Review of Current Practices and Needs to Inform Public Presentation of Animal Usage for Scientific Purposes in Australia

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Executive Summary

The goal of this study is to make a case for the collation of national statistics relative to the use of animals for scientific purposes. The current situation is that relevant statistics are collected by states and territories in a non-uniform format, only four of these jurisdictions make the statistics publically available, and there is no national collation. This should be compared to 27 member nations of the EU who currently each assemble their national scientific animal statistics according to a mutually agreed format. It could also be compared to Canada with 10 provinces, each with their own legislature, with scientific animal statistic collation done by one agency, the Canadian Council of Animal Care. The lack of Australian statistics results in a lack of ability for national planning for resource investment in this field and there are no transparent statistics for informed discussion and debate.

In making recommendations international systems were examined along with existing systems in the Australian states and the best these had to offer, internationally and nationally, was utilized.

In line with the situation pertaining currently in the EU and New Zealand this review recommends a much more objective assessment of the severity of impact on animals than is currently the situation within the Australian jurisdictions. It takes into account the degree and duration of impact and recommends that impact be assessed retrospectively. The measurement and statistical recording of impact/severity levels enables animal using scientists, AECs, institutions and legislators to target the areas of greatest severity in terms of measures that fall within the 3Rs (Replacement, Reduction, and Refinement). Interested members of the public are more concerned with severity of impact than any other factor and this assessment informs them in an appropriately transparent manner.

Ten purposes of use are recommended. These were gathered from purposes of use currently included within Australian jurisdictions and are reflective of the purposes relevant to the Australian scientific animal use scene.

The study proposes the presentation of statistics in terms of combinations of degrees of impact and purposes of use against category of animal.

A proposal is to use statistics to promote the positive aspects of ethical oversight, including assessing the proportion of animal ethics proposals that are improved by ethical oversight and quantitatively assessing the implementation of the 3Rs. It is proposed that 3Rs implementation is assessed once per approved proposal as that proposal is concluded. With small institutions this may have to be done manually. The continuing evolution of IT research management systems relative to animal ethics management in Australia has considerable potential to facilitate this process in many institutions.

Re collation of scientific animal use statistics two Commonwealth agencies that undertake national statistics compilations are identified. They are the Australian Bureau of Agricultural and Resource Economics and Sciences (ABARES) and the Australian Bureau of Statistics (ABS). Recent conversations with state legislators identified that they are currently under-powered in relevant human resources re scientific animal statistical collection and changes to their current state practices could present considerable challenge. It is felt that a preferred system would be the direct collection of relevant statistics by the Commonwealth agency from the institutions and subsequent return of respective figures to each state.

Introduction

Purpose of the study

Currently Australia does not have a nationwide compilation of statistics relative to the use of animals used for scientific purposes. This project aims to inform work to design and implement a national system to publicly report animal use for research and teaching under the *Australian code of practice for the care and use of animals for scientific purposes* (The animal Code) 7th edition 2004, in light of international practice and with an eye to demonstrating ethical oversight under existing Australian arrangements.

National facts and figures allow for informed debate and discussion and for planning and investment for Australia's education and research effort. They are also scrutinised by animal lobby groups concerned over unjustifiable welfare impacts on the animals involved. The project will examine systems in place elsewhere in the world, with regard to national harmonisation and cogent 'hazard' or 'severity' grades. It will also review scientific animal use statistics currently collated by the Australian states and territories. Statistics used for other matters by skilled agencies (Australian Bureau of Statistics and Australian Bureau of Agricultural and Resource Economics and Sciences) and emerging issues such as translational research and evidence-based biomedicine will provide cues.

Recommendation 2.30 of the 1989 report on Animal Experimentation of the Senate Select Committee on Animal Welfare stated:

> The Committee recommended that the Commonwealth, State and Territory Governments publish annually accurate and comprehensive information on the extent and forms of animal experimentation conducted within their respective jurisdictions. In addition, government authorities should provide some analysis of the statistics to make them meaningful to the public and to reduce the risk of misinterpretation.

The introduction to Chapter 2 in Section 2.1 of that senate report notes: 'Few statistics are kept of the extent and range of animal experimentation conducted in Australia. Consequently, the Committee does not have accurate figures on the number of experiments or the number of animals of each species which have been used in experiments. It also follows that the Committee does not know with any degree of accuracy whether the use of animals in experiments is increasing or decreasing.' Interestingly were a similar Committee to convene today, they would find that the situation 24 years on is very similar and they would still have difficulty assessing national trends in animals used for scientific purposes.

The need for facts and figures has evolved since 1989 because the operating environment has evolved. Animal Ethics Committees (AECs) are firmly established as the most efficacious tool for relevant public policy within Australia. The primary responsibility of AECs is to ensure, on behalf of institutions, that all care and use of animals is conducted in compliance with the *Australian Code of Practice for the Care and Use of Animals for Scientific Purpose*s (2004). The Code has been the subject of six revisions since 1969 and is nearing the end of its seventh revision as this document is being prepared. A tenet central to the Code is the concept of the 3Rs. The 3Rs was first introduced by Russell and Burch (1959) as a concept of replacement, refinement and reduction in a way in which animal welfare is taken into account by diminishing or eliminating the pain and discomfort to animals used for scientific purposes. Cooperation for the progressive improvement of humane animal care and use, as embodied in the 3Rs, can be hindered by the absence of reliable and contemporary statistics. Indeed Smyth (1978) proposed categorising experimental procedures and

collecting national statistics as a way to prioritize efforts for the development of the 3Rs. His scale, taking into account pain and distress, appears to be the first of its kind.

Facts and figures are required for public forums where diverse opinions operate, and the Senate Select Committee mention of the need for provision of analysis of the statistics to make them meaningful to the public is of significance here. They are also necessary for planning investment into and management of an increasingly important national resource, particularly at a time when translational research is becoming dominant. It should be noted that statistics inappropriately used can obscure key elements of how animal use has evolved in this sector. The AAWS-commissioned TNS report Attitudes Towards Animal Welfare (2006) on public attitudes on animal welfare reported that research supports the need for public awareness raising and the provision of balanced information on animal welfare issues in Australia. It also reported that, for this sector, animal use was generally accepted although 'overall there was real sense among participants that although little is known about what actually happens to animals in research, that 'someone' must be looking after animals used for these purposes.' Some participants questioned whether regulations were in place to ensure the wellbeing of these animals, while others assumed this must be the case. This, very likely is a reflection of the Australian public's general lack of knowledge of the true legislative situation regarding animals in research and teaching, and such knowledge could be readily expanded by the publication of a national statistical report which emphasises AEC function, the 3Rs and the emphasis of the Code. Commenting on the need for a balanced discussion John Hadley (2012) recently stated: 'From a public policy point of view, widespread ignorance about animal research is not good. As John Stuart Mill pointed out, good public policy is the product of informed debate after exposure to challenging issues. Thus, if we want to strike the right balance between scientific progress and animal welfare, we need to expose animal use data to people who are not partisans of one side or the other.'

The current situation in Australia

States and territories have been collecting statistics relevant to the use of animals for a number of years but the Commonwealth has not played a part in this, hence harmonisation is lacking and a national uniform system for collation, analysis, and reporting has not occurred. Currently four of these jurisdictions do not make their statistics publically available. The result is a compromised capacity to respond to contemporary needs at a national level and a misperception that Australia has a substandard approach to animals used in research and teaching. Indeed, the current reporting mechanisms may have actualised the potential for misinterpretation. We do not have national statistics on animal welfare standards as a basis to benchmark Australia's relevant animal welfare outcomes. A principal aim must be the presentation of data in a way that is meaningful to the public and that can convey as far as possible appropriateness of use and manifestations of responsible oversight by AECs within the terms of the Code. Current reporting mechanisms do not inform the public of the nationwide positive impact of ethical oversight before animals are allowed to be used for such purposes, and fail to provide benchmark information on how patterns of animal use have changed through implementation of best analytical practice in science and the application of the 3Rs.

Broad methodology for the study

The project will use the Australian perspective to critically review all aspects of how the statistics of animals used for scientific purposes are collated and used in selected other countries implementing a national approach, with the aim of considering what might best be used in an Australian context. Concurrently, Australian state and territory scientific animal statistics collection methodology will be examined and where considered appropriate will be incorporated into the framework.

The idea is not to necessarily import other frameworks in their entirety but to compare the way other countries report on features that would be applicable under Australian conditions to develop a suggested framework that:

1) Provides for a nationally consistent reporting format on animal use for application by organisations performing animal-based research and teaching.
2) Is presented in a clearly transparent manner.
3) Provides an analytical process that is applied to those data in order to derive and present information on:
    - the levels of impact of approved research activities (in categories);
    - the purpose of animal use relative to animals used for scientific purposes;
    - the levels of impact by purpose;
    - the positive impact of ethical oversight on animal use (this might be ascertained by recording changes of trend over time, but also levels of impact by purpose to inform best 3R targeting strategy);
    - the future needs of researchers in terms of probable patterns of research being undertaken.

Impact assessment (also known as severity assessment) is of particular significance to animal-based scientists, animal ethics committees, regulators and interested members of the public and will be examined in detail later in this study. At this stage of the project it suffices to refer to a paper by Fenwick et al (2011) who felt that severity classification serves four main purposes:

- as a tool to assist animal ethics committees in ethical review;
- education of animal users about concepts for humane animal experimentation;
- provision of data to inform the public about scientific animal use;
- and provision of data to inform national policies.

The authors found that currently, eleven countries use severity classification systems. These systems have developed in various ways, depending on each country's process for overseeing the use of animals in science, as well as the particular aspects emphasised by those individuals who have championed their implementation. Interestingly Australia was included, but in the absence of national figures the publication used those of NSW.

The deliverable for the present proposal is a review of international best practice, together with an examination of current Australian state and territory practices, looking at different ways to present an objective assessment of the uses and outcomes from animal-based research in order to meet the intended outcome from the 1989 Senate Committee report and in light of the TNS research findings.

The end-objective is buy-in from the jurisdictions for a national system for reporting facts and figures about ethically endorsed scientific animal use. The sequence in mind for the deliverable is clearance by AAWS, Australian Animal Welfare Advisory Committee (AAWAC) endorsement and then submission up the administrative line to the Standing Council on Primary Industries. A recommended way forward will be sought; it is apparent that there will need to be ongoing funding

Standing Council on Primary Industries for the preparation of national facts and figures for animal use for scientific purposes.

Other countries used for comparative purposes

Information provided at six World Congresses on Alternatives and Animal Use in the Life Sciences between 1996 and 2011 initially directed attention to closely examining systems from Canada, New Zealand, the UK, the Netherlands and Germany. It became apparent that the 2010/63/EU Directive (European Union (EC) 2010 Directive 2010/63/EU of the European Parliament and the Council of 22 September 2010 on the Protection of Animals Used for Scientific Purposes: European Commission: Brussels, Belgium) was going to impact on the statistics collected within the UK, the Netherlands and Germany from 2013, so as regards the Netherlands and Germany reference will only be made to the way statistics are collected prior to the implementation of the EU Directive. The UK Home Office has developed stakeholder consultation documentation concerning the implementation of the Directive and this provides an interesting insight into the developing process. Interestingly, in a review of international systems of classifying the severity of scientific animal use, Fenwick et al (2011) initially looked at severity classifications from eleven countries before looking more closely at the classification systems from Canada, New Zealand, and the UK.

The Canadian Council of Animal Care and Animal Use Statistics

Introduction

Canada has 10 provinces, each with their own legislature, with scientific animal statistic collation compiled by one agency, the Canadian Council of Animal Care. The Canadian Council of Animal Care has been recognised as being an international leader across many aspects of best practice for the care use of animals for scientific purposes. Since 1996, the annual survey of animal use for scientific purposes in Canada is published using the data collected in the *Animal Use Data Form* (AUDF) format (data was collected in a different format between 1975 and 1995). The 2010 Canadian figures (Canadian Council of Animal Care Survey of Animal Use (2010)) are reproduced in detail in **Appendix A** to illustrate how statistics relative to the use of animals for scientific purposes can be meaningfully presented.

Table I lists the number of animals used by species, important statistics for a national collection and closely following a format that Australian institutions use in reporting to their governing bodies.

Tables II lists numbers of animals used in 2010 by participants according to category of invasiveness. The importance of categories of invasiveness (in other countries termed severity or impact) has been briefly mentioned earlier in this project and will be discussed in more depth subsequently. Table 111 lists the 2010 number used under purpose of animal use. Purpose of animal use is an essential figure for stakeholders. To demonstrate how statistics might be collated in a meaningful way the description of this CCAC system includes animal numbers in the majority of tables, rather than just outlining what the tables contain**.**

The key for categories of invasiveness is:

B Experiments which cause little or no discomfort or stress.

C Experiments which cause minor stress or pain of short duration.

D Experiments which cause moderate to severe distress or discomfort.

E Experiments which cause severe pain near, at, or above the pain tolerance threshold of unanaesthetised conscious animals.

The key for purpose of animal use is:

PAU = 0 Breeding Colony/Stock - Animals held in breeding colonies (e.g., fish, rodents) that have not been assigned to a particular research, teaching or testing protocol.

PAU = 1 Studies of a fundamental nature in sciences relating to essential structure or function (e.g., biology, psychology, biochemistry, pharmacology, physiology, etc.).

PAU = 2 Studies for medical purposes, including veterinary medicine, that relate to human or animal disease or disorders.

PAU = 3 Studies for regulatory testing of products for the protection of humans, animals, or the environment.

PAU = 4 Studies for the development of products or appliances for human or veterinary medicine.

PAU = 5 Education and training of individuals in post-secondary institutions or facilities.

Re the purpose of use, the CCAC consider (G. Griffin personal communication, 2012) that these purpose categories are not perfect but never the less have proved valuable in determining where

animals are used and in combination with categories of invasiveness, where the most severe pain and distress is likely to occur.

Table IV combines purpose of use and category of invasiveness. The combination of purpose of animal use and degree of invasiveness again allows the CCAC to target its 3Rs education towards the areas of greatest need. It allows the CCAC to determine whether the number of animals in the most severe categories is changing. It informs the public in a transparent manner about the things that are most likely to concern them. It also allows informed policy development.

Table V lists the **number of animals used by species** in 2010 by participants in the CCAC programs for each **Purpose of Animal Use** according to the **Category of Invasiveness.** It is important to stress that each purpose of use has a separate table. For comparative purposes tables relative to purposes of animal use 2, studies for medical purposes, including veterinary medicine, that relate to human or animal disease, are reproduced in **Appendix A** as well as the table relative to animal use 3, studies for regulatory testing of product for protection of human animals or the environment. The public, generally speaking, are more accepting of research that relates to potential improvement of human and animal health than they are of animal based research that they see falling into the realms of toxicity testing and comparison of the two tables are interesting.

The value of the CCAC statistics

These types of statistics can be used for a variety of purposes. Public concern can be of significant political importance and that concern tends to concentrate on certain areas. Animals used for toxicity testing is very high in the range of public concern, so in that light a significant figure to comment on is that the number of animals used for toxicity testing is 28.7% of those used for medical and veterinary research. Given the sensitivities concerning toxicity testing this initially looks significant. On further examination it is evident that Canada has a very strong fishing industry and this is evidenced by 272,898 fish being used for fish disease research and 103,889 being used for toxicity testing. For medical/veterinary research in Canada fish numbers used are the second most common species used after mice. For toxicity testing numbers of fish used are more than double the next most used species, rats, at 48,580.

As far as the public are concerned, the animals that tend to be most emotive within the British Commonwealth are non-human primates and domestics animals, dogs and cats in particular. Interested members of the public are going to be particularly concerned with purpose of use and the level of invasiveness involving these species. Non-human primate use tends to be particularly emotive and with regard to the CCAC 2010 report Table 111 (Number of animals used according to purpose of use), it can be readily seen that 4629 non-human primates were used. Of these 785 were used within PAU level 1 (Studies of a fundamental nature in science such as biology). 929 were used within PAU 2 (Studies for medical purposes, including veterinary medicine). 2701 were used within PAU 3 (Studies for regulatory testing of products for the protection of humans, animals, or the environment. 110 were used within PAU 4 (Studies for the development of products or appliances for human or veterinary medicine). 104 were used within PAU 5 (Education and training of individuals in post-secondary institutions or facilities. Regulatory testing of products using animals, as stated previously is a particularly contentious public issue and many would question why non-human primates would be used for this purpose. That in 2010 in Canada 2,701 non-human primates were used for toxicity studies would undoubtedly alarm Canadians concerned about this. That none fell into category E (experiments which cause severe pain near, at or above the pain tolerance threshold of unanaesthetised conscious animals) and 12% fell into category D

(experiments which cause moderate to severe distress of discomfort) would be of some comfort to the concerned public. This leaves 88% that experienced minor stress or pain or little or no discomfort or stress, and are statistics that the public might take comfort in knowing. Looking to use statistics to promote the 3Rs, the 12% in category D experiments could then act as a focal point for legislators to concentrate on reducing in terms of application of the 3Rs. Replacement of testing of non-human primates by using non-animal methodology would be a very desirable outcome, but in so saying, it is recognised that a sometime significant period of time is spent in the validation of non-animal replacements for product testing. Animal rights groups can paint a picture of every animal used for research purposes dying an extremely painful and stressful death. The public availability of these statistics is obviously able to paint a more accurate picture.

Table VI lists animal use by province and in the Australian scenario one could envisage a similar situation collecting animals by state and territory.

The CCAC also publishes trends in animal use.

Re total numbers of animals used by participants the number used in 1993 was 2,593,681. By 1997 this fell to 1,471,611 but then increased to 3,375,027 by 2009. The introduction and trend of increasing use of genetically modified rodents is responsible for the increase from 1997. The use of cats, dogs and non-human primates for the same period shows a marked drop (approximately 50% reduction) from the late 1975 to 1980 and a fairly steady national use at the same level since then.

CCAC statistics from an Australian improvement perspective

On the face of it the CCAC statistical compilation appears to offer much that might be used in an Australian scientific purposes national statistical compilation. Are there deficiencies and might there be elements that can be improved upon? (G. Griffin, personal communication, 2012) from the CCAC felt that were she to develop a system de novo she would not necessarily collect information on severity in the same manner. She felt that it is important to look at both the level of pain and stress and the duration, which she felt was not well captured in the current system. The 1997 CCAC guidelines on transgenic animals asked for them to be identified separately (something the CCAC is still trying to implement) and also that the creation of GM animals not be assigned to Category of Invasiveness (CI) D until their phenotype has been established. However they struggled to have these animals re-categorised once their phenotypes were known. The CCAC noted that it seemed difficult for institutions to revisit the protocol before the annual renewal. This resulted in higher number of animal use in CI(D) which has the potential to lead to the perception that significantly more animals are experiencing pain and distress than is actually the case. In the next iteration of the guidelines they hope to overcome this by asking GM animals to be given a welfare status, and for this to be taken into account when assigning a CI to the protocol describing the experiments they will be used for. The other factor Gilly Griffin felt Australia might want to take into consideration is whether or not we would want prospective or retrospective reporting. Currently in Canada the numbers of animals used are reported and although they ask for submission of approved and actual numbers, protocols are assigned a CI at the time of approval, and reassignment is not commonly the norm, so the data reports the potential level of pain and distress experienced by the animals.

Before leaving the Canadian scene it is worth noting that the University of British Columbia publically released its 2010 and 2011 statistics of animals involved in research. The 14 December

2012 media release (UBC releases 2011 statistics on animals involved in research (2012)) by Helen Burt, UBC's Associate Vice-President of Research and International upon the release of the 2011 figures) is worth quoting:

'For the second year, the University of British Columbia has published the total number of animals involved in research, their major species groupings, as well as their purpose of use and the degree of invasiveness of the research activities.'

UBC is the only Canadian university to publish its animal research statistics annually, based on its reporting to the Canadian Council for Animal Care (CCAC), the national body which oversees ethical use of animals in science and publishes national statistics.

UBC first published 2010 animal research statistics last October. In August 2012, it was also the first university in Canada to release a detailed assessment report by the CCAC.

'Research involving animals has advanced fundamental knowledge of the world we live in and contributed to medical advances that benefit humans and animals alike,' says Helen Burt, UBC Associate Vice President Research and International.' The release of 2011 animal research statistics is in keeping with our commitment to responsible transparency and respectful dialogue on animal research. UBC complies with national standards of animal care. In its 2010 assessment of UBC animal care facilities, the CCAC commended UBC for its $100 million investment in improving facilities. UBC is committed to humane care and developing research methods that reduce, refine and replace the use of animals wherever possible. All proposed research projects involving animals are closely reviewed by ethics committees comprising research experts, licensed veterinarians and community representatives.'

This statement in releasing the statistics conveyed the 3Rs message as well as stating a commitment to transparency and respectful dialogue and it said something about the representative composition of its animal ethics committees. One might feel that it did much to enhance the University of British Columbia's image within the broader community.

New Zealand Animal Use Statistics

Introduction

New Zealand has a similar scientific animal use profile to Australia. Bayvel (2004) outlining the New Zealand and Australian experience and perspective in statistics relative to the use of animals for scientific purposes noted that New Zealand and Australia had both established systems for the collection, collation and publication of animal use statistics. The Australian compilation was done by states and territories with no centralised Commonwealth compilation. In New Zealand the collection of data was first mandated in 1987, and was continued by regulations made under the Animal Welfare Act 1999. During the 1990s the National Animal Ethics Advisory Committee (NAEAC) played a key role working with the Ministry of Agriculture and Forestry to revise the information to make it more meaningful and informative and this has been ongoing. Bayvel noted that in New Zealand research communities are operating in an environment where there is considerable political, public and media interest in the use of live animals in research, testing and teaching. The statistics of such animal use, particularly the number of animals that experience significant negative welfare aspects are obviously a focus of interest. He noted that a consistent approach to the collection and evaluation of this statistical information is also vital to enable accurate interpretation of trends to be carried out. Information on invasiveness and severity enables a focus to be placed on areas where application of the Three R's can provide maximal animal welfare benefit.

The NZ MAF Animal Welfare publication, *Animal use statistics* (2010) states that the statistics supplied to MAF are collated prior to being passed to the National Animal Ethics Advisory Committee (NAEAC) for publication in its annual report. Each institution is responsible for its own returns and the relevant Sample Form for Annual Return to MAF (**Appendix B)** contains 9 boxes. All sections except Box 6 are self-explanatory. Box 6 requires further explanation and this is drawn directly from the 2010 Animal Use Statistics publication.

Purpose classifications

The New Zealand animal use statistics have 11 purpose classifications:

1) Teaching
2) Species conservation
3) Environmental management
4) Animal husbandry
5) Basic biological research
6) Medical research
7) Veterinary research
8) Testing
9) Production of biological agents
10) Development of alternatives
11) Other

Grading of impact

The 2010 MAF publication states that its purpose is to provide an overall estimate of the impact or invasiveness of each animal use by selecting the appropriate grade. The grades must reflect the summed impacts of both the initial state of the animal and the induced effect of the experimental procedure, not the induced effect alone.

The examples below cover, for each level of impact, the five domains of potential animal welfare compromise introduced by Mellor and Reid (1994) and the next two sentences are quoted directly from that paper: The first four domains are largely physical or functional encompassing potential *nutritional, environmental, health* and *behavioural* compromises. Sensory inputs from these domains result in subjective experiences in the fifth *mental* domain. Impacts on animals within any one experiment may come from more than one domain. These examples are not exhaustive or definitive, but are a guide only. It should also be noted that, in carrying out a cost-benefit analysis, it may be decided that the impact of a procedure on the animal is so great that it should not proceed, no matter what the potential benefit is. Researchers and AECs should use their knowledge and judgement in determining the impact of procedures on animals.

Grading the manipulation(s) clearly requires a value judgement to be made by the applicant. This is verified subsequently (or amended) by the AEC. The experience of the investigator, and the quality of the environment in which the manipulation is carried out may alter the grading that is selected.

The grading provided in the annual statistics should reflect the actual impact of the manipulation on an animal rather than that proposed prior to the experiment i.e. it should be assessed at the end of each project for each animal. The grades should be applied to individual animals, or to groups of animals receiving different treatments, within an experiment rather than to an experiment as a whole.

The National Animal Ethics Advisory Committee understands that some inconsistencies may occur when judgements are made on the impacts of procedures on animals; this will not seriously distort the overall picture. It is expected that an honest assessment is made.

Grade A – 'No impact or virtually no impact'

Examples:

- **Mental state:** Field observations of grazing behaviour on farms, or benign handling of tame and trained animals which are familiar with all personnel and procedures and with the place where the procedures are conducted.
- **Food/water:** Animals kept outdoors eating their usual food in appropriate amounts; grazing trials on treated pastures; offering supplements to naturally available food; provision of complete, balanced rations to meet all nutritional requirements of animals maintained indoors.
- **Environmental challenge:** Exposure to ambient conditions which are within the thermo neutral range; reduced barometric pressures which do not cause increases in red blood cell production.
- **Disease/injury/functional impairment:** Studies of healthy uninjured animals which are kept in physical conditions which do not themselves lead to injuries such as lameness or compression sores; studies to establish normal characteristics of healthy animals.
- **Behaviour:** Studies of wild or undomesticated animals in their natural habitats; field studies of domesticated animals.

Grade B – 'Little impact'-Manipulations of minor impact and short duration

Examples:

- **Mental state:** Experiments on completely anaesthetised animals which do not regain consciousness; simple venepuncture or venisection; injection of non-toxic substances; skin tests which cause low level irritation without ulceration/erosion; feeding trained animals by orogastric tube; movement of free-range domesticated animals to unfamiliar housing; minor restrictions of water and/or feed intake beyond the normal period of satiation.
- **Food/water:** Water priming for kidney function tests; short-term overall food intake restrictions or excesses which are within usual tolerance levels for the species; short-term changes in dietary composition which cause no clinical signs of deficiency or toxicity, but which would cause such symptoms in the longer term.
- **Environmental challenge:** Exposure to levels of cold or heat which are outside the thermo neutral range, or barometric pressures which increase red blood cell production, but which remain within the capacity of the animals to adapt and do not lead to debility in the long term.
- **Disease/injury/functional impairment:** Studies of vaccines using killed pathogens; tuberculosis tests; induction of mild fever without other debilitating effects; induction of subclinical parasitism; healing of minor superficial incisions, cuts or wounds; minor surgical and/or pharmacological modification of homeostatic capacity (e.g. creation of non-obstructive gut fistulae; splenectomy; endocrine gland removal with complete and permanent hormone replacement therapy); physical conditions which cause transient lameness of low intensity, mild compression sores or abrasions.
- **Behaviour:** Mild and short-term physical restraint; keeping free-range domesticated animals in a yard; movement of free-range domesticated livestock to unfamiliar housing; operant conditioning with positive reinforcement in barren laboratory environments; benign preference tests in unnatural surroundings.

Grade C – "Moderate impact"

Includes manipulations of minor impact and long duration or moderate impact and short duration

Examples:

- **Mental state:** Recovery from major surgeries like thoracotomy, orthopaedic procedures, hysterectomy or gall bladder removal with effective use of analgesics; surgical procedures on conscious animals but with the use of local anaesthesia and systemic analgesic; movement of excitable free-range domesticated livestock to unfamiliar housing; short term capture, handling and restraint of wild or semi-domesticated animals that exhibit marked flight responses; moderate restrictions of water and/or feed intake beyond the normal period of satiation.
- **Food/water:** Simulation of usual overall intake restrictions often experienced by pregnant/lactating ruminants during cold winters or drought; dietary induction of milk fever in cattle; induction of mild deficiency or toxicity signs by feeding diets containing inadequate or excessive amounts of essential nutrients.
- **Environmental challenge:** Short-term exposure to severe extremes of cold or heat which would lead to collapse if prolonged.
- **Disease/injury/functional impairment:** Studies of live vaccines; induction of clinical parasitism; induction of mild reversible infectious diarrhoea; moderate surgical and/or pharmacological modification to homeostatic capacity (e.g. limited gut resection; endocrine gland removal with delayed or incomplete hormone replacement therapy); physical conditions which cause minor chronic lameness or other injuries; studies of the effects of infectious or toxic agents that cause rapid death without distress.

- **Behaviour:** Medium-term restrictions of instinctive behaviour; medium-term holding of ruminants in a metabolism crate; long-term restraint leading to the development of reversible stereotypies; changing social group composition.

Grade D – "High impact"

Includes manipulations of moderate impact and long duration or high impact and short duration

Examples:

- **Mental state:** Recovery from major surgery under anaesthesia without the use of postoperative analgesics; marked social or environmental deprivation; longer term capture, handling, restraint or housing, without the use of tranquilisers, of wild or semi-domesticated animals that exhibit marked flight responses.
- **Food/water:** Dietary induction of advanced pregnancy toxaemia in sheep or ketosis in dairy cattle; dietary induction of advanced signs of nutrient deficiency or excess; severe deleterious effects of dietary toxins; severe restrictions of water and/or feed intake beyond the normal period of satiation.
- **Environmental challenge:** Prolonged exposure to severe cold or heat which would lead to failure of thermoregulation and collapse, but the exposure is terminated just before those outcomes.
- **Disease/injury/functional impairment:** Studies of severe facial eczema; induction of severe diarrhoea or severe infectious pneumonia; protracted or irreversible pharmacological modification of homeostatic capacity (e.g. chemical induction of diabetes mellitus without replacement therapy); marked surgical modification of homeostatic capacity (e.g. extensive gut resection; cutting of sensory or motor nerves serving large areas of the body from which no self-mutilation injury results; precise lesioning of limited areas of the brain but with intervention before collapse); physical conditions which cause moderate chronic lameness or other injuries; studies of the effects of infectious and toxic agents which cause either a protracted death with minor distress or a rapid death with moderate distress.
- **Behaviour:** Application of marked and repeated noxious stimuli from which escape is impossible; prolonged periods (several hours or more) of close physical restraint; marked alterations to the perceptual or motor functions of animals to test consequent behaviour.

Grade E – "Very high impact"

Manipulations of high impact and long duration

Examples:

- **Mental state:** Conducting major surgeries without the use of anaesthesia on control animals in assessing efficacy of analgesics; testing the efficacy of analgesics in animals with severe induced pain.
- **Food/water:** Experiments which cause animals to die from poisoning by toxins in the diet; protracted and severe restrictions on water and/or feed intake.
- **Environmental challenge:** Purposeful exposure of conscious animals to lethal extremes of cold, heat or barometric pressure which duplicate naturally occurring conditions.
- **Disease/injury/functional impairment:** Studies of methods for killing pest animals; cutting of sensory or motor nerves serving large areas of the body from which self-mutilation injury results; evaluation of vaccines where death is the measure of failure to protect; studies of the effects of infectious or toxic agents which cause either a protracted death with marked distress or a rapid death with severe distress.
- **Behaviour:** Application of marked and repeated extremely noxious stimuli from which escape is impossible; prolonged periods (several hours or more) of close physical restraint.

It is important to reflect that informed international opinion has moved towards reasoning grading provided in the annual statistics should reflect the actual impact of the manipulation on an animal

rather than that proposed prior to the experiment i.e. it should be assessed at the end of each project for each animal. Therefore the grading becomes retrospective rather than prospective and the New Zealand system does this. Another very important consideration to note with the New Zealand grading of manipulations is that the duration of the impact as well as the immediate effect of the impact is taken into account in assessing the grading. It will be remembered that Griffin in evaluating the CCAC system felt that system in future development would ideally take into account the duration of the impact in assessing severity of a procedure.

Williams et al (2006) reported on review into the operation and effectiveness of the scale devised by Mellor and Reid (1994). The 2006 paper also reported on the extent to which it fulfils the purposes for which it was devised. Concerns had been raised about a probable lack of consistency across institutions in the way the scale had been applied. This could have resulted in both under and over-assessment of the impact of manipulations. It had become apparent that the purposes of the scale were not well understood by some using it resulting in use in a way that prevents the degree of flexibility and judgement under the five domains as intended in the original paper.

Williams et al subsequently found:

- The basis of the Mellor and Reid (1994) paper remains appropriate.
- The name of the categorisation system should be the "impact scale".
- The current 5 point system should be enlarged by the addition of a sixth category which includes procedures that must not be carried out under any circumstances.
- To ensure greater accuracy where individuals or groups within an experiment are likely to experience significantly different impacts, they should be graded on an individual or group basis, rather than a whole of experiment basis as suggested originally by Mellor and Reid.
- Animal manipulations in biotechnology are adequately covered by the present system and the addition of special categories is not necessary.
- An exhaustive list of manipulations with recommended gradings is not advisable.
- A requirement should be made for the predicted impacts of manipulations to be considered at the end of each study to ensure that the actual impacts as assessed by researchers, animal care staff, animal welfare officers and AEC's, are supplied in the annual statistical returns to MAF.

Bayvel et al (2007) outlined the New Zealand experience with severity assessment over the period 1987-2007 and stated that information relating to the number and relative severity of live animal manipulations, undertaken for research testing or teaching is extremely valuable in relation to the high degree of political and public interest in this sensitive public policy area. They also stated that the information can be used to target as priorities for research those areas of animal usage which involve the greatest animal welfare compromise.

European Union Pre Directive 2010/63/EU

EU animal use statistics prior to 2013

Directive 2010/63/EU came into effect January 1 2013 and will be discussed in detail subsequently. However it is important to consider the situation applying in the EU prior to this because it is felt that the evolution of a new EU system may provide a valuable lead in the way Australia might proceed.

The Sixth Report from the Commission to the Council and the European Parliament on the Statistics of the number of animals used for experimental and other scientific purposes in the member states of the European Union COM (2010) provides an overview of the number of animals used in the EU in 2008 for experimental and other scientific purposes. The objective of the (EU) report is to present to the Council and the European Parliament, in accordance with Article 26 of Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes, the statistical data on the number of animals used for experimental and other scientific purposes in the Member States of the EU.This report includes data from all 27 Member States, submitted in the agreed format by all countries. The Commission reports every three years. The next report should be due in 2013 and should present 2011 EU figures.

Part A is the compilation and overview of the data of 2008 and is made up in 8 broad tables, each of these tables having sub-components. The rationale behind the different tables is:

Table 1 - Number of animals used in relation to their place of origin (origin versus species)

The Directive makes provisions with regard to the minimum standards to be maintained by the supplying and breeding establishments. Consequently, it can be said that animals obtained from the registered breeding or supplying establishment should have received at least the level of care as required by the Directive.

Table 2 - Number of animals used in experiments for selected purposes (purpose versus species)

This table gives an insight into the areas of activities where animals are used. Also, it indicates how the uses of different species and the numbers of animals vary according to purpose.

Table 3 - Number of animals used in toxicological and other safety evaluations (products versus species)

European legislation sets a high level of protection for the human and animal health and the environment. This is also true for third countries, so additional testing may be required when the product is destined for export. This table further expands on the area of toxicology.

Table 4 -Number of animals used in experiments for studies on human and animal diseases (main categories versus species)

An important area of research is to increase the understanding of diseases and defects. This table demonstrates how animals are used in some key areas of research. It is also worth noting that some testing is carried out to increase understanding of animal diseases only.

Table 5- Animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine.

Table 6 – Origin of regulatory requirements for animals used in toxicological and other safety evaluations

In trade, within the EU and internationally, manufacturers are obliged to comply with the requirements of the importing country. These particular tables allow the identification of where the legislative requirements originate and of how well the international harmonisation process is progressing. As harmonisation advances, there should be a trend in the numbers towards the column headed 'any combination'. The same applies to harmonisation between national and EU requirements.

The statement is made that these tables should also be referred to when drafting new legislation, to increase the awareness of the implications of new legal requirements on animal testing.

Table 7 - Number of animals used in toxicological and other safety evaluations

Table 8 – Type of toxicity tests carried out for toxicological and other safety evaluations of products

These two tables give an understanding of the types of tests required and performed on animals.

They give information on where research on alternative methods could be focused. The tables are designed to highlight key indicators, such as numbers and species in relation to the type of test (the degree of pain and suffering). Indication of the product type gives an interesting explanation as to who are the main "customers" for these types of animal tests.

The introduction of validated and accepted *in vitro* animal alternative methods will probably affect the figures in these tables. The tables can therefore assist in estimating the degree of the implementation of such methods.

That four of the tables are related to toxicological and quality control of products is in marked contrast to the Australian and New Zealand situations. This undoubtedly reflects the amount of toxicity testing done in the EU using animals and the concern that the public have for such testing. In a different forum this is echoed by a very significant part of the program of successive World Congresses on Alternatives and Animal Use in the Life Sciences being devoted to alternatives to the use of animals for toxicity testing.

Part B is the data and summary of the comments submitted by the 27 member states.

The key findings from the report are:

- The total number of animals used for experimental and other scientific purposes in 2008 (with one Member State reporting for 2007) is just above 12.0 million.
- Rodents together with rabbits represent more than 80% of the total number of animals used in the EU. Mice are the most commonly used animal accounting for 59% of the total use, followed by rats at 17%.

- As stated in the fourth and fifth statistical reports no Great Apes were used for scientific purposes in the EU in 2008. The total number of animals used for experiments in the EU in 2005 was 12.1 million.

With regard to the 6th Report to the European Commission, each of the 27 nations provides a verbal report to accompany their statistics. It is of interest to provide a brief overview of the reports of the UK, The Netherlands and Germany. At successive World Congresses on Alternatives and Animal Use in the Life Sciences these three countries have been very active in promoting the 3Rs.

United Kingdom

The User Guide to Home Office Statistics of Scientific Procedures on Living Animals (2012) states that in the United Kingdom the use of animals in scientific procedures is regulated by the Animals (Scientific Procedures) Act 1986, an animal protection measure that requires licensing and oversight of all places, projects and personnel involved in such work. Under the 1986 Act the Home Office must inform Parliament of the authorised annual use made in Great Britain of animals in scientific procedures (separate information is produced for Northern Ireland under devolved arrangements). This is done through the presentation of a detailed annual statistical report. The data collection (along with corresponding collection of data for Northern Ireland by DHSSPS) enables the UK to meet requirements for data to be supplied to the EU. Detailed information on the work of individual project licence holders is not readily identifiable in the annual statistics. Where a further breakdown of the 'other' species categories are not given in the commentary this is to safeguard the confidentiality of the establishment and the licence holder.

The latest report at the time of writing, Statistics of Scientific Procedures on Living Animals Great Britain 2011 (2012) relates to scientific procedures performed using live animals subject to the provisions of the Animals (Scientific Procedures) Act 1986, during the year 2011. Central to the report are 16 tables, although it should be noted that 6 of these tables have sub-components.

Table 1 is concerned with scientific procedures by species of animal and primary purpose of the procedure.

Table 1a details animals used by species of animal and primary purpose of the procedure

Table 2 details scientific procedures listed by Schedule 2 listed species and source of animals

Table 3 details scientific procedures by species of animal and genetic status

Table 4 details scientific procedures by species of animal and target body system

Table 5 details scientific procedure by species of animal and level of anaesthesia

Table 6 details scientific procedures (non-toxicology) by species of animal and field of research

Table 6a details animals used (non-toxicology) by species of animal and field of research

Table 7 details scientific procedures (non-toxicology) by species of animal and production of biological materials

Table 8 details techniques of interest. (This was taken from the organisation chart outlining the relations ship between the tables but the table could not be found from within the report.

Table 9 details scientific procedures (toxicology) by species of animal and toxicological purpose

Table 9a details animals used (toxicology) by species of animal and toxicological purpose

Table 10 details procedures (toxicology) by species of animal and type of legislation

Table 11 details scientific procedures (toxicology by species of animal and type of toxicological test: all purpose.

The Netherlands

The Royal Netherlands Academy of Arts and Sciences (KNAW), the Association of Universities in The Netherlands (VSNU), and the Netherlands Federation of University Medical Centres (NFU) wrote an Animal Experiments Openness Code in 2008 in an effort to foster mandatory openness and dialogue concerning animal testing by means of self-regulation. They state that the uninitiated public is mainly interested in:

- Why animal experiments are necessary to meet the research aims
- The ethical considerations involved
- The relevance of animal experiments to mankind
- The availability of alternative methods;
- The suffering of the laboratory animals
- What happens to them after experiments are concluded

They go on to discuss the need for openness and whether increased openness will put people involved in the use of animals for scientific purposes at greater risk. They state that reports from Sweden and Denmark, where there is more openness on the subject than in The Netherlands, do not suggest that researchers or institutions are at greater risk. They also note that when UK institutions pursued a policy of non-disclosure that it was counterproductive and UK institutions and enterprises have therefore deliberately pursued a policy of greater openness in recent years. Central to an openness policy is the national publication of meaningful statistics relative to the use of animals for scientific purposes.

With regard to The Netherlands statistics the following was taken from the Sixth Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union COM(2010) 511

87 establishments completed the registration form.
These establishments can be categorized as follows:

a) Universities and university hospitals	15
b) Other hospitals, regional public health laboratories	1
c) Public health research institutes	8
d) Agricultural and veterinary research institutes	8
e) Other research institutes	4
f) Industries and companies	40
g) Schools for vocational training	8
h) Breeders	3

The following statistics are interesting with regard to The Netherlands in 2008.

In 2008, according to the EU Tables, the total number of animals used in the Netherlands was 501,056. This was 1.6% (10,060) less than the number of animals used in 2007 (513,423).

The total number of genetically modified animals that was used was 83,097. When split up into species, the numbers of genetically modified animals used were:

- 81,089 mice
- 284 rats
- 81 rabbits
- 225 amphibians
- 1,418 fish.

In 2008 the number of animals used for toxicological and other safety evaluation decreased by 24.7% (13,431) compared to the number used in 2007.

With regard to discomfort, data has to be registered after an experiment has been performed. This includes data on the degree of discomfort.
As a consequence of the animal experiments performed in 2008:

- 33.66% of the animals experienced minor discomfort;
- 28.52% of the animals experienced minor/moderate discomfort;
- 25.05% of the animals experienced moderate discomfort;
- 9.11% of the animals experienced moderate/severe discomfort;
- 3.63% of the animals experienced severe discomfort and
- 0.03% of the animals experienced very severe discomfort.

Germany

In the German section of the 2010 European report with regard to 2008 statistics the statement is made that Germany is making a major contribution towards the development of test methods which do not involve animal experiments. A leading part in this process is played both by the Federal Ministry of Education and Research, with its scheme to promote the development of methods to replace animal experiments and by the Central Office for the registration and assessment of methods replacing and supplementing animal experiments, which this year is celebrating its 20th anniversary.

In 2008 in Germany the number of vertebrates used for experimental and other scientific purposes increased by 2.1% to 2,021,782. At almost 87%, rodents constitute the largest group of animals used in experiments. In particular, mice account for 65% and rats for 19%. The next largest groups comprise rabbits at 4.8%, fish at 3.3% and birds at 2.8%. All other species taken together account for 2.2% of the animals used.

The German 2008 figures included some comparisons with 2007. Compared with the previous year, the number of Old World monkeys, New World Monkeys and Prosimians fell by 152 to 2,263. The largest proportion of these animals (1,858) was used for toxicological tests and other safety tests on products and appliances for human, dental and veterinary medicine. Apes were not used.

Compared with 2007, the number of dogs and cats used fell by 340. For basic biological research the number of fish used fell by 88,760 and the number of rats by 18,122.
In contrast, the number of mice rose by 41,775 and the number of amphibians by 5,676. In total, 68,519 fewer animals were used in basic biological research.

For the research and development of products and for the manufacture and/or quality control of products for human, dental and veterinary medicine, 858,395 animals were used – an increase of 122,052 compared with the previous year.

The EU Post Directive 2010/63/EU

Directive 2010/63/EU intent

Directive 2010/63/EU of the European Parliament and of the Council of 27 September 2010 is concerned with the protection of animals used for scientific purposes. It develops on previous directives. The directive contains procedures of relevance and considerable significance for future collection of statistics. In particular (quoting from the Directive):

(22) To enhance transparency, facilitate the project authorisation, and provide tools for monitoring compliance, a severity classification of procedures should be introduced on the basis of estimated levels of pain, suffering, distress and lasting harm that are inflicted on the animals.

(24) When developing a common format for reporting purposes, the actual severity of the pain, suffering, distress or lasting harm experienced by the animal should be taken into account rather than the predicted severity at the time of the project evaluation.

With regard to general provisions of the same document Article 15, relative to classification of severity of procedures states:

1. Member States shall ensure that all procedures are classified as 'non-recovery', 'mild', 'moderate', or 'severe' on a case- by-case basis using the assignment criteria set out in Annex VIII.

2. Subject to the use of the safeguard clause in Article 55(3), Member States shall ensure that a procedure is not performed if it involves severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.

Annexe VIII describes severity classification of procedures and is included in detail in **Appendix C**

Implementation of Directive 2010/63/EU re prospective and retrospective reporting

National Competent Authorities for the Implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes Working document on a severity assessment framework Brussels, 11-12 July 2012, is of interest. This document is the result of the work of the two EWG meetings, discussions with the Member States, as well as legal input from the Commission on the understanding of a severity assessment framework, its components, participants and working tools and methods. It was endorsed by the National Competent Authorities for the implementation of Directive 2010/63/EU at their meeting of 11-12 July 2012.

In a general back ground statement this document stated "Directive 2010/63/EU on the protection of animals used for scientific purposes requires that a prospective assessment is made on the severity of each procedure in a Project (Article 15)and that a severity classification is assigned, which may be either "non-recovery", "mild", "moderate" or "severe". Annex VIII provides guidance on the factors to be taken into account in the consideration of prospective severity and provides some examples in each severity category.
Article 54 on reporting requires that for statistical information, the actual severity of the pain, suffering, distress or lasting harm experienced by the animal must be reported (in contrast to the prospective assessment, or prediction, of severity made at the time of the project evaluation). In addition, the actual severity of any previous procedures will be a key consideration in determining whether or not an animal can be reused in further procedures (Article 16).

The main benefits of retrospective assessment, monitoring, assessing and recording actual severity include improved transparency as resulting statistics should better reflect the cost to the animals.

UK Changes Following Transposition of European Directive 2010/63/EU

The UK Statistics of Scientific Procedures on Living Animals: Changes Following Transposition of European Directive 2010/63/EU (2013) document is of significance in so much as it invites discussion relevant to the transitional phase. It details that The Animals in Science Regulation Unit of the Home Office have developed a consultation document seeking comment on proposed new arrangements for the collection and publication of data on the use of animals for scientific purposes required under Directive 2010/63/EU on the protection of animals for scientific purposes. At the time of writing the closing date for responses is 17 April 2013. A summary report is to be published on the consultation and its outcome. The new requirements are transposed by section 21A of the Animals (Scientific Procedures) Act 1986, as revised by Amendment Regulations 2012 (SI 2012/3039) made on 18 December 2012.

Section 21A is worth recording here. It is important to note that as a preface to this version of the Act the Home Office states that it should be treated as a working document and is provided for information purposes only. The following is section 21A lifted from the Act:

21A Statistics and reporting 64
(1) In each year, beginning with the year 2015, the Secretary of State must by 10 November:

(a) Collect and publish statistical information on the use of protected animals in regulated procedures during the previous year;
(b) Lay that information before Parliament; and
(c) Send that information to the European Commission.

(2) The statistical information must include information:

(a) On the actual severity of the regulated procedures, and
(b) On the origin and the species of any primates used in regulated procedures.

(3) The Secretary of State must each year send to the European Commission information on the methods of killing that have been specified in section 2C licences for the purposes of section 15A(2)(b).

(4) The Secretary of State must by 10 November 2018, and by 10 November in every fifth year thereafter, send to the European Commission information on the implementation of the Animals Directive (and, in particular, Articles 10(1), 26, 28, 34, 38, 39, 43 and 46 of the Directive).

Relative to this the Home Office have produced a consultation (2013-statistics-consultation read only) document to seek the comments of interested parties with a closing date for responses being 17 April 2013. In this document they state that the proposal is to replace current UK data collection with the new EU requirements thereby harmonising the UK data collection with other Member States. They state that the information required will differ in a number of respects from the current UK statistics:

- The new format will require the collection and publication of information about the actual severity of the procedures carried out,
- A procedure must be counted in the year it is completed, not the year in which it started.
- It is proposed that information on anaesthesia will no longer be collected, the belief being that the current data is misleading and that severity data will be much more informative.

- It is intended that duplicate tables for animals and procedures will not be published since equivalent information will be deduced by the number of reuses.
- Genetic status will specifically identify animals used for the creation of a new genetically altered line but will no longer differentiate between mutant and GM animals.
- The primary purposes will reflect those in the Directive but additional data (e.g. in relation to human and veterinary medicine) will be captured in greater detail in subsequent tables.
- In relation to research, fields of research are largely being replaced by the system under study and basic research
- Basic research will be differentiated from translational or applied research.
- In relation to regulatory use and routine production, there will be some reduction in information on the production of biological materials but quality control testing will specifically include details about batch safety and potency testing, and pyrogenicity testing.
- It is intended to request numbers of animals to be judged sub-threshold at the end of a procedure, the belief being that this will produce additional valuable data.

As concerns reporting on actual severity new standard project licence condition 10 requires that, on completion of a procedure, a suitably qualified person must classify the actual severity as 'non-recovery', 'mild', 'moderate', or 'severe' using the criteria set out in Annex 8 to the Directive. Annex 8 has previously been detailed in this document. The requirement to classify actual severity in the UK applies with effect from 1 January 2013, although it is not a requirement to report this for procedures ending in 2013. The unit never the less may collect some information from selected licence holders to enable some experience of severity reporting before it becomes mandatory from 1 January 2014. A series of regulated procedures applied to an animal for a particular purpose is to be treated as constituting a single regulated procedure.

The Unit may consider retaining a limited number of current information requirements not included in the new EU requirements in an additional table. They say these might include tobacco, alcohol and household product testing, or techniques such as ascites production where they say they are interested in monitoring the progress of the 3Rs. The justification of what to include here would be on the grounds of animal welfare or being of special scientific or public interest. It would be expected that in a demographic of strong animal welfare interest as is apparent in the UK that public interest would be the strong motivator in the inclusion of alcohol, tobacco and household product testing.

Timeframes for the Home Office implementation of the new requirements are important in so much as they may give an indicator of expected timeframes for the introduction of an Australian wide scheme for recording and publishing statistics relevant to the use of animals for scientific purposes. In January 2014, the data collected for 2013 on animal use (excluding severity data) must be submitted. In January 2015, the data collected for 2014 on animal use including actual severity must be submitted to the Home Office. By 10 November 2015 the Home Office must lay the statistics before Parliament and send them to the European Commission. They acknowledge that some double counting of procedures will occur, for example when a procedure spans the 2013 and 2014 reporting years and is reported as staring in 2013 and reported again on completion in 2014.

Australia-Current Situation by State

As discussed earlier in this document statistics pertaining to the use of animals used for scientific purposes are collected by states and territories. Latest statistics were found for New South Wales (2010), Victoria (2011), South Australia (2009) and Tasmania (2011). Queensland has not published such statistics since 2004. Western Australia has not released relevant statistics since 2007. Statistics for the Australian Capital Territory and the Northern Territory could not be found in the public domain.

New South Wales

The NSW Animal Research Review Panel Annual Report for 2010-2011(2011) Appendix G contains calendar year 2010 figures. Central to this are 10 categories of purpose and 9 categories of procedure. The categorisation of procedure gives an indication of the invasiveness or the impact of the work involved.

The following purposes are listed:

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.

The procedure categories with guidelines used for classification are:

1. **Observation involving minor interference**
   Animals are not interacted with, or where there is interaction, it would not be expected to compromise the animal's welfare any more than normal handling, feeding etc. There is no pain or suffering involved
2. **Animal unconscious without recovery**
   Animal is rendered unconscious under controlled circumstances (ie not in a field situation) with as little pain or distress as possible. Capture methods are not required. Any pain is minor and brief and does not require analgesia. Procedures are carried out on the unconscious animal, which is then killed without regaining consciousness.
3. **Minor conscious intervention**
   The animal is subjected to minor procedures that would normally not require anaesthesia or analgesia. Any pain is minor and analgesia usually unnecessary, although some distress may occur as a result of trapping or handling.
4. **Minor surgery with recovery**
   The animal is rendered unconscious with as little pain or distress as possible. A minor procedure such as cannulation or skin biopsy is carried out and the animal allowed to recover. Depending on the procedure, pain may be minor or moderate and postoperative analgesia may be appropriate. Field capture by using chemical restraint methods is also included here.

5. **Major surgery with recovery**
   Animal is rendered unconscious with as little pain or distress as possible. A major procedure such as abdominal or orthopaedic surgery is carried out and the animal allowed to recover. Postoperative pain is usually considerable and at a level requiring analgesia.

6. **Minor physiological challenge**
   The animal remains conscious for some, or all, of the procedure. There is interference with the animal's physiological or psychological processes. The challenge may cause only a small degree of pain/distress, or any pain/distress is w quickly and effectively alleviated.

7. **Major physiological challenge**
   The animal remains conscious for some, or all of the procedure. There is interference with animal's physiological or psychological processes. The challenge causes a moderate or large degree of pain/distress that is not quickly or effectively alleviated.

8. **Death as an endpoint**
   This category applies only in those rare cases where the death of the animal is a planned part of the procedures. Where predictive signs of death have been determined and euthanasia is carried out before significant suffering occurs, the procedure may be placed in category 6 or 7.

9. **Production of genetically modified (GM) animals**
   This category is intended to allow for the variety of procedures that occur during the production of genetically modified animals. It effectively includes **all** animals used in GM production, other than the final progeny, which are used in a different category of procedure.

In the report a very good series of graphs are subsequently used to illustrate number of animals used for a particular purpose against procedures. For example, regarding research: human or animal biology, an initial graph presents number of animals used against the nine procedures. The number used is given against the broad category of laboratory animal (eg reptiles, primates, amphibians, aquatic birds, laboratory mammals etc). Four subsequent graphs relating to research: human or animal biology provide a breakdown of laboratory mammal species, breakdown of domestic mammal species, breakdown of bird species, and breakdown of primate species against procedure. As an example for laboratory mammals the breakdown is: mouse, rat, guinea pig, rabbit, hamster, ferret, and other.

In the report there is a table on animal use for lethality testing in 2010. 6 such tests were reported for 2010, 4 involving mice, 1 involving guinea pigs and 1 involving Northern Trout Gudgeon. Lethality testing has the capacity to attract the interest of a section of the public. In the interests of transparency it is important that such testing is reported. The table includes an outline of the number of animals used, the numbers that died or were euthanized, the procedure, the justification (e.g. required by regulation) and alternatives that might have been considered. In each case it was stated alternatives were not available.

The annual report of the NSW Animal Research Review panel covers a variety of valuable information such as relevant legislation, AEC oversight, accreditation and licencing and initiatives in the 3Rs along with the publication of annual statistics. One of the perceived benefits of releasing transparent scientific animal use statistics is the opportunity to get positive messages to the public, and this report does this well. Ostensibly the majority of the public are not well versed in the diversified measures included within the Australian Code that protect the welfare of animals used for scientific purposes. Appendix H of this NSW report, which immediately follows the statistical report gives practical examples of methods used to implement the 3Rs (Replacement, reduction and

refinement) and is a good example of the sort of information that should be released in conjunction with a scientific animal statistical use report.

Victoria

Statistics of Animal use in Research and Teaching (2012)
Victoria, Report Number 29, 1 January 2011 to 31 December, 2011
Compiled by Bureau of Animal Welfare, Biosecurity Victoria, Department of Primary Industries

The following tables are used:

Table 1: numbers of animals used by type of animal and project purpose

Table 2: numbers of animals used by type of animal and source

Table 3: numbers of animals used by type of animal and particular procedure

Table 4: numbers of animals used by type of animal and impact of procedure

Table 5: numbers of animals used by type of animal and project benefit

Table 6: numbers of animals used by type of animal and deaths

Table 7: numbers of animals used by project purpose and project benefit

Table 8: numbers of animals used by project purpose and project impact

Table 9: numbers of animals used by project purpose and particular procedure

Table 10: numbers of animals used by project purpose and source

Table 11: numbers of animals used by impact of procedures and project benefit

Table 12: numbers of animals used by impact of procedures and particular procedures

Table 13: specified animals used in breeding colonies

The Victorian report includes the following purposes and procedures:

Purpose

- Education
- Environment
- Animal management/production
- Improve human/ animal health welfare
- Understand human/animal biology

Procedures:

- Animal unconscious without recovery
- Observational study minor interference

- Minor physiological challenge
- Minor intervention, no anaesthesia
- Minor operative procedures recovery
- Surgery with recovery
- Major physiological challenge
- Death as an end point

It is of interest that in Table 4 the wording 'impact of procedure' is used. It acknowledged that the procedures are an indication of level of impact.

South Australia

The February 2011 "Animals used for Research and Teaching in South Australia 2009" lists the following purposes and procedures:

Purpose:

- The Understanding of Human or Animal Biology
- The Maintenance and Improvement of Human or Animal Health and Welfare
- The Improvement of Animal Management or Production
- The Achievement of Educational Objectives
- Environmental Study

Procedures

- Observational Studies Involving Minor Interference
- Animal Unconscious without Recovery
- Minor Conscious Intervention without Anaesthesia
- Minor Operative Procedures with Recovery
- Surgery with Recovery
- Minor Physiological Challenge
- Major Physiological Challenge
- Death as an Endpoint

Queensland

Animal use statistics have not been published since 2004. The following has been obtained from questions asked by the Queensland 2012 Animal Use Statistics Report Information (2013)

Purpose of animal use

- Understanding of human or animal biology
- Maintenance and improvement of human or animal health
- Improvement of animal management or production
- Achievement of educational objectives
- Environmental study

Procedure categories

- Observational Studies Involving Minor Interference
- Animal Unconscious without Recovery
- Conscious intervention (minor without anaesthesia)
- Surgery with Recovery
- Minor Physiological Challenge
- Major Physiological Challenge
- Death as an endpoint

Tasmania

Animal Research Statistics Tasmania Annual Report Number 16 (2011) details the Tasmanian scientific animal use statistics for 1st January -31st December 2011 and was produced in September 2012. The statistics are well presented and advantage is taken to summarise relevant animal research legislation, summarise the function of AECs, and also the 3Rs. A summary is given of annual reporting requirements.

Purposes listed in the 2011 Tasmanian report were:

- Education
- Environmental study
- Health and welfare
- Management and production
- Understanding biology

Procedures listed are;

- Observation involving minor interference
- Minor conscious procedure
- Minor operative procedure with recovery
- Major surgery with recovery
- Minor physiological challenge
- Major physiological challenge
- Animal unconscious without recovery
- Death as an endpoint

Western Australia

The questions asked were ascertained from the WA Department of Agriculture and Food Renewal of Licence to Use or Supply Animals for Scientific Purposes (2013). Reporting of fish is not mandatory under current WA legislation. There is a specific form for Death as an Endpoint Research reporting.

The following 8 purposes are applicable:

- Stock maintenance
- Stock breeding (Genetically modified)
- Education
- Research: human or animal biology

- Research: human or animal health and welfare
- Research: animal management or production
- Research: environmental study
- Product testing

The following 9 procedures are applicable

- Observation involving no or minor interference
- Animal unconscious without recovery
- Minor conscious intervention
- Minor surgery with recovery
- Minor physiological challenge
- Major surgery with recovery
- Major physiological challenge
- Death as an endpoint
- Production of genetically modified animals

Comparison of Purposes and Procedures between New South Wales, Victoria, South Australia, Tasmania, Queensland and Western Australia

Concerning purpose of use four of the six states (Vic, SA, QLD, and Tas) list the same five purposes. NSW lists 10 purposes. WA lists 8 purposes. A comparison with what is presented by the Australian states re purpose of use will be compared with international practice later in the document.

The categorisation of procedure aims to give an indication of the degree of invasiveness or the impact of the work involved. Re procedure NSW, Vic, SA, Tas, WA and Qld ask the same eight initial questions; Tasmania has a slightly different order but the procedures are largely the same. NSW and WA have an additional procedure, production of genetically modified (GM) animals. This general uniformity re procedure is good in the current context however AEC's should be continually seeking to reduce, in terms of application of the 3Rs, the number of studies with a significant degree of invasiveness. Does this prospective assessment that does not take into account duration of pain and suffering allow optimal assessment of the degree of invasiveness with subsequent good opportunity for implementation of the 3Rs? It doesn't, and it does not fare well in comparison with the EU directive, what New Zealand has, and the situation that personnel within the CCAC would like to move towards.

Input from Australian Animal Welfare Bodies

Three animal welfare organisations were asked for their opinion by email of what major requirements should be considered for inclusion in a national statistics compilation relative to the use of animals for scientific purposes. Replies were received from Humane Research Australia and RSPCA, Animals Australia did not reply. The emails received in reply are summarised below:

Humane Research Australia

For some years Humane Research Australia has been trying to assemble national figures relative to the use of animals for scientific purposes. The CEO of HRA, Ms Helen Marsden was asked for comment and this is her reply:

'We absolutely agree that national statistics are essential for transparency. We have for some time been very frustrated at the lack of national figures and by the difficulty we have had in obtaining state and territory figures and believe that the final stats that HRA provides are not an accurate representation of the number of animals used in Australia, but are merely indicative based on previous figures that were available.'

In our view, the most essential requirements would be as follows:

- Stats to be provided on a timely basis (they are often years in arrears)
- Consistency in state/territory reporting (some are very detailed while others merely provide numbers of species)
- NSW figures to be more straightforward. Currently we need to manually calculate every category to establish the actual numbers used.
- More accurate description of the purpose of research. For example 'understanding human or animal biology' and 'maintenance and improvement of human or animal health and welfare' are both very general terms and should at the very least differentiate whether it is humans or other animals that the research is intended to benefit.

Whilst admitting it is unlikely to be provided, we would also welcome the following extra data:

- The names of the institutions that conducted the research (in relation to numbers and purposes)
- Whether the research was publicly funded.
- Details of whether the research resulted in any beneficial outcome.
- Citation rate
- Inclusion of animals used by government and defence forces

It is true that the final statistics that HRA produce cannot be accurate with figures unavailable from two states and two territories It is true that there is a long time gap between the end of a year and the production of statistics in most jurisdictions, although this may reflect current resources that are committed to the production of relevant statistics in each jurisdiction. That graphs are used extensively may make the NSW figures more difficult to establish actual numbers. A more accurate description of the research is given in some of the overseas reports.

The names of institutions using animals for scientific purposes in Tasmania are listed and it would appear in the interests of transparency that all institutions using animals for scientific purposes could be listed at the end of a national report. It is not hard for interested parties to find out who is undertaking animal based research in Australia. To name institutions in relation to each study would introduce a degree of complexity that is deemed unnecessary. The amount of public funding spent

on animal based research might be considered as a total figure. It is difficult to see how this would be done logistically on a project by project basis; again, the degree of detail considered practical in a national report needs to be considered. Beneficial outcomes are something that different sectors might define differently. Relative to biomedical research a university would regard an increase in knowledge as a beneficial outcome. Members of the public might expect a demonstrable outcome in terms of findings that could benefit human and/or animal health. Citations of particular animal based research could occur over a long period of time and would present considerable logistics problems. In the interests of obtaining total figures for Australia and in the interests of transparency it would seem essential that all government use of animals for scientific purposes be included in the Australian statistics.

The RSPCA

The opinion of the RSPCA is deservedly well respected within Australia and its annual scientific seminar brings together leading figures to explore latest developments in animal welfare research. A significant number of Category C members on Australian Animal Ethics Committees are members of RSPCA. Dr Bidda Jones, Chief Scientist of RSPCA Australia, stated that RSPCA would very much support the key elements identified as being fundamental to national statistics on animals used for scientific purposes. These included a transparent system uniformly applicable across Australia, that central to the system would be degrees of severity assessed by levels of impact including duration and based on retrospective assessment, and that the statistics should be presented in a timely manner. She suggested that it would be helpful to begin with measuring the implementation of the 3Rs, and see whether a model for the statistics can provide the answers.

Consideration of Inclusions in an Australian National Reporting Scheme

In the light of previous discussion, what are the considerations for inclusion in a robust national statistical reporting scheme? The major factors to be considered are:

- A uniform system for reporting the use of animals for scientific purposes should apply across Australia and result in a Commonwealth wide statistical compilation.
- The framework should provide for a nationally consistent reporting format on animals use for application by Australian organisations using animals for scientific purposes.
- The system should classify uses of animals based on types of purpose of scientific procedure.
- It should classify procedures on the degrees of severity (invasiveness) and these should be assessed by level of impact and duration.
- The degrees of severity (invasiveness) should be based on what actually happens (retrospective assessment).
- Provision of an analytic process that is applied to the data in order to derive and present information on the positive aspects of ethical oversight on animal use.
- A basic tenet of the positive aspects of ethical oversight is the 3Rs concept. A quantitative measure of implementation of the 3Rs should be considered for inclusion.
- Provision of a process that derives and presents changed patterns of animal use.
- Presentation of statistics in a timely manner.
- In the interests of transparency consideration should be given to the inclusion of names of all institutions using animals for scientific purposes, although there should be no inclusion of specific animal use details listed against an institution.

Summary of overseas aspects that Australia might use

Australia, not having a nationwide system of its own, could beneficially examine aspects of statistical collection from the international systems that have been outlined here. At the same time consideration needs to be given to the retention of that which is of value within the current Australian State's animal use statistics

The Canadian Council of Animal Care has for a considerable period set scientific animal care standards across a range of parameters that set an example for much of the rest of the World and its statistics system has much of value. The purpose of animal use is well documented. The categories of invasiveness are comprehensive although they don't reflect the duration of pain and distress and the figures relative to invasiveness are prospective, rather than retrospective. The CCAC system therefore relies on the assessment of degrees of pain and suffering prior to the study, rather than an assessment of animals during the study

New Zealand animal use statistics were first mandated in 1987 and continued to be made more meaningful and informative during the 1990s and further enhanced since. Information on invasiveness and severity enable a focus to be placed on areas where application of the 3Rs can provide maximal animal welfare benefit. The grading of manipulations are therefore a key focus point in the New Zealand system and cover for each level of impact of the five domains of potential animal welfare compromise introduced by Mellor and Reid (1994). The grading reflects the actual impact of the manipulation on an animal rather than that proposed prior to the study. It is a retrospective rather than a prospective process. It is also important to note that the New Zealand impact assessment also takes into account the duration of pain and distress, and this is considered essential to include in a realistic assessment of impact.

The Sixth Report from the Commission to the Council and the Europe Parliament on the statistics of the number of animals used for experimental and other scientific purposes in the member states of the EU (2010) has aspects that are of interest. Notable are that four of the tables are related to toxicological and other safety evaluations of products. This of course reflects the considerable amount of toxicological testing involving animals in the EU, and although considerable progress is being made concerning non-animal replacements it is expected that the EU will need to continue to report animals used in toxicological studies. In contrast Australia does little in the way of toxicological studies using animals, although this document will need to consider how that use is best reported.

With regard to the EU of particular relevance to the Australian scene in animal use statistical reporting is Directive 2010/63/EU of the European parliament and the Council, of 27 September 2010. As outlined more comprehensively earlier in this report, this directive develops on previous directives and is concerned with protection of animals used for scientific purposes. In the interests of enhancing transparency, facilitating project authorisation and to provide tools for monitoring compliance, a severity classification of procedures is to be introduced on the basis of estimated levels of pain, suffering and lasting harm inflicted on the animals. Importantly for reporting processes, the actual severity of the levels of pain, suffering and lasting harm inflicted on the animals are to be taken into account rather than the predicted severity at the time of the project evaluation. This is a retrospective rather than a prospective system. There are four severity classifications: Non-recovery, mild, moderate, and severe and examples relative to each classification are extensively listed.

To gain some idea of the implementation of the Directive it is of considerable interest to observe the early stages of consultation re necessary change within the UK Statistics of Scientific Procedures on Living Animals. The Animals in Science Regulation Unit of the Home Office have developed a consultation document seeking comment on the proposed new arrangements for the collection and publication of relevant data under the directive. Of considerable interest is an outline of where it is anticipated the information required will differ from that currently collected. These have been previously detailed in ten dot points and will not be reiterated here but will need to be taken into account when looking at all aspects that might gainfully be incorporated into an Australian system.

How Does this Compare with Data Currently Available within Australian States and Territories?

Degrees of invasiveness/severity

Commentators world-wide identify inclusion of degrees of invasiveness (internationally also known as levels of severity or grading of impact) as being of central importance to national scientific animal use statistics in so much as there is a high degree of public and political interest in pain and distress as well as enabling a prioritisation of 3Rs effort by researchers, AECs and legislators. Are the Australian statistics currently collected by states and territories reflecting an assessment of degrees of invasiveness? Relatively recent published statistics were found for four states and territories, New South Wales, Victoria, South Australia, and Tasmania. Queensland last published relative statistics in 2004. Questions asked by Queensland have been obtained from questions asked within the Queensland DAFF 2012 Animal Use Statistics Report Information. Similarly WA questions have been ascertained from the 2013 WA Department of Agriculture and Food renewal of a licence to use or supply animals for scientific purposes. Within the Australian states the categorisation of procedure aims to give an indication of the degree of invasiveness or the impact of the work involved. Re procedure NSW, Vic, SA, and Qld ask the same eight initial questions; Tasmania has a slightly different order but the procedures are principally the same. NSW and WA have an additional procedure, production of genetically modified (GM) animals.

These procedures are:

- Observation involving minor interference
- Animal unconscious without recovery
- Minor conscious intervention
- Minor surgery with recovery
- Major surgery with recovery
- Minor physiological challenge
- Major physiological challenge
- Death as an endpoint
- Production of genetically modified (GM) animals (NSW and WA only)

The ninth procedure included by NSW and WA is production of genetically modified animals. This effectively includes all animals used in GM production, other than the final progeny, which are used in different categories of procedure. With the widespread use of GM rodents in particular in biomedical research in Australia and a degree of contention about the use of GM organisms in society this should be included in an Australian wide scientific animal use statistics report. In line with the UK consultation document it would be deemed to be prudent to include all mutant animals (e.g. those produced by chemical mutagenesis) as well as GM animals. The EU directive removes this differentiation by using the phrase 'genetically altered animals.'

The major consideration at this point is the procedures as used by states outlined above sufficient for providing the maximal amount of pertinent information for an Australia wide system as far as levels of severity are concerned? Or do we need to take elements from the Canadian, New Zealand or EU models?

Initially we need to look at summaries of the Canadian, New Zealand and mandated EU systems and their categories of invasiveness.

Summarising the earlier CCAC data the Canadian system has four categories of invasiveness:

- Experiments which cause little or no discomfort or stress
- Experiments which cause minor stress or pain of short duration
- Experiments which cause moderate to severe distress or discomfort
- Experiments which cause severe pain near, at, or above the pain tolerance threshold of unanaesthetised conscious animals

The 2010 Canadian survey publication has three tables that involve categories of invasiveness. They are:

- Number of animals used in 2010 by CCAC participants according to the category of invasiveness
- Number of animals used in 2010 by CCAC participants according to purpose of animal use and category of invasiveness
- Number of animals used in 2010 by CCAC participants for each purpose of animal use according to the degree of invasiveness

It should be remembered that the current Canadian analysis re invasiveness does not take into account the duration of pain and suffering and is done prospectively rather than retrospectively, but the ability of the Canadian analysis to deliver relevant information needs to be considered when evolving an effective Australian system.

The New Zealand system has five levels of impact based on the five domains of potential animal welfare compromise introduced by Mellor and Reid (1994). As well as being retrospective the New Zealand grading system takes into account duration and is summarised as follows:

- Grade A-No impact or virtually no impact
- Grade B-Little impact, further defined as manipulations of minor impact and short duration
- Grade C-Moderate impact which includes manipulations of minor impact and long duration or moderate impact and short duration
- Grade D-High impact which includes manipulations of moderate impact and long duration or high impact and short duration
- Grade E-Very high impact which are manipulations of high impact and long duration

The New Zealand scientific animal use profile is not significantly different from our own, so at this point it is worth assessing how these procedures compare with the five New Zealand animal use statistics severity of manipulations grading? Firstly, these Australian procedures do not take into account the duration of pain and distress. Secondly, they are relatively narrow parameters which do not take into account the five domains of animal welfare compromise, nutrition, environment, health, behaviour and mental state. The following are taken into account within New Zealand animal use statistics to assist in accurately assigning animals to an impact grade:

- Mental state
- Food/water
- Environmental challenge
- Disease/injury/functional impairment
- Behaviour

Across the range of Australian scientific animal use it is felt that use of the five New Zealand severity gradings would provide a more accurate national picture for the production of statistics that could ultimately be used to provide a more meaningful focus of the 3Rs across the scientific animal use spectrum. The current Australian state procedures are largely biomedically focused. They are not so well suited to accurate description of animal welfare compromise for example in nutritional, animal production, animal disease, behavioural, and long term studies.

As a matter of interest would the above common 8 Australian state procedures fit into the New Zealand manipulations grading? It seems they would:

Australian States Procedure	**NZ Manipulation Grading**
Observation involving minor interference	Grade A or B
Animal unconscious without recovery	Grade B
Minor conscious intervention	Grade B
Minor surgery with recovery	Grade B
Major surgery with recovery	Grade C
Minor physiological challenge	Grade B
Major physiological challenge	Grade D

Death as an endpoint Grade E

The EU Directive 2010/63/EU has four severity levels:

- Unconscious, no recovery
- Mild
- Moderate
- Severe

A good number of examples are listed under each of these classifications to facilitate making decisions as to which category is appropriate.

In the light of these summaries, in answering the question about the adequacy of the current system used by Australian states, we also need to take into account what overseas commentators see as being the principal reasons for establishing severity scales.

Williams et al (2006) from a New Zealand perspective state that a severity scale is of significance to four interested parties, animal based scientists, animal ethics committees, regulators and the public they go on to expand where the need arises in each of these groups:

Animal-based scientists need to assess the invasiveness of their manipulations as an integral part of seeking approval to undertake them. Evaluating invasiveness gives an indication of the harm that may be done to the animals. Conducting a harm benefit analysis is a pivotal part of achieving approval for a proposed manipulation. This ensures that the potential adverse effects on the animals used are greatly outweighed by the benefits accrued from the work. This way of justifying the work is in compliance with the utilitarian ethical basis for using animals in research, testing and teaching.

Animal ethics committees are required to undertake a harm-benefit analysis for each application to manipulate animals in research, teaching and testing. This too relates to the utilitarian ethical mode of assessing the justification for such animal use as proposed in applications to each committee. It also allows members of the AEC to help to ensure that the principle of refinement, or minimisation of harm, is fulfilled.

Regulators require it because it confirms that such assessments are indeed being undertaken in compliance with the Animal Welfare Act, and this can be demonstrated by the public release of annual statistics showing the range of invasiveness of approved manipulations.

Interested members of the public desire knowledge of this kind in order to be reassured that:
(1) excessively invasive manipulations are not being conducted in a high proportion of the animals,
(2) very invasive manipulations are properly justified,
and (3) within the full range of severity, the majority of manipulations have been at the bottom end of the range where the impacts are very low (benign) with few negative consequences.

Griffin et al (2010) from a Canadian perspective have the same four principal uses outlined.

It is apparent that the information currently collected by the Australian states cannot effectively inform these four interested parties to anything like the same degree that the New Zealand, or mandated EU categories of invasiveness do, and the Canadian system, lacking as it currently does a duration of pain and distress inclusion and a retrospective assessment, still has much to offer. The Australian procedures which purport to show levels of invasiveness are precisely that, procedures! They do not effectively ensure scientists take into account the amount and duration of pain and

suffering or the duration of it. They do not enable AECs to make a really effective judgement re the harm-benefit analysis for each application. The current procedures don't really allow regulators to make an effective pronouncement re compliance with the legislation. The Australian public quite frankly currently would be hard put to really know what happens to animals used for scientific purposes and regrettably the chance to portray the effectiveness of the procedures contained in what amounts to a Code of good international standing is being lost.

The conclusion from the preceding paragraph is that an Australian statistical compilation relevant to the use of animals for scientific purposes must utilise a process that logically assesses impact that includes duration of that impact and is done retrospectively. Interestingly section 2.2.39 of the Code, relevant to final reporting on a concluded project, sub-section (iv) states that the report should advise on conclusions as to how procedures in future projects could be modified to reduce any impact on animal welfare. That could be answered much more accurately than is currently possible using a retrospective assessment of the impact on animals, utilising the logical assessment provided by the New Zealand system, and including assessment of duration of the impact.

Purpose of Use:

Purpose of use is an integral part of scientific animal use statistical compilations and careful consideration needs to be given as to what purposes of use are of critical importance to an Australian statistical compilation. Although the current Australian situation is a fragmented one, in the interests of not disrupting the current jurisdiction's systems more than necessary it is felt close attention should be given to retaining what is valuable within the Australian jurisdictions as regards purpose of use. This notwithstanding, the purposes of use listed within the Canadian, New Zealand and UK systems will be examined to ascertain if there are purposes not currently listed within the Australian jurisdictions that might add value to the system, or if the naming of purposes in those countries might convey more meaning re clear interpretation of purpose.

The Canadian system has 6 categories of purpose:

1) Breeding Colony/Stock - Animals held in breeding colonies (e.g., fish, rodents) that have not been assigned to a particular research, teaching or testing protocol.
2) Studies of a fundamental nature in sciences relating to essential structure or function (e.g., biology, psychology, biochemistry, pharmacology, physiology, etc.).
3) Studies for medical purposes, including veterinary medicine, that relate to human or animal disease or disorders.
4) Studies for regulatory testing of products for the protection of humans, animals, or the environment.
5) Studies for the development of products or appliances for human or veterinary medicine.
6) Education and training of individuals in post-secondary institutions or facilities.

The New Zealand animal use statistics have 11 purpose classifications:

1) Teaching
2) Species conservation
3) Environmental management
4) Animal husbandry
5) Basic biological research
6) Medical research

7) Veterinary research
8) Testing
9) Production of biological agents
10) Development of alternatives
11) Other

The UK animal use statistics have the following 9 primary purposes:

1) Fundamental biological research
2) Applied studies-human medicine or dentistry
3) Applied studies-veterinary medicine
4) Protection of man, animals or environment
5) Education
6) Training
7) Forensic enquiries
8) Direct diagnosis
9) Breeding of GM or HM animals

Within the Australian States listed previously the following are the collective 11 purposes:

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.
11. Stock breeding (Genetically modified)

WA had stock breeding (GM) included and it is therefore listed as a separate item here.

Four states currently limit their purpose to five categories. They do not include the production of genetically altered animals, toxicological testing, stock breeding as such, stock maintenance or diagnostic procedures. It keeps the purpose statistics relatively simple but is it sufficient to give an appropriately accurate picture? The production of genetically altered animals is a large part of biomedical research in terms of numbers of animals used and is not without animal welfare concerns. It surely warrants a separate purpose category. Toxicological testing using animals for the purpose of protection of man animals and the environment is a scientific animal use that sections of the public have concerns about. Such testing is not on a large scale in Australia but given potential controversy, needs to be documented separately. Stock breeding includes the production of laboratory animals used in research and teaching as well as domestic animals specifically bred for research and teaching. It does not include the final progeny that are allocated to other purposes. It does include the animals that are designed to be final progeny, but are culled without being allocated. The numbers are significant and need to be included in credible statistics involving the use of animals for scientific purposes. Given that this document is advocating a

separate genetically altered animal category stock breeding would not include genetically altered animals. Relative to production of biological products, in 2010 NSW (the only state where these figures were available) listed approximately 17000 animals, predominantly avian use. This is not insignificant and therefore needs to be included. Stock maintenance is not a category of purpose that needs to be included. Stock that is maintained is mostly allocated to another purpose and a significant problem with having a stock maintenance category is that animals can be easily counted twice. Those that are culled before being issued need to be included in the stock bred category.

Across the purposes listed here from the Australian states, and also considering the purposes listed in the scientific animal use statistics of Canada, New Zealand and the UK, what purposes of scientific animal use are considered essential to an Australian system?

1) **Education and training**: On a global scale animals used for education and training have been significantly replaced by non-animal alternatives. There are still some situations where replacements are not an option, such as veterinary training and training in wildlife research and this category of purpose must be included.
2) **Stockbreeding**: Animals will need to continue to be bred for biomedical research on the one hand and agricultural research on another. This only includes animals used to produce progeny, not the final progeny which are subsequently allocated for other purposes.
3) **Genetically altered animal production**: This must include genetically modified animals (Recombinant DNA technology), and also must include those produced by chemical mutagenesis. The numbers of genetically modified rodents currently used in Australian biomedical research are significant and come with their own animal welfare considerations.
4) **Environmental/species conservation research**: Includes all wildlife research, often with implication for species conservation. This type of research has the potential to draw public attention, usually in a positive manner.
5) **Basic biological research**: Studies of a fundamental nature in sciences relating to essential structure or function, and may contribute to the foundations of medical research. The list is not comprehensive, but includes for example behavioural studies, physiological studies, studies on development, and genetic studies.
6) **Human and/or animal health and welfare research**: animal based studies that directly relate to human or animal diseases and disorders.
7) **Production of biological products**: These may be used in man or animals. Examples include the production of vaccines and antisera and serum gonadotropin, and diagnostic products developed from animals.
8) **Protection of man, animals and the environment**: Broadly known as toxicological or toxicity testing, this is often regarded as the most controversial use of animals for scientific purposes and therefore has a propensity to attract the attention of a section of the public who push strongly for methods that use alternatives to animals.
9) **Animal management or production research**: Research to achieve improvement in production technologies in livestock enterprises.
10) **Diagnostic/forensic research**: Includes animals used in research of diagnostic procedures and also forensic research, with an example of the latter using purpose killed pigs to study organ deterioration as a model for human decomposition.

Two states in Australia already include education and training, stockbreeding, genetically altered animal production, environment/species conservation research, human or animal health and welfare, production of biological products, diagnostic procedures, protection of man, animals and the environment and diagnostic procedures. The other 4 states include 5 of these. Animal management and production research is currently included under other categories in the state systems but this category is considered to be a required separate entity given Australia's

situation with regard to livestock based research. Basic biological research would currently fall within the state category, research: human or animal biology.

Presenting Information on the Positive Aspects of Ethical Oversight on Scientific Animal Use

There are two ways that scientific animal use statistics may be used to present information that demonstrates the positive aspects of ethical oversight:

1) The number of animal proposals that are modified as a result of Animal Ethics Committee review relative to the total number of proposals reviewed per annum.

2) Using statistics to demonstrate the implementation of the 3Rs

AEC Review and Subsequent Proposal Improvement

Modifications result from AECs assessing proposals to ensure that the proposals meet the requirements of all relevant sections of the Code (in accordance with Code section 2.2.18) and therefore AEC assessment improves the quality of the proposal, particularly in animal welfare terms. By comparing the number of proposals that are modified per annum within an institution against the total number of proposals assessed, a ready measure of the positive aspects of AEC review from a Code implementation viewpoint can be obtained.

To convey an idea of the extent of positive modification by an AEC the figures below present the degree of modification of proposals by the Australian National University Animal Experimentation Committee over a three year period 2010-2012 (From unpublished ANU AEEC Annual Reports to ANU Council 2010-2012).

Year	Proposals Considered	Proposals Modified	% Proposals Modified
2010	59	49	83.05%
2011	73	69	94.52%
2012	64	58	90.62%

Using Statistics to Demonstrate the Implementation of the 3Rs

Russell and Burch (1959) proposed the principles of Replacement, Reduction and Refinement (most often referred to as the 3Rs) as the key strategies to provide a systematic framework to achieve the goal of humane experimental techniques. Today throughout the world the principles of the 3Rs are embedded in legislation which governs the use of animals in science.

David Smyth (1978) proposed categorising experimental procedures and collecting national statistics on animal experiments in a way to prioritise efforts for the development of the 3Rs. The measurement and statistical recording of impact/severity levels enables researchers, AECs, institutions and legislators to target the areas of greatest severity in terms of measures that fall within the 3Rs. In examining overseas systems it has not been possible to find a country that in its national scientific animal reporting system specifically reports on the degree of 3Rs implementation, and this has its critics in some quarters. For example the NC3Rs (NC3Rs Evaluation Framework 2012) organisation felt that the UK national annual statistics figures in their current form do not make manifest the impact of 3Rs efforts. The organisation states despite the

importance of the 3Rs concept, there have been few efforts to systematically benchmark progress in the 3Rs which they felt was surprising given the interest that animal research attracts. They state that "this has led to concerns about the commitment of the scientific community to the 3Rs and animal research continues to be one of the most contentious issues in science."

Dialogue accompanying the presentation of scientific animal use statistics can present an overview of the use of the 3Rs. Appendix H of the 2010-2011 NSW Animal Research Review Panel Annual Report (2011) does this well when it gives examples of methods used to implement the 3Rs.
Earlier (Page 11) reference was made to the University of British Columbia publically releasing its statistics of animals used in research and the media release included the following words: "UBC is committed to humane care and developing research methods that reduce, refine and replace the use of animals wherever possible."

However rather than summarising 3Rs implementation is there a better way to directly demonstrate 3Rs implementation in statistical terms? We feel there is, and that it can be achieved if the right questions are asked!

The 3Rs in an Australian Context

In discussing the 3Rs and their implementation in Australia we need to first discuss the more common 3Rs examples that occur in an Australian context:

Replacement

This should allow for complete replacement of animal based studies by a non-animal alternative, but also allows for partial replacement where components of an animal based study are replaced by non-animal alternatives. There are therefore two sub-categories:

i) The number of studies that are totally replaced using non-animal alternatives.
ii) The number of experiments where animal use was partially replaced with an alternative method.

Reduction:

Reduction usually occurs by way of good statistical design but also occurs through the use of a methodology that reduces the number of animals. Production proposals may demonstrate reduced numbers by breeding techniques, while education/teaching may also use reduction methods. Examples include:

i) The number of Primary Investigators that utilised a statistician to review their experimental design before submission to the AEC, or are able to clearly demonstrate a good knowledge of statistical design in their AEC proposal.
ii) The number of proposals that clearly demonstrate that they will (prospective assessment) or have (retrospective assessment) reduced the number of animals required to gain valid data.
iii) The number of production proposals that have implemented advanced breeding techniques or management plans to reduce the number of surplus animals.
iv) Education protocols that have reduced the number of animals for a particular teaching exercise, such as the use of camera and microscope systems that allow projection to a screen and recording of procedures.

Refinement

This would include proposals refined by the Primary Investigator or AEC. The following areas and examples are included to illustrate the point that there are many opportunities for refinement in the field of animals used for scientific purposes:

Refinement of surgical techniques

Using the latest techniques that aim to minimise the duration of the procedure, recovery time and overall impact to the animal's welfare e.g. laparoscopic surgery

Refinement of anaesthesia methods

Selection of anaesthetics that have a quick induction, wide safety margin, rapid recovery and minimal negative implications for the research e.g. isoflurane delivered by a vaporiser

Refinement of analgesia delivery

The delivery of analgesics at the appropriate time in a procedure that give maximal pain relief for the species in question, with a high safety margin and minimal negative impact on specific research.eg buprenorphine administered in a gel to rodents for ongoing pain relief.

Refinement of animal monitoring during a high impact intervention

Three examples are given:

- The use of clinical score sheets to ensure tailored and consistent monitoring
- The use of telemetry systems
- Increased frequency of monitoring

Refinement of humane end points

Two examples are given:

- The use of clinical score sheets to assist in determining humane endpoints
- The conducting of small pilot studies to ensure proposed endpoints are humane?

Refinement of experimental techniques by using equipment that minimises animal intervention

Four examples are given:

- The use of telemetry systems
- The use of non-invasive body temperature sensors
- The use of advanced animal imaging systems
- The use of microscopes and camera systems that allow for projection to a screen and subsequent recording of procedures

Refinement in animal housing

Two examples are given:

- The introduction of paper to rodent bedding to allow for biologically relevant environmental enrichment in the form of thermo-neutral nest building.
- The use of Individually Ventilated Cages (IVCs) to provide a rodent environment that protects animals from pathogens and in which the micro-environment is considerably improved relative to that of a static micro-isolator.

The majority of Australian institutions can demonstrate good performance in the Refinement R, such as better anaesthetics, the implementation of good analgesic regimes, higher standards of caging and housing, the implantation of biologically relevant environmental enrichment, the use of humane endpoints exemplified by the effective use of clinical score sheets, and comprehensive disease prevention schedules, to name a few. A good number of Australian institutions would be able to demonstrate a very good level of implementation of the Replacement R in the use of animals for education. Some can indicate that they have at least partial replacement in some biomedical research programs and that some have education programs to move that forward. Concerning the Reduction R, Australian institutions can demonstrate that with an improvement in the statistical design of animal based studies there can be relative reduction in the number of animals used. Others may demonstrate that laboratory techniques may harvest, for example, a considerable increase in a particular cell type from a mouse, thereby decreasing significantly the number of mice needed.

Currently two Australian states, NSW and Victoria ask questions relative to the 3Rs, although they ask it in summary form, not on a proposal by proposal basis. Australian scientific animal statistics collations by states and territories are not currently asking questions that give a direct quantitative indication of the implementation of the 3Rs by Australian institutions. In the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (7th Ed.2004) we have a Code that is lauded by many observers overseas, as witnessed at successive World Alternative Congresses. The 3Rs are a basic tenet of the Code. An Australian wide scientific animal statistical compilation needs to ask Australian institutions direct questions relating to 3Rs implementation. The degree of implementation of the 3Rs at individual institutions could then be incorporated into their annual reports to their governing body, to the respective states and territories to which they report, and to the national statistical compilation.

The question will be asked: 'How can this be undertaken with minimal imposition on researchers, AECs, and institutional animal ethics administrators?'

Implication for researchers

With regard to researchers, AECs already ask investigators to consider replacement alternatives. They also ask investigators to justify the numbers of animals requested and in so doing look for justification in terms of good statistical design. Questions are asked relevant to housing, anaesthetics where applicable, analgesics where applicable, harm minimisation, animal supervision/monitoring and euthanasia methods. All these are relevant to refinement implementation, so in fact proposals already ask these questions. The investigator may not always recognise that refinement is in fact incorporated a number of times in a proposal and that is a situation that can be greatly helped by relevant education programs. An example might serve to illustrate the implementation of 3Rs in a particular proposal: Mice are proposed to be used in an immunology study. Part of the study that was historically performed on mice can be partially replaced with cell culture. The development of a multiplex fluorescent-based in vivo cytotoxic cell assay reduces the number of mice needed to give the same number of cells 100 fold-we have reduction. The mice are housed in cages with bedding incorporating paper strips. This allows for biologically relevant nest building enrichment- an example of the refinement R. Mice are anaesthetised with isoflurane delivered via a vaporiser which gives rapid induction and rapid recovery and a high level of safety-again an example of refinement. The mice are infected with an arbovirus and monitored closely from the 8th to the 22nd day via a clinical score sheet- again an example of refinement. With research teams thinking more about the 3Rs there is potential to move towards a more desirable state of researchers engaging to greater degree with the 3Rs.

Some of this 3Rs information can be captured as part of the retrospective assessment process required for impact determination. Similarly it can also be captured in the final report for projects that are completed or discontinued. Investigators are already asked to report on this because it is required under 2.2.39 of the 2004 Code which states that the report should advise on:

(i) *Whether the stated aims were achieved;*

(ii) *Whether the number of animals used varied from the number approved and if so why any major discrepancies occurred.* Experience in recent years is that investigators often use fewer animals than was originally approved on biomedical proposals and the retrospective assessment in this situation would indicate implementation of the reduction R.

(iii) *Whether the wellbeing of the animals was consistent with that anticipated in the proposal.* Refinement measures that improved the wellbeing of the animals, in addition to those outlined in the proposal may have been implemented during the course of the study and could be summarised here.

(iv) *Conclusions as to how procedures in future projects could be modified to reduce any impact on animal welfare.* This question asks for modifications which by, definition, would allow for 3Rs recommendations.

(v) *Details of publications and presentations that have resulted from the project.*

Implications for AECs

This would not add to the workload of AEC's but rather would facilitate their consideration of 3Rs implementation when considering proposals.

Implications for Institutional Animal Ethics Officers

Institutional animal ethics officers would collect the 3Rs information from three sources:

(1) From approved proposals post-AEC meeting
(2) Additional 3Rs measures included in amendments
(3) Additional 3Rs measures recorded in the Final Report for Projects (2004 Code 2.2.39)

This sounds like a significantly increased work load for institutional ethics officers. To avoid duplication it would be done **once** per proposal, once **that proposal is completed**. It would need to be done manually in some, usually smaller, institutions with a small proposal turnover. Researchers could be asked to identify 3Rs implementation at the conclusion of the approved study. Many larger institutions are moving towards IT enterprise systems that if well designed can have questions inserted that address the collection of these 3R statistics without a significant increase in workload on behalf of the animal ethics officer. **At the conclusion of each proposal** the occurrence of replacement (including partial replacement), reduction, and refinement measures would be recorded for that proposal. It is proposed that implementation of each 3R be recorded against that concluded proposal. The annual institutional return would need to record the number of implementations of each of the 3Rs for each concluded protocol. The opportunity to demonstrate an increased degree of 3Rs implementation is greater in biomedical and toxicological research than for example in wildlife research or research relative to livestock production, although an opportunity to implement 3R measures should not be abrogated in the case of the latter. It is conceivable that a particular approved proposal could include partial replacement, two examples of reduction and six or more examples of refinement.

What would be recorded by each state and territory, and nationally?

The proposal is that the Commonwealth annual returns would ask the institutions to record the implementation of replacement (complete or partial), reduction, and refinement measures for each completed proposal as outlined above. It is proposed that quantitative 3Rs implementation be recorded by purpose into two groups:

Group 1

- Human and/or animal health and welfare research
- Basic biological research
- Protection of man, animals and the environment
- Genetically altered animal production
- Basic biological research
- Diagnostic/forensic research

Group 2

- Environmental/species conservation research
- Education and training
- Stock breeding

- Animal management or production research

Group 1 purposes are those that are perceived more sensitive by sections of the public and, generally speaking, have been associated with an increased implementation of the 3Rs. Group 2 purposes are generally perceived by public interest groups as being less invasive. There may be less opportunity to implement all the 3R options that are open to the Group 1 purposes of use, however implementation of the 3Rs should be used at every opportunity and therefore this needs to be recorded in a 3Rs quantitative assessment.

It is proposed that at a state and territory level the Group 1 average implementation of 3Rs be recorded and similarly with group 2 purposes of use the average implementation of the 3Rs should be recorded. Interesting comparisons might be made between institutional 3R implementations within a state.

Summary of the significant benefits of 3Rs reporting in a national system.

The 3Rs are the key strategies to provide a systematic framework to achieve the goal of humane animal based research. By recording 3Rs implementation initially at an institutional level AECs, their institution, and subsequently state, territory and national scientific animal use statistics have a recognizable Code based mechanism for recording and analysing the uptake of measures that ensure best practice towards optimal animal welfare in animals used for scientific purposes. We have not been able to find any other country that systematically measures implementation of the 3Rs in this way. Were Australia to incorporate this in a national scientific animal statistical compilation it would reinforce the ideals of the Code, it would encourage institutional increase in implementation of the 3Rs, and it would be a statistic that could demonstrate to the public the degree of institutional engagement with animal welfare ideals.

Conclusions Relating to the Format of an Australian Scientific Animal Use Statistics Report

The 8 essential inclusions

Based on preceding discussion in this document we are in a position to outline the recommended format of an Australian Scientific Animal Use Statistics Report. The recommendation is broadly based on the CCAC format but differs in the method of reporting of impact on animal, the purposes of use, percentage of proposals modified by AECs, and the quantitative reporting of 3Rs implementation. It needs to include:

1) Total number of animals used annually by category of animal. 2) Number of animals by category of animal used annually by level of impact.

3) Number of animals by animal category used annually by purpose.

4) Number of animals used annually according to purpose of use and level of impact.

5) The number of animals used by category for each purpose of animal use according to level of impact.

6) The number of proposals modified by AEC review against total approved proposals

7) Quantitative recording of the implementation of replacement, reduction and refinement measures.

8) Number of animals by category of animal used annually within each Australian State and Territory.

Definitions

At this point it is appropriate to obtain an appreciation of how the compilation would occur and to define, or redefine:

(i) the categories of animals,
(ii) the five levels of impact,
(iii) the ten purposes of use, the latter two previously identified in this document as being essential to an Australian statistical compilation.

(i) Category of Animal

For the purpose of statistical analysis a category of animal may be a species e.g. guinea pig, but it may also be a collective e.g. fish. For the purposes of the Australian scientific animal statistical compilation it is suggested that the categories used currently by Australian States and Territories be used as much as possible. The list of categories below is based on the NSW categories listed in the 2010-2011 ARRP Annual Report, and it is noted that this format is closely followed by a number of States and Territories.

Laboratory mammals

- Mice
- Rats
- Guinea pigs
- Hamsters
- Ferrets

Domestic mammals

- Sheep
- Cattle
- Pigs
- Horses

- Goats
- Deer
- Cats
- Dogs
- Other domestic animals

Birds

- Poultry
- Exotic Captive
- Exotic Wild
- Native Captive
- Native Wild
- Other birds

Aquatic animals

- Fish
- Cephalopods
- Marine Mammals

Reptiles

- Lizards
- Snakes
- Turtles and Tortoises
- Other reptiles

Non-human primates

- Marmosets
- Macaques
- Baboons
- Other primates

Native mammals

- Macropods
- Possums and gliders
- Native rats and mice
- Dasyurids
- Wombats
- Koalas
- Monotremes
- Bandicoots
- Bats
- Other native mammals

Exotic zoo animals

Exotic feral mammals

- Camels
- Cats
- Cattle
- Goats
- Hares
- Horses
- Mice
- Pigs
- Rabbits
- Rats

- Dingo/Wild Dogs
- Foxes
- Other exotic feral mammals

(ii) Levels of Impact

As mentioned earlier (page 13) the New Zealand scientific animal use profile does not differ significantly from our own and the levels of impact used by the New Zealand animal use statistics include duration of impact and are assessed retrospectively, and it was therefore felt that the five levels of impact used in that system should be used in an Australian statistical compilation. They are:

- **Grade A**-No impact or virtually no impact
- **Grade B**-Little impact, further defined as manipulations of minor impact and short duration
- **Grade C**-Moderate impact which includes manipulations of minor impact and long duration or moderate impact and short duration
- **Grade D**-High impact which includes manipulations of moderate impact and long duration or high impact and short duration
- **Grade E**-Very high impact which are manipulations of high impact and long duration

(iii) Purpose of Use:

Ten purposes of use felt essential to an Australian system (page) and based principally on NSW and WA existing purposes are:

1) Education and training
2) Stockbreeding
3) Genetically altered animal production
4) Environmental/species conservation research
5) Basic biological research
6) Human and/or animal health and welfare research
7) Production of biological product
8) Protection of man, animals, and the environment
9) Animal management or production research
10) Diagnostic/forensic research

Inclusions

1) Number of Animals Used Annually According to Purpose of Use and Level of Impact

Following the Canadian model this would simply list the level of impact in the vertical axis of a table and list the purpose of animal use horizontally along the top of the table. The equivalent Canadian table lists total numbers of animals rather than breaking down animal numbers into categories.

2) Number of animals by category of animal used annually by level of impact.

The animal categories that are deemed to be more sensitive by the public re their use for scientific purposes are undoubtedly non-human-primates, dogs and cats in that order. The use of very high impact or high impact procedures in any category of animal, but particularly in those three, are going to focus scrutiny on 3Rs implementation to reduce the level of impact.

Undoubtedly the public release of such statistics has the potential to attract a degree of controversy, but in the interests of transparency it is important that these statistics are made available to public scrutiny. It is important that the release of these impact statistics is accompanied by dialogue that discusses implementation of the 3Rs to reduce the impact on animals.

3) Number of animals by animal category used annually by purpose.

Purpose of use is central to any scientific animal use statistic. The ten categories of animal use outlined appear to cover all purposes of scientific animal use currently occurring within Australia. The two areas that are most sensitive to public scrutiny are genetically altered animal production and protection of man, animals and the environment. The vast majority of genetically altered animals are rodents and allow investigation of the animal's genome in a targeted manner. The evolution of large numbers of strains of rodents and the need for breeding colonies of each has been principally responsible for the increase in numbers of animals used for scientific purposes in recent years. Protection of man, animals, and the environment is perhaps better known by the more evocative term, toxicology studies. Australia's involvement in these types of studies is very small compared with North America and the EU.

4) Number of animals used annually according to purpose of use and level of impact.

This simply lists level of impact in the vertical column and purpose of use in the horizontal column. Total animal numbers are used. There is no division of animals into categories

5) Number of animals used by category for each purpose of animal use according to level of impact.

The Canadian system records the number of animals used by category for each purpose of animal use according to level of impact. This requires a separate table for each purpose and with the recommendation that the Australian system has ten purposes is a lot of extra statistical information. However it should be considered because it does provide information that is of considerable interest and significance. The Canadian example of non-human primate use in toxicology previously noted that 88% were subject to minor stress and pain provides a good example.

6) Using statistics to promote the positive aspects of ethical oversight

The proposal is to use statistics to promote the positive aspects of ethical oversight, including assessing the proportion of animal ethics proposals that are improved by ethical oversight and quantitatively assessing the implementation of the 3Rs. As discussed earlier no other national statistical compilation appears to record the implementation of the 3Rs. The Code asks that AECs consider the 3Rs in assessing proposals and a number of relative questions are already being asked. In quantitatively recording 3Rs implementation at an institutional level, AECs and the institution have recognizable Code based mechanisms for recording and analysing the uptake of measures that ensure best practice towards optimal animal welfare in animals used for scientific purposes.

7) Number of animals by category of animal used annually within each Australian State and Territory.

It is a logical conclusion to a national statistical compilation to record number of a animals used by category against each State and Territory

The Physical Collation of Australian Wide Statistics

It is apparent that an Australian wide statistical compilation involving the use of animals for scientific purposes will need to be collated by a central agency. Because of the needs of annual reporting to meet State and Territory legislation each jurisdiction could be responsible for the collection of data relative to that jurisdiction in accord with a uniform process as outlined in this document. However discussions with relevant state officers at the July 2013 Australian and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART) conference indicated that the collection of animal scientific animal use statistics is currently an onerous task demanding a considerable amount of time and the indication was that some jurisdictions would lack adequate human resources to collect statistics in a changed format. In the interests of a timely uniform collection of relevant data it therefore seems the recommendation should be that a central agency should collect data directly from institutions and school administration agencies across Australia and return respective compilations to state authorities on completion.

Initially four central agencies are identified as either having a current strong involvement in policy regarding the use of animals for scientific purposes or currently collating Commonwealth statistical data.

They are:

- The National Health and Medical Research Council-NH&MRC
- The Australian and New Zealand Council for the Care and Use of Animals for Scientific Purposes-ANZCCART
- Australian Bureau of Agricultural and Resource Economics and Sciences –ABARES
- The Australian Bureau of Statistics-ABS

NH&MRC

The NHMRC develops policy and guidelines to ensure that the highest ethical standards apply to NHMRC funded research involving the use of animals. The strategic intent of the NH&MRC is to work with others for the health of all Australians, by promoting informed debate on ethics and policy, and to provide knowledge based advice. It is primarily responsible for the Australian code of practice for the care and use of animals for scientific purposes (2004) and also Guidelines to promote the wellbeing of animals used for scientific purposes; the assessment and alleviation of pain and distress in research animals.

It was felt that NH&MRC might be the organization to best collate scientific animal statistics but it became apparent in discussions with senior officers that it does not have the resources to do so.

ANZCCART

ANZCCART was established in 1987 in response to concerns in the wider and scientific community about the use of animals for scientific purposes. Its main role is to provide leadership in developing community consensus on ethical, social and scientific issues relating to the use of and wellbeing of animals in research and teaching. As an independent body that consults widely ANZCCART provides well researched information to scientific organisations and to the community at large.

ANZCCART's core business is concerned with the use of animals for scientific purposes and it might seem a logical body to collate the national statistics, but it has a staff of two people and lacks the resources necessary to collate the national statistics.

ABARES

The Australian Bureau of Agricultural and Resource Economics and Sciences is a research bureau within the Department of Agriculture, Fisheries and Forestry and provides professionally independent research, analysis and advice for government and private sector decision-makers on significant issues affecting Australia's agriculture, fisheries and forestry industries. ABARES was formed following the merger of the Australian Bureau of Agricultural and Resource Economics (ABARE) and the Bureau of Rural Sciences (BRS) in 2010. Both ABARE and BRS had a strong history in contributing to private and public sector decision-making through their research, analysis and statistical collections. It is apparent that ABARES could do the collation. Their profile and work program 2012-13 strongly suggests an agricultural, fisheries and forestry's emphasis, although the statistical analysis experience could prove valuable for the compilation of national statistics relevant to the use of animals for scientific purposes.

ABS

The Australian Bureau of Statistics is Australia's official statistical organisation. It assists and encourages informed decision-making, research and discussion within governments and the community, by providing a high quality, objective and responsive national statistical service. It collects a wide range of statistical information. It undertakes the Australian Census and has been undertaking surveys to collect estimates from Australian organisations of R&D expenditure and human resources devoted to R&D in Australia since 1978. The results allow the nature and distribution of Australia's R&D activity to be monitored by government policy analysts and advisers to government, businesses and economists. The diversity of statistical analysis accomplished by the ABS is impressive

A phone conversation with a representative of the ABS indicated that the Bureau could be used as an advisory body re the collection of the statistics of the use of animals for scientific purposes but did not dismiss the direct collation of the relevant data.

Sequence for Implementation of the National Statistical Collection

The end-objective is buy-in from the jurisdictions for a national system for reporting facts and figures about ethically endorsed scientific animal use. The sequence in mind for the deliverable is clearance by AAWS, Australian Animal Welfare Advisory Committee (AAWAC) endorsement, and then submission up the administrative line to the Standing Council on Primary Industries. It is apparent that Commonwealth government funding will be necessary for the ongoing collation of the national statistics relevant to Australia's scientific animal use.

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Appendices

Appendix A: Statistical Tables Relative to the Canadian Council of Animal Care Survey of Animal Use (2010)

Referring to the 2010 analysis, the following tables are collected and analysed:

1. **Table I:** Number of Animals Used in 2010 by Participants in the CCAC Programs
2. **Tables II and III:** Number of Animals Used in 2010 by Participants in the CCAC Programs According to the Category of Invasiveness (II) and According to the Purpose of Animal Use (III)
3. **Table IV:** Number of Animals Used in 2010 by Participants in the CCAC Programs According to the Purpose of Animal Use and the Category of Invasiveness
4. **Table V:** Number of Animals Used in 2010 by Participants in the CCAC Programs for each Purpose of Animal Use According to the Category of Invasiveness
    a. Purpose of Animal Use 1
    b. Purpose of Animal Use 2
    c. Purpose of Animal Use 3
    d. Purpose of Animal Use 4
    e. Purpose of Animal Use 5
5. **Table VI:** Number of Animals Used in:
    a. Atlantic Provinces (Nova Scotia, New Brunswick, Prince Edward Island, Newfoundland)
    b. Québec
    c. Ontario
    d. Western Provinces (Manitoba, Saskatchewan, Alberta, British Columbia)

Table I lists the number of animals used by species, important statistics for a national collection and following a format that Australian institutions would use in reporting to their governing bodies.

Tables II lists numbers of animals used in 2010 by participants according to category of invasiveness. The importance of categories of invasiveness has been briefly mentioned earlier in this project and will be discussed in more depth subsequently. Table 111 lists the 2010 number used under purpose of animal use. Purpose of animal use is an essential figure for stakeholders. To demonstrate how statistics might be collated in a meaningful way the description of this CCAC system includes animal numbers in the majority of tables, rather than just outlining what the tables contain.

The key for categories of invasiveness is:

B Experiments which cause little or no discomfort or stress.

C Experiments which cause minor stress or pain of short duration.

D Experiments which cause moderate to severe distress or discomfort.

E Experiments which cause severe pain near, at, or above the pain tolerance threshold of unanaesthetized conscious animals.

The key for purpose of animal use is:

PAU = 0 Breeding Colony/Stock - Animals held in breeding colonies (e.g., fish, rodents) that have not been assigned to a particular research, teaching or testing protocol.

PAU = 1 Studies of a fundamental nature in sciences relating to essential structure or function (e.g., biology, psychology, biochemistry, pharmacology, physiology, etc.).

PAU = 2 Studies for medical purposes, including veterinary medicine, that relate to human or animal disease or disorders.

PAU = 3 Studies for regulatory testing of products for the protection of humans, animals, or the environment.

PAU = 4 Studies for the development of products or appliances for human or veterinary medicine.

PAU = 5 Education and training of individuals in post-secondary institutions or facilities.

Table II and III: Number of Animals Used in 2010 by Participants in the CCAC Programs according to the **Category of Invasiveness** (Table II) or the **Purpose of Animal Use** (Table III)

Table II: Number of Animals Used in 2010 by Participants in the CCAC Programs according to the Category of Invasiveness

Category of Animals		**Category of Invasiveness**				
		B*	**C***	**D***	**E***	**TOTAL**
Amphibians		15,616	33,500	20,620	0	**69,736**
Cats		**1,737**	**1,447**	**1,254**	**0**	**4,438**
	Purpose-bred	497	81	76	0	**654**
	Non-purpose-bred	1,240	1,366	1,178	0	**3,784**

Cephalopods		4	1	0	0	**5**
Chinchillas		5	22	120	0	**147**
Dogs		**4,341**	**4,460**	**1,548**	**32**	**10,381**
	Purpose-bred	575	1,408	384	8	**2,375**
	Non-purpose-bred	3,766	3,052	1,164	24	**8,006**
Domestic Birds		152,914	12,488	10,772	3,569	**179,743**
Farm Animals		60,635	19,076	5,808	307	**85,826**
Fish		746,436	462,755	148,522	58,329	**1,416,042**
Fur Animals		1,437	125	482	28	**2,072**
Gerbils		65	44	30	0	**139**
Guinea Pigs		8,236	3,313	1,364	10,716	**23,629**
Hamsters		536	945	1,436	12	**2,929**
Marine Mammals		445	1,352	0	12	**1,809**
Mice		133,278	326,383	624,414	48,631	**1,132,706**
Miniature Swine		52	98	15	18	**183**
Nonhuman		924	2,986	695	24	**4,629**

Primates					
Rabbits	914	3,532	2,100	22	**6,568**
Rats	50,990	91,422	115,775	2,713	**260,900**
Reptiles	719	4,030	1,072	0	**5,821**
Canadian Wild Animals	33,168	54,425	12,755	2,131	**102,661**
Other Non-Canadian Animals	373	346	0	0	**719**
Total	**1,212,825**	**1,022,750**	**948,753**	**126,755**	**3,311,083**

Table III: Number of Animals Used in 2010 by Participants in the CCAC Programs according to the Purpose of Animal Use

Category of Animals		Purpose of Animal Use					
		PAU 1*	**PAU 2***	**PAU 3***	**PAU 4***	**PAU 5***	**TOTAL**
Amphibia		65,467	1,768	40	0	2,461	**69,736**
Cats		**160**	**767**	**0**	**529**	**2,982**	**4,438**
	Purpose-bred	37	109	0	487	21	**654**
	Non purpose-bred	123	658	0	42	2,961	**3,784**

Cephalopods		0	0	0	0	5	**5**
Chinchillas		0	142	0	0	5	**147**
Dogs		**770**	**1,380**	**3,070**	**600**	**4,476**	**10,381**
	Purpose-bred	265	68	1,446	450	146	**2,375**
	Non purpose-bred	505	1,397	1,624	150	4,330	**8,006**
Domestic Birds		32,642	11,791	1,161	125,875	8,274	**179,743**
Farm Animals		29,119	23,284	761	21,480	11,182	**85,826**
Fish		947,452	272,898	103,889	10,635	81,168	**1,416,042**
Fur Animals		574	1082	14	363	39	**2,072**
Gerbils		40	22	0	22	55	**139**
Guinea Pigs		1,932	1,435	7,663	12,295	304	**23,629**
Hamsters		1,200	1,259	12	326	102	**2,929**
Marine Mammals		1,797	12	0	0	0	**1,809**
Mice		584,741	367,696	44,228	111,097	24,976	**1,132,706**

Miniature Swine	27	28	72	11	45	**183**
Nonhuman Primates	785	929	2,701	110	104	**4,629**
Rabbits	1,204	2,052	1,756	1,169	387	**6,568**
Rats	108,054	57,622	48,580	38,135	8,677	**260,900**
Reptiles	5,034	2	300	0	485	**5,821**
Canadian Wild Animals	95,963	2,224	404	0	4,070	**102,661**
Other Non-Canadian Animals	511	200	0	0	8	**719**
Total	**1,877,472**	**746,678**	**214,651**	**322,677**	**149,605**	**3,311,083**

Re the purpose of use, the CCAC found the categorisation into 5 different purposes has proved valuable in in determining where animals are used and where the most severe pain and distress is likely to occur. They consider that these categories are not perfect but have helped in in being able to target their three R's education efforts in the areas of most need. They also answer public questions that are often asked.

Table IV combines purpose of use and category of invasiveness

Table IV: Number of Animals Used in 2010 by Participants in the CCAC Program according to Purpose of Animal Use and the Category of Invasiveness

Category of	**Purpose of animal use**

invasiveness*	**PAU 1***	**PAU 2***	**PAU 3***	**PAU 4***	**PAU 5***	**TOTAL**
B	579,893	233,106	84,505	50,518	74,728	**1,022,750**
C	497,624	288,205	61,097	69,627	32,229	**948,782**
D	786,361	206,523	14,199	163,168	42,574	**1,212,825**
E	13,594	18,844	54,850	39,364	74	**126,726**
Total	**1,877,472**	**746,678**	**214,651**	**322,677**	**149,605**	**3,311,083**

The CCAC requires institutional animal care committees (ACCs) to ensure that any potential pain and/or distress is minimized. Anaesthetics and analgesics must be used; any exceptions require scientific justification and ACC approval.

The combination of purpose of animal use and degree of invasiveness again allows the CCAC to target its 3Rs education towards the areas of greatest need. It allows the CCAC to determine whether the number of animals in the most severe categories is changing. It informs the public in a transparent manner. It also allows informed policy development.

Table V lists the number of animals used in 2010 by participants in the CCAC programs for each **Purpose of Animal Use** according to the **Category of Invasiveness.** For comparative purposes tables relative to purposes of animal use 2, studies for medical purposes including veterinary medicine that relate to human or animal disease, will be reproduced here, as well as the table relative to animal use 3, studies for regulatory testing of product for protection of human animals or the environment. The public, generally speaking, are more accepting of research that relates to potential improvement of human and animal health than they are of animal based research that they see as falling into the realms of toxicity testing and comparison of the two tables are interesting.

Table V: Number of Animals Used in 2010 by Participants in the CCAC Programs for each Purpose of Animal Use according to the Category of Invasiveness

b. Purpose of Use 2

Category of Animals	**Category of Invasiveness**

		B*	C*	D*	E*	TOTAL
Amphibia		90	1,318	360	0	**1,728**
Cats		**100**	**345**	**322**	**0**	**767**
	Purpose-bred	6	64	39	0	**109**
	Non purpose-bred	94	281	283	0	**658**
Cephalopods		0	0	0	0	**0**
Chinchilla		0	22	120	0	**142**
Dogs		**406**	**86**	**973**	**0**	**1,465**
	Purpose-bred	0	37	31	0	**68**
	Non purpose-bred	369	55	973	0	**1,397**
Domestic Birds		2,866	2,518	3,058	3,349	**11,791**
Farm Animals		6,739	1,742	14,655	148	**23,284**
Fish		152,795	108,163	3,137	8,803	**272,898**
Fur Animals		924	27	117	14	**1,082**
Gerbils		6	10	6	0	**22**
Guinea Pigs		81	663	541	150	**1,435**
Hamsters		294	359	606	0	**1,259**
Marine Mammals		0	0	0	12	**12**

Category of Animals	Category of Invasiveness				
	B*	**C***	**D***	**E***	**TOTAL**
Mice	25,904	96,036	239,951	5,805	**367,696**
Miniature Swine	0	23	5	0	**28**
Nonhuman Primates	493	197	239	0	**929**
Rabbits	257	775	998	22	**2,052**
Rats	6,926	13,884	36,291	521	**57,622**
Reptiles	0	2	0	0	**2**
Canadian Wild Animals	129	1,449	626	20	**2,224**
Other Non-Canadian Animals	30	170	0	0	**200**
Total	**233,106**	**288,205**	**206,523**	**18,844**	**746,678**

Table V: Number of Animals Used in 2010 by Participants in the CCAC Programs for each Purpose of Animal Use according to the Category of Invasiveness

c. Purpose of Use 3

Category of Animals		Category of Invasiveness				
		B*	**C***	**D***	**E***	**TOTAL**
Amphibia		0	40	0	0	**40**
Cats		**0**	**0**	**0**	**0**	**0**
	Purpose-bred	0	0	0	0	**0**

Category of Animals		Category of Invasiveness				
		B*	**C***	**D***	**E***	**TOTAL**
	Non purpose-bred	0	0	0	0	**0**
Cephalopods		0	0	0	0	**0**
Chinchilla		0	0	0	0	**0**
		169	**2,640**	**261**	**0**	**3,070**
Dogs	Purpose-bred	146	1,059	241	0	**1,446**
	Non purpose-bred	23	1,581	20	0	**1,624**
Domestic Birds		856	0	125	180	**1,161**
Farm Animals		176	483	102	0	**761**
Fish		0	13,001	53,549	37,339	**103,889**
Fur Animals		0	0	0	14	**14**
Gerbils		0	0	0	0	**0**
Guinea Pigs		6,956	561	146	0	**7,663**
Hamsters		0	0	0	12	**12**
Marine Mammals		0	0	0	0	**0**
Mice		3,728	22,624	2,371	15,505	**44,228**
Miniature Swine		0	72	0	0	**72**
Nonhuman Primates		64	2,311	326	0	**2,701**

Category of Animals	Category of Invasiveness				
	B*	**C***	**D***	**E***	**TOTAL**
Rabbits	152	1,435	169	0	**1,756**
Rats	2,052	40,779	3,929	1,800	**48,580**
Reptiles	0	300	0	0	**300**
Canadian Wild Animals	46	239	119	0	**404**
Other Non-Canadian Animals	0	0	0	0	**0**
Total	**14,199**	**84,505**	**61,097**	**54,850**	**214,651**

Appendix B: Sample Form for Annual Return to MAF, New Zealand

ANIMAL MANIPULATION FIGURES: **Period: 2010**

ONE SPECIES PER SHEET PLEASE

Name of Institution:

1. Animal Type:

2. Source of animals:	No. Used
Breeding unit	
Commercial	
Farm	
Born during project	
Captured	
Imported into New Zealand	
Public sources	
Total	

3. Status of animals:	No. Used
Normal/conventional	
SPF/germ free	
Diseased	
Transgenic/chimera	
Protected species	
Unborn/prehatched	
Other	

4. Purpose:	No. Used
Teaching	
Species conservation	
Environmental management	
Animal husbandry	
Basic biological research	
Medical research	
Veterinary research	
Testing	
Production of biological agents	
Development of alternatives	
Other	

5. Re-use:	No. Used
No prior use	
Previously used	

6. Grading:	New	No. Used
No impact	A	
Little impact	B	
Moderate impact	C	
High impact	D	
Very high impact	E	

7. Alive:	No. Used
Retained [by your institution]	
Returned [to owner]	
Released [to the wild]	
Disposed of [e.g. to works or rehomed]	
Total Alive	

8. Dead:	No. Used
Total Dead	

9. Total manipulated/used:	

Nil Return:	

Completed by: please print clearly
Designation:
Signature:

We agree that these statistics may be released if requested under the Official Information Act.	Yes	No

Appendix C: Directive 2010/63/EU of the European Parliament and of the Council of 27 September 2010 Annex VIII

SEVERITY CLASSIFICATION OF PROCEDURES

The severity of a procedure shall be determined by the degree of pain, suffering, distress or lasting harm expected to be experienced by an individual animal during the course of the procedure.

Section I: Severity categories

Non-recovery:

Procedures which are performed entirely under general anaesthesia from which the animal shall not recover consciousness shall be classified as 'non-recovery'.

Mild:

Procedures on animals as a result of which the animals are likely to experience short-term mild pain, suffering or distress, as well as procedures with no significant impairment of the well-being or general condition of the animals shall be classified as 'mild'.

Moderate:

Procedures on animals as a result of which the animals are likely to experience short-term moderate pain, suffering or distress, or long-lasting mild pain, suffering or distress as well as procedures that are likely to cause moderate impairment of the well-being or general condition of the animals shall be classified as 'moderate'.

Severe:

Procedures on animals as a result of which the animals are likely to experience severe pain, suffering or distress, or long- lasting moderate pain, suffering or distress as well as procedures, that are likely to cause severe impairment of the well- being or general condition of the animals shall be classified as 'severe'.

Section II: Assignment criteria

The assignment of the severity category shall take into account any intervention or manipulation of an animal within a defined procedure. It shall be based on the most severe effects likely to be experienced by an individual animal after applying all appropriate refinement techniques.

When assigning a procedure to a particular category, the type of procedure and a number of other factors shall be taken into account. All these factors shall be considered on a case-by-case basis.

The factors related to the procedure shall include:

— type of manipulation, handling,

— nature of pain, suffering, distress or lasting harm caused by (all elements of) the procedure, and its intensity, the duration, frequency and multiplicity of techniques employed,

— cumulative suffering within a procedure,

— prevention from expressing natural behaviour including restrictions on the housing, husbandry and care standards.

Examples are given in Section III of procedures assigned to each of the severity categories on the basis of factors related to the type of the procedure alone. They shall provide the first indication as to what classification would be the most appropriate for a certain type of procedure.

However, for the purposes of the final severity classification of the procedure, the following additional factors, assessed on a case-by-case basis, shall also be taken into account:

— type of species and genotype,

— maturity, age and gender of the animal,

— training experience of the animal with respect to the procedure,

— if the animal is to be reused, the actual severity of the previous procedures,

— the methods used to reduce or eliminate pain, suffering and distress, including refinement of housing, husbandry and care conditions,

— humane end-points.

Section III:

Examples of different types of procedure assigned to each of the severity categories on the basis of factors related to the type of the procedure

1. Mild:

(a) administration of anaesthesia except for the sole purpose of killing;

(b) pharmacokinetic study where a single dose is administered and a limited number of blood samples are taken (totalling < 10 % of circulating volume) and the substance is not expected to cause any detectable adverse effect;

(c) non-invasive imaging of animals (e.g. MRI) with appropriate sedation or anaesthesia;

(d) superficial procedures, e.g. ear and tail biopsies, non-surgical subcutaneous implantation of mini-pumps and transponders;

(e) application of external telemetry devices that cause only minor impairment to the animals or minor interference with normal activity and behaviour;

(f) administration of substances by subcutaneous, intramuscular, intraperitoneal routes, gavage and intravenously via superficial blood vessels, where the substance has no more than mild impact on the animal, and the volumes are within appropriate limits for the size and species of the animal;

(g) induction of tumours, or spontaneous tumours, that cause no detectable clinical adverse effects (e.g. small, subcutaneous, non-invasive nodules);

(h) breeding of genetically altered animals, which is expected to result in a phenotype with mild effects;

(i) feeding of modified diets, that do not meet all of the animals' nutritional needs and are expected to cause mild clinical abnormality within the time-scale of the study;

(j) short-term (< 24h) restraint in metabolic cages;

(k) studies involving short-term deprivation of social partners, short-term solitary caging of adult rats or mice of sociable strains; EN 20.10.2010 Official Journal of the European Union L 276/77

(l) models which expose animals to noxious stimuli which are briefly associated with mild pain, suffering or distress

(m) a combination or accumulation of the following examples may result in classification as 'mild':

(i) assessing body composition by non-invasive measures and with minimal restraint;

(ii) monitoring ECG with non-invasive techniques with minimal or no restraint of habituated animals;

(iii) application of external telemetry devices that are expected to cause no impairment to socially adapted animals and do not interfere with normal activity and behaviour;

(iv) breeding genetically altered animals which are expected to have no clinically detectable adverse phenotype;

(v) adding inert markers in the diet to follow passage of digesta;

(vi) withdrawal of food for < 24h in adult rats;

(vii) open field testing.

2. Moderate:

(a) frequent application of test substances which produce moderate clinical effects, and withdrawal of blood samples (> 10 % of circulating volume) in a conscious animal within a few days without volume replacement;

(b) acute dose-range finding studies, chronic toxicity/carcinogenicity tests, with non-lethal end-points;

(c) surgery under general anaesthesia and appropriate analgesia, associated with post-surgical pain, suffering or impairment of general condition. Examples include: thoracotomy, craniotomy, laparotomy, orchidectomy, lymphadenectomy, thyroidectomy, orthopaedic surgery with effective stabilisation and wound management, organ transplantation with effective management of rejection, surgical implantation of catheters, or biomedical devices (e.g. telemetry transmitters, minipumps etc.);

(d) models of induction of tumours, or spontaneous tumours, that are expected to cause moderate pain or distress or moderate interference with normal behaviour;

(e) irradiation or chemotherapy with a sub-lethal dose, or with an otherwise lethal dose but with reconstitution of the immune system. Adverse effects would be expected to be mild or moderate and would be short-lived (< 5 days);

(f) breeding of genetically altered animals which are expected to result in a phenotype with moderate effects;

(g) creation of genetically altered animals through surgical procedures;

(h) use of metabolic cages involving moderate restriction of movement over a prolonged period (up to 5 days);

(i) studies with modified diets that do not meet all of the animals' nutritional needs and are expected to cause moderate clinical abnormality within the time-scale of the study;

(j) withdrawal of food for 48 hours in adult rats;

(k) evoking escape and avoidance reactions where the animal is unable to escape or avoid the stimulus, and are expected to result in moderate distress.

3. Severe:

(a) toxicity testing where death is the end-point, or fatalities are to be expected and severe pathophysiological states are induced. For example, single dose acute toxicity testing (see OECD testing guidelines);

(b) testing of device where failure may cause severe pain, distress or death of the animal (e.g. cardiac assist devices);

(c) vaccine potency testing characterised by persistent impairment of the animal's condition, progressive disease leading to death, associated with long-lasting moderate pain, distress or suffering;

(d) irradiation or chemotherapy with a lethal dose without reconstitution of the immune system, or reconstitution with production of graft versus host disease;

(e) models with induction of tumours, or with spontaneous tumours, that are expected to cause progressive lethal disease associated with long-lasting moderate pain, distress or suffering. For example tumours causing cachexia, invasive bone tumours, tumours resulting in metastatic spread, and tumours that are allowed to ulcerate;

(f) surgical and other interventions in animals under general anaesthesia which are expected to result in severe or persistent moderate postoperative pain, suffering or distress or severe and persistent impairment of the general condition of the animals. Production of unstable fractures, thoracotomy without adequate analgesia, or trauma to produce multiple organ failure;

(g) organ transplantation where organ rejection is likely to lead to severe distress or impairment of the general condition of the animals (e.g. xenotransplantation);

(h) breeding animals with genetic disorders that are expected to experience severe and persistent impairment of general condition, for example Huntington's disease, Muscular dystrophy, chronic relapsing neuritis models;

(i) use of metabolic cages involving severe restriction of movement over a prolonged period;

(j) inescapable electric shock (e.g. to produce learned helplessness);

(k) complete isolation for prolonged periods of social species e.g. dogs and non-human primates;

(l) immobilisation stress to induce gastric ulcers or cardiac failure in rats;

(m) forced swim or exercise tests with exhaustion as the end-point.