Dear Malcolm France

Re: Animal-Free Science Advocacy (AFSA) Submission National Statistics Options Paper

Thank you for the opportunity to contribute to this important project. AFSA's preferred reporting option is outlined below with justification for this preference, followed by additional comments related to the Options Paper.

AFSA PREFERENCE: **Option 3 Collection and reporting of statistics would be managed entirely by a national entity which would publish national data and provide each jurisdiction with the data required for them to perform local regulatory functions.**

This aligns with international practices in the US, Canada, UK, EU, and New Zealand, allows state regulatory agencies to maintain access to the full reporting data to assist with auditing requirements, provides accountability at a state and territory level and aids budgetary planning, amongst other functions.

This option offers the benefits of providing a degree of separation via the national entity to facilitate independence from the state regulators, ensures consistency amongst states and territory reporting, overcomes the issue of some states not collating data, simplifies reporting for institutions working across states and territories, and will provide a much-needed national overview of animal use, purpose and severity.

Whilst implementation of option 3 may require amendment to state and territory regulatory requirements to ensure common reporting requirements across jurisdictions, AFSA sees this as an advantage, as it will mandate data collation and reporting where it is currently absent, thus increasing transparency and is a relatively minor amendment which is achievable.

With this option, AFSA suggests there is an onus on both the national entity and the state regulatory agencies to analyse the data, and in the case of the state and regulatory agencies, to take action in response to any identified trends. As there is no national body with oversight for animal use in research and teaching, the national entity may not automatically be expected to make recommendations or act upon the national data it collates; however, there may be scope for this dependent on which national entity is selected and the agency's broader remit.

In order for this option to proceed, it is likely that financial contributions will be required by state and territory regulators to co-fund the national entity. In AFSA's view, this could be generated by an increase in animal research/breeding license fees which could be directed to reporting costs. Additionally, state and territory regulators should contribute financially directly. A national reporting system would reduce some administrative workload from the state and territory regulators and ideally this saved time could be allocated to increased oversight of the license holders and their research protocols.

AFSA expect some resistance to national reporting on the grounds that it may generate additional workload; to researchers, state and territory regulators and potentially a national entity, at a time where resources are scarce. However, as emphasised in the Options Paper, the Australian Code for

the Care and Use of Animals for Scientific Purposes[1] (the Code) already requires researchers and animal care staff to keep records of animals used or bred for scientific purposes, and option 3 would remove dual reporting for projects across multiple jurisdictions. These records must be made available to the institution, the AEC and authorised external reviewers. The Code also sets out responsibilities for annual reporting on project outcomes. There is a need to ensure this information is utilised to best effect. If a researcher cannot commit the time and resources to reporting, the research should not be approved in the first instance. In AFSA's view, if a regulatory agency does not have capacity to accurately report and publish animal use data and this capacity cannot be expanded upon, the number of licenses issued should be reduced to enable this to be accurately and thoroughly managed in a timely manner.

Additionally, significant public expenditure has been allocated to previous Australian Animal Welfare Strategy working groups and resulting papers, as well as State and Senate Inquiries (as descripted in the options paper) and therefore it is reasonable to expect a return on this financial investment with concrete commitment to and resourcing of a national reporting system.

Additional Comments

Pg 13 Please include the Centre for Alternatives to Animal Testing in the quotes section/recommendations section. A centre for alternatives could help to reduce animal numbers and provide financial support for reporting and was also a recommendation from 1989 Senate Inquiry.

Pg 20 New Zealand What list referred to in sentence 3 under NZ section, please clarify. "Items" to be reported? Are these animals? Please clarify as animals are not items. Please outline specifically that non-human primates are not used or why they are missing from the species list for New Zealand.

Pg 22 USA Please acknowledge why this is severely behind in the US and why we should certainly not go backwards on any of our species categories.

Pg 23 Consultation Process

Can the issues paper please be included in an appendix.

How many submissions were received by the 22 universities who had not signed the Openness Agreement?

Pg 24 Overall Findings What regulatory barriers are perceived; can specific examples be cited?

Pg 30: Governance and Operations

Should a 3Rs Centre be established in Australia, this centre could potentially take on either a governance or operations role for national reporting.

ANZCCART would be our preferred option at least in the interim, subject to receiving sufficient funding and resourcing to enable this.

[1] https://www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes

Pg 32 Funding- 'It was noted that national reporting would not be within scope for NHMRC'.

It is in scope for NHMRC to be at least a part-funder given that they are responsible for leading writing and revisions to the Code and a core funder of animal research in Australia.

Pg 35: Reporting Categories General Considerations- A feature that is considered important is 'Accounting for Australian research that is conducted at or contracted to overseas institutions.

AFSA would support this data be collated, including country research is conducted in, species, number of animals, severity and purpose. We would also like to see reporting of the breeding and supply of any research animals sourced from overseas to be used in Australian research or teaching.

Pg 35 Activities to be Reported- It is the same issue in human trials that are observational (and involve standard routine care) they still require ethical approval however can have a waiver of consent if meeting strict criteria.

Pg 37 Major Categories Species Dingos must be included on the list as a Native Mammal

Pg 39 Purpose Categories

Needs to include purpose category/criteria "projects with commercial benefit"

Many projects that receive ethical approval from Research Institutes or Universities are being conducted independently for a commercial purpose/gain. No category reflects this.

Also suggest to add 'requested by journals for publication requirement 'as a purpose.

What does 'testing' mean? Suggest this is defined.

Pg 40: 'Purpose categories found elsewhere include forensic enquiries (EU, UK) and toxicology (Switzerland), neither of which are likely to have more application in Australia'.

AFSA recommends that toxicology be includes as a purpose category, if anything, it is useful to obtain actual data as to whether no toxicology research is occurring (potentially may be in chemicals research and impact on fish populations etc) and to capture data should toxicology research/testing increase in future.

Pg 40 Breeding Any killing of "surplus" animals must be reported.

Currently, Victoria issues Specified Animal Breeding licenses. A Specified Animals Breeding Licence only applies to guinea pigs, rats, mice, rabbits and primates. It is not clear what data is being collated or reported about non-specified animals bred or supplied for animal use. AFSA suggests the breeding license be extended to cover all animals used in research, including dogs and cats.

Pg 41 Animals used in teaching

Should the data for use of animals in teaching for primary and secondary schools not be included in national reporting statistics, AFSA recommends that the state school AEC annual reports are made public to increase transparency. AFSA holds concerns that animals used in schools may still be subject to harm from mishandling, inappropriate housing conditions or in the case of chicken

hatching programs, killed if the rooster cannot be rehomed. Chicken hatching programs raise welfare concerns, including risks of power failure causing chick deaths from lack of warmth, inappropriate handling leading to chick fatalities, and inadequate care for sick chicks. Additionally, chicks may face stress and potential mistreatment if taken home by students[2].

Pg 45 Source of animals

AFSA would like to see the number of animals held at breeding facilities/colonies accounted for in national reporting, as per the Victorian reporting (currently for 'specified' animals).

Pg 47 Fate of animals

Fate for each animal should be a mandatory reporting requirement (actual fate as opposed to the intended fate).

Pg 50 Source of Funding

AFSA would support a high-level indicator such as number of NHMRC- funded projects that required AEC approval in the reporting year, and the number that didn't, expressed as a % of overall projects. It should also be a consideration to add projects that received 3Rs funding via any NHMRC scheme (as advertised by NHMRC that this is available), as funding for development and validation of alternatives could include dual use of animals and this is an important distinction to make.

Pg 51 Reporting cycle

AFSA is in agreement that the collated national statistics should be published no later than six months after the latest reporting deadline (this is currently not the case, and it is recommended that the Code be amended to reflect this reporting requirement).

Pg 51 Techniques of special interest

Suggest monoclonal antibody collection, nose-only smoke exposure, forced swim test, tail suspension test, xenotransplantation research, induction of traumatic brain injury and primate neurological research are added.

Pg 53 Listing of Institutions

A list of institutes and the species they use should be provided at a minimum. As per the discussion document, this is published by Tasmania, and there should be no limitation to it being published elsewhere. However, AFSA anticipates resistance from state and territory regulators based on our experience of attempting to obtain this information in NSW and Victoria.

Pg 54 Non-Technical Summaries (NTS)

These are required in other jurisdictions. If there are concerns regarding additional workload, amendments could include shortening, using a modified template or utilising the lay summary provided to the AEC. However, NTS should be mandatory and can ensure a higher degree of accountability to the public and in searching for alternatives, which is of public interest according to

[2] https://kb.rspca.org.au/knowledge-base/what-are-the-animal-welfare-issues-with-chick-hatching-in-schools/

the ANZCCART Commissioned *Survey on Community Attitudes* (2022[3]). Option to trial with specific species, for example non-human primates, dogs and cats of particular concern to the public. This could have the benefit of better-informed AECs too. Note that commercial on confidence should not be an exception- can be redacted. Can still be scientifically or ethically questionable and this needs to be transparent. Information from NTS about how and why alternatives were sought/not identified can be very valuable to assist with development of alternatives and identify focus areas.

Pg 54 Including Non-Animal Methods

This could very simply include what replacement options had been considered (if any) in the AEC application and justification for why the experiment should proceed if not. It can also include a funding source, e.g. does your university provide funding for development of NAMs. Does this project include funding for 3Rs (scholarships, awards, other funding sources, NFP etc). Examples of NAMs used as part of the overall project would help facilitate knowledge sharing and confidence in NAMs.

Pg 55 Unexpected Adverse Events

AFSA recommends that the number of adverse events are included, or at very least, the number of adverse events resulting in unexpected deaths, as a means on monitoring where occurs most frequently and if there are reductions.

Currently, there is no public reporting of sanctions and prosecutions for animal welfare violations under the Code and related legislation and AFSA would like to see this incorporated into national reporting. An example if evident through the USDA Public Search Tool which reveals inspection reports and enforcement actions.

Pg 55 Operation of AECs.

AFSA would like to see minimal information supplied such as number of applications reviewed, amended or rejected given that there is limited transparency as to the effectiveness of AECs elsewhere.

Additional Comments

Terminology is extremely important when reporting and in terms of categorising animals. AFSA encourages clear reporting in terms of avoiding terms such as sacrificed or euthanised if the animal is killed at the end of the research or as a result of being surplus bred and avoiding categorisations such as laboratory mammals or laboratory mice[4].

Suggest investigation on the research governance system for human clinical trials and comparing that system to the potential reporting models. It has recently transitioned to a national system, 'national

[3] ANZCCART Survey on Community Attitudes | ANZCCART | University of Adelaide
[4] https://www.sciencedirect.com/science/article/pii/S0022103124000416 and https://theconversation.com/people-believe-lab-animals-have-less-mental-capacity-than-other-animals-research-shows-240490

mutual acceptance (NMA) scheme' which requires a Human Research Ethics Application via NHMRC, so perhaps some insights can be considered, please see:
https://www.clinicaltrialsandresearch.vic.gov.au/national-mutual-acceptance