



Please comment on as many of as few of the following as you wish:

In general terms:

1. Do you agree that research institutions should report statistics on animals used in research?
Strongly agree
2. What are your reasons for this?
 - For accountability, as animal testing is permissible only by law, under a democratic system and also particularly as some animal research is funded by taxpayers
 - To enable identification of trends in numbers, species used, level of invasiveness and other key data
 - To measure effectiveness of the 3Rs, including between states and compared with other countries/regions of the world
 - To inform AFSA's advocacy and guide where our efforts are most needed
 - To inform a realistic timeframe by which animal-use may be phased out or highlight what is needed to reach that goal.
 - Under the Code investigators have to record anyway
 - To bring Australia's reporting in line with other developed countries /regions of the world
 - Nationally consistent reporting is a key recommendation from the [2023 CSIRO Non-Animal Models report](#) (Recommendation 2: Develop national data collection standards on the use of animals in scientific research, teaching and testing) and the [2022 NSW Inquiry into medical research using primates and other animals](#) (Recommendation 10 That the NSW Government engage with the Australian Government at a ministerial level to advocate for nationally consistent reporting requirements on the use of animals in medical research including the separate and discrete reporting of animals involved in observational studies).

If your organisation conducts research involving animals:

1. Do you feel change to the current system for reporting and publishing statistics is needed and if so, what change(s) would you like to see?
2. Do you think these changes should be a low, medium or high priority?

N/A


In relation to national reporting:

1. Would you support a move towards nationally consistent reporting and publishing of animal use statistics across all Australian state and territory jurisdictions?

Strongly support

There are currently significant inconsistencies in the publication of the statistics between states which is making it impossible for states to compare themselves with other states or for

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the government, policy makers, researchers, funding bodies and the public to have an informed view about the use of animals across Australia. A mandatory, consistent reporting system is vital for this to be achieved.

This would also bring Australia in line with other developed countries/regions of the world, reassuring those within and outside Australia that the use of animals in research is well regulated. It would also enable third parties to compare Australia fairly with the rest of the world. If the opportunity was taken to also make the reporting content as similar as possible to the other regions this would add further international consistency and enable a fair comparison. For example, according to [Taylor and Rego Alvarez \(2019\)](#), if Australia's (estimated) animal use numbers were adjusted to EU definitions (at 3.2 million animals in 2015) it would be the 5th largest user of animals in the world, even accounting for estimates for China and the (incomplete) USA and Japan (Canada was the 4th highest). However, largely in part to the reporting by some states of observational studies its reported use was 9.9 million animals, in theory placing it above Canada in 4th. Thus, not only is it imperative that Australia reports properly (as it is a major user of animals in research in the world) but it is important that the definition of animal and procedure is clear -and preferably consistent- with other animal using nations such that any comparison is as fair as it can be. Removal of the need to count potentially two thirds of animals that are used in observational studies is a huge resource saving that should hopefully compensate the effort to nationalise the statistics.

2. If so:


- Would you like to see the model used in your home state or territory applied across all jurisdictions or would you propose an amended or a different model (e.g. is there one from another state or overseas you would like to see used instead)?

See attached proposal of a potential model. It builds on the models used in NSW, Tasmania or Victoria and adds best practice from the regions of Europe, the USA and Canada, which are summarised for background in the Appendix to our proposal. We felt it was important to maintain consistency with current practice in those states where the reporting elements are fit for purpose and to only change or add elements that would add important 3Rs information and transparency for the public.

- Should a move towards nationally consistent reporting be low, medium or high priority?

High priority. This has been a long-standing gap with no solution reached. Currently, some states and territories are not reporting at all, and this is not acceptable, especially since investigators have to count their animals anyway.

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3. If you are **not** supportive of nationally consistent reporting, why is this?
N/A
4. For about 10 years now, researchers in EU countries and the UK have been required to publish non-technical summaries of approved projects. The stated aims of this requirement include enhanced transparency, avoiding the spread of misinformation, supporting the sharing of good practice in the 3Rs, and supporting evidence-based policy making. Do you think something like this should be considered for Australia?

Definitely. A [2022 community survey](#) revealed that a large majority of participants care about the use of animals but feel uninformed. Specifically, 64% of participants expressed interest in learning more about research into alternatives to animal use, and 70% wanted more information on efforts to improve the welfare of animals used in research. Non-technical summaries would be one way of achieving greater transparency.


NTS can:


- Help inform the public on what is being done to animals and why, more than can be provided by the statistics
- Act as a mechanism to avoid duplication by other researchers
- Be used to share best practice on the 3Rs, particularly if retrospective review is added

NTS have been published in the UK since 2005 on a voluntary basis, mandatory since 2013. Mandatory publication definitely helps otherwise there are gaps in knowledge and the public is not fully informed. More serious or contentious research may be more likely to not have an NTS if there is a choice about whether to publish. Publication rates by the UK and EU member states have been really variable as has the quality of the content, see review by [Taylor et al. 2018](#), Researchers really struggle to be honest and clear particularly about the harms the animals may experience. Further guidance by the Commission was found to have improved the quality in a follow up review, but the adverse effects section was still inadequate in more than half of the NTS from Germany and the UK ([Taylor et al. 2024](#)). That paper included a checklist for authorities to ensure that all elements of the NTS had been properly completed.

The centralised publication of the NTS by the Commission has helped enormously with the accessibility and timely publication of the NTS. It is notable though that it is difficult to match the NTS with the annual statistics because projects tend to cover more than one year and there will be some time delay between starting the project and the end use of the animals. In the EU, some NTS have to indicate that a retrospective review at the end of the project is required and a [summary](#) of the results of this will be added to the NTS. This is good but unfortunately this only applies to severe projects or those using primates so the learnings for everyone on the 3Rs that this review would provide are limited in the EU. We recommend

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that Australia has a retrospective review of all projects and that the results of this are published. A review of the outcomes of the project is already required to be submitted to the AEC under the Code.

It is worth noting that project applications (with commercially sensitive information or personal details redacted) are available from public authorities including universities under Access to Document legislation in the EU and Freedom of Information legislation in the UK. This has not caused any increase in violent behaviour towards institutions or individuals. For many years, Denmark used to publish parts of each project application on their website but seemed to have reverted to substituting this with the NTS.


5. Any other comments.

Suggestions for additional information that could be provided in the statistical report:

- **Fate of the animals.** This is of interest to the public who are particularly keen to know if dogs and cats are rehomed where possible. It is also important that the public are informed that most animals are killed at the end of the procedure (so they cannot be rehomed). There is no reason why fate cannot also be reported if animals are counted at the end of the procedure. Under the Code investigators have to outline the 'provisions of the animals at the conclusion of their use' anyway.
- **Source of the animals.** Source is important as it is relevant to the 3Rs (capture, transport, etc), particularly for species of interest such as cats, horses, dogs and monkeys who may not be bred for purposes. It is suggested that Australia could take this opportunity to prohibit the use of domestic dogs and cats from non-authorized breeders (excluding owner volunteered animals), restrict the import of non-human primates and prohibit use of wild caught animals from outside Australia.
- **Animal use by institution.** Identification of institutions (and their animal use numbers) occurs in the USA, Tasmania and The Netherlands at least. Canada provides a list of all institutions that are CCAC registered. This provides full transparency to the public and policy makers who have an interest and a right to know what is happening in their state, especially that which is being funded by their taxes. In the UK (and the intention for Canada) the number of types of institution are given as a minimum. Because the UK measured this we know that the number of procedures has halved in commercial companies over the last 20 years and doubled in universities; facts like these are extremely useful to be able to gauge uptake of the 3Rs. We have found no direct link between increased transparency and direct action by animal rights activists, in fact the indication is that the more information that is provided the more the level of activity, and even interest, decreases. Troubling animal rights activity in the EU at least has not been

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an issue since the early 2000s, despite a significant increase in transparency over this time.

Operational considerations

Please comment on as many of as few of the following as you wish:

- Oversight and governance


It would be appropriate for the NHMRC to provide oversight, but I do not think they will willingly take on this responsibility due to resourcing capacity and on the account that not all animal research is funded by the NHMRC. The Australian Bureau of Statistics would seem a suitable agency, but this would likely need to be in collaboration with either or both the federal Department of Health or the federal Department of Agriculture. This would depend on whether the data to be collected and reported is primarily for biomedical use or broader purposes. Alternatively, if there is a leading state agency (potentially NSW DPI) that is prepared to collate and publish all state statistics, the other states and territories could pay them for this service. The development of the [national Australian Animal Welfare strategy](#), which will include an animals in research and teaching working group, may identify other options.


Where there is a lack of national harmonisation in other areas of animal welfare such as farm animal welfare, a national taskforce has been established and this could be an option for the use of animals in science. The [Animal Welfare Task Group](#) (AWTG) promotes the national consistency of farm animal welfare regulations across jurisdictions and oversees the development and review of standards and guidelines for farm animals. It resolves animal welfare policy and regulatory matters which have national and inter-jurisdictional scope and delivers on animal welfare priorities of national interest referred to it by the Agricultural Senior Officials' Committee (AGSOC). Membership is made up of representatives from each of the state and territory government departments responsible for animal welfare and the Department of Agriculture, Fisheries and Forestry. The New Zealand Ministry of Primary Industries participates in an observer capacity.

The AWTG is responsible for:

- Maintaining the Australian Animal Welfare Standards and Guidelines Development Framework
- The coordination of reviews of Model Codes of Practice for the Welfare of Animals and conversion to Australian Animal Welfare Standards and Guidelines
- Delivery of animal welfare priorities of national interest as referred by AGSOC.

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- Liaising with state and territory regulators/ Regulatory considerations

If it is a voluntary scheme, some states and territories may not comply or cooperate. Suggest the Code be amended to require nationally consistent animal use data collection and reporting, and this should then be incorporated into state and territory animal welfare legislation. It should be noted that in some states and territories the responsible Ministry is Environment rather than Agriculture.

Regulatory considerations

- Funding (set-up costs and ongoing operation)
Records of the numbers of animals used by each investigator is already a requirement under the Code. So, the additional burden is with the collation and publication of the statistics by the state and/or nationally. This should be a relatively minor cost after initial set up, needed only once per year. In Europe at a country level this is funded by license fees (project, establishment and/or personal), but at the EU level is just absorbed as part of the Directorate's responsibly for animal experiments.
- Implementation (staging?)
Most states that report are reporting time periods 2-4 years retrospectively so could set a future date- potentially commencing January 2027/8 to enable jurisdictions to complete and report on current cycles and for Code to be amended.
- Data management:
 - Hosting, URL and webpage maintenance
 - IT systems
 - Security, backup, privacy and confidentiality
 - Data entry, collating and formatting
- Other administration:
 - Stakeholder liaison
 - Communications, social media, handling enquiries

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Content and coverage of reporting

Please comment on as many of as few of the following as you wish:

What species should be covered?

- Mammals
- Fish
- Amphibians
- Cephalopods
- Decapod crustaceans
- Stage of development?
- Other?

It is important to count all animal species and life stages that have the capacity to experience pain, distress and lasting harm. The species are all captured in the Code already except for decapod crustaceans. These are nonetheless already reported by Victoria, New Zealand and Switzerland.

Fish and amphibians capable of free feeding and unborn mammals and unhatched birds/reptiles in their last third at a minimum of gestation/incubation should also be counted as there is strong evidence that these are sentient, particularly if they are extracted from the mother/egg. Estimates for juvenile fish and amphibians are acceptable.

What research areas should be covered?

- Biomedical
- Wildlife/conservation
- Agricultural/racing
- Companion animal
- Animals in teaching
- All of the above?
- Other?

This is the wrong approach to the question. All procedures used in research, testing and education that are likely to cause pain, distress or lasting harm (including euthanasia at the end) should be included. One then creates categories of use to best explain the uses of those animals.

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The definition within the Code is adequate:

Scientific purposes: all activities conducted with the aim of acquiring, developing or demonstrating knowledge or techniques in all areas of science, including teaching, field trials, environmental studies, research (including the creation and breeding of a new animal line where the impact on animal wellbeing is unknown or uncertain), diagnosis, product testing and the production of biological products.

We are suggesting that the same categories of use that are currently used in NSW are used, with some modifications. This is because, whilst not quite in line with the way purposes are described in the EU, this best describes the main uses of animals in Australia, where environmental research and animal management research dominate. Furthermore, the descriptors used in NSW arguably actually make more sense to the public than some of the EU ones. It is important however, to separate out higher education from training and to include regulatory testing as a separate category.

It is also important to count animals used in GA breeding (as in NSW and WA). Furthermore, it is important to consider the use of subcategories within the main purpose categories, as in the EU, as this provides further information on specific uses (areas of medical research for example) as well as enabling researchers and policy makers to drill down on specific tests, or areas of testing, that are particularly pertinent to the 3Rs such as types of regulatory tests and legislative requirement. We haven't suggested these subcategories at this stage, but we have included the EU ones in the spreadsheet. In the EU, the Commission brought together key stakeholders (such as are being consulted here) to work together to come up with suitable subcategories.

If there is broad agreement, AFSA would be supportive of observational research/non-invasive research being excluded from the statistics to enable fairer comparison with other jurisdictions.

Reporting on animal breeding

- What should be reported?
- Requirements for in-house breeding vs external supplier
- Wastage

In terms of the 3Rs and the public, what matters is harmful animal research. In our opinion this includes any use of animals that cause pain, suffering, distress, or lasting negative impact, including death—without any clear benefit to the animals themselves. Most other regions are also moving towards counting all these uses and anyway these animals have to be recorded by investigators under the Code. Reporting them adds important information that is relevant to the 3Rs. The EU requires the reporting of all animals bred and not used in 5 yearly reports but actually breeders are

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required to keep records annually. It is simpler for researchers to get used to reporting all animals that they have to count annually anyway. It provides complete transparency of all animal use in laboratories and will enable researchers and policy makers to ascertain where animal efficiencies need to be made.

We are proposing that the purpose categories (already in use by NSW and WA) should reflect all normal and GM animals bred (and not used in further experiments) and that adding a 'killed for tissues' field in the impact/severity category would cover any remaining animals that are killed.

Animal welfare impact

- How should this be reported?
- Categories of impact?
- Use of pain management

On balance we think the advantage of keeping the current system of reporting procedural impact rather than retrospective severity is more honest, more informative and less prone to subjectivity and error and that this balances out any advantage in appearing consistent with Europe. There are known problems with severity assessment in Europe and the use of only three categories (where most harmful research falls in the 'moderate' category anyway) has also been criticised. It is by no means guaranteed that there would be any consistency with Australia and other countries using a severity system despite the use of the same categories. In the Appendix it is already noted that the US considers injection as cat C no pain and Canada cat B little or no pain, whereas the EU considers this 'mild', for example. You need less guidance for researchers if you maintain the existing categories, which are already being used with remarkable consistency across the states.

The suggestion is to report all animals at the end of their use so that fate can also be reported. Researchers would therefore have to report the 'worst' intervention any animal received if receiving more than one, so the reporting would be retrospective.

Consideration should be given to adding a category of whether pain relief was applied. This occurs in the USA. It is of particular interest to the public and would add another layer of information related to severity to that provided by the 'impact categories'. It also allows for assessment of areas where the 3Rs (refinement) are being applied (e.g. major surgery) and where they need to be applied (e.g. where animals are used in major interventions and pain relief is not compatible with the aims of the study).

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Other initiatives to be covered

- What other initiatives should be reported on?
- 3Rs initiatives?
- Rehoming?

Suggestions for additional information that could be provided on an annual mandatory, nationally consistent basis:

- **Institutional annual reports** on compliance with the Code (as required in the Code, with [voluntary](#) publication currently), including, the number of projects authorised, how many were rejected/amended, funding of 3Rs initiatives, examples of 3Rs adherence and initiatives within each project, as per the examples given in the NSW report, any relevant policies, performance of the AEC, summaries of external reviews/inspection reports, any rehoming. We note that inspection reports (in theory) are obtainable in the US under Freedom of Information requests.
- **Retrospective assessments** of research projects, noting that these are required to be produced under the Code anyway, with the additional recommendation that they should be made publicly available.
- **Annual report of the state/government** on measures taken to fund and/or promote the 3Rs including levels of funding of 3Rs research (split by replacement, reduction and refinement) and support for any international 3Rs related initiatives.

Reporting cycle

- Calendar year, financial year or other?

AFSA propose calendar year. All other countries report annually. It is important that the publication is as soon after the end of the year as possible, certainly within that following year, otherwise the statistics are old news and policy makers cannot react in a timely way.

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