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Submitted to Survey: Australian code for the care and use of animals for scientific purposes
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Individual or institution?

1 Are you responding as an individual or on behalf of an institution?

On behalf of an institution (Skip to question 7)

About your institution

7 What is the name of your institution?

Name of institution:

People for the Ethical Treatment of Animals (PETA) Australia

8 What type of institution or organisation are you responding on behalf of?

Type of institution:

Animal advocacy group

If 'Other', please specify below:

Survey questions

9 What are the CRITICAL issues that should be addressed during the review of the Code?

critical issues with the 8th edition of the Code:

We are writing on behalf of People for the Ethical Treatment of Animals (PETA) Australia, PETA UK, and PETA US in response to the National Health and Medical Research Council's (NHMRC) request for information on issues for consideration in their review of the Australian Code for the Care and Use of Animals for Scientific Purposes ('the Code').

While PETA entities advocate for the immediate end to experiments on animals, we recognise that this is not always pragmatically or immediately achievable within current regulatory frameworks, and therefore we engage constructively in dialogue to help strengthen regulatory systems so that animal use can be transparently monitored, accountability mechanisms enforced, and opportunities for replacement actively advanced. The scientists and policy experts who work for PETA entities have a proven track record of productively assisting many international regulatory and government agencies and companies. This assistance includes providing expert opinions, regulatory advice, and technical support in a broad range of fields, including the development of roadmaps to phase out animal testing. PETA values the opportunity to provide our commentary, and given the breadth and depth of the expertise of PETA entity scientists, we believe that a valuable contribution to later consultation can also be made.

Australia is thought to have the fourth-highest rate of animal use in science in the world, using an estimated 5.3 million animals per year (Timoshanko et al 2017), however there are also estimates that it could be more than 10 million animals per year (Animal Free Science Advocacy, 2023), with New South Wales using the most nationally (Knight, 2013). The exact figure is unknown because there is no national system for collating statistics on animal use or what projects have been authorised by institutions (Merkes and Buttrose, 2019). Only some states publish figures on animal use (Animal Welfare Victoria, 2025) and the requirement for institutions to publish reports of compliance or external review is voluntary (Clause 2.1.10 of the Code). In addition to this, there is a significant lack of transparency and openness regarding even basic information, and Freedom of Information requests are denied by state governments or obstructed by universities (Timoshanko et al 2017). This has led to poor awareness among the Australian public that animals are even used in experiments in Australia (Humane Research Australia, 2013; Timoshanko et al 2017), and heavy criticism of the current regulatory frameworks (Merkes and Buttrose, 2019; Timoshanko et al 2017). Restrictions on the dissemination of information regarding animal use impede transparency and openness, obstruct public debate, and can even promote mistrust in the regulatory system, preventing stakeholders from contributing effectively to reducing animal suffering and promoting the use of non-animal methods. Therefore, the NHMRC's review of the Code is a welcome opportunity to foster more open and transparent processes for regulating the breeding and use of animals in scientific procedures and make recommendations for greater responsibility for oversight at the federal level.

Our recommendations for revising the Code draw on established practices and international regulatory frameworks. In regard to animal testing, it has been noted that "one of the highest legal standards for animal welfare currently prevails in the EU and UK" (Kleinschmidt-Doerr et al, 2025). Therefore, many of the recommendations within this response are based on regulatory processes in the UK and EU countries individually or the EU as a whole. This approach aims to align the Code with global benchmarks and, where feasible, advance beyond them to set a higher standard for science, transparency and animal welfare.

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10 Are there any CRITICAL gaps in the guidance provided in the Code?

Critical gaps in the Code:

Please find below a non-exhaustive list of recommendations to bring the Code into line with international regulatory processes, and where possible, to go further and lead the way in regulating animal use in a more open and transparent manner.

ENHANCE TRANSPARENCY AND ENSURE SHARING OF INFORMATION ABOUT BEST PRACTICE BY PUBLISHING INFORMATION ABOUT THE REGULATION OF ANIMALS USED IN SCIENCE

To enhance transparency and accountability in the use of animals for scientific purposes in Australia, it is imperative that the NHMRC substantially increase the scope and detail of publicly available information regarding national animal use and regulatory oversight at a national level. The Code only makes recommendations for publishing Animal Ethics Committee (AEC) information on a voluntary basis (e.g., Clause 2.1.10.). At a minimum, the publication of the following data in the public domain should include:

Annual national statistics:

Annual national statistics on the number and species of all animals used in scientific procedures, disaggregated by research purpose, severity classification of procedures (i.e., projects should report whether procedures are considered mild, moderate, severe, or non-recovery), and type of procedure. For examples of categories of information collected, see Animals in Science Statistics published by the United Kingdom (UK, Home Office, 2025a). This should include the development of a centralised, publicly accessible database, managed at federal level, such as the European Union's (EU's) Animal Use Reporting System (ALLURES), which provides harmonised, searchable data on animal use across member states (European Commission, 2023). Such a system would enable benchmarking, trend analysis, and international alignment in transparency and welfare reporting.

In the EU, breeders and institutions must report not only the number of animals used in experiments annually, but every five years they must also report the number of animals bred, not used and killed, to the responsible state-level authorities. These then transfer the data to the responsible federal ministry, who publish this along with the annual statistics. Since 2021 in Germany, these figures are collected and published annually, which subsequently, has resulted in a "sharp decline" in so-called 'surplus' animals (Federal Institute for Risk Assessment, 2024). Statistics should also be collected and published on animals bred but not used in scientific procedures in Australia to ensure the full scope of animals impacted is apparent and provide metrics for reducing animals bred but not used then killed.

Approved project applications:

To promote openness and transparency, all project applications approved by the institutional AEC should be made publicly available in a national database (with sensitive information, such as commercial interests, redacted where appropriate). Publishing these projects for public scrutiny allows for greater accountability in the regulatory process. It also supports the consistent application of best practice within a rapidly evolving scientific landscape. By enabling ongoing evaluation of harm–benefit assessments (HBA) and reinforcing the requirement to apply the principles of replacement, reduction, and refinement (the '3Rs'), publication ensures that approved projects remain accountable throughout their duration.

Non-technical summaries:

Non-technical summaries (NTS) should be obtained and published at national level for all approved projects, similar to the UK (Home Office, 2025b), or EU models (European Commission, no date), to provide clear, accessible explanations of research objectives, expected benefits, and animal welfare considerations, thereby enhancing public accountability and transparency of technical scientific content with projects. NTS should be linked to the national database of approved projects described above. A review of the NTS was recently carried out in the UK and provides recommendations for enhancing accessibility should such a system be implemented in Australia (Animals in Science Committee, 2025a).

Annual reports of regulatory activity:

There should be national, annual reporting on compliance and enforcement data, including the number and frequency of inspections (including whether they were announced or unannounced), any breaches identified (including self-reported non-compliances), and details of corrective actions taken under the Code. Under the current Australian Code, establishments/institutions are required to undergo an external review of their animal care and use processes at least once every four years, with the external reviewer selected by the institution itself (Clause 6). This arrangement does not provide a sufficiently independent or frequent level of scrutiny to reliably detect compliance issues or emerging animal welfare concerns that need to be addressed promptly, or maintain pace with scientific advancements to inform best practice. Strengthening both the independence of reviewers so they are overseen at a federal level, and the frequency of reviews to at minimum annually, would better ensure that welfare standards are consistently upheld across institutions. In the UK, the Animals in Science Regulation Unit publishes annual reports detailing its regulatory activity, demonstrating the value of transparent reporting in strengthening oversight and public trust (Home Office, 2025c). The United States Department of Agriculture goes a step further by making available inspection reports in an online public database, detailing the number and species of animals pertaining to that inspection, which can be searched by licensee/registrant, animal, date, or non-compliance topic (USDA Animal and Plant Health Inspection Service, no date). However, not all sentient species are covered by US law (and therefore the database), so there is still significant room for improvement.

Guidance:

Ensuring public access to guidelines and standards, along with regular updates on emerging best practices, is essential. The UK provides an example of this approach: the Home Office publishes a comprehensive suite of Technical Advice Notes that cover topics such as animal reuse, rehoming, working with wild-caught animals, care and accommodation standards, efficient breeding of genetically altered animals, and severity assessment and recording (Home Office, 2025d). In addition to technical guidance, the UK Government also commissions expert advice on specialised and developing scientific areas—such as the use of human material in animals—and makes these reports publicly available while engaging in consultations with stakeholders and the wider public (Animals in Science Committee, 2025b).

Publication of the information presented above would bring Australia into line with, and in some areas surpass, the data collection and transparency practices adopted in other countries. It would share leading practice, strengthen accountability for how and why animals are used, and enable informed scrutiny by experts.

HARMONISING NATIONAL STANDARDS AND REPORTING AND STRENGTHENING REGULATORY OVERSIGHT OF PROTECTED SPECIES

The authorisation process for project applications should include review at both the institutional (i.e., by AECs) and national federal levels (such as by the NHMRC). A two-tier system that introduced national oversight in addition to institutional level oversight—similar to the system used in the UK—would help ensure consistent, high-quality standards across all institutions, rather than leaving approval processes to vary between states or individual establishments. A national regulator (perhaps with regional state/territory offices) can provide independent scrutiny, reduce the risks associated with self-regulation, and ensure that ethical and welfare standards are applied uniformly, particularly the requirements for a HBA and compliance with the 3Rs. The current system, whereby the Code is adopted within state/territory laws, but without federal oversight, means there is poor harmonisation of the Code across Australia, allowing for potential inconsistent regulation, variable enforcement, and limited transparency. A national regulator would harmonise standards, ensure consistent application of the Code, and serve as a central source of transparent reporting, expert guidance, and enforcement, which strengthens public trust and accountability across the entire system.

Ensuring a robust authorisation process for project applications, including HBA, that demonstrates that replacement is being prioritised as the most important of the 3Rs:

Around the world, it has been documented that the rigour with which the requirement for replacement is assessed is poor (Jørgensen et al, 2025; Pippin et al, 2025; Rawle, 2023), while in Australia, it goes largely publicly undocumented (Merkes and Buttrose, 2019; Timoshanko et al 2017). Once a project using animals has received funding, it will likely be approved by institutional and national review bodies, meaning that the onus for expertise in replacement and non-animal methods lies, erroneously, with those reviewing funding applications rather than with those involved in the project application review process. A 2023 report published by the UK's National Centre for the Replacement, Refinement and Reduction and Animals in Research notes that "Replacement does not seem to be covered well by any of the review processes", and suggestions for replacement from the regulator or establishment review bodies are rare, often because those involved in the review of animal experiments "do not (and could not) have sufficiently detailed knowledge of the full breadth of the scientific areas they need to cover to know for every application whether appropriate and practicable replacement technologies are available" (Rawle, 2023).

Therefore, in addition to national oversight, regulators should publish clear criteria for how they, and institutional AECs, approve animal use. This should include guidance on carrying out the HBA, on how the availability of non-animal methods was assessed, and how they were deemed unsuitable where authorising animal use. For each project application to an AEC and/or national regulator, decision documents should be published alongside that evidence:

- any direct, one-to-one replacement methods considered and, if rejected, the basis for that decision;
- additional opportunities to employ non-animal approaches by modifying methodology (non-direct replacements), including what factors facilitated or impeded their uptake of such approaches; and
- whether the research question could be addressed differently (e.g., via data reuse, in vitro, in silico, or human-relevant methods) to avoid or limit animal use.

At both institutional and national levels, project review panels must include individuals with expertise in non-animal methods, and their input should be formally documented in the decision record. This ensures that evidence and expertise on available non-animal approaches are systematically assessed before any animal use is authorised. Project applications should be published for a time-limited public comment period before authorisation. Under the EU REACH regulation, any testing proposal involving vertebrate animals must be published by the European Chemicals Agency, and third parties are given a 45-day public commenting period to submit scientifically valid information before a decision is made (European Chemicals Agency, no date). Following this model, allows external experts—including specialists in non-animal methods, clinical translation, and research ethics—to provide targeted guidance on the HBA, anticipated translational value (where relevant to human outcomes), and the alignment with the 3Rs. Opening applications to external scrutiny brings in expertise that may extend beyond the knowledge and experience of project review panels. Current requirements for AEC's approving projects omit expertise in non-animal methods (Clause 2.2.4 of the Code).

Ongoing evaluation and recording of a project's ability to meet harm-benefit requirements—and its compliance with the obligation to replace animal use wherever possible (Clauses 1.18–1.20 of the Code) — also remains essential throughout the project's lifetime, in line with Clause 1.20 of the Code. Systematic consideration of non-animal methodologies is supported in the EU by tools such as the Biomedical Models Hub (BimmoH), which consolidates the largest collection of scientific references on human-biology-based research models. By bringing these resources together, BimmoH helps researchers design studies that are more human-relevant, more translatable, and potentially able to avoid the use of animals altogether (European Commission Joint Research Centre Data Catalogue, 2025).

Alongside a stronger two-tier evaluation process for project applications and ongoing oversight throughout a project's lifetime, all projects should also undergo retrospective assessment. In the EU, such evaluations help identify lessons learned, demonstrate scientific progress, and highlight opportunities to refine or avoid future animal use (European Union Agency for Asylum, 2015; Taylor et al, 2024). Retrospective reviews should verify whether the project met its stated objectives, whether animal use and actual severity were justified, and how the results will inform improved study design. These

assessments should be published for all projects and clearly linked to the original project application, creating a transparent feedback loop that drives better quality research and reduces unnecessary animal use over time. Some recent recommendations for enhancing accessibility of retrospective evaluations have been published by the UK (Animals in Science Committee, 2025).

Establish independent advisory bodies with expert panels, including those with expertise in non-animal methods:

In the UK, there is a specialist advisory body to the government (a “non-executive advisory Non-Departmental Public Body”), the Animals in Science Committee (ASC), which provides independent, impartial advice to the UK Government on all matters relating to the use of animals in scientific procedures (Animals in Science Committee, 2026b). The ASC are also responsible for advising, promoting, and sharing best practice with institutional Animal Welfare and Ethical Review Bodies (AWERBs) who operate similarly to AECs. The government regularly commissions the advisory body for specialist advice on animals used in science as scientific knowledge evolves (Animals in Science Committee, 2026a). Such advisory bodies should also have experts in non-animal methods (Animals in Science Committee, 2026b). In the EU, each member state has its own national committee that operate in a similar manner to the UK’s ASC. These national committees are established to ensure a consistent and coherent approach to project evaluation and review across each Member State. They provide advice to competent authorities (national regulators) and institutional animal-welfare bodies, helping to promote the 3Rs. At EU level, these national committees form a network that facilitates the exchange of best practices across countries, supporting harmonised standards and continuous improvement in animal welfare oversight. Australia currently lacks the national coherence and independent scrutiny found in the UK and EU systems and therefore a similar network of committees should be implemented at state level in Australia, formed of multistakeholder expert members.

Revise the definition of ‘animal’ to include decapods in the Australian Code for the Care and Use of Animals for Scientific Purposes:

Decapod crustaceans (including crabs, lobsters, crayfish, and shrimp) are recognised as sentient in the scientific literature (Birch et al, 2021) and in the animal welfare policies of other countries, for example, the UK (Animal Welfare (Sentience) Act 2022), Norway, Switzerland, Austria, Germany, Italy, (Crustacean Compassion, 2026) and in some Australian states (RSPCA Australia, 2026). In the UK, the Department for Environment, Food & Rural Affairs (Defra) commissioned a review of the scientific literature to determine whether there was sufficient evidence for their inclusion within the Animal Welfare (Sentience) Act 2022. Including decapods under regulation of scientific procedures was a key recommendation from the report. Defra has also emphasised the importance of ensuring that the definition of ‘animals’ is consistent across legislation, including legislation regarding scientific use of animals, noting that without this, there are “concerns that the welfare of sentient animals may be adversely impacted...[in] harmful scientific procedures” (Animal Sentience Committee, 2026). Without the inclusion of decapod crustaceans, anyone can use them in procedures without any training or oversight. The NHMRC should be entrusted with introducing a policy that seeks to treat all sentient animals equally, and not permit a potential two-tier system of animal welfare in which some sentient animals are treated as lesser than others. Additionally, guidance must be provided to accompany the Code for how decapods may be used in scientific procedures, their care, accommodation and killing methods that cause the least suffering.

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11 What approaches used in the Code work well?

What works well in the Code?:

N/A

12 What approaches used in the Code do NOT work well?

What does not work well in the Code?:

Please find below a non-exhaustive list of recommendations to bring the Code into line with international best practice, and where specific areas of animal use can be ended or regulations strengthened.

PRIORITY AREAS FOR ENDING THE USE OF ANIMALS

Implement a policy ban on the forced swim test (FST) for all uses, with immediate effect:

In this test, small animals are placed into a beaker of water where they swim frantically in search of an escape. Researchers record how long it takes before they stop swimming and start to float under the inaccurate assumption that it can reveal information about human mental health conditions. The FST has been widely criticised on grounds of animal welfare and for its lack of validity, reproducibility and translatability (Barai et al, 2026; Molendijk and de Kloet, 2015; Reardon, 2019; Sewell et al, 2021; Trunnell and Carvalho, 2021). Facilities that continue to authorise the FST appear to do so in breach of Clause 1.15 of the Code, which states that “[p]rojects that are not scientifically valid must not be performed” (National Health and Medical Research Council et al, 2013). The test is already prohibited in New South Wales (Animal Research Act 1985 (NSW) s 47(3)(a)), restricted in the UK with plans to eliminate all uses (Animals in Science Committee, 2023; Home Office, 2025e, 2025f; Trunnell et al, 2024; UK Parliament, 2025), and around the world top universities and major pharmaceutical companies have rejected the test, including University of Melbourne, La Trobe University, University of Western Australia, Macquarie University, University of South Australia, University of Adelaide, Johnson & Johnson, Sanofi, Bayer, GlaxoSmithKline, AbbVie Inc., Roche, AstraZeneca, Novo Nordisk A/S, Boehringer Ingelheim, Pfizer, Amgen, and Bristol Myers Squibb (PETA US, 2025a). The Australian Research Council also endorsed a decision by the NHMRC that prohibits funding any experiments that use the test to model human depression in order to study “depression-like behaviour” or anxiety disorders and their treatment (National Health and Medical Research Council, 2023). And the Australian Veterinary Association has issued a policy stating that it “does not support the use of forced swim tests on animals in medical research” (Australian Veterinary Association, 2025). It is time to eliminate the remaining uses of the FST in Australia by implementing a national policy ban.

Implement a policy ban on the use of animals in sepsis induction experiments, with immediate effect:

Sepsis affects tens of millions of people worldwide, killing thousands of Australians every year (Sepsis Australia, no date). In Australia, sepsis imposes a substantial economic burden annually, with direct healthcare costs around \$700 million and indirect costs surpassing \$4 billion (Australian Sepsis Network, 2025). Yet, despite decades of research and the discovery of hundreds of drugs that work in animals, these have been ineffective in humans, with targeted and effective treatments remaining elusive (Collins, 2013). It is now widely recognised that sepsis induction models using animals poorly replicate human sepsis (Buras et al, 2005; Joffre, 2023; Rittirsch et al, 2007; Ruiz et al, 2016; Verma, 2016; Ward, 2012). Sepsis induction studies using animals also cause immense suffering, with animals often receiving no supportive care, including fluids, pain relief, or ventilation – standard when treating humans – and will endure pain, fever and organ failure before they are killed (Bara and Joffe, 2014; Buras et al, 2005; Esmon, 2004; Fink, 2014; Joffre, 2023; Nemzek et al, 2008; Ruiz et al, 2016; Ward, 2012). Recognising these issues, US agencies are already phasing out the use of animals to model human sepsis (Hays, 2024; PETA US, 2025b; Trunnell, 2025; USFDA, 2025). Australia must not be left behind. The review of the Code presents a golden opportunity to align with scientific evidence and international progress by ending the use of animals in sepsis induction studies and direct researchers to use superior non-animal methods that reflect the human condition.

Implement a policy ban for all experiments using animals to investigate human health issues of intimate partner violence, including strangulation and traumatic brain injury procedures (TBI), with immediate effect:

During these experiments, animals, including pregnant females, may receive traumatic head or brain injury from striking the animal's skull with weights (Sgro et al, 2025), or be restrained in a “non-fatal strangulation device” where weights are suspended from their necks (Sun et al, 2025), in an attempt to mimic human domestic violence. Some animals are also exposed to repeated daily trauma (Allen et al, 2025). Such studies have recently been conducted in at least one Australian university, Monash University, and future TBI studies at Melbourne University are being funded by the NHMRC with at least \$1.5 million in public money (National Health and Medical Research Council, 2025; PETA US, 2025c, 2025d; Sun et al, 2025). And there is a historical precedent for such trauma studies at Australian universities, such as using live lambs to investigate shaken baby syndrome by exposing lambs to a forceful back-and-forth vigorous shaking of the head (Sandoz et al, 2012). Despite some biological similarities, humans and other species such as rats, differ significantly in brain morphology, function, and structure (Neuron Development, no date). Additionally, the psychological and social dimensions of trauma

resulting from domestic violence are individualised, nuanced, and deeply intertwined with human experiences, which cannot be replicated in rats—especially given our limited understanding of their cognition (Pisula and Modlinska, 2023; The Guardian, 2025). Scientific evidence underscores that while animals can exhibit stress responses, they do not possess the same cognitive and emotional frameworks as humans to process and manifest trauma in comparable ways (Flandreau and Toth, 2018). Consequently, conclusions about human physiological and psychological trauma based on such experiments on animals, including Monash’s rat strangulation and TBI experiments, run a high risk of invalid clinical conclusions (Safer Medicines Trust, 2025; Zhang et al, 2024). Alongside concerns about scientific necessity, the nature of these studies is ethically indefensible, particularly when scientifically viable, human-based tools already exist, including advanced TBI imaging technologies and computational models (Irimia, 2024; Lin and Yuh, 2022), which offer robust non-invasive alternatives to animal testing, providing human-relevant insights for patients.

Implement a policy ban on the use of animals for investigating the effects of alcohol, tobacco, nicotine and vaping products, with immediate effect: Animals are still used to test alcohol, tobacco and nicotine products in Australia. In such tests, rodents may be confined to narrow tubes and forced to inhale toxic substances for up to six hours each day for several years (PETA UK, 2022), used in experiments in attempt to understand human adolescent binge drinking (Costa et al, 2024), or experience daily or chronic exposure to e-cigarette vapour to study withdrawal (Thorpe et al, 2023). In the EU, the European Commission Scientific Committee on Health, Environmental and Emerging Risks stated that, in light of the EU policy banning animal studies for chemicals to be used in voluntary products such as cosmetics, animal studies are not endorsed to assess the safety of tobacco additives (Scientific Committee on Health, Environmental and Emerging Risks, 2016). In addition, Belgium, Estonia, Germany, Slovakia, and the UK already prohibit the use of animals for the development and testing of tobacco products because of ethical concerns (German Federal Ministry of Justice, 2006; Glasa, 2004; Parve, 2004; Service public de Wallonie, 2018; Home Office, 2017) and Australia must keep pace with such international policy developments.

Around the world, hazard assessment of tobacco products increasingly employs innovative non-animal methods, including the exposure of cell and tissue cultures to whole cigarette smoke or e-cigarette vapour at the air–liquid interface, cell transformation assays, and genomic analyses (Clippinger et al, 2018; Manuppello and Sullivan, 2015; Moore et al, 2020). These techniques have been used to investigate cytotoxicity, genotoxicity, inflammation, and gene expression and are more relevant to actual human exposure than are animal tests that have historically under-predicted the hazards of tobacco. Given Australia’s recent reforms to strengthen the regulation of smoking and vaping (the Public Health (Tobacco and Other Products) Act 2003 (Cth); Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2004 (Cth)), it is essential that national animal research policy be brought into alignment by prohibiting the use of animals for testing nicotine, tobacco, and vaping products. Such alignment would ensure regulatory coherence, uphold ethical standards, and reflect contemporary public health priorities.

Implement policy bans, with immediate effect, on the use of animals in the following tests: pyrogenicity testing, skin irritation/corrosion, eye irritation/corrosion, skin sensitisation, acute fish toxicity:

To modernise safety assessment while upholding animal welfare and scientific standards, regulators should prohibit the use of live animal tests for pyrogenicity, skin irritation/corrosion, eye irritation/corrosion, skin sensitisation, and acute fish toxicity, and mandate the use of validated non-animal new approach methodologies (NAMs). For pyrogenicity, replace the rabbit pyrogen test and horseshoe crab–derived assays with human-relevant monocyte activation tests (MAT) and recombinant Factor C methods, which are more humane and scientifically appropriate for detecting human pyrogens (PETA US, 2025e). For skin irritation and corrosion, adopt reconstructed human epidermis and related in vitro strategies already embedded in international guidance (e.g., OECD TG 431/435/439 and IATA) (OECD, 2014; PETA Science Consortium International e.V.: skin irritation and corrosion testing, no date). For eye irritation/corrosion, retire the unreliable and painful Draize rabbit eye test in favour of accepted non-animal methods (e.g., RhCE, BCOP, ICE, STE, macromolecular tests) whose performance have been shown to be as or more reflective of human biology than the rabbit test (PETA US, no date; PETA Science Consortium International e.V., 2024). For skin sensitisation, require defined approaches that combine in chemo/in vitro assays (e.g., DPRA/ADRA, KeratinoSens™, hCLAT) aligned with OECD guidance, thereby eliminating animal-based LLNA/guinea pig tests (PETA Science Consortium International e.V., 2025a). For acute fish toxicity, use non-animal approaches (e.g., fish cell–based assays) to replace acute fish tests, while maintaining environmental protection goals. Collectively, these measures align regulatory practice with available non-animal methods, reduce/end animal suffering, and improve human relevance and reproducibility of safety decisions (PETA Science Consortium International e.V., 2025b). Plans for ending these tests are already in place internationally: in 2025 the UK government announced plans to end the use of animals in these tests due to the availability of non-animal methods, with plans for promoting international acceptance of such methods (UK Department for Science, Innovation and Technology et al, 2025). In Australia, while there are restrictions on some of these tests for cosmetics testing, they may still be used for other purposes, or if the chemical ingredients of the cosmetic also have other uses. Our recommendations for these uses are below.

Close loopholes that undermine Australia’s animal testing for cosmetics ban and implement a full ban on the testing on animals of household products and their ingredients:

Despite the introduction of the Industrial Chemicals Act 2019 (Cth), significant regulatory gaps remain that continue to permit the use of animals for testing chemical ingredients used in cosmetics (Clause 7 of the Code). Specifically, the Act exempts ingredients with multiple end uses—such as those also incorporated into household cleaners, paints, or air fresheners—thereby allowing animal testing to occur even when these substances are also found in cosmetic products. Furthermore, under the current framework, cosmetic products sold in Australia may contain ingredients subjected to mandatory animal testing in overseas jurisdictions, including China, provided that companies supply supplementary non-animal test data where deemed appropriate (PETA Australia, 2020). The legislation also permits ongoing reliance on historical animal test data generated prior to 1 July 2020, thereby entrenching legacy animal data in regulatory submissions. Importantly, the Act applies only to cosmetic ingredients, not finished products, allowing further potential for regulatory circumvention (Animal-Free Science Advocacy, 2020). Taken together, these loopholes weaken the intended effect of the reforms and underscore the need for comprehensive legislative amendment to ensure that Australia’s cosmetic sector is fully aligned with contemporary expectations for animal-free science. In 2023 the UK government clarified their position of exclusive use chemicals ingredients stating “no new [projects] will be granted for animal testing of chemicals that are exclusively intended to be used as ingredients in cosmetics products” (Home Office, 2023), thereby closing a similar loophole that existed in the UK.

Implement policy bans on the use of animals for the production of antibodies for research, regulatory, diagnostic and therapeutic applications, with immediate effect:

In light of the scientific advances, human relevance, and superior reproducibility of non-animal–derived antibodies, regulators should prohibit the use of animals for the development and production of research, diagnostic, regulatory, and therapeutic antibodies and require validated recombinant, sequence-defined antibodies and mimetics (e.g., phage display–selected binders) as the default (Groff et al, 2020; PETA Science Consortium International e.V.: recombinant antibodies, no date). Animal-derived antibodies contribute substantially to irreproducibility and batch variability, use millions of

animals worldwide, and the procedures used often cause severe suffering, despite non-animal methods for generating and producing antibodies having been available for years (European Commission Joint Research Centre, 2020a; 2020b; Viegas Barroso et al, 2020). Whereas recombinant antibodies, generated from defined DNA sequences and selected entirely in vitro, deliver lot-to-lot consistency and target specificity that improve scientific and regulatory decision-making. This position is aligned with the EU Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) whose 2020 report concluded that non-animal-derived antibodies are equal or superior in quality (specificity, affinity, stability, reproducibility) and recommended that EU Member States no longer authorise animal immunisation for antibody generation where robust scientific justification is lacking (European Commission Joint Research Centre, 2020a; 2020b; Viegas Barroso et al, 2020). This standard should be mirrored to ensure international regulatory coherence and compliance with 3Rs principles.

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13 Are there any other comments that you would like to make?

Other comments:

OTHER AREAS FOR CONSIDERATION

Review current international restrictions on specific animal use, care and accommodation, for consideration within the Australian Code for the Care and Use of Animals for Scientific Purposes:

Across the UK and the EU, enhanced legislative protections apply to specific animal species used in scientific procedures, including:

• In the UK, any proposed project involving non-human primates, dogs, cats, or horses must undergo independent scrutiny by the statutory Animals in Science Committee prior to the authorisation of a project, ensuring that heightened ethical and scientific thresholds are met (Animals (Scientific Procedures) Act 1986).

• In the EU, additional statutory restrictions apply to the use of great apes, endangered species, and stray or feral domestic animals, reflecting their elevated welfare status and the principle that their use is permissible only under the most exceptional and scientifically justified circumstances (Directive 2010/63/EU).

• Regulatory frameworks further require that all primates be sourced exclusively from self-sustaining colonies or from second-generation (F2) captive-bred populations, thereby reducing reliance on wild-caught animals and aligning with international commitments to conservation and welfare (Home Office, 2025g).

• Provisions address the sentience and developmental status of embryonic, foetal, and larval forms, providing specific guidance on permissible procedures, welfare considerations, and thresholds for regulatory oversight (Directive 2010/63/EU). The sentience status of embryonic birds should also be considered.

• Detailed, species-specific guidance governs the housing, care, environmental enrichment, accommodation, transport, and humane killing methods applicable to animals used in scientific research, ensuring consistent application of welfare standards across establishments (Directive 2010/63/EU).

• There are also prohibitions on the use of live animals in primary and secondary education, recognising that such practices fail to meet contemporary ethical standards and are unnecessary for educational purposes (Directive 2010/63/EU; Norecopa, 2024; PETA UK, no date). The NHMRC must end the use of all live animals for primary and secondary education sectors (Clause 4 of the Code).

PHASING OUT EXPERIMENTS ON ANIMALS

For decades, extensive research has demonstrated the poor translation of basic and applied research, and predictive failures in safety and efficacy testing, arising from the use of animals to understand human disease and test therapeutics. Inherent species differences mean that other animals cannot reliably serve as analogues for understanding human disease and developing safe and effective treatments for humans. Systematic reviews published in peer-reviewed journals document the limitations of translating results from studies using animals into treatments for humans across numerous disease areas (PETA UK, 2022).

The urgent need to transition away from using animals in research, testing, education and training, and towards human-relevant non-animal approaches is changing policies around the globe, and the benefits to animal welfare, public health, scientific advancement, and the economy are widely recognised (European Citizens' Initiative, 2023; European Food Safety Authority, 2022; Innovate UK, 2015; Kleinschmidt-Doerr et al, 2025; Meigs et al, 2018; Müller, 2024).

In the EU, Recital 10 sets the tone of the overarching goal of Directive 2010/63/EU on the Protection of Animals Used for Scientific Purposes: "the final goal of full replacement of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible to do so". This ambition is being put into practice. The European Commission has committed to developing a roadmap aimed at phasing out animal testing for chemical safety assessments (European Citizens' Initiative, 2023). Most recently the UK government has published a roadmap to accelerate the phase out of the use of animals in all but exceptional circumstances, by driving "the creation of a wide range of new and validated alternatives used in discovery and translational

research, and new approach methodologies used for chemical and environmental testing, and safety and toxicity testing of potential new human and veterinary medicines" (UK Department for Science, Innovation and Technology et al, 2025a; 2025b). Around the world, similar strategies are being put forward to phase out animal use and accelerate a transition to animal-free science, including the Netherlands (Transition Programme for Innovation without the use of animals, no date; Utrecht University, 2024), and the US (National Institutes of Health, 2024; Nuwer, 2022; United States Environmental Protection Agency, 2021, 2026). A New South Wales legislative committee agreed that a similar strategy must be adopted for transitioning to animal-free research and that greater emphasis must be placed on funding such research (Parliament of New South Wales, 2022). To be at the forefront of global science and innovation, Australia now needs a nation-wide government-led strategy to phase out experiments on animals and prioritise advanced non-animal methods.

The Research Modernisation Deal by PETA Entity Scientists:

The first step in creating a successful strategy is developing a roadmap – with an ambitious timeframe, clear milestones, and achievable goals – to reduce and ultimately phase out experiments on animals. PETA entity scientists have produced the Research Modernisation Deal (see PETA UK, 2022; versions are also available for the EU, France, Germany, India, the Netherlands, and the United States), which provides policymakers with a detailed strategy comprising six actions that can be used to develop such a roadmap while also accelerating the uptake and further development of non-animal methods. The RMD calls for:

- The immediate elimination of animal use in areas for which animals have already been shown to be poor and unreliable predictors for humans, and have impeded progress;
- Conducting critical scientific reviews to identify the areas in which the use of animals has failed to advance human health and should therefore be ended;
- The implementation of transparent, robust prospective and retrospective evaluations for all projects using animals and a public commenting period;
- Collaboration with organisations and agencies globally to harmonise and promote international acceptance of non-animal testing methods for regulatory testing requirements;
- An increase in funds for non-animal studies and a decrease in funds for animal studies;
- Education and training of researchers and regulators on the benefits of and how to use non-animal testing approaches.

The appendices to the RMD cover over 40 areas of animal use that can either be ended immediately or prioritised for replacement, the implementation of which would make an impactful initial step. With the Code review, now is an opportune moment to make a lasting impact on the Australian science sector and reap the associated benefits across industry, employment, the economy, public health, and animal welfare.

The Expertise of PETA Entity Scientists:

PETA entities have a network of scientists and policy experts who can offer considerable breadth and depth of knowledge regarding the development of a roadmap. The wide range of expertise of PETA entity scientists spans biochemistry and ecotoxicology to epidemiology, and animal welfare and behaviour. These scientists around the world are actively involved in the development, validation, global implementation, and harmonisation of alternatives to testing on animals and have worked behind the scenes with many scientists and industry and regulatory agencies, providing advice and technical support in a range of fields, including phasing out the use of experiments on animals. Just a few of the organisations PETA entities have worked with include the European Food Safety Authority, the European Chemicals Agency, the EURL ECVAM, the US Environmental Protection Agency, and the US Interagency Coordinating Committee on the Validation of Alternative Methods. PETA UK was one of the leading organisations behind the European Citizens' Initiative "Save Cruelty Free Cosmetics – Commit to a Europe Without Animal Testing", which led the European Commission to initiate its roadmap to ending regulatory testing on animals (European Citizens' Initiative, 2023), and PETA UK is actively involved in this ongoing work. It stands ready to assist with the development and implementation of a plan to phase out experiments on animals and accelerate the uptake and further development of non-animal methods in Australia.

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