledges the work of the NHMRC, state and territory agencies and the Department of the Environment in ensuring that research on primates is performed to the highest ethical standard and that the welfare of research animals is paramount.

1.88 The committee also notes the concerns of stakeholders about the effect of a ban on imports on the long-term viability of the three nationally funded primate breeding facilities. The committee also considers that a ban on imports would significantly affect current research as well as Australia's ability to respond to emerging public health issues.

1.89 While there was evidence of the development of viable alternatives to the use of primates in some areas of research, it appears that these alternatives are yet to reach a stage where they can replace research using primates.

1.90 Given the implications for scientific and medical research being conducted in Australia, the committee considers that the bill should not be passed.

Recommendation 1

1.91 The committee recommends that the Senate not pass the Environment Protection and Biodiversity Conservation Amendment (Prohibition of Live Imports of Primates for Research) Bill 2015.

**Senator Linda Reynolds CSC
Chair**

