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HUMANE SCIENCE

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Maintaining social license in a changing world

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Contents

Information and communication of animal research

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There has been increasing attention on the unsettling lack of reproducibility of published scientific findings, from both *in vitro* and *in vivo* studies. Some sources have even stated that "Most published findings are false" (Ioannidis 2005). Even though this might be an exaggeration, evidence shows that costs of drug development have increased due to wasted clinical trials that were based on pre-clinical trials that could not be reproduced (Begley & Ellis 2012). It is not surprising that basic science can sometimes be difficult to reproduce as the protocols and design of experiments often lacks standardisation. However, even highly standardised tests, such as the OECD test guidelines, have reproducibility issues. Public data from the European Chemicals Agency's (ECHA) online dossier show that chemicals tested in OECD test guideline (TG) 405, the Draize rabbit eye test (OECD 2012), at best could reproduce negative results with 94% reproducibility and severe eye irritants (category Type 1) with 73% reproducibility (Luechtefeld et al. 2016a). Category 2A and 2B (severe irritation but reversible before 21 days and less severe irritation than 2A and reversible) could only be reproduced with 33% and 16%, respectively, despite being the same test in the same species with highly standardised protocols. Furthermore, adding additional tests for classification of chemicals does not necessarily improve the confidence in the results (Luechtefeld et al. 2016b). Chemicals with at least two sensitisation studies in Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) dossiers showed that the Mouse Local Lymph Node Assay (LLNA), TG 429 (OECD 2010), a frequently used TG for skin sensitisation, only came to the same chemical classification as other tests about 77% of the time. This means that the development of new tests such as *in vitro* alternatives cannot be expected to perform better if direct comparison with these tests is made (Luechtefeld et al. 2016b). It also illustrates the difficulties risk assessors face when making decisions. A 2001 study evaluated primary data for trichloroethylene (TCE) to determine if it is a carcinogen or not (Ruden 2001). The dataset consisted of 29 risk assessment documents that analysed both human and animal data. The conclusion was very heterogenic, as four of the documents reported TCE to be a carcinogen and six reported it to be a non-carcinogen, while 19 of the documents were equivocal due to dispersed data from animal and human data. The two main reasons for the different opinions were bias in study selection and different interpretation/evaluation of the data.

The National Institutes of Health (NIH) recently outlined initiatives to address the lack of reproducibility of research findings (Collins & Tabak 2014). Several factors contributed to the issue, such as bias in study selection and design, differing data interpretation/evaluation, and lack of proper reporting (Thayer et al. 2014). Bias occurs when a systematic error or derivation from the truth is introduced into results or their interpretation (The Cochrane Collaboration 2011). The bias can take place at each step of the research study sequence, such as design, conduct, analysis, and reporting.

So what are some examples of different bias and how can they be limited? During the design of the experiment, selection bias can occur. This means that at the start of the experiment, participants in the study groups differ enough to confound the eventual interpretation of the results. The remedy is to randomise the test subjects so participants have an equal chance of being assigned to experimental versus control groups (The Cochrane Collaboration 2011).

When conducting the experiment there is a risk of performance bias. This can happen when research personnel are aware of which intervention was administered to which participants, leading to differences in the way they carry out the study. The remedy in this case is to blind the subjects for the person conducting the experiments (The Cochrane Collaboration 2011).

Attrition and exclusion bias can occur during analysis of research data. One example is if there are systematic differences between the groups, for example, due to loss of participants in one group. This bias is difficult to remedy; careful documentation and reporting of attrition, however, will limit the error (The Cochrane Collaboration 2011).

One of the most common biases is selective reporting, i.e., the failure to report all data. Scientists tend to report only results that support their hypotheses. The remedy here would be to report all planned outcome measures. However, to announce results that contradict each other can make the study look weak and might be difficult to publish. The same applies for negative data (non-observed effect data), as very few journals are willing to publish these findings (publication bias).

Another issue for the reproducibility of findings is poor reporting of completeness. This should be one of the easiest challenges to address, as several journals have reporting quality checklists to follow (Thayer et al. 2014). However, despite these checklists and the development of several guidelines and practices (such as Animal Research: Reporting of *In Vivo* Experiments (ARRIVE) (Kilkenny et al. 2010), the Gold Standard Publication Checklist (Hooijmans et al. 2010), the NINDS/NIH report (Landis et al. 2012), recommendations for non-standard studies (Klimisch et al. 1997), ToxRTool funded by the European Commission (Schneider et al. 2009), Qualichem *in vivo* (Maxim and van der Sluijs 2014), guidance for the use of non-standard *in vivo* studies (Beronius et al. 2014), and good cell culture practice (GCCP) (Eskes et al. 2017; Pamies et al. 2017)), the conduct of experiments in scientific journals are often indefinite. There is a substantial overlap across guidance documents for assessing reporting completeness for both *in vivo* and *in vitro* studies, which is why the lack of complete reporting is even more surprising (Samuel et al. 2016). In fact, our own experience doing systematic reviews has shown that very few publications fulfill the reporting criteria in these documents.

How can we then improve the reproducibility of our studies? One suggestion is to take an evidence-based approach and to use systematic reviews (Thayer et al. 2014). The core principles of an evidence-based approach are transparency, consistency, and objectivity (Hoffmann et al. 2014). The systematic review is a tool used in evidence-based approaches and differs from a narrative review. The narrative review has a subjective weighing of evidence that provides limited information on the literature search strategy and why some studies are included and others not. The review topic is often unfocused or overly broad and gives limited attention to its own bias and quality. It rather focus on the author's own opinion and does not consider all existing evidence. A systematic review is instead a critical assessment and evaluation of all research studies that address a particular issue. Before the collection of studies takes place there need to be clear criteria and questions to determine if a study qualifies for inclusion or not. This gives the systematic reviews an organised method of locating, assembling, and evaluating a body of literature on a particular topic.

The general steps to perform an evidence practice are to first formulate an answerable study question and decide on a study design and levels of evidence needed to answer that question (Dawes et al. 2005). The second step is performing a systematic literature search to retrieve the best evidence available. There needs to be critical and systematic appraisal of evidence for the selection of studies to be included. The next step is the translation and application of the results in practice and policy making with the final part being evaluation of study performance.

In summary, there are several major contributors to the lack of reproducibility of published scientific findings such as high risk of bias, poor reporting completeness and publication bias. Some of these challenges can be overcome by using an evidence-based approach as it would strengthen reviews (evidence synthesis), assessment of bias external validity, and test performance. The evidence-based approach can also be a useful tool to combine and weigh evidence of studies and to improve reporting adequacy. The bottom line is that such an approach would lead to better science, better evidence, assessment and reporting, and ultimately lead to better decisions.

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Lack of Reproducibility:

- Many *in vivo* and *in vitro* studies are not reproducible.
- "Most current published research findings are false" (Ioannidis, 2005, PLoS Med 2(8):e124).
- Costs of drug development have increased due to wasted clinical trials based on pre-clinical trials that could not be reproduced (Begley and Ellis, 2012, Nature Vol 483).

Example 1: OECD guideline test

Predictivity of same test in SAME animal species

Example: reproducibility of Draize eye irritancy test in rabbits

Tab. 3: Conditional probability of Draize evaluations given a previous test result
Substances filtered to those with at least two Draize studies and extractable eye irritation category in REACH registrations 2008-2014 (491 substances).

Prior Type	1	2A	2B	Non	Total
1	73%	16.1%	0.4%	10.4%	46
2A	4.2%	32.9%	3.5%	59.4%	138
2B	0.2%	4%	15.5%	80.2%	86
Non	1.1%	3.5%	1.5%	93.9%	400

Luechtefeld et al. ALTEX 33(2), 2016

Example 2: OECD guideline tests

Classification agreement using different validated OECD tests

Example: Skin sensitization assays

Tab. 1: Classification agreement on chemicals with at least two sensitization studies in REACH dossiers from 2008-2014
Studies found by searching for all studies with *studytype* = Buehler, GPMT, Patch-Test or LLNA.

	Buehler	GPMT	Patch-test	LLNA
Buehler	95.1% (344 chem.)	91.6% (364 chem.)	87.8% (58 chem.)	78.8% (212 chem.)
GPMT		93% (624 chem.)	90.5% (107 chem.)	77.4% (403 chem.)
Patch-test			92.1% (24 chem.)	78.3% (40 chem.)
LLNA				88.5% (296 chem.)

Luechtefeld et al. ALTEX 33(2), 2016

Example 3: Narrative Review of TCE

Trichloroethylene (TCE) example

- Is it a carcinogen? (suspected since 1975)
- Extensive (but "difficult") database
- 29 risk assessments (reviews) analyzed (human + animal data)
- What did multiple reviews of same topic show?

Reasons for differences across risk assessments

- bias in study selection (incomplete and idiosyncratic)
- different data interpretation/evaluation

Rudén C. The use and evaluation of primary data in 29 trichloroethylene carcinogen risk assessments. Regul. Toxicol Pharmacol 2001; 34: 3-16.

Why are there reproducibility issues?

Perspectives **Editorial**

Intersection of Systematic Review Methodology with the NIH Reproducibility Initiative

Kristina A. Thayer,[1] Mary S. Wolfe,[1] Andrew A. Rooney,[1] Abee L. Boyles,[1] John R. Bucher,[1] and Linda S. Birnbaum[2]

Research Study Sequence

Risk of bias/ Methodological quality/ Internal validity

Reporting Quality/Completeness

Bias: "Systematic error or deviation from the truth, in results or interference."

Methodological quality: The extent to which the design and conduct of a study is likely to have prevented systematic errors (bias) and, as a result, identified "the truth" in its results and inferences.

Internal validity: The extent to which the design and conduct of study minimizes bias and systematic error

Adapted from Cochrane Handbook, ver. 5.1.0 2011

Limiting Risk of Bias

Selection Bias

Was administered dose or exposure level adequately randomized to study subjects?

At the start of a study, participants in the study groups differ enough to confound the eventual interpretation of the results.

=> results from failure to randomly assign study participants to treatment groups.

=> participants don't have an equal chance of being assigned to experimental vs. control group.

=> Remedy: *randomization*

Limiting Risk of Bias

Performance Bias

Were experimental conditions identical across study groups?

Were the research personnel blinded to the study group during the study?

Research personnel are aware of which intervention was administered to which participants, leading to differences in the way they carry out the study.

=> Participants are treated differently.

=> Remedy: *blinding* of research personnel.

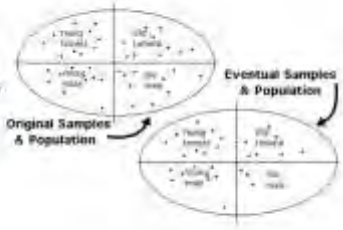
Limiting Risk of Bias

Attrition/Exclusion Bias

Were outcome data complete without attrition or exclusion from analysis?

Systematic differences in the loss of participants (to follow up) between groups

Remedy: e.g., careful documentation, analysis, and reporting of attrition



Limiting Risk of Bias

Selective Reporting Bias

Were all measured outcomes reported?

Failure to report all planned outcome measures.

E.g. reporting only results that support author's hypothesis

Remedy: reporting all planned outcome measures

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High Risk of Bias → High Systematic or Random Error → Spurious Variability → Difficult to Reproduce

Poor Reporting Completeness → Difficult to Reproduce

Implementing remedies to improve the reporting of key aspects of study methodology is perhaps the easiest challenge to address given that reporting quality checklists are available… An increasing number of journals … are now providing more explicit guidance to authors on items that should be reported when submitting papers.

JOHNS HOPKINS Thayer et al., 2014, EHP

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Reporting completeness: Examples of relevant guidance

Author	Year	Note
Kilkenny et al.	2010	ARRIVE
Hooijmans et al.	2011	Gold Standard Publication Checklist
Landis et al.	2012	NINDS/NIH
Klimisch et al.	1997	Non-standard studies
Schneider et al.	2009	ToxRTool
Maxim & van der Sluijs	2014	Qualichem *in vivo*
Beronius et al.	2014	non-standard in vivo studies

Adapted from Samuel et al., Environment International, 92–93 (2016) 630–646

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Commonly proposed criteria for assessing reporting completeness of *in vivo* and *in vitro* studies.

Criteria	% of total (N=12)
Study purpose/objectives	58
Justification for model	58
Study design	83
Defined experimental outcomes	67
Housing & feeding/maintenance conditions	83
Statistical analysis	100
Results	75
Results interpretation/discussion	50

Adapted from Samuel et al., Environment International, 92–93 (2016) 630–646

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Johns Hopkins University Center for Alternatives to Animal Testing

Risk of bias elements in individual studies: Reported ("Y" and "N") versus not reported ("?")

article code	1 (Reporting) is it mentioned that the experiment was randomised?	2 (Bias) Was the allocation sequence adequately generated and applied?	3 (Bias) Were the groups similar at baseline or adjusted for confounders?	4 (Reporting) is it mentioned that the exp was blinded (level unknown)	5 (Bias) Was the allocation adequately concealed?	6 (Bias) Are the animals randomly housed during the experiment ?	7 (Bias) Were the caregivers/ investigators during the course of the exp. adequately blinded ?	8 (Bias) Were animals selected at random during outcome assessment ?	9 (Bias) Was the outcome asssessment adequately blinded ?	10 (Bias) Were incomplete outcome data adequately addressed?	11 (Bias) Was the study apparently free of other problems that could cause a high risk of bias?	12 (Reporting) is a power / sample size calculation shown?
Dwornik 1965	Y	N	Y	N	?	?	?	?	?	?	?	N
Fioné 1981	N	?	?	N	?	?	?	?	?	?	?	N
Fretts 1965	N	?	?	N	?	?	?	?	?	?	?	N
Hui 2014	N	?	?	N	?	?	?	?	?	?	Y	N
Lehmann 1971	N	?	?	N	?	?	?	?	?	?	Y	N
Matsubara 1983	N	?	?	N	?	?	?	?	?	?	Y	N
McBride 1974	N	?	?	N	?	?	?	?	?	?	?	N
McBride 1976	Y	?	?	N	?	?	?	?	?	?	?	N
McCredie 1973	N	?	?	N	?	?	?	?	?	?	?	N
Obbink 1963	N	?	?	N	?	?	?	?	?	?	?	N
Geniger 2006	N	?	?	N	?	?	?	?	?	?	Y	N
Singis 2014	N	?	?	N	?	?	?	?	?	?	?	N
Zhao 2010	Y	?	?	N	?	?	?	?	?	Y	?	N
Teo 2004 - 1	N	?	?	N	?	?	?	?	?	Y	Y	N
Teo 2004 - 2	N	?	?	N	?	?	?	?	?	Y	Y	N
Szabo 1978 rats	Y	?	?	N	?	?	?	?	?	Y	Y	N
Szabo 1978 rabbits	Y	?	?	N	?	?	?	?	?	Y	Y	N
Sterz 1987	N	?	?	N	?	?	?	?	?	?	Y	N
Staples 1963	?	?	?	N	?	?	?	?	?	?	Y	N
Schumacher 1968	N	?	?	N	?	?	?	?	?	?	?	N
Pern 1965	N	?	?	N	?	?	?	?	?	?	?	N
Solelli 1997	N	?	?	N	?	?	?	?	?	?	?	Y
Obbink 1964	N	?	?	N	?	?	?	?	?	?	?	N
King 1962	N	?	?	N	?	?	?	?	?	?	?	N
Keplinger, 1974	N	?	?	N	?	?	?	?	?	?	?	N
Kennedy, 1968	N	?	?	N	?	?	?	?	?	?	?	N
Jonsson, 1972	N	?	?	N	?	?	?	?	?	?	?	N
Husain, 1970	N	?	?	N	?	?	?	?	?	?	?	N
Stokes 1975	Y	?	?	N	?	?	?	?	?	?	?	N

JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH

N = 29

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Evidence Based Approaches

- Core principles: **transparency, consistency, objectivity**
- **Limits bias** in the review of all relevant studies on a specific topic
- **Concisely summarizes** the literature on a specific topic for decision-makers and non-experts
- **Identifies gaps** in evidence
- Through feedback, encourages
  - needed research
  - better conducted and reported studies
- **Leaves room for professional judgment** in how to apply the review's conclusion to policy or practice

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Narrative Review vs. Systematic Review

Informal "weighing of evidence"

- limited details on
  - literature search strategy
  - why some studies were included or excluded
- the review topic is often unfocused or overly broad
- limited attention to review's own bias/quality
- subjective weighing of evidence

Seek to ensure transparency, objectivity, consistency

- critical assessment and evaluation of all research studies that address a particular issue
- organized method of locating, assembling, and evaluating a body of literature on a particular topic using a set of specific criteria

General Steps to Perform an Evidence Based Practice

1. Formulate an answerable study question, study design and levels of evidence needed to answer the question
2. Systematic retrieval of the best evidence available (**systematic literature search**)
3. Critical and systematic appraisal of evidences including
   - Selection of studies to be included
   - Meta-analyses
4. Translation and application of results in practice and policy making
5. Evaluation of study performance

Adapted from Dawes M, et al. (2005) BMC Med Educ 5 (1): 1

Summary

- Major contributors to the lack of reproducibility
  - High Risk of Bias
  - Poor Reporting Completeness
  - Publication Bias
- Evidence-based approaches can strengthen:
  - reviews (evidence synthesis)
  - assessment of bias, external validity, test performance
  - combining (weighing) evidence
  - reporting adequacy
- Bottom line:
  - better science
  - better evidence assessment and reporting
  - leading to better decisions

Social license of freshwater use

Mike Joy
Institute of Agriculture and Environment, Massey University, Palmerston North, New Zealand.

New Zealand's freshwater systems; rivers, lakes, groundwater and wetlands are all suffering immense ecological impacts. Almost all lowland waterways in the North Island and on the East-Coast of the South Island are significantly or severely impacted. These declining freshwater ecosystems are all impacted by the usual drivers implicated globally in freshwater degradation; vegetation clearance; damming of rivers; invasive fish introductions; agricultural run-off; urban and industrial wastewater discharges; and over-allocation of water abstraction rights. The single best indicator of the extent of degradation waterways have suffered in New Zealand is the shocking reality that three-quarters of native fish taxa are listed as threatened or at risk. To see clearly what the contemporary riverine freshwater quality and ecosystem health issues are, maps of water quality in New Zealand released by NIWA and others reveal that the declines are all associated with intensive farming dominated catchments. The four-fold increase in dairy production over the last few decades, while impressive, was unfortunately achieved mainly through massive increases in the importation and indigenous production of fossil-fuel derived nitrogen fertiliser, and the importation of fossil phosphate fertiliser and Palm kernel extract. The impacts of this are now seen in freshwaters, estuaries and nearshore environments, and the cost of this virtually uncontrolled intensification is being borne by the public and not the industry. Thus, the social license of the dairy industry has been well and truly lost, and because of the lag time of diffuse nutrient movement in many places worse is yet to come. The realisation of these impacts has heightened public sensitivity to water issues; the recent angry and widespread response to water bottling consents is a good example. While the response from government to the loss of social license has moved on from denial it has still been ineffectual and political.

Mike Joy BSc, MSc (1st class hons), PhD in Ecology is a Senior Lecturer in Ecology and Environmental Science at the Ecology group-Institute of Agriculture and Environment Massey University Palmerston North. He researches and teaches freshwater ecology, especially freshwater fish ecology and distribution, ecological modelling bioassessment and environmental science. He has and continues to supervise many Masters and PhD students doing research into freshwater ecology, with topics from native fish ecology to farmers' attitudes to sustainability.

Mike has published many papers in scientific journals, many international as well as articles and op-eds for newspapers and magazines. He has authored many reports for Regional Councils and Ministry for the Environment, and has developed a number of bioassessment tools and associated software used by many North Island Regional Councils.

Mike is an outspoken advocate for environmental protection in New Zealand and has received a number of awards. These include an Ecology in Action award from the New Zealand Ecological Society, and an Old Blue award from Forest and Bird; the 2009 Environmental New Zealander of the Year by North and South magazine; Manawatu Evening Standard 2012 person of the year; the 2013 Tertiary Education Union New Zealand Award of Excellence for Academic Freedom and contribution to Public Education, the 2013 Charles Fleming Award for environmental work from the Royal Society of New Zealand and in 2015 the Morgan Foundation inaugural River Voice Award.

Social license of freshwater use

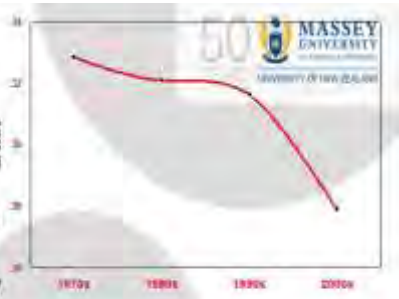
- The truth about water quality in NZ - the indicators of a crisis (some myth busting)
- The drivers of the crisis
- The social licence issue
- The future for a social license around freshwater

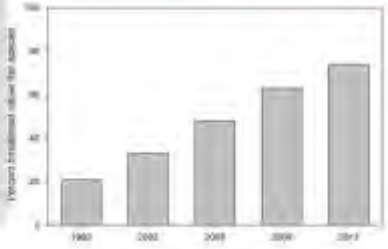
Freshwater crisis symptoms

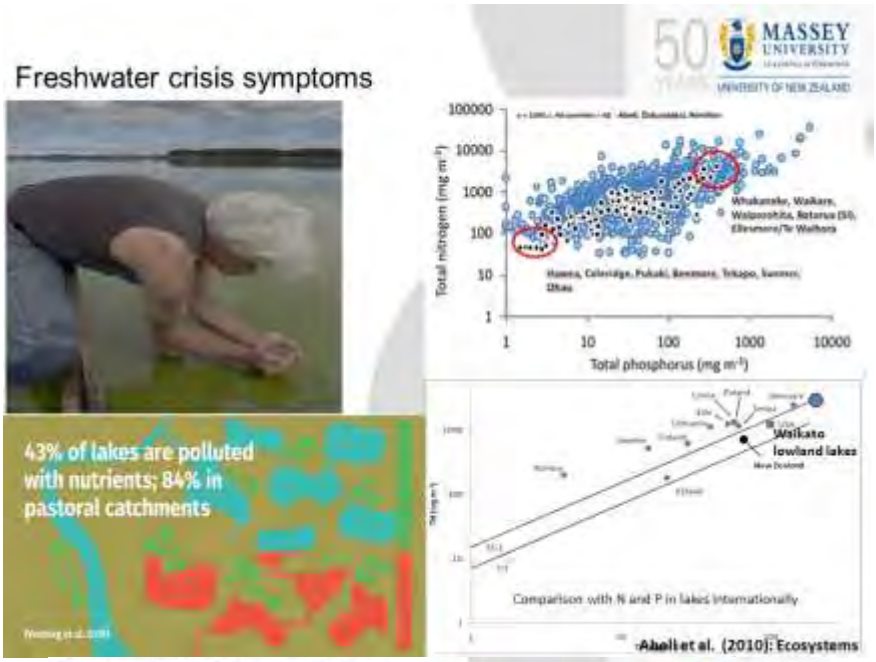
- 74% of freshwater fish threatened

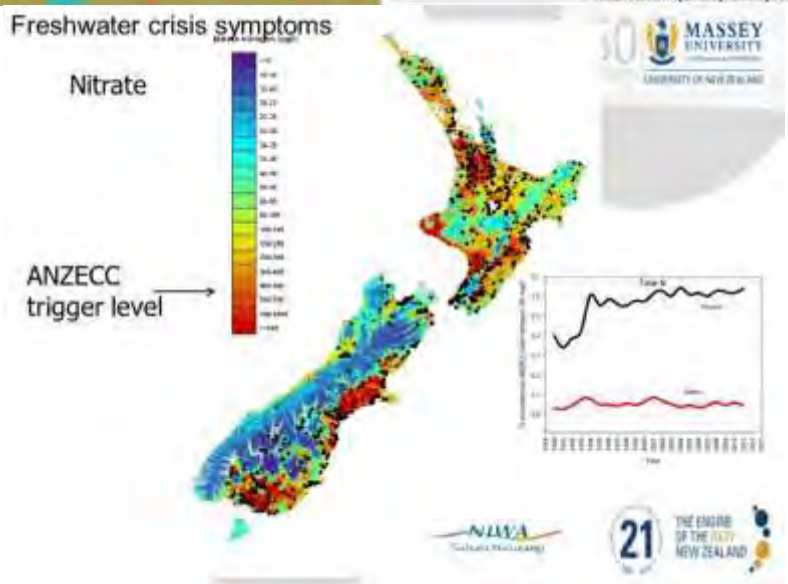
- + crayfish and kakahi too - gone by 2050

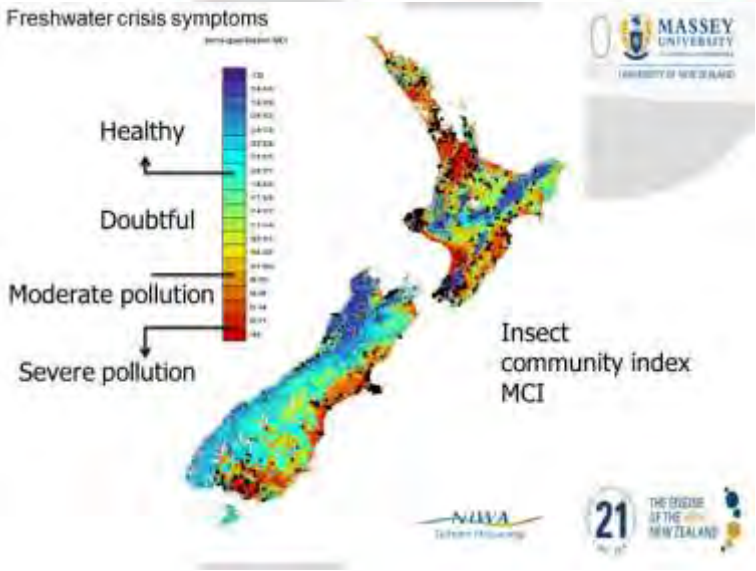
- no protection under law for native freshwater fish






Freshwater crisis symptoms
43% of lakes are polluted with nutrients; 84% in pastoral catchments
Total nitrogen (mg m⁻³)
Total phosphorus (mg m⁻³)
Whakamoke, Waikare, Waipoorhita, Rotorua (S), Ellesmere/Te Waihora
Hawea, Coleridge, Pukaki, Benmore, Tekapo, Ruataniwha, Ohau
Waikato lowland lakes
Comparison with N and P in lakes internationally
Abell et al. (2010): Ecosystems
MASSEY UNIVERSITY


Freshwater crisis symptoms
Nitrate
ANZECC trigger level
MASSEY UNIVERSITY
NIWA


Freshwater crisis symptoms
Healthy
Doubtful
Moderate pollution
Severe pollution
Insect community index MCI
MASSEY UNIVERSITY
NIWA

Freshwater crisis symptoms

Human health

Pathogens E. coli & Nitrate

18 – 34K NZers contract waterborne diseases p.a.

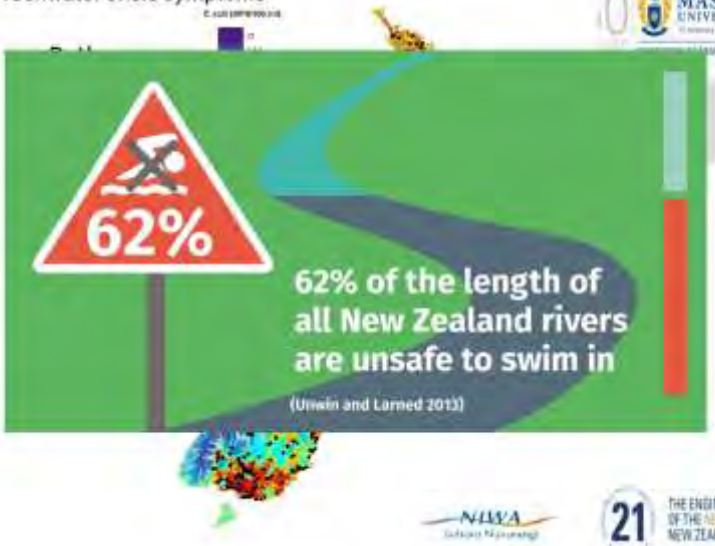
NZ now has the OECD highest frequency per-capita incidence of waterborne diseases - cryptosporidiosis, campylobacteriosis, cryptosporidiosis and salmonellosis (Crypto strongly linked to dairy)

Canterbury now has some of the highest rates of gastrointestinal disease in the world

Some Ashburton residents already have N levels in drinking water exceed WHO (pregnant women and bottle fed babies can't consume)

-benthic cyanobacteria mats deadly killing dogs and horses and one day children)

Freshwater crisis symptoms



Freshwater crisis symptoms

1160 J. P. Julian et al.: River water quality responses to land use intensity

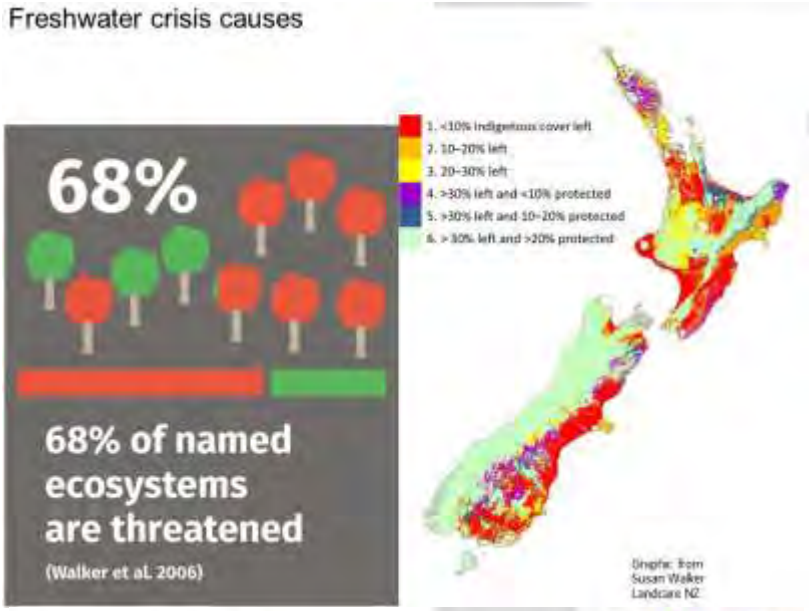
Table 6. River water quality trends from 1989 to 2014. The table reports numbers of sites (out of 77) in different categories of water quality time trend. All variables were flow-adjusted except flow and water temperature. Significant trends were taken to be those with a p value ≤ 0.05 in the seasonal Kendall test. Meaningful trends were taken to be those that also had a magnitude (RSKSE) greater than 1 % per year.

Direction of trend	River water quality variable (1989–2014)											
	Q	T_w	DO	COND	pH_w	CLAR	TURB	CDOM	TP	DRP	TN	NO_x
Meaningful increase	1	0	0	4	0	29	17		8	17	27	24
Significant increase	4	23	6	48	12	5	1		6	3	6	5
No significant trend	67	54	42	19	48	39	59	56	52	49	39	37
Significant decrease	5	2	29	6	17	2	0	13	4	5	5	1
Meaningful decrease	5	0	0	0	0	2	0	6	7	3	2	12

1989 – 2014 NRWQN 77 sites

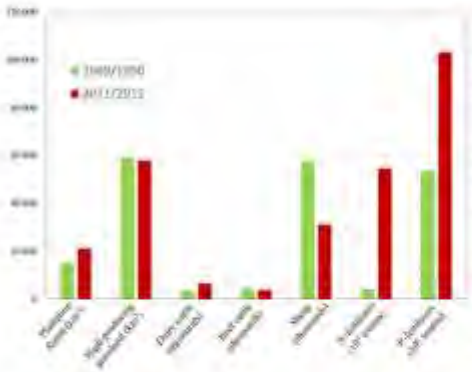
DRP 17 worse 3 better
Total N 27 worse 2 better

Freshwater crisis causes



Freshwater crisis – causes

Our freshwater crisis – the recent causes



More than twice as many dairy cows

Slightly less beef, half as many sheep

10 times as much N fert

Twice as much P fert.

Figure 2. Changes in land use areal coverage, livestock, and fertilizer inputs across New Zealand 1989/1990 vs. 2011/2012. Nitrogen fertilizers include urea and ammonium sulfate. Phosphorus fertilizers include superphosphate and diammonium phosphate.

Our freshwater crisis – the causes

Table 8. Stepwise regressions of water quality variables (median values) on landscape descriptors (forward selection, $p<0.05$). Signs of coefficients indicate whether the relationship is proportional (+) or inverse (−). Int is model intercept. Scatter plots that characterize the primary and secondary explanatory variables are displayed in Fig. 5.

Water quality variable	Step	Landscape variable	Model estimate	Multivariate sequential r^2
CLAR	1	HG	−0.03	0.17
	2	OW	0.18	0.27
	3	Q_{95}	−0.01	0.35
	4	PF	−0.05	0.39
	Int		3.16	
TN	1	$SUD_{CattleBeef}$	77.05	0.62
	2	HG	4.26	0.68
	3	PF	5.16	0.69
	4	SC_{95}	1.80	0.72
	Int		−33.95	
NO_3	1	$SUD_{CattleBeef}$	86.15	0.58
	Int		62.65	
TP	1	$SUD_{CattleBeef}$	5.47	0.41
	2	PF	0.64	0.52
	Int		7.75	
DRP	1	$SUD_{CattleBeef}$	2.23	0.31
	2	PF	0.38	0.48
	Int		1.14	

SUD = density dairy and beef
PF = plantation forestry

Our freshwater crisis – the causes

"The greatest negative impact on river water quality in NZ in recent decades has been high-producing pastures that require large amounts of fertiliser to support high densities of livestock"

Julian, J.P., de Beurs, K.M., Owsley, B., Davies-Colley, R.J., and Ausseil, A.G.E. (2017) River water quality changes in New Zealand over 26 years: responses to land use intensity. Hydrology and Earth System Sciences 21(2), 1149-1171. (page 1167)

Our freshwater crisis – the causes

- "The downstream effects from farms are leading to chaos and huge damage to the environment and people's health in New Zealand ....
- matching stock numbers to pasture growth is the secret, and keeping the two in balance will limit greenhouse gas emission as well".
- "Any animal additional to what a farm's pasture can support will be a cost and not add to profit".
- Imere Fidler http://www.3.nzherald.co.nz/the-country/news/article.cfm?c_id=18&objectid=11891043 http://www.nzherald.co.nz/index.cfm?objectid=11907054&ref=twtnzh

Our freshwater crisis – the causes

Dairy in NZ 2017:

- "Decisions which seemed justifiable to many at the time, now, with hindsight, look decidedly flawed"...
- "The consequence is that we have the wrong cows, the wrong dairy systems, the wrong product mix, a raft of environmental issues, and too much debt...
- ...perhaps most important, is dairy has lost its social licence from the broader community".

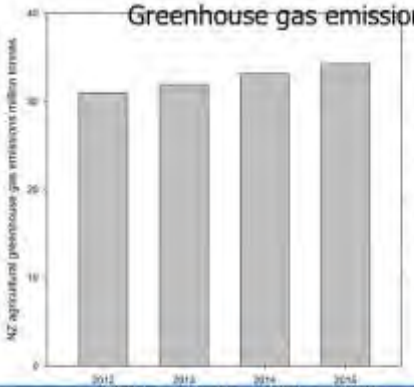
- Lincoln University agri-food systems Professor Keith Woodford

NZ dairy externalities

'Back of the envelope' insights - 2014 SCION

		Forest	Dairy
	Hectares	28,000	26,600 grazable
LAND	Land value	10,000 $/ha	35,100 $/ha
	Yield/unit	678 m³	950 kg milk solids/ha
	Price range	89 to 102 $/m³	5 to 9 $/kg milk solids
PROFIT	Surplus range	22 to 32 million $/yr	-6 to 96 million $/yr
	Profitability of labr	0 %	13 %
	Manufactured Product	67,550 t pa	38 million kg whole milk
		275,268 green tonnes m³	
	30-year avg. export price	737 $/t	7 $/kg milk solids
		404 $/m³ timber	5 $/kg whole milk
	Manufacture&exports	181 mill $/yr	179 million $/yr
	Employment: Upstream	88 emp/forest/yr	415 emp/farm/yr
	Downstream	330 emp $/yr	375 emp/plant/yr
	Phosphorus	0.05 kg/ha/yr	1 kg/ha/yr
	Nitrogen discharge	3 kg/ha/yr	54 kg/ha/yr
	Nitrogen price	400 $/kg	400 $/kg
	Carbon emitted/stored	11 t CO_2e/ha/yr seq	10 t CO_2e/ha/yr emitted
	Carbon price	7 $/t CO_2e	7 $/t CO_2e
EXTERN	Externality	31 million $/yr	18 million $/yr

Greenhouse gas emissions from Ag



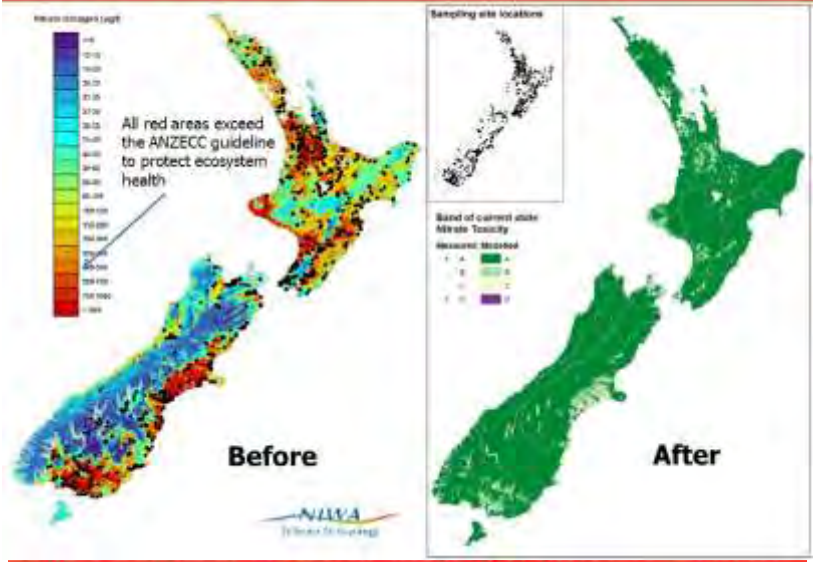
New Zealand's greenhouse gas emissions are set to double between 1990 and 2030 – and even with a carbon price of $50 a tonne, we could still be short of our Paris Agreement pledge by 143 million tonnes. (~ 2-3 years worth)

	Yield: Total (t) / ha	Yield: Gross Energy (GJ) / ha	Yield: Protein (kg) / ha	GHG emission (kg CO_2 Eq.) / tonne of product	FCA Energy input (GJ) / tonne of product	Water use (lt produced from irrigation) (litres) / kg of product
NZ Dairy	1.2	35	500	10,000	20	10,000
NZ Arable (wheat)	7.5	120	800	700	2.5	250

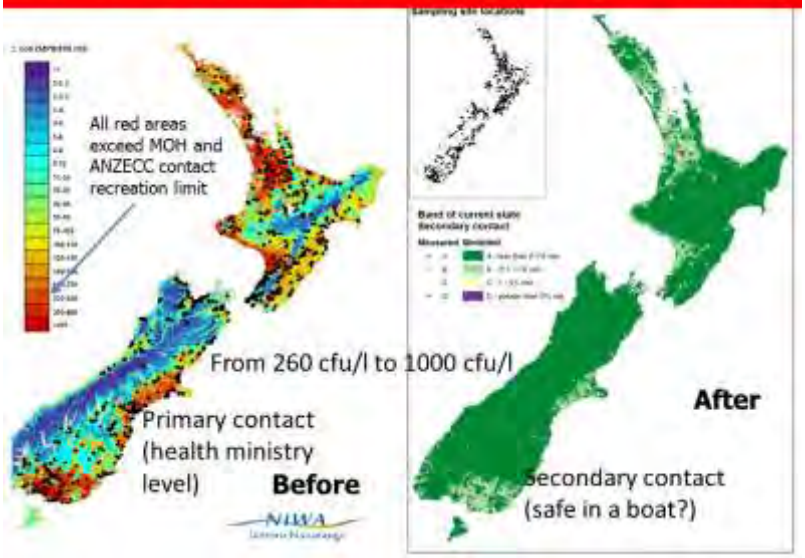
The government/industry resposnse to the crisis?

Exempt agriculture from ETS, the National Policy Statement – "a freshstart for freshwater?

"A fresh start for freshwater" NPS objectives 2014: (making the problem disappear)



"A fresh start for freshwater" NPS objectives 2014: (making the problem disappear)



The government response to the crisis the NPS

Just added MCI but severely polluted is bottom line and requirement is to maintain or improve

What is not in the National Objectives Framework:
meaningful ecosystem health limits or measures, physical impacts, groundwater, estuaries, offshore impacts, benthic cyanobacteria, pathogens, clarity.

Social license?

majority or respondents said of all New Zealand features lakes and rivers worst managed & 2/3rds believed that dairy farming was culprit (NZ Geographic)

What will fix the problems and get the social license back?

- The NPSfw?
- Will voluntary accords and farmer initiatives? (97% fenced and billions spent by farmers)
- Clean-up funding?
- What about the global situation?

Food production now – the threats to social license

Worlds land mammals by weight

Smil, V. 2003. The Earth's Biosphere: Evolution, Dynamics, and Change The MIT Press

Graph by Shaun Lee

So what will give the social license back?

Carrots, sticks or disruption?

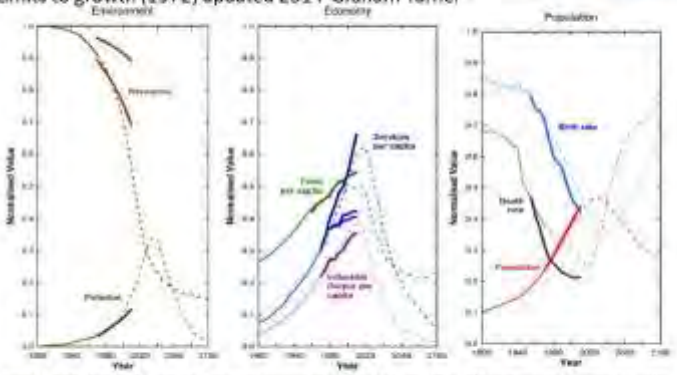
The future

- WARNING - global head of agribusiness at KPMG Ian Proudfoot is predicting a milk price decline. He said soon there will soon be 10 or more non-animal based protein or nutrition options competing with milk in supermarket chillers
- When it comes to the environment the regulators are not setting rules now consumers are, and the consumers demands will make the regulators rules seem easy - "we can whinge and man about it in the end consumers will win".

Solutions:

We can have managed change or continue to stick our heads in the sand the choice is ours, do nothing and it wont be a nice end

Limits to growth (1972) updated 2014 Graham Turner



Thanks to:

Massey University

Freshwater activist friends students & colleagues all over New Zealand

Experiences from the United Kingdom on a Concordat on Openness on Animal Research

Roger Morris
King's College London, United Kingdom

In the United Kingdom, consideration of whether and how experimental animals should be used in research has gone from violent confrontation and intimidation to civilised discussion and rationally-defensible practice. How this change in social license came about is summarised below. I use the acronym ALF (Animal Liberation Front) to cover all militant anti-vivisectionist groups operating in the UK at that time.

Phase 1: Prior to 2005, violence was threatened and delivered via car bombs and beatings. A few scientists spoke publically about their research (e.g. Colin Blakemore at Oxford University and Clive Page at King's College London) but overall the response of the scientific community to head-line grabbing images and films of cruelty to experimental animals was intimidated silence. A national anti-terrorist unit was formed, and by August 2005, all violent protesters were jailed. In the view of the police, a return to violence was very unlikely, but organised mass protests remained.

Phase 2: Despite the police assurances, the scientific community and university leadership remained reluctant to explain the use of animals in research. The Science Media Centre (SMC)[1] and Understanding Animals in Research (UAR)[2] sponsored by Research Councils, Wellcome and the pharmaceutical industry, set out to find scientists who would carry the argument publically. I became involved.

It was clear, with every interview and press article, that the more general failure of scientists to engage on this topic led journalists, the public, and our university students, to believe that experimental animals suffered the range of distressing experiences portrayed by the ALF, leaving the public to question whether animal suffering could be justified by the resulting medical advances. There was no public appreciation that the vast majority of experimental animals suffered little or no pain, nor any appreciation of the extent to which alternative approaches led the way in most experimental programmes, with living animals used only to gain information that could not be obtained in isolated preparations.

Led by the SMC and UAR, we went on the attack. The annual publication of animal usage, at that point showing marked annual increases as transgenic animals expanded the range of *in vivo* experimentation, had been the cue for the ALF to issue uncontested press releases. The SMC organised a press conference at which the Home Office Chief Inspector gave the overall figures, complemented by a couple of scientists who explained the underlying research, thereby converting the accompanying press coverage from being dramatically negative, to being reasoned and positive. The annual press conference continues to this day. The more pro-active approach was expanded by scientists working with science journalists to produce thoughtful articles explaining the role of experimental animals in various research programmes and their contribution to treatment of human disease[3]. By November 2008, when Oxford's new animal facility was opened, an event that had been targeted by the ALF, Oxford scientists spoke openly about their work (including with primates) to the press, describing a very different situation from that depicted by the protesters. The days of uncontested claims of cruelty were over; scientists (including two highly articulate PhD students at University College London) increasingly explained their research to the press.

[1] http://www.sciencemediacentre.org/

[2] http://www.understandinganimalresearch.org.uk/

[3] http://www.independent.co.uk/news/science/of-mice-and-medicine-in-defence-of-animal-experiments-2372843.html

Phase 3: Full Transparency in Practice: These interviews alone failed to convince the public, who demanded proof, not assertion, that experimental animals were well cared for. A turning point came in 2008 when King's College London allowed small groups of MPs and press to visit their animal houses and see the state of the experimental animals. We invited the Home Office Minister in charge of animal experimentation, along with other interested MPs and interested journalists, to visit our animal houses, and in particular to visit the marmoset unit since this was undoubtedly the most contentious unit at King's College London, in which marmosets rendered Parkinsonian by an injection of MPTP were used to optimise the regime of delivery of L-Dopa to human Parkinson patients. This is well described by Robin McKie in the Guardian[4]. These visits notably converted politicians and journalists from antagonism to support for this research, seen for instance in an initial *Mirror* article dictated by anti-vivisectionist propaganda[5] being followed by a far more informed and measured description[6] after we invited the journalist and his sub-editors and their photographer to tour and film in the marmoset unit. This approach has been followed by other universities (see UAR website). For instance, when Leicester University prepared to open its new animal facility, only to find the anti-vivisectionists were mounting a major demonstration, they invited the Mayor and councillors, and the local press, to inspect the facility, see the animals, and learn about their use. This completely defused the anti-vivisectionist protest, gained very positive local and national support, and continues with tours arranged for local school groups[7].

Phase 4: Concordat on Openness on Animal Research: The drive to formalise an agreement between researchers, funders and the public on transparency of research involving animals grew, led by UAR and the SMC working closely with the Wellcome Trust, MRC and BBSRC, and Government. It emerged in stages, from 2005 on. Appendix A is a 2012 statement of commitment to producing the Concordat, signed by 15 universities, 9 major funders, 5 major pharmaceutical firms, and 11 professional organizations. The resulting 2014 Concordat, now with 116 signatures, can be found at https://www.cam.ac.uk/files/concordat.pdf . On-going information on the state of the Concordat is provided at http://www.understandinganimalresearch.org.uk/policy/concordat-openness-animal-research/.

Phase 5: Facilitating a broader cultural change. Stages 2-4 have dealt with larger scale press and institutional changes. Concomitant with them were changes at the institutional level in explaining the role of animals in research in outreach programmes and our science courses. The BBSRC, jointly with the pharmaceutical industry, funded 3 lectureships at King's College London (and a few other universities) specifically for scientists who used *in vivo* methods in physiology and pharmacology, with the condition that they would actively engage with the public at all levels. They did so very effectively, *inter alia* putting on dissection classes using animals killed for other reasons, and devising an ingenious kit to demonstrate cardiovascular physiology and pharmacology on water fleas. This was initially in outreach sessions but has now been scaled up for schools. In our teaching courses we explain the role of animal experimentation. There has been a notable change in our relationship with our students and the wider public, with trust and respect of science and scientists restored.

Over the period from 2005 on, the major obstacle to transparency in the use of animals in research has usually been institutional caution. Scientists and the animal house technicians have had to take the lead, first in convincing their institution to allow them to speak publically, and further to open their facilities where possible to interested groups of press, MPs and the public. Not all signatories of the Concordat have actively supported their scientists in making their research transparent, but overall the effect is very apparent.

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[4] https://www.theguardian.com/science/2013/oct/13/lab-where-marmosets-are-given-parkinsons

[5] http://www.mirror.co.uk/news/uk-news/five-britains-top-universities-named-7283980

[6] http://www.mirror.co.uk/news/uk-news/see-inside-monkey-testing-centre-3618664

[7] http://www2.le.ac.uk/offices/press/press-releases/2014/march/biomedical-research-facility-with-animals-opens-its-doors-to-schools-for-the-first-time

Conclusion: The atmosphere in which the debate on the appropriate use of animals in research in the UK has changed remarkably over the past decade. The IPSOS-Mori poll of public opinion shows only a third of the public think they are effectively informed, but on a subject like this, one third is probably near-maximal[8]. It has required individuals to provide the initial lead, and opportunities for publicity to be grasped, but the current breadth and effectiveness of the commitment to transparency is very evident in the UAR web site. This is a far more positive and sustainable social license for biological/biomedical science than was the case up to 2005.

[8] https://www.ipsos.com/ipsos-mori/en-uk/attitudes-animal-research-2016

Appendix A:

Declaration on Openness on Animal Research

The life sciences sector is at the forefront of developing ground breaking treatments and cures which transform the lives of humans and animals. To do this we need to increase understanding of normal biological functions and disease. Where possible, we use cells grown in a lab, computer models and human volunteers. When this isn't possible, research may involve animals. When we need to use animals, we strive to reduce the number needed, and seek to develop viable alternatives.

Public acceptance of the use of animals in research has been strong over the last decade. Public scrutiny has also played an essential role in building the world-leading ethical framework that supports our research and ensures it meets the highest welfare standards, only using animals where no alternative exists.

Confidence in our research rests on the scientific community embracing an open approach and taking part in an on-going conversation about why and how animals are used in research and the benefits of this. We need to continue to develop open dialogue between the research community and the public.

We, the undersigned, commit to work together to establish a Concordat that will develop principles of openness, practical steps and measurable objectives which will underpin a more transparent approach to animal research.

Painful truths: what systematic reviews reveal about the utility of animal research

Andrew Knight
SAFE, PO Box 28110, Kelburn 6150, Wellington 6011, New Zealand

After standardising to match European Union (EU) definitions of animals and experimental procedures, it was estimated that 127 million living non-human vertebrates were used worldwide for scientific and educational purposes in 2005. This remains the most robust, evidence-based global estimate available (Knight 2008a; Taylor *et al.* 2008). The figures for Australia and New Zealand were 2.4 million and 261,000 respectively, making them the fourth and 28th-largest national users of laboratory animals in 2005 (Knight 2013).

The most recent figures at the time of writing described 2015. 9.9 million animals were used in Australia (HRA 2016), and 225,000 animals were used in New Zealand (MPI 2016), although these latter figures have not been standardised to match EU definitions. The Australian figure, for example, was increased by NSW counting 4.1 million native animals used in environmental studies which involved observation only (HRA 2016). Clearly, very large numbers of animals continue to be used within Australian and New Zealand research.

Additionally, animal research incurs other costs. The very substantial financial and scientific resources consumed by animal research are consequently unavailable to other fields, some of which – such as preventative healthcare or human clinical research – might well be expected to produce substantial public health benefits.

Ongoing societal approval for the use of these animals and research resources rests on the principle that the subsequent benefits are substantial, and represent the best use of limited research resources. However, the best available evidence indicates that much animal research fails to meet these standards.

Clinical and toxicological predictivity of animal research

A large number of systematic reviews of animal research have examined its utility for advancing human healthcare. Of 20 published systematic reviews examining human clinical utility located during a comprehensive search, animal models demonstrated significant potential to contribute toward clinical interventions in only two cases, one of which was contentious. Seven additional reviews failed to demonstrate utility in reliably predicting human toxicological outcomes, including those associated with the greatest public health concerns, such as carcinogenicity and teratogenicity. Results in animal models were frequently equivocal, or inconsistent with human outcomes (Knight 2011).

Numerous additional reviews have since yielded similar results. Baker and colleagues (2014) examined human neurological diseases. Extensive animal studies have yielded relatively few human treatments (Cheeran *et al.* 2009; Vesterinen *et al.* 2010). Similarly, despite the efficacy of over 1,000 treatments in animal models of multiple sclerosis, very few have progressed to the marketplace (Vesterinen *et al.* 2010). This usually indicates concerns about human safety or efficacy. Numerous other examples exist (e.g. stroke studies: Cheeran *et al.* 2009).

Limitations of animal models

A variety of factors appear responsible for poor translation of animal outcomes into human patients. These limitations arise both from the animal models themselves, and from the ways in which they are used.

Fundamental biochemical differences result in interspecies differences in absorption, distribution, metabolism, and elimination pathways or rates, which may alter *toxico- or pharmacokinetics* (i.e. bodily distribution). *Toxico- and pharmacodynamics* (mechanisms of action and biological effects) may be similarly affected. Jointly these factors may alter organ systems that are impacted, and the nature and magnitude of those effects (Hartung 2008; Knight 2011).

Biological variability and predictability for diverse human populations are frequently compromised by restriction to single rodent strains, young animals, and single sexes. Common human co-morbidities and lifestyle risk factors are usually lacking (Hartung 2008; Knight 2011).

Additionally, many toxicity tests rely on *maximum tolerated doses* (above which acute toxicity-related effects preclude further dosing), and chronic dosing. Whilst maximising sensitivity to toxins, thereby minimising false negative results, these conditions can also overwhelm physiological defences effective at more environmentally realistic doses, resulting in false positive outcomes (Gold *et al.* 1998; Hartung 2008; Knight 2011).

Furthermore, animals used in laboratories commonly experience a significant array of stressors incurred during handling, restraint, and other routine laboratory procedures, and particularly, the stressful routes of dose administration common to toxicity tests. Combined with environmental stressors (e.g. due to limited space and environmental enrichment) and social stressors (e.g. due to aggressive interactions between conspecifics), these represent a significant body of stressors. These can alter physiological, hormonal, and immune status, and even cognitive capacities and behavioural repertoires, in ways which are not always predictable (Balcombe *et al.* 2004; Balcombe 2006; Baldwin & Bekoff 2007).

Flaws of study design and conduct

Additionally, numerous recent studies and systematic reviews have confirmed the existence of significant methodological flaws, in most published animal experiments (e.g. Knight 2008b). Indeed, no systematic reviews have demonstrated that a majority of animal studies, when assessed against appropriate objective criteria, were of good methodological quality.

In particular, a number of design features must be included within animal experiments, to minimise the potential for bias. Hoojimans *et al.* (2014) described 10 types of bias that have the potential to influence animal experimental results, which they grouped into selection bias, performance bias, detection bias, attrition bias, reporting bias, and other sources of bias.

Many of these flaws are highly prevalent within animal studies. Kilkenny and colleagues (2009) conducted one of the largest and most comprehensive systematic surveys to date, assessing the experimental design, statistical analysis and reporting of 271 published animal experiments. Some were funded by leading grant agencies within the United Kingdom and United States.

Details such as animal strain, sex, age and weight are all scientifically important and can potentially influence results (Obrink & Rehbinder 2000; Alfaro 2005). Nevertheless, in many cases these were omitted.

Knowledge of planned treatment (or lack thereof) is one of a number of factors that can unconsciously influence the assignment of animals to treatment groups. Accordingly, randomised selection of animals for treatment groups is mandated, to ensure that outcome differences are most likely due to treatment effects (Festing & Altman 2002; Festing *et al.* 2002). Nevertheless, such randomisation was reported in only 12% of these studies.

Another crucial feature of good experimental design concerns the assessment of outcomes. Where qualitative judgements occur, it is crucial that assessors are blinded to the treatment (or lack, thereof), of animals assessed – lest such knowledge subtly affects their judgement (Festing & Altman 2002). Nevertheless, only 14% of all papers that reported qualitative assessment of outcomes, also reported the use of blinding. More recently, similarly low rates of measures designed to minimise bias were found in an even larger study (Vogt *et al.* 2016).

Many factors can affect experimental outcomes, so the incorporation of measures to minimise sources of bias are crucial to ensuring the reliability of research results. Animal research reviews from the field of emergency medicine have demonstrated that estimates of treatment efficacy are significantly reduced in studies that incorporate mechanisms to reduce risks of bias (Bebarta *et al.* 2003; Macleod *et al.* 2008). Similar results have been found in numerous other studies. Animal studies incorporating the fewest measures to minimise bias tend to report the greatest effect sizes, demonstrating that such effects are not entirely real, and are partly due to bias (Macleod *et al.* 2005; Crossley *et al.* 2008; Vesterinen *et al.* 2010; Rooke *et al.* 2011; Hirst *et al.* 2014). The widespread failure to utilise mechanisms such as randomisation and blinding appears to result in false expectations of treatment efficacy, with the results that reported outcomes in animals often fail to translate into humans.

Another problem commonly observed by Kilkenny et al. (2009) concerned the transparency of reporting, and the robustness of statistical analysis. Almost 60% of surveyed publications were deficient in these areas. Most studies failed to provide sample sizes, or adequate justifications of these. And yet, studies using too many animals waste lives. Conversely, the results of underpowered studies (with insufficient experimental subjects) cannot be extrapolated to wider populations with sufficient certainty. Accordingly, power analyses or other simple calculations are widely used in human clinical trials, to ensure sufficient subjects (but few extras) are present, to be able to detect biologically important effects. The same principles should apply to animal studies (Dell *et al*. 2002; Festing & Altman 2002).

Improving research quality

In 2010 Kilkenny and colleagues proposed the Animal Research: Reporting of In Vivo Experiments (ARRIVE) guidelines. These comprised a checklist of 20 items, designed to provide minimum information on experimental variables such as the number and characteristics of animals used (such as species, strain, sex, and genetic background); housing and husbandry conditions; and the experimental, statistical, and analytical methods employed. Multiple measures to reduce bias were listed, including random allocation of animals to experimental groups, blinded outcome assessment, statistical justifications of sample sizes, and the reporting of animals excluded from analyses, exclusion criteria, and any investigator conflicts of interest.

Kilkenny et al. proposed that these items should be included within all scientific publications reporting animal research, thereby allowing critical assessment of methods and results. Other authors have proposed similar guidelines and checklists (e.g. Hoojimans et al. 2010).

The ARRIVE Guidelines have since been endorsed by over 1,000 research journals (including those published by the Nature Publishing Group, PLoS, and BioMed Central) (Reichlin *et al.* 2016). They have been endorsed by major UK funding agencies (including the Wellcome Trust, the Biotechnology and Biological Sciences Research Council, and the Medical Research Council), and they also form part of the US National Research Council Institute for Laboratory Animal Research guidelines (Baker *et al.* 2014).

Despite this, a number of studies have demonstrated that compliance with such guidelines remains poor (Baker & Amor 2012; Landis *et al.* 2012; Schwarz *et al.* 2012; Reichlin *et al.* 2016).

Compliance with each of the 3Rs, and with the ARRIVE guidelines and other best practice standards, during the design, conduct and reporting of experiments, should be mandatory. Standards should cover animal sourcing, housing, environmental enrichment, socialisation opportunities, appropriate use of anaesthetics and analgesics, handling, non-invasive endpoints, and a range of measures to minimise bias and ensure methodological quality. Full compliance should be necessary for securing research funding, ethical approval, licencing of researchers, facilities and experimental protocols, and publication of subsequent results.

Measures such as these would all increase the reliability of research results, and would facilitate their use within systematic reviews. It might allow us to accurately predict treatment effects within the animal species under study, and to address the current inability to reproduce many animal study results (Reichlin et al. 2016).

However, interspecies differences will still remain in absorption, distribution, metabolism, and elimination pathways or rates, resulting in differing toxico- or pharmaco- kinetics and -dynamics, and subsequently, differences in the organ systems affected, and in the nature and magnitude of those effects. Such factors, which reflect the intrinsic complexity of living organisms, will continue to pose barriers to extrapolation to humans, that may remain insurmountable, in many cases.

Conclusions

Animals are rarely responsible for human health or societal challenges, many of which are of our own making and preventable. Animal advocacy organisations such as SAFE, along with numerous animal ethicists (e.g. Regan 1987; Nobis 2011), do not consider it ethical to harm animals in our attempts to address these.

Nevertheless, millions of animal lives are annually consumed by animal research, along with very substantial research and financial resources, which are subsequently unavailable for human clinical or other research fields. Inaccurate human predictions resulting from poorly designed animal studies threaten patient and consumer safety, delay the development of efficacious clinical interventions, and deny potentially useful chemicals to society.

The essence of the scientific method is a willingness to engage in critical scrutiny - even of one's own practice. Instead of uncritically assuming the benefits of animal research, researchers should subject it to much more rigorous and critical evaluation. Poorly designed, conducted and reported animal research should never be considered acceptable. A broad range of measures should be implemented to substantially improve methodological quality and 3Rs compliance, and to maximise reliability of subsequent results (Knight 2011).

Social license to conduct animal research depends on ensuring that the societal benefits exceed its very substantial costs. Where such research fails to meet the harm-benefit standards expected by

society it should clearly cease, with resources directed into more promising and justifiable fields of research and healthcare.

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Legal perspectives on social license

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Research, testing and teaching involving non-human animals (RTT) in New Zealand is almost completely regulated by Part 6 of the Animal Welfare Act 1999, and it is recognised as one of the most progressive RTT regimes in the world.
[1] Those involved in RTT, might thus reasonably expect that both the regulation of RTT and this international recognition are sufficient to guarantee the societal perception of RTT as a legitimate activity. Few researchers, however, would agree that society as a whole views RTT in a positive light, and indeed, a majority are "bothered" by the use of animals in RTT.[2]

One explanation for the gap between the legality of RTT and the lack of social acceptance is a deficiency in 'social license'. This paper will first explain the concept of social license, why a gap between social license and legal license is an issue, and finally, how legal reform has and can assist in securing that social license.

Defining social license

'Social License' or its equivalent 'Social License to Operate' is a relatively new concept, having its origin in the mid-1990s in mining, oil and gas development.[3] Although it takes a variety of different forms, this paper will assume the 'three-strand' model adapted by John Morrison (Morrison 2014). This model of social license sees the legitimacy of an activity as not only contingent on *legal license* (legal permission to undertake an activity), but also *political license* (where necessary, governmental permission to undertake an activity) and *social license* (community permission to undertake an activity).[4] This means that despite possessing legal authority to engage in an activity, that activity will nevertheless lack true legitimacy until it has community understanding and acceptance.

Initial scepticism of the concept is perhaps understandable. As Luke Malpass (Malpass 2013) has noted: "New Zealand already has a 'social license to operate' and it is made up of laws passed by Parliament, consisting of elected representatives and the courts that enforce them. For anyone caring about the rule of law, the social license is a concept that should be viewed with suspicion."[5] However, as Morrison notes, if legal license was all an activity needed to secure legitimacy, the dilemmas facing organisations engaging in 'controversial' activities would not exist.[6] As I will explain in the next section, social license is a useful way of explaining why different uses of animals attract different levels of controversy, despite each having legal license.

[1] See for example, the World Animal Protection Index, which gives New Zealand an 'A' ranking for its legislative provisions involving animals in research (accessible at http://api.worldanimalprotection.org/sites/default/files/api_new_zealand_report_0.pdf).
[2] Williams VM, Dacre IT & Elliott M (2007) 'Public attitudes in New Zealand towards the use of animals for research, testing and teaching purposes' 55 *New Zealand Veterinary Journal* 61, 65.
[3] 'Gehman J, Lefsrudm LM., Fast' S (2017) 'Social license to operate: Legitimacy by another name? 60 *Canadian Public Administration*, 293, 293.
[4] Morrison J (2014) *The Social License: How to Keep Your Organization Legitimate* (Palgrave MacMillan), 18-23.
[5] Malpass L (2013) 'Rule of Law or Social License to Operate' *The National Business Review*, 16 August 2013, accessible at https://nzinitiative.org.nz/insights/opinion/rule-of-law-or-social-license-to-operate/
[6] Morrison, above n 4, 18.

Social license and animals

It is clear that, if the owner of a companion cat fulfils his or her obligations under section 10 of the Animal Welfare Act 1999 – namely ensuring that the physical, health, and behavioural needs of the cat are met – that owner has legal license to own and care for the cat. More than this, however, the owner has *social* license to do so. Owning and keeping a cat as a companion is a common and socially acceptable practice. This makes her activity – owning a cat – truly legitimate. Legal license and social license in this regard operate in synergy: the owner who neglects his or her cat not only loses legal license (insofar as such neglect is a breach of section 10 of the Animal Welfare Act) but also loses social license, since neglect of companion animals is unacceptable to most in the community, and attracts significant admonition and opprobrium.

Not all uses of animals enjoy such synergies between legal and social license. For example, in recent years, uses of animals in rodeo events has arguably lost significant amounts of social license where once it enjoyed widespread support (or at least, indifference).[7] This is notwithstanding the legal license for rodeo events has remained unchanged during this period, or if anything, increased after the Code of Welfare for Rodeos (specifying best practices and minimum standards for rodeo under the Animal Welfare Act 1999) was instituted in 2014.[8] Similarly, where the use of bobby calves in dairy farming was once uncontroversial, revelations and exposure of several incidents in 2015-2016 led to "public revulsion" over the "rough-handling" of bobby calves.[9] In contrast to the rodeo example above, however, the withdrawal of social license consequently led to the withdrawal of legal license. In response to the incidents (and public opprobrium) new, specific regulations were promulgated to prohibit the conduct in question.[10] Evidence of the rapid shift in social and legal license is evinced by "hundreds" of dairy farmers in Taranaki alone being unable to meet the requirements of those regulations when they were introduced on 1 August 2017.[11] This indicates that hitherto socially and legal acceptable practices first became socially unacceptable, but then also legally unacceptable with the former driving the latter.

These examples demonstrate a link between social and legal license, and the reaction of those groups affected by the withdrawal of that social license regarding the bobby calf issue indicated such a link: eight different industry representative groups worked with government in response to the revelations.[12] Whereas that may simply be implicit acknowledgement of the importance of social license, its recognition is increasingly explicit, with Australian Dairy Farmers noting that "having a social license to operate involves not only doing what we think is the "right thing" for the environment,

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[7] SPCA New Zealand (2016) 'Survey shows many Kiwis support rodeo ban' 29 August 2016, https://www.rnzspca.org.nz/news/38-press-releases/408-survey-shows-many-kiwis-support-rodeo-ban

[8] National Animal Welfare Advisory Committee, *Code of Welfare: Rodeos* (accessible at: https://www.google.co.nz/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwiW5tvR0cHWAhWBmJQKHcEXAuMQFggqMAA&url=https%3A%2F%2Fwww.mpi.govt.nz%2Fdmsdocument%2F4810-rodeo-animal-welfare-code-of-welfare-2014&usg=AFQjCNGfqeNeQ8DR_sU4koFf9PvopTn3bw

[9] Stuff.co.nz, 'Heavy hitters come out to ban rough handling of bobby calves' 4 December 2015, http://www.stuff.co.nz/business/farming/dairy/74764184/heavy-hitters-come-out-to-ban-rough-handling-of-bobby-calves .

[10] Animal Welfare (Calves) Regulations 2016.

[11] RNZ National 'Hundreds of farmers won't meet bobby calf laws', 31 March 2017, http://www.radionz.co.nz/news/country/327875/hundreds-of-farmers-won%27t-meet-bobby-calf-laws

[12] DairyNZ, the Meat Industry Association, Federated Farmers, the Road Transport Forum, the New Zealand Petfood Manufacturers Association, the Dairy Companies Association of New Zealand, the New Zealand Veterinary Association: Stuff.co.nz, 'Heavy hitters come out to ban rough handling of bobby calves' 4 December 2015, http://www.stuff.co.nz/business/farming/dairy/74764184/heavy-hitters-come-out-to-ban-rough-handling-of-bobby-calves .

animal welfare, and food and nutrition but also ensuring our industry has the confidence and trust of communities on environmental, social and economic issues."[13]

Accordingly, whether formally or not, it is clear that social license has the capacity to explain the gap between a legal ability to engage an activity, and the community's perception of the legitimacy of that activity. RTT has had an almost overwhelming legal license for its entire existence in New Zealand. There was a complete exemption for any "bona fide research worker" from the provisions of the Animal Protection Act 1960,[14] and only in 1987 were regulations introduced to create the precursor of the system we have today.[15] Part 6 of the Animal Welfare Act, in allowing decentralised and individual decision-making on RTT applications by Animal Ethics Committees (AECs) (subject to certain criteria),[16] whilst simultaneously providing for centralised oversight by the National Animal Ethics Advisory Committee (NAEAC),[17] is a sophisticated legal framework. In addition, by providing for the 3Rs as a lodestar and purpose of the entire regime, it has progressive credentials.[18] If legal license sufficed to guarantee the legitimacy of an activity, then the presence of Part 6 ought to ensure that the public recognise and accept the RTT regime as legitimate. Of course, in reality, there is a legitimacy gap: numerous groups oppose the very existence of any RTT in New Zealand, and the first "top of mind" thoughts that New Zealanders have about RTT are the cruelty it poses to the animals involved (34 per cent) or simply not agreeing with the practice (22 per cent).[19] Despite having legal license, this public opposition means that RTT does not have sufficient social license to be considered truly legitimate.

The law: inhibiting and enhancing social license

The work undertaken by Williams et al (Williams *et al.* 2007) in their survey of public attitudes toward RTT in New Zealand shows there is a correlation between this lack of social license and the knowledge of the RTT regulatory system.[20] The sophistication of the legislative framework surrounding RTT is perhaps a factor: individual decisions on RTT applications are often hidden from the public, and are instead reported as part of globalised statistics compiled by NAEAC when undertaking its oversight function.[21] The headline numbers in those statistics – and sometimes the sensational aspects in the statistics – are often the only information about RTT conveyed to the public on a regular basis. Accordingly, when the 2015 Animal Use Statistics were released in December 2016, the *New Zealand Herald* reported that two cheetahs were used in research and 225,310 animals were used in RTT overall.[22] Since that information came from global statistics, there was no information about how the cheetahs were used in RTT and, moreover, that headline number was not broken down by category or intensity. The information asymmetry that results from such reporting, combined with the general lack of knowledge about RTT – only eight per cent in Williams et al's (Williams *et al.* 2007) survey knew "a lot" or a "fair amount" about the legislative framework – goes a long way to explaining why there is a lack of social license in this area. The sophistication of the RTT framework leads to opacity, and that opacity hinders the knowledge required to secure social license for RTT.

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[13] Australian Dairy Farmers: http://www.australiandairyfarmers.com.au/policies-and-project/animal-social-license-to-operate

[14] Animal Protection Act 1960, s 19(1)(d).

[15] Animal Protection (Codes of Ethical Conduct) Regulations 1987.

[16] Animal Welfare Act 1999, s 100.

[17] Animal Welfare Act 1999, s 63.

[18] Animal Welfare Act 1999, s 80.

[19] Williams *et al.* 2007, above n 2, 64.

[20] Williams *et al.* 2007, above n 2, 67.

[21] Ministry for Primary Industries (2015) 'Statistics on the Use of Animals in Research, Testing and Teaching in New Zealand in 2015' www.mpi.govt.nz/document-vault/15346 .

[22] *New Zealand Herald* (2016) 'Cheetahs used in New Zealand animal research', 24 December 2016 http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11770984

However, if this legislative framework partially contributes to the lack of social license, legislative reform also provides an example of how the law can secure social license. Since the enactment of the Animal Welfare Act in 1999, there have been three instances where legislative reform has created ad hoc exceptions to the permissible scope of RTT in New Zealand. In each instance, the public conversation surrounding that reform has indirectly secured social license for the RTT *not* the subject of reform: by discussing what RTT the public deems impermissible, there is tacit acceptance that the remaining scope of RTT is permissible.[23] Thus, the presumptive ban on RTT involving non-human hominids in 1999,[24] the ban on animal testing of psychoactive substances,[25] and the ban on animal testing of cosmetic testing,[26] whilst all discrete, ad hoc exceptions to New Zealand's RTT regime, cumulatively assist in demarcating the permissible scope of RTT – that which has greater (but not absolute) social license.

The presumptive ban on RTT on non-human hominids and ban on RTT for cosmetics were undeniably symbolic: New Zealand never has – and was not planning upon – using non-human hominids in RTT[27] or animals for cosmetic testing. However, symbolism remains important, and it is the conversation that surrounds such reform that is critical in securing social license. Regarding psychoactive substances, that conversation was pointed. SPCA Auckland spokesperson Bob Kerridge of SPCA Auckland stated that: "[psychoactive substances are] a product that is of no benefit to humans. In addition to doing considerable harm to the animals, it has no beneficial outcome whatsoever. Therefore, [the testing] should not be allowed."[28] The implicit premise of the statement is that other uses of animals for RTT are necessary and may have beneficial consequences. The public, in protesting against these specific instances of RTT – rather than protesting against RTT in its entirety – is likewise giving tacit acceptance and social license to the idea of RTT in general.

In contrast to the purely symbolic legislative reforms regarding non-human hominids and cosmetics, however, the ban on using animals to test psychoactive substances would have significant, real-world consequences. The ban essentially took the form of the Psychoactive Substances Expert Advisory Committee not considering any data that involved animal testing when considering such substances for approval.[29] Since this was the only data available to the Committee, this had the indirect effect of preventing any psychoactive substances from being introduced into New Zealand's regulated psychoactive substances market. The black market for such substances that flourished in the vacuum created by this state of affairs is widely considered to have led to unregulated and unapproved psychoactive substances causing a number of deaths.[30] Whilst the conversation about these unintended consequences of preventing RTT for psychoactive substances to date has been limited, it presents an excellent opportunity to engage with the public about issues surrounding RTT.

Regardless of whether these examples of legislative reform are symbolic or significant, they each show the capacity for the law to force a public conversation about the utility and desirability of RTT in general; a conversation that the existing legal framework ironically hinders. Viewed instrumentally in

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[23] Dixon-Woods M and Ashcroft RP (2008) "Regulation and the social license for medical research" *Med Health Care Philos* 11: 381-391; Olsson IAS, (2010) "Legislation, social license and primate research" *EMBO Rep* 11: 9.
[24] Animal Welfare Act 1999, s 85; see also Brosnahan P (2000)'New Zealand's Animal Welfare Act: What's its Value Regarding Non-Human Hominids ' 9 *Animal Law* 185.
[25] Psychoactive Substances Act 2013, s 12.
[26] Animal Welfare Act 1999, s 84A.
[27] Brosnahan 2000, above n 24, 191.
[28] Stuff.co.nz, 'Dogs facing death for legal highs' 2 December, 2012 http://www.stuff.co.nz/national/8025166/Dogs-facing-death-for-legal-highs
[29] Psychoactive Substances Act 2013, s 12.
[30] Stuff.co.nz, 'Psychoactive Substances Act could have prevented synthetic harm, says Dunne', 15 August 2017 https://www.stuff.co.nz/national/crime/95782397/psychoactive-substances-act-could-have-prevented-synthetic-harm-says-dunne

this way, researchers should embrace these moments of legislative reform and the opportunity they present to engage in thorough, detailed and non-sensationalised conversations about RTT.[31] Only through this public engagement will RTT secure greater social license than it presently possesses.

Conclusion

At first glance, 'social license' may seem a concerning example of corporate doublespeak, and it may indeed simply be a modernised term for the far more common and accepted idea of 'legitimacy' in organisational theory.[32] Nevertheless, applying Morrison's ideas of social license is a useful way to explain why there is a gap between the legality and community acceptance of some uses of animals but not others. As the bobby calf analysis above shows, those involved in activities where that gap is present ignore it – and the lack of social license – at their peril.

The law is partially responsible for the gap and the lack of social license in RTT. The complex legal framework regulating RTT is effective, but also leads to opacity. However, law reform in RTT shows what is required to reduce that gap, even if complete closure is impossible. The conversations surrounding that reform illuminated the purpose and ideas surrounding RTT, and this is what is critical to securing social license. Whilst Coleman (Coleman 2014) is undoubtedly correct that "it is simplistic to assume that better 'education' of the public will lead to more positive public attitudes to animal experimentation",[33] positive attitudes are not necessary for securing social license. A simple understanding from the community should suffice to ensure the gap between legal and social license does not grow to a dangerous level. As Williams et al (Williams *et al.* 2007) note about their survey respondents: "while a slight majority felt less comfortable when they learned about the numbers of animals used each year in New Zealand, nearly three-quarters of them felt more comfortable when the membership of an AEC was explained to them."[34] Understanding, and feeling comfortable, with New Zealand's sophisticated RTT legislative framework may be all that is required, and while legislative reform provides opportunities for that understanding to occur, undoubtedly it must also come from a willingness by NAEAC, AECs and researchers to be a little more open about what they do, and why they do it.

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[Note: a copy of Dr Rodriguez Ferrere's presentation can be found at https://prezi.com/view/CnmnjrRDLuRTCxCX9C83/]

[31] Olsson 2010, above n23.
[32] Gehman *et al.* 2017, above n 3, 301.
[33] G Coleman, 'Public attitudes to animal research' (2004) *Proceedings of the ANZCCART 2003 Conference*, 78, cited by Williams *et al.* 2007, above n 2, 67.
[34] Williams *et al.* 2007, above n 2, 67.

Trends in media coverage of animal research

Dacia Herbulock
Science Media Centre, New Zealand

Speaking publicly about animal research -- is it risky? Perceptions vary widely within the scientific community. Some voice concerns about attracting unwelcome attention or even becoming targets for animal rights extremists. Others champion the need to break with a tradition of secrecy and provide more and better information to the public.

Media coverage of issues relating to animal research can focus a sometimes uncomfortable degree of scrutiny on standard practices and extreme cases. However, the 2014 Concordat on Openness contends that maintaining public support for animal research requires a proactive approach from research organisations, including a commitment to enhanced communication with the media.

This talk explores these tensions through recent examples of media coverage of animal research in New Zealand and Australia, drawing on reflections from conversations with leading journalists and media officers on the front lines of these issues.

Dacia Herbulock is Senior Media Advisor at the Science Media Centre (New Zealand), an independent resource centre promoting evidence-based media coverage of emerging issues where science meets society. She joined the SMC at its launch in 2008, bringing experience in radio, film, documentary, television news and science writing in the United States, China and New Zealand.

She designs and delivers the Science Media Centre's national series of media training and science communication workshops for researchers. She also facilitates an ongoing series of newsroom 'expert encounters' that pair journalists with scientists to discuss issues like balance in media reporting of scientific evidence, conflicts of interest and emerging technologies.

In 2017, she joined Victoria University of Wellington as an Adjunct Research Fellow. Her research interests are in public perceptions of science and technology and developing evidence-based advice for science communication practitioners.

THEMES IN MEDIA COVERAGE OF ANIMAL RESEARCH

"it's an easy story"
"hatchet jobs do happen"
"slanted stories are a natural outcome"

"EXPOSING" SECRETIVE RESEARCH

The Sydney Morning Herald Environment

Baboons used in 'Frankenstein-like' medical experiments

Hundreds of primates have been imported into Australia for experiments, while animals are also bred specifically for medical research at the National Health and Medical Research Council baboon colony in Wallacia, in the west of Sydney, and marmoset and macaque colonies in Churchill, Victoria.

Otago Daily Times

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"Animal testing causes unnecessary pain and suffering in animals, and produces false results, which ultimately harms humans," he said.

University Deputy Vice-Chancellor Professor Richard Blaikie said the term "false results" was "extremely misleading".

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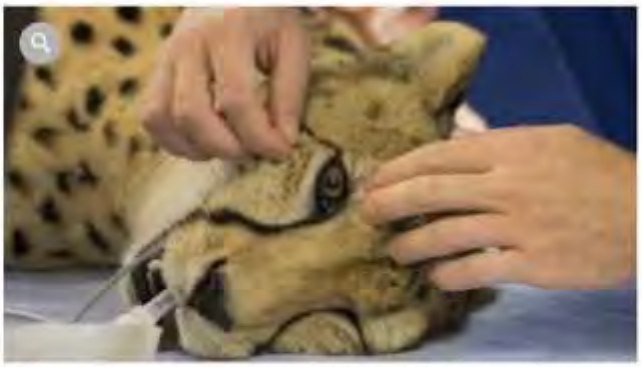
Cheetahs used in New Zealand animal research



By: Simon Plumb

"a bit like GMOs...seen as risky"
"it's like talking to anti-vaxxers"
"climate scientists get death threats too"

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Science
Opinion

You might find my research using monkeys abhorrent, but it could save your life

James Bourne

A parliamentary bill to ban the importation of monkeys for scientific research not only stimulates medical progress, but primes wellbeing

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MPs unanimously support animal testing ban

Updated at 1:35 pm on 1 April 2015

MPs have unanimously supported a ban on animal testing in New Zealand for finished cosmetic products and their ingredients.

stuff.co.nz

Campaign to stop animal test requirement

LAURA WALTERS
Last updated 14:51, May 25 2015

The New Zealand Anti-Vivisection Society is calling for a change to government regulations that support animal testing.

"pictures of animals suffering always cause a strong reaction"
"fraught for researchers"
"hard to win"

EMOTIVE IMAGES RATE WELL

NEW ZEALAND

Live pigs shot in head at University of Otago

IFLSCIENCE!

Pigs Shot In The Head For Science

9.9K SHARES Share on Facebook Share on Twitter

Daily Mail AUSTRALIA

Outrage as five live pigs are shot in the head with a handgun after being strapped to a table for New Zealand study into suicides

HUFFPOST

SCIENCE

Researchers Shot Pigs In The Head To See The Blood Spatter Patterns

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NEW ZEALAND

How did shooting pigs in head get go-ahead?

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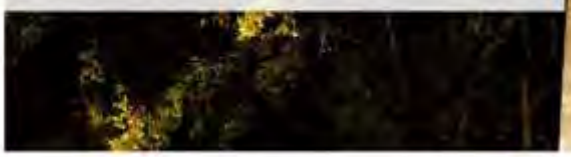
Forensics first for Masters student



When Masters student **Gemma Radford** was offered the chance to build a model of cranial back-spatter, wild horses probably couldn't have kept her from turning it down. The Anatomy and Structural Biology graduate had always wanted to work in forensics, but never dreamt she'd get the opportunity to work on a world-first project so soon in her research career.

Gemma's Masters project is the construction of a cranial back-spatter model, funded by crown research institute Environmental Science and Research (ESR). Her supervisor Professor Jules Kieser has, together with some of his postgraduate students, been working with ESR Forensics for a number of years on projects ranging from blood-spatter and wounding to

Scientists defend testing on animals

News > Dunedin

They can be your best friend or even considered a member of the family. But every year in New Zealand hundreds of thousands of animals are used for scientific research purposes, and two Otago academics who have experimented on animals say science could not progress without them.

As an undergraduate student in Texas, Prof Rhonda Rosengren worked in a university animal laboratory, and spent her time cleaning out baboon cages and travelling to remote pounds to collect stray dogs for scientific research purposes.

"Driving around Texas picking up emaciated dogs from run-down pounds was a horrible job, but someone had to do it. And it's a

"animal studies...keep it vague"
"pre-clinical models"
"caveats are buried at the bottom"

HYPE IN MEDIA RELEASES

Themes from interviews with media officers, journalists

- Aware that it is a controversial, emotive issue, fraught for researchers
- Voiced clear understanding of reasons backing need for it
- Expressed personal views in favour / very neutral
- Sceptical of press releases, claims from lobby groups

Themes from interviews with media officers, journalists

- However, universally wary of colleagues' handling of issue

- Particular concern about junior reporters tendency to sensationalise

- Pictures of animal harm will always attract strong ratings

- Acknowledged one-sided stories, hatchet jobs do happen

Themes from interviews with media officers, journalists

- Difficulty getting other side of story when allegations of mistreatment raised

- Hard to find scientists to comment, institutions try to shut down coverage

- Handled differently from other issues

- Independently drew parallels to climate change, GMOs, anti-vaxxers

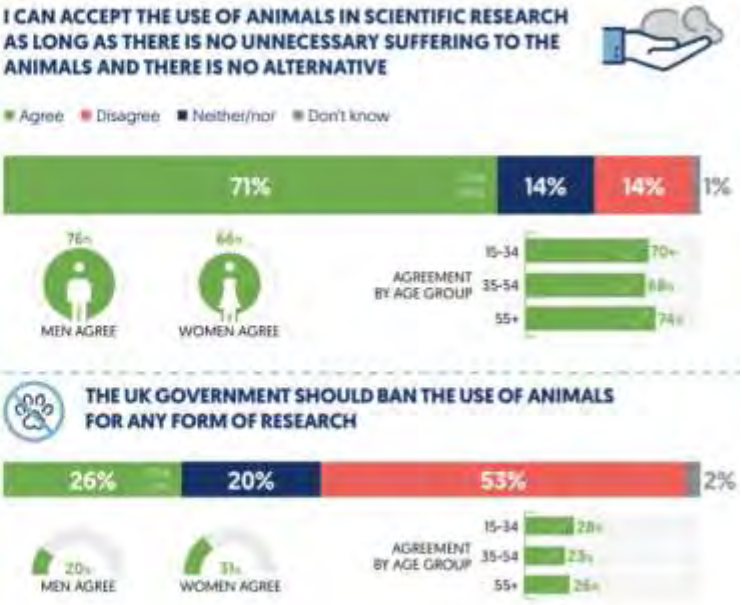
Themes from interviews with media officers, journalists

- Most journalists called for end to secrecy, researchers should be up front

- Should acknowledge suffering where it occurs rather than trying to minimise

- Openness effectively removes the power of exposé framing


PUBLIC ATTITUDES TO
ANIMAL RESEARCH 2016
ACCEPTANCE
TRUST
AWARENESS
INTEREST


I CAN ACCEPT THE USE OF ANIMALS IN SCIENTIFIC RESEARCH AS LONG AS THERE IS NO UNNECESSARY SUFFERING TO THE ANIMALS AND THERE IS NO ALTERNATIVE
Agree
Disagree
Neither/nor
Don't know
71%
14%
14%
1%
MEN AGREE
WOMEN AGREE
AGREEMENT BY AGE GROUP
15-34
35-54
55+
THE UK GOVERNMENT SHOULD BAN THE USE OF ANIMALS FOR ANY FORM OF RESEARCH
26%
20%
53%
2%
MEN AGREE
WOMEN AGREE
AGREEMENT BY AGE GROUP
15-34
35-54
55+

Operating a National Animal Ethics Committee under state based licences

Sharyn Zrna
Animal Research Ethics Coordinator, CSIRO, Australia

Abstract

This paper seeks to explain some of the differences that exist in the way Australian States and Territories manage the licencing of research involving animals from an administrator's perspective within an institution that operates nationally. It seeks to highlight areas where synergies could be implemented with the goal of ensuring continued compliance with the Australian Code for the Care and Use of Animals for Scientific Purposes (Code) and state and territory legislation.

CSIRO

Australia's Commonwealth and Industrial Research Organisation (CSIRO), is a Government entity with around 5000 staff. Its research, including work involving animals, is conducted in all parts of Australia and overseas.

The model for using animals in research in Australia requires two things: compliance with the Australian Code for the Care and Use of Animals for Scientific Purposes (Code) and a License to use animals for research purposes. These licenses are issued by state and territory government departments to cover the animals residing in their jurisdiction.

To accommodate its multi-jurisdictional research, CSIRO has an Animal Ethics Committee (AEC) that is licensed in all eight Australian States and Territories.

This multijurisdictional approach creates administrative challenges for institutions and AECs, and some of these are highlighted in this paper.

Legislation

Table 1 presents the differing legislation that applies to research involving animals in Australia.

Table 1. Legislation covering the use of animals in research in Australia

State/Territory	Legislation
Australian Capital Territory (ACT)	Animal Welfare Act 1992 (pt 4)
New South Wales (NSW)	Animal Research Act 1985 Animal Research Regulations 2010
Northern Territory (NT)	Animal Welfare Act (section 42)
Queensland (Qld)	Animal Care and Protection Act 2001
South Australia (SA)	Animal Welfare Act 1985 (Pt 4)
Tasmania (Tas)	Animal Welfare Act 1993 (Pt 4)
Victoria (Vic)	Prevention to Cruelty of Animals Act 1986 (Pt 3) Prevention to Cruelty of Animals Regs 2008 (Pt 4)
Western Australia (WA)	Animal Welfare Act 2002

Definition of an animal

The Code defines an animal as 'any live non-human vertebrate (that is, fish, amphibians, reptiles, birds and mammals encompassing domestic animals, purpose-bred animals, livestock and wildlife) and cephalopods'. In Victoria, the Prevention of Cruelty to Animals Act extends this definition to include live adult decapod crustaceans, that is, lobster, crab and crayfish. There is no requirement to have a license for research involving fish in SA (and possibly WA), although from an institution's point of view, CSIRO requires all research involving fish to be covered by animal ethics approvals. The ability to publish in quality journals is extinguished if prior AEC approval has not been obtained for research involving fish, regardless of where the research was conducted.

Licenses

The associated costs and the duration of licenses to use animals for research differs. Table 2 shows the state/territory department that issue the licenses, plus the yearly cost and maximum duration of a license.

Table 2. Issuing body, costs and maximum duration of licenses to use animals in research in Australia

State/Territory	Issuing Body	Cost/yr	Max. time
ACT	Transport Canberra and City Services	$314	3 years
NSW	Dept. of Primary Industries	$233	3 years
NT	Dept. Primary Industries and Resources	$33	3 years
Queensland	Dept. of Agriculture and Fisheries	$471	3 years
SA	Dept. of Environment Water and Natural Resources	$40	2 years
Tasmania	Dept. of Primary Industries, Parks, Water and Environment	$135	3 years
Vic	Agriculture Victoria	$262	4 years
WA	Dept. of Agriculture and Food	$100	3 years

License types

Of the licenses presented in Table 2, those from WA, SA, Tasmania, the NT and the ACT cover all activities involving animals in research in those jurisdictions, that is, whether the work is in a laboratory, or is a field-based activity or involves animal breeding. As long as the activity has the appropriate AEC approval, it is covered under these licenses.

In Victoria, three license types apply. A Scientific Procedures Premises License (SPPL) is required for work done at a facility/facilities. When the research is being conducted on animals in the field, then a Scientific Procedures Fieldwork License (SPFL) is required. When animals are used for breeding, then a Specified Animal Breeding License (SABL) is required.

In New South Wales, the Department of Primary Industries is licensed as an Accredited Animal Research Establishment, and all facilities where animal research will occur must be specified in the license application. This license covers both facilities and fieldwork activities. An additional license is required to breed animals.

Conditions – AEC composition

In SA, there is a condition of license that the AEC membership must include a person described in section 2.2.5 of the Code, that is, 'a person responsible for the routine care of animals within the institution'. This is listed as a 'should' in the Code, but is a condition of License in South Australia. They are commonly referred to as Category E members in SA.

Conditions - Notifications

For activities involving animals in the field, four states impose conditions of license which are summarised in Table 3. The WA department provides a form that must be completed before the work commences detailing the research animals and the location of research. In Victoria there is also the requirement to complete a notification form before the activity commences, and in addition to animal species, number and location of research, information must be provided on how the research activity will be monitored by the AEC. If the research is to be conducted in Tasmania, then an email is sent to the Department of Primary Industries, Parkes, Water and Environment (DPIPWE) before activity commences. For field projects occurring in NSW, a list of approved projects must be supplied to the Animal Research Review Panel, Department of Primary Industries, Animal Welfare Branch before 31 December each calendar year.

Table 3. States applying licencing conditions for field based activities

State	**Fieldwork notification requirements**
WA	Submit a fieldwork notification form before activity commences
Victoria	Submit a fieldwork notification form before activity commences including details of how the activity will be monitored
Tasmania	Send an email before activity commences
NSW	Provide a list of approved field projects by 31 December

Nomenclature

The nomenclature an AEC must use to refer to an approved research activity by an AEC is summarised in Table 4. This information comes from the relevant state or territory legislation (as noted in Table 1).

Table 4. Nomenclature used for an AEC approved activity as well as the maximum approval period and renewal options

State/Territory	**Name**	**Duration**	**Renewal**
ACT	Authorisation	3 years	Yes
NT	Permit	2 years	Yes
Queensland	Approval to use	Not stated	Not stated
SA	Approve	Not stated	Not stated
Tasmania	Approve	Not stated	Not stated
Victoria	Not stated	Not stated	Not stated
WA	Approval	Not stated	Not stated
NSW	Animal Research Authority	Not stated	12 months

For an approved activity involving animals occurring in the ACT, a 3 year maximum Authorisation can be provided by an AEC. A renewal of the approval can be granted by the AEC to continue this work after the 3-year maximum approval period.

In the NT, the AEC issues a Permit for a maximum of 2 years, and the AEC can issue a renewal of the research for another 2 years by supplying a new Permit.

In Queensland, SA, Tasmania, Victoria and WA, there is no maximum period for which an AEC can approve a research project using animals documented in the legislation and the nomenclature used to describe that an AEC has approved a research activity involving animals is not defined.

NSW has a different approach. The nomenclature used is an Animal Research Authority, and this can only be issued by the AEC for a maximum of 12 months. So whilst an activity may be approved for 3 years, the paperwork to prove the research has been approved for 3 years needs to be re-issued every 12 months.

A project example

So what does this mean in practice? Imagine a project is submitted to an AEC that involves research using animals in all Australian states and territories. For the purpose of the exercise, 3 species will be used – koalas, sea bass and lobsters (unlikely I know, but please humour me). After careful consideration, an appropriately licensed AEC has approved this research.

The following administration is required for this research activity in order to comply with all licenses and associated legislation.

- A 2 year permit in the Northern Territory that is renewed the day after it expires to cover the 3rd year of the approved activity.
- An Animal Research Authority for NSW that is re-issued every 12 months.
- An Approval document in Victoria that includes lobsters.
- A single approval document to cover all other jurisdictions.
- A fieldwork notification sent to Western Australia and Victoria before the work commences.
- An email to the Tasmanian Department of Primary Industries, Parks, Water and Environment before the work commences.
- A notification to the NSW Department of Primary Industries before 31 December.
- And all considered at an AEC meeting that included a person with responsibility for the daily care of animals to comply with the condition of license in SA.

In addition, appropriate permits are required for the use of wildlife. These are obtained from various state/territory departments and require that AEC approval has been provided for the activity before making an application for a permit. Permits are also required for work in Commonwealth waters.

Requirements for AEC reporting

All jurisdictions require the completion of a calendar year annual report on the operations of the AEC. This includes information on the projects that have been conducted in that calendar year, and information is collected on animal species, animal numbers, project procedures and the purpose of the research. Some reports request information on the activities discussed at each AEC meeting; others request information on AEC members present and absent at each meeting; some ask for the findings of any external reviews conducted, some ask the specifics about unexpected adverse events. Some reports take hours to compile, others take weeks.

Table 5 shows the five purposes of research that are used in AEC annual reports to regulators in SA, ACT, NT, Queensland and Victoria.

Table 5. Purpose of research classifications used in AEC reporting to SA, ACT, NT, Queensland and Victoria

	Purpose of research using animals
1	The understanding of human or animal biology
2	The maintenance and improvement of human or animal health and welfare
3	The improvement of animal management or production
4	The achievement of educational objectives
5	Environmental Study

As per Tables 6, 7 and 8, there are additional purpose classification options to describe animal use in WA, NSW and Tasmania respectively. These include the 5 purposes listed in Table 5, albeit presented in a somewhat different way.

Table 6. Purpose of research classifications used in AEC reporting to WA

	Purpose of research using animals
1	Animals held
2A	Stock breeding (genetically modified)
2B	Stock breeding (not genetically modified)
3	Education
4	Research: Human or animal biology
5	Research: Human or animal health and welfare
6	Research: Animal management or production
7	Research: Environmental Study
8	Product testing

Table 7. Purpose of research classifications used in AEC reporting to NSW

	Purpose of research using animals
1	Stock breeding
2	Stock maintenance
3	Education
4	Research: Human or animal biology
5	Research: Human or animal health and welfare
6	Research: Animal management or production
7	Research: Environmental Study
8	Production of biological products
9	Diagnostic procedures
10	Regulatory product testing

Table 8. Purpose of research classifications used in AEC reporting to Tasmania

	Purpose of research using animals
1	Human biology research
2	Animal biology research
3	Human health research
4	Animal health research
5	Animal management/production research
6	Animal welfare research
7	Environmental/ecology research
8	Commercial products development research
9	Wildlife (native and introduced) research

10	Achieve teaching/educational objectives
11	Production of biological products
12	Other-please specify

It is very difficult to capture jurisdictional specific information for an activity on a single AEC project application form.

The other challenge is that because jurisdictions collect their animal use data differently, it is very difficult to get an accurate picture of the numbers of animals used in research nationally. It is interesting to note that because of the different ways jurisdictions collect animal use numbers, SA has decided not to ask license holders to report animal use numbers. For critics of animal use in any capacity, this may suggest that as a nation we are hiding what we do. The social license to use animals in research must require that we be transparent to the community. We must find common ground to ensure we can present an accurate and informative annual report to the nation on how animals were used in research and how many were used. It does not seem arduous, but the development of a common annual report for all AECs to use for all jurisdictions would be the first step.

AEC membership changes

Table 9 shows the various administrative requirements relating to a change in AEC membership. The 3 forms referred to in table 9 (submitted to NSW, Queensland and Victoria) are all different. This again seems like an area where synergies could be achieved, perhaps simply through the development of a single form that could be sent to multiple jurisdictions.

Table 9. State and territory requirements for AEC membership changes

State/Territory	Changes to membership requirements
ACT	Nil
NSW	Complete form and have candidate endorsed by the Animal Research Review Panel before commencement– send CV for Category B members
NT	Nil
Queensland	Complete form and have candidate endorsed by Queensland Department of Agriculture and Fisheries prior to commencement – send CV for Category B members
SA	Nil
Tasmania	Advise by email
Vic	Complete form and have candidate endorsed by Agriculture Victoria before commencement – send CV for Category B members
WA	Advise by email

Summary

There are multiple additional areas where there is minimal synergy in the ways licencing adherence requirements are governed in Australia. This paper is about initiating a conversation for ways to streamline the administration of Australian AECs that operate in multiple jurisdictions. It would be very disappointing for beneficial research involving animals to be stopped because of administration oversight leading to license withdrawal, but with our current system I fear it is a possibility.

There is an opportunity for ANZCCART and NHMRC to provide leadership in this area through a process that can bring all the relevant state and territory parties together to agree upon some areas of commonality that will not only reduce administrative burden, but provide greater clarity and

transparency regarding the use of animals in research across Australia. These could include: common project procedures nomenclature; a common National template for AEC annual reporting; and a common AEC member nomination form.

These would be some very small steps that might one day lead to something huge – a fully national approach.

Sharyn Zrna has been employed by CSIRO since 1993 except for a 4-year stint in the Australian Wine Industry where she met her winemaker husband. She studied Chemistry and Aquatic Biology at Deakin University in Warrnambool Victoria, Australia where she obtained her Bachelor of Applied Science with Honours. Her initial work experiences were in aquatic ecotoxicology, pesticide chemistry and soil and water analysis. She then managed and facilitated human research trials involving ileostomy participants to determine foods that contain resistance starch. In order to remove herself from working in the laboratory she agreed to become the Executive Officer of an Animal Ethics Committee. Six years on and she is the Executive Officer of three AECs and is the CSIRO Animal Research Ethics Coordinator.

Assessment of housing density, space allocation and social hierarchy of laboratory rats on behavioural measures of welfare

Timothy Barker[1], Rebecca George[1], Gordon Howarth[1,2], Alexandra Whittaker[1]
[1]School of Animal and Veterinary Sciences, The University of Adelaide, Roseworthy Campus, Australia
[2]Gastroenterology Department, Children, Youth and Women's Health Service, Adelaide, Australia.

Minimum space allowances for laboratory rats are legislated based on weight and stocking rates, with the understanding that increased housing density encourages crowding stress. However, there is little evidence for these recommendations, especially when considering positive welfare outcomes. This study consisted of two experiments which investigated the effects of housing density (rats per cage), space allocation (surface area per rat) and social rank (dominance hierarchy) on the ability to perform simple behavioural tests.

Male Sprague Dawley (SD) rats (n = 64) were allocated to either high-density (n = 8) or low-density (n = 8) cages. The second experiment investigated the effects of surface area. SD rats (n = 40) were housed in dyads in either the large (n = 10) or small (n = 10) cage. In both experiments, animals were tested on a judgment bias paradigm, with their responses to an ambiguous stimulus being ascribed as optimistic or pessimistic. Animals were also tested on open-field, novel-object recognition and social-interaction tests. Recordings were taken from 1700 to 2100h daily for rat observation and social rank establishment.

Dominant animals responded with significantly more optimistic decisions compared to subordinates for both the housing density ($P < 0.001$) and space allocation ($P = 0.0015$) experiments. Dominant animals responded with increased social affiliative behaviours in the social-interaction test, and spent more time in the centre of the open-field test for both experiments. No significance was detected between housing density or space allocation treatments. These findings suggest that social rank is a significantly greater modifier of affective state than either housing density or space allocation. This finding has not yet been reported and suggests that future drafts of housing guidelines should consider animal social status in addition to floor space requirements.

Housing Guidelines

- Approximately 300,000 rats are used per year
- Relative uniformity on housing regulations
- *The Guide for the Care and Use of Lab Animals*
  (United States)
- *EC Directive 2010/63/EU*
  (Europe and United Kingdom)
- *Evidence-based data is lacking*
  (Resolution on Accommodation and Care of Lab Animals)

EU Guidelines:
Min. Floor Area and Height

Species	Body Weight (g)	Minimum Enclosure Size (cm²)	Floor Area per Animal (cm²)	Minimum Enclosure Height (cm)
Mice	< 20	330	60	12
	20 - 25	330	70	12
	25 - 30	330	80	12
	> 30	330	100	12
Rats	< 200	800	200	18
	200 - 300	800	250	18
	300 - 400	800	350	18
	400 - 600	800	450	18
	> 600	1500	600	18
Hamsters	< 60	800	150	14
	60 - 100	800	200	14
	> 100	800	250	14
Guinea Pigs	< 200	1800	200	23
	200 - 300	1800	350	23
	300 - 450	1800	500	23
	450 - 700	2500	700	23
	> 700	2500	900	23

Housing Density versus Space Allocation

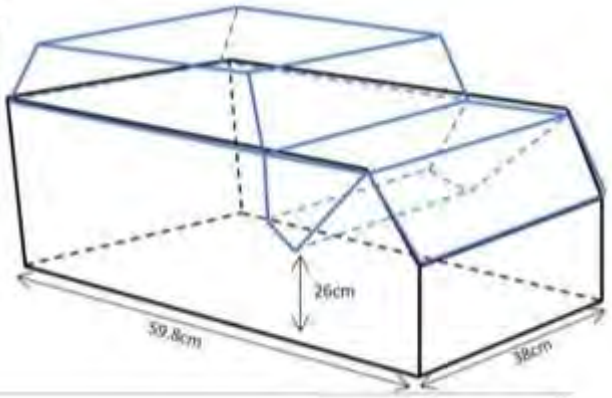
- Housing density and space allocation are often confounded
  - Experiment 1 (Housing Density)
    - 64 Sprague-Dawley rats (n=8)
    - High density housing versus Low density housing.
    - Change in housing density, space allocation remains the same.
  - Experiment 2 (Space Allocation)
    - 40 Sprague-Dawley rats (n=10)
    - Large cages versus Small cages
    - Change in space allocation, housing density remains the same.

Our Study

- To assess different housing parameters...
  - Housing Density
  - Space Allocation
  - Social Class
- On an array of behavioural measures to identify welfare
  - Open Field
  - Novel-Object Recognition
  - Social-Interaction
  - Cognitive Bias

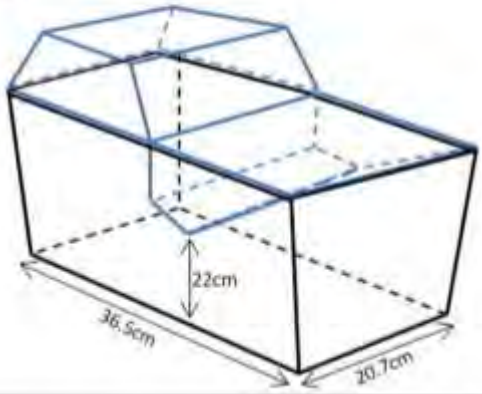
High Density Caging

- Eurostandard type IV
- 6 rats per cage (n = 8 cages, 48 total animals)
- 59.8cm x 38cm x 26cm = 2,280cm²
- 380 cm² per 450g animal



Low Density Cages

- Eurostandard type IIL
- 2 rats per cage (n = 8 cages, 16 total animals)
- 36.5cm x 20.7cm x 22cm = 755.55cm²
- 377.75 cm² per 450g animal



Experiment 1 – Summary

High Density Cages

- Eurostandard type IV
- 6 rats per cage
- 380 cm² per 450g animal
- More social interactions

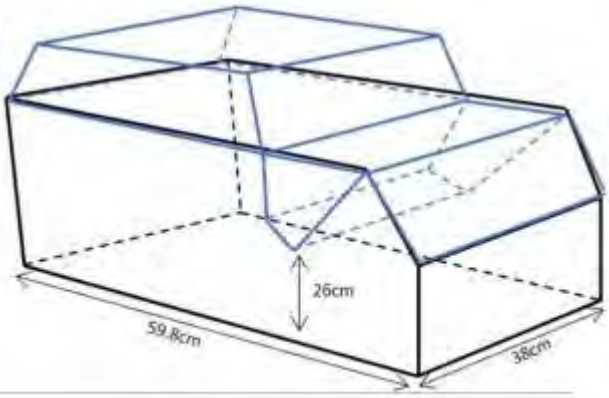
Low Density Cages

- Eurostandard type IIL
- 2 rats per cage
- 377.75 cm² per 450g animal
- Fewer social interactions

How does an increase in housing density affect animal welfare when each animal is afforded equal floor area?

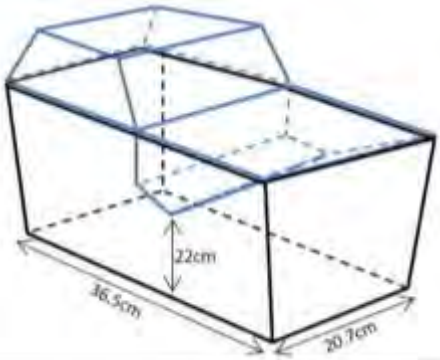
Large Cages

- Eurostandard type IV
- 2 rats per cage (n = 10 cages, 20 total animals)
- 59.8cm x 38cm x 26cm = 2,280cm²
- 1140 cm² per 450g animal



Small Cages

- Eurostandard type IIL
- 2 rats per cage (n = 10 cages, 20 total animals)
- 36.5cm x 20.7cm x 22cm = 755.55cm²
- 377.75 cm² per 450g animal



Experiment 2 – Summary

Large Cages

- Eurostandard type IV
- 2 rats per cage
- 1140 cm² per 450g animal
- Equal social interactions

Small Cages

- Eurostandard type IIL
- 2 rats per cage
- 377.75 cm² per 450g animal
- Equal social interactions

How does an increase in space allocation affect animal welfare when housing density does not change?

Social Rank Establishment

- Cages video recorded for 6 hours over 5 days .
  - Recording all taken in the dark photoperiod (1600-2400 hours)
- A random, 10 minute section of recording was used to analyse the behaviour of a single rat (observed rat).
- Interactions between the observed rat and every cage-mate were examined to determine the dominance relationship.

Social Rank Establishment – Ethogram*

Functional category	Behavioural elements
Agonism	
Aggression	Bite; chase; pinning rat on its back; aggressive groom; aggressive sideways; upright; mounting, pull tail
Defence	Pinned on back; defensive sideways; flight with and without pursuit
Social Investigation	Sniffing nose, mouth, head, shoulders, back, flank, anogenital area, belly, tail
Other social behaviour	Attend; push past; shove, allogroom

*Hurst JL, Barnard CJ, Hare R, Wheeldon EB, West CD. Housing and welfare in laboratory rats: time-budgeting and pathophysiology in single-sex groups. Anim. Behav. 1996;52(2):335-60

Social Rank Establishment – Dominance Status

Social Class	Definition	n
Dominant (D)	Dominant over all cage mates – dominant in every dyad	16
Dominant subdominant (DS)	Mostly dominant – dominant in most dyads, not all	14
Subordinate subdominant (SS)	Mostly subordinate – subordinate in most dyads, not all	22
Subordinate (S)	Subordinate to all cage mates – subordinate in every dyad	12

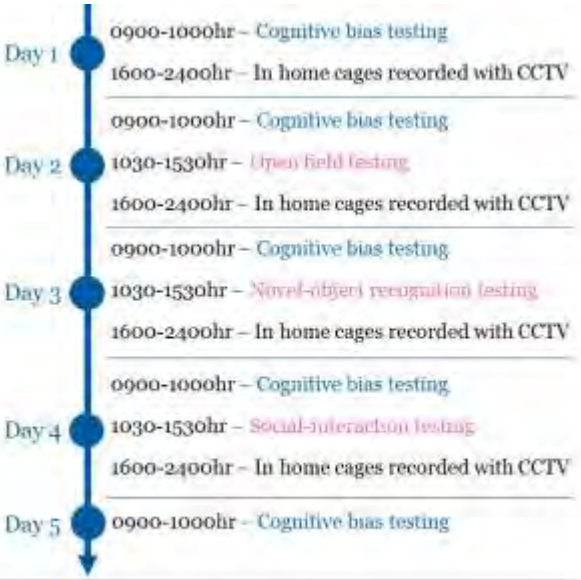
*Housing density experiment

Social Class	Definition	n
Dominant (D)	Dominant over all cage mates – dominant in every dyad	20
Subordinate (S)	Subordinate to all cage mates – subordinate in every dyad	20

*Space allocation experiment

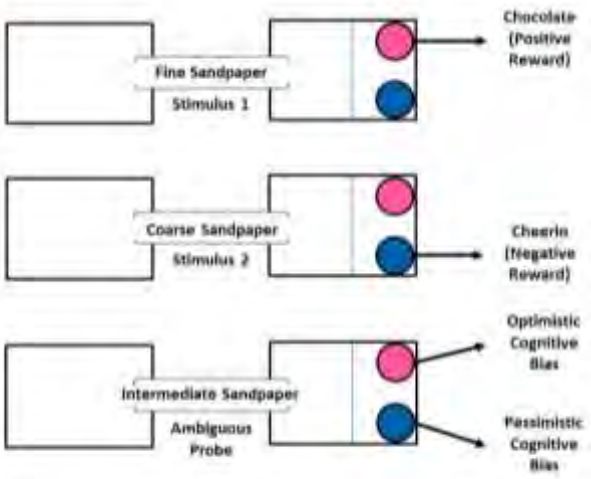
Behavioural Array

- When each animal of the cage is minimum 450 grams, behavioural testing commenced.
- Testing occurred over 5 days



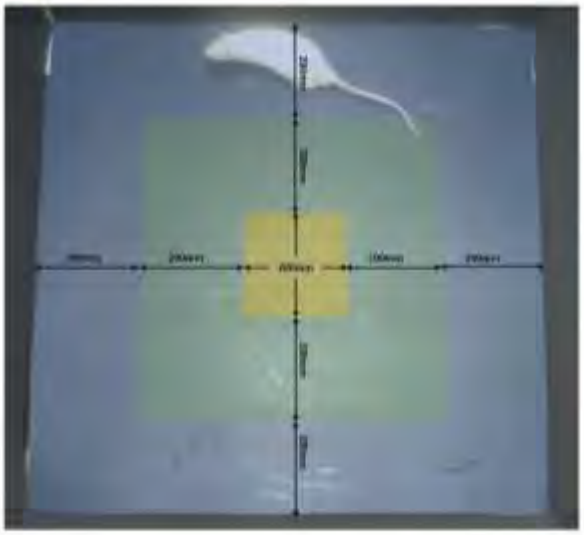
Cognitive Bias Test

- Uses animal judgment to ambiguity to identify animal affective state.
- Pessimistic cognitive biases are indicative of animals in a negative affective (emotional) state



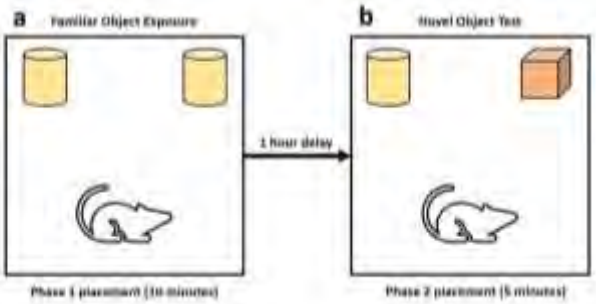
Open Field Test

- General locomotor activity and anxiety
- Rodents willing to explore centre confines of test show decreased anxiogenic tendencies



Novel-Object Recognition Test

- Animals have a preference to explore novelty
- Greater time exploring the familiar object is a sign of cognitive impairment in animals suffering chronic stress

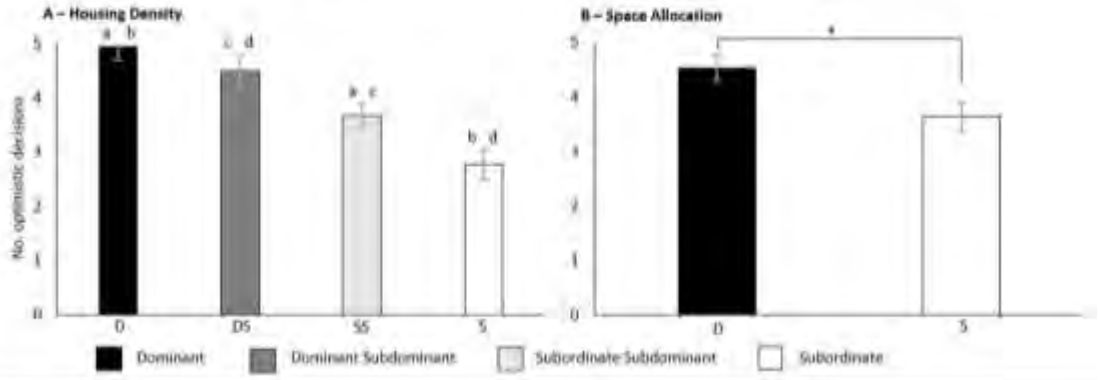


Social-Interaction Test

- Measure of social exploration of target rat to an unfamiliar
- Social avoidance behaviours are commonly associated with neophobia, anxiety and depression

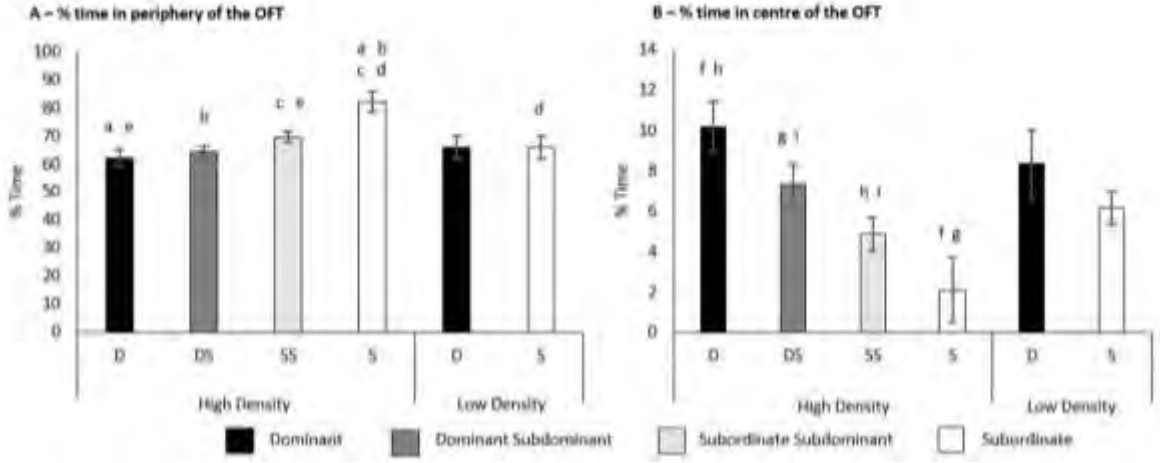
Results: Cognitive Bias Data

For both experiments, subordinate and subdominant-subordinate rats responded with significantly fewer optimistic biases



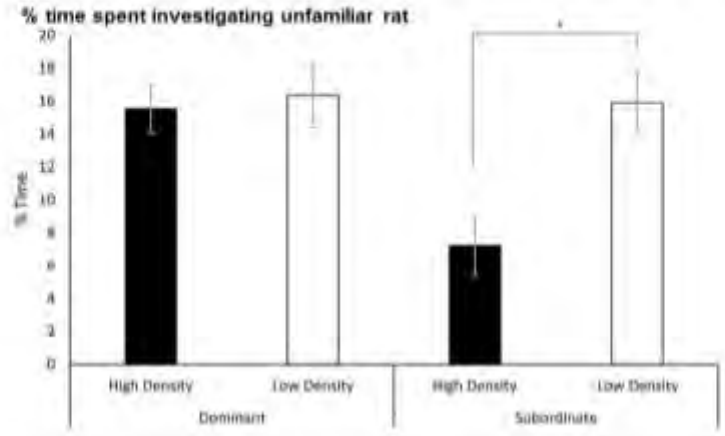
Results: Open Field Data

Subordinate animals of the high-density cages responded with significantly greater anxiety-like responses to the OFT



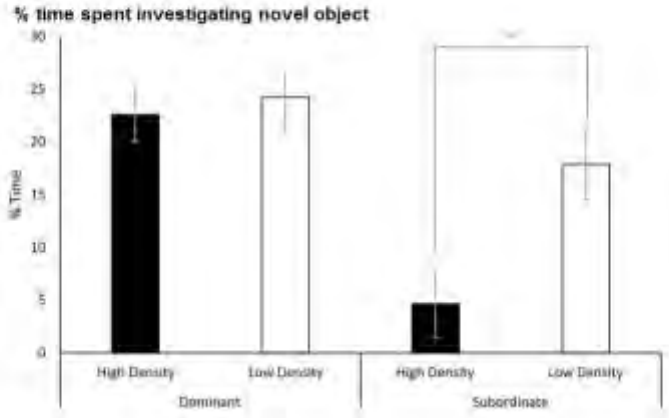
Results: Social-Interaction Data

Subordinate animals in high-density cages responded with a significantly decreased percentage of time investigating the unfamiliar rat in the SIT



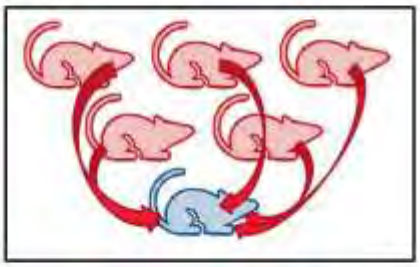
Results: Novel-Object Recognition Data

Subordinate animals in high-density cages responded with decreased percentage of time interacting with the novel-object in the NORT

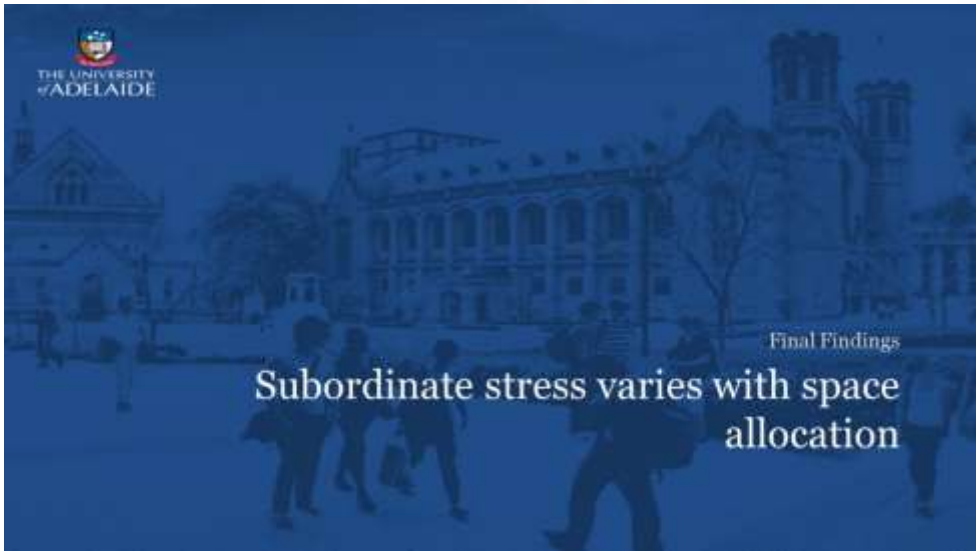


Subordinate stress varies with housing density

- Subordinate rats in high-density cages experience more acts of aggression than subordinate rats in low density cages.

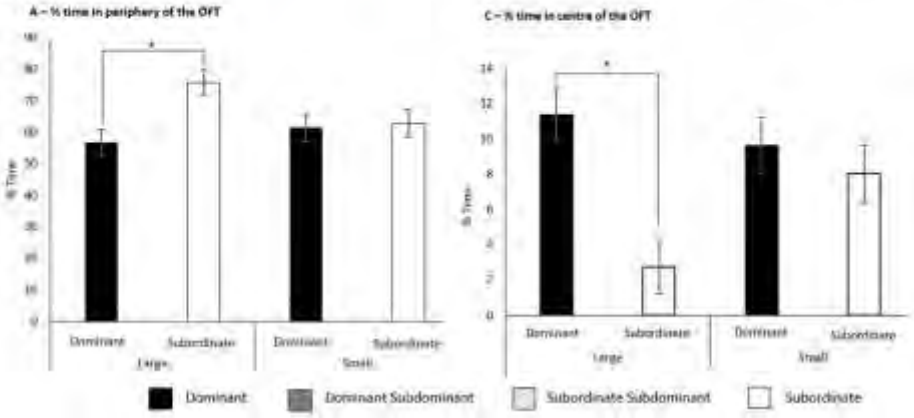


"Larger group sizes of rats lead to increased number of anxiety-like behaviours expressed by the subordinate rats"



Results: Open Field Data

Subordinate animals of the large cages responded with significantly greater anxiety-like responses to the OFT



Subordinate stress varies with housing density

- No significant differences observed at all, between dominant and subordinate animals in the small cages compared to those in the large cages, contrary to expectations.

Subordinate animals **with greater surface area allocation respond with increased anxiety-like behaviours**

Main Findings and Conclusions

- More animals per cage and greater surface area allowance results in subordinate animals responding with increased anxiety-like behaviours.
- Housing guidelines should not only be based on surface area allowance and number of animals per cage.
- The data suggests that housing guidelines should also consider dominance status.

Need to consider the effects of crowding stress versus subordination stress