Regulation Review Committee
Parliament of New South Wales

Report on the Animal Research Regulation 1995

Report No 13/51
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Abbreviations

the Act	Animal Research Act 1985 [Note: In this report the Act includes the amendments made by the Animal Research Amendment Act 1997]
the Code	Australian Code of Practice for the Care and Use of Animals in Scientific Research [Note: in this report the Code includes the most recent amendments made to that Code]
Ethics Committee	Animal care and Ethics Committee
the Panel	the Animal Research Review Panel
the POCTA Act	Prevention of Cruelty to Animals Act 1979
NPWS	National Parks and Wildlife Service
RIS	regulatory impact statement

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[1] The Committee also had the benefit of examining all written submissions made to NSW Agriculture in connection with the regulatory impact statement and the regulatory proposal. Copies of these were supplied to the Committee by NSW Agriculture in accordance with the requirements of the Subordinate Legislation Act.

Functions of Regulation Review Committee

The Regulation Review Committee was established under the Regulation Review Act 1987. A principal function of the Committee is to consider all regulations while they are subject to disallowance by Parliament. In examining a regulation the Committee is required to consider whether the special attention of Parliament should be drawn to it on any ground, including any of the following:

(a) that the regulation trespasses unduly on personal rights and liberties;
(b) that the regulation may have an adverse impact on the business community;
(c) that the regulation may not have been within the general objects of the legislation under which it was made;
(d) that the regulation may not accord with the spirit of the legislation under which it was made, even though it may have been legally made;
(e) that the objective of the regulation could have been achieved by alternative and more effective means;
(f) that the regulation duplicates, overlaps or conflicts with any other regulation or Act;
(g) that the form or intention of the regulation calls for elucidation; or
(h) that any of the requirements of sections 4, 5 and 6 of the Subordinate Legislation Act 1989, or of the Guidelines and requirements in Schedules 1 and 2 to that Act, appear not to have been complied with, to the extent that they were applicable in relation to the regulation.

The Committee may, as a consequence of its examination of a regulation, make such reports and recommendations to each House of Parliament as it thinks desirable.

A further function of the Committee is to report from time to time to both Houses of Parliament on the program for the staged repeal of regulations under the Subordinate Legislation Act 1989. Under this legislation all regulations currently in force in NSW are being re-examined, on cost benefit and cost effectiveness principles, starting on a chronological basis with the oldest of the regulations.

The staged repeal process involves the automatic repeal of existing regulations (except where exempt) made before 1 September 1990 in a staggered process commencing on 1 September 1991. Regulations made after 1 September 1990 are automatically repealed (unless their repeal is postponed) five years after they are made. The Animal Research Regulation 1995 was made in connection with that process.

Chairman's Foreword

This report is not an assessment of the merits of using animals for scientific research. As Ms Bernadette Tobin pointed out in her evidence, the present law proceeds on the assumption that some form of experimentation on animals is ethically permissible. The Committee's role was to look at the effectiveness of the regulatory controls that authorise such experimentation. These are contained in the Animal Research Regulation 1995.

The Committee's Report identifies several areas where substantial improvements can be made and it makes specific recommendations as to the action that should be taken in each case.

The Committee found that the public were given insufficient time by NSW Agriculture to consider the regulatory proposal and adequate consultation did not take place. In future the Animal Research Review Panel should be afforded a far greater role in the development of regulations.

A major project that should be undertaken by the Panel in the next two years is an in-depth review of the operation of animal Ethics Committees to determine how efficiently they are carrying out their functions in regard to promoting the principles of replacement, reduction and refinement. There is insufficient information available at present to judge this.

Evidence presented to the Committee showed that there is a need for species-specific codes of best practice to be developed for the housing of common laboratory animals in order to assist applying the principles of the code in the laboratory situation. Again, the Committee makes appropriate recommendations to cover this.

The Committee's inquiry showed that the Prevention of Cruelty to Animals Act is currently not being enforced in research institutions. This situation is contrary to Parliament's clearly expressed intention. The Committee recommends that the Minister for Agriculture take action to amend sections 25 and 26 of the Prevention of Cruelty to Animals Act to permit authorised officers, such as RSPCA inspectors, to have access to research institutions to make random checks.

The Committee in its inquiry was given helpful co-operation by the Animal Research Review Panel and research institutions permitted inspections of their premises when requested. I express my appreciation to those members of the public and departmental staff who took time to prepare submissions on the various issues and to attend and give evidence before the Committee. This Report contains a large number of recommendations which, when implemented, will add strong support to the regulatory system governing animal research in New South Wales.

Doug Shedden MP
Chairman
Regulation Review Committee

Recommendations

Recommendation 1: That the Minister for Agriculture put in place guidelines to ensure that the public are adequately consulted and given sufficient time to make comments and submissions on regulatory proposals affecting the Animal Research Act and Regulations and that NSW Agriculture include each year, in its annual report, a statement as to compliance or otherwise with those guidelines (Part 4, pp 4-12).

Recommendation 2: That the Minister for Agriculture pursuant to section 9(d) of the Animal Research Act 1985 confer on the Animal Research Review Panel the additional function of participating in the settlement of all future regulatory proposals under that Act and of being responsible, with NSW Agriculture, for recommending to the Minister the final form of any new or amending regulations proposed to be made under the Animal Research Act 1985 (Part 4, pp 4-12).

Recommendation 3: That the provisions of regulation 6 of the Animal Research Regulation 1995 be amended to make it mandatory in any case where an Ethics Committee has more than four members, that categories C plus D represent no less than one third of the members (Part 6, pp 14-17).

Recommendation 4: That a regulation be made under the Animal Research Act to require an Ethics Committee to document the basis of its decision in regard to a research proposal in accordance with Appendix 6 (Part 6, pp 18-21).

Recommendation 5: That the Minister for Agriculture seek the appointment to the Animal Welfare Committee of the National Health and Medical Research Council of a person trained in the discipline of philosophical ethics (Part 6, pp 22-25).

Recommendation 6: That Regulation 10 of the Animal Research Regulation 1995 be repealed (Part 6, pp 25-26).

Recommendation 7: That the Animal Research Review Panel carry out in the next 2 years an in-depth review of the operation of Animal Ethics Committees to determine whether they are carrying out their duty under paragraph 2.2 of the Australian Code to ensure that all animal care and use within research institutions incorporate the principles of replacement, reduction and refinement. That report should be tabled by the Minister in Parliament (Part 6, pp 26-32).

Recommendation 8: That the issues raised by Parnell Laboratories in its submission be examined by the Minister for Agriculture in conjunction with the competition policy review of the Animal Research Act with a view to determining whether they should be placed on the agenda of a forthcoming Ministerial Council Meeting (Part 6, pp 26-32).

Recommendation 9: That the Animal Research Review Panel should:

(a) take action to ensure the availability of species-specific codes of best practice for the housing of common laboratory animals;

(b) ensure that NSW manufacturers and retailers of pens, cages and containers used in animal research in NSW are clearly advised as to the requirements of the Australian code;

(c) advise each research institution and Ethics Committee of their obligations to ensure that animal accommodation complies with the Code;

(d) within the next 3 years, complete a survey of the adequacy of housing in each of the accredited research institutions and prepare a report on the findings and action taken by it. That survey should also examine the feasibility of introducing a system of accreditation for animal housing. The report should be tabled in Parliament by the Minister (Part 7, pp 34-39).

Recommendation 10: That the current accreditation practices of the Panel should be reviewed by the Minister. An examination should be made of options that would ensure a detailed assessment of institutions and licensees is carried out in conjunction with the act of accreditation or licensing. A regulation should be made under section 62 of the Animal Research Act with respect to the procedures to be followed by the Panel in relation to the investigation of applications for accreditation or licensing. This should be done as soon as practicable so that Parliament can satisfy itself as to the adequacy of the investigation procedures (Part 8, pp 40-43).

Recommendation 11: The Committee recommends that NSW Agriculture examine whether section 20 of the Animal Research Act should be amended so as to allow the making of a regulation requiring applicants for accreditation and licences to disclose offences committed under relevant interstate acts (Part 8, pp 40-43).

Recommendation 12: The Committee recommends that the Animal Research Regulation be amended to require accredited institutions and licensees to notify the Animal Research Review Panel within 30 days of changes in particulars for accreditation or licensing (Part 8, pp 40-43).

Recommendation 13: That the Animal Research Act be amended to give members of the Panel in the course of their duties the right to enter designated land within the meaning of section 3 of that Act (Part 9, page 44).

Recommendation 14:

(a) That the National Parks and Wildlife Service expedite the computerisation of its records relating to the issue of s120 licences and draw up guidelines to be followed by its officers for the administration of those licences;
(b) That the National Parks and Wildlife Service undertake a study to evaluate the costs and benefits of the s120 licensing scheme and that this assessment be tabled in Parliament by the Minister within 12 months;
(c) That animal research proposals involving the use of native animals be considered by an Ethics Committee prior to their referral to the National Parks and Wildlife Service;
(d) That the National Parks and Wildlife Service follow up with the Code Liaison Group the discrepancies that exist between the changes recommended by the National Parks and Wildlife Service and the text of the present code (Part 10, pp 45-49).

Recommendation 15: That the review of fees by the Panel be re-activated and finalised, by the making of an amending regulation within 6 months from this report (Part 12, pp 52-53).

Recommendation 16: That sections 25 and 26 of the Prevention of Cruelty to Animals Act 1979 be amended so as to permit authorised officers to inspect research institutions (Part 13, pp 54-56).

Recommendation 17: That an amendment be made to the Animal Research Act to permit

such persons or organisations as may be prescribed by regulation to have access to research institutions at half yearly intervals under conditions approved by the Minister for Agriculture (Part 15, pp 58-59).

Recommendation 18: That an examination be made by NSW Agriculture of whether it would be in the public interest for a register to be set up under the Animal Research Regulation in which certain research particulars could be recorded to enhance the Government's objectives of greater transparency of experimentation (Part 15, pp 58-59).

Recommendation 19: That, from the point of view of transparency and Parliamentary scrutiny, a regulation be made under section 62 of the Animal Research Act with respect to the procedures to be followed by the Panel in relation to the investigation of complaints referred to it under the Act (Part 15, pp 58-59).

Recommendation 20: That the Minister for Agriculture seek advice from the Crown Solicitor on whether a complainant is protected from an action of defamation in the event of lodging a complaint in accordance with the Animal Research Act (Part 15, pp 58-60).

Recommendation 21: That the proposal for a national reporting format be actively pursued by the Minister for Agriculture with a view to gaining consensus on a standardised reporting scheme. If agreement cannot be reached with the other States within 12 months, NSW should introduce its own revised scheme (Part 16, pp 61-65).

Recommendation 22: That regulation 22 of the Animal Research Regulation be reviewed by the Parliamentary Counsel to determine if it accords with the intentions of the Animal Research Review Panel and NSW Agriculture (Part 17, pp 66-67).

Recommendation 23: That the Animal Research Review Panel and NSW Agriculture assess the costs and benefits of requiring school-based establishments to submit annual returns in accordance with regulation 26 (Part 17, pp 66-69).

Recommendation 24: That the Animal Research Review Panel and NSW Agriculture review the current arrangement governing the monitoring of animal research in school-based institutions with a view to improving those arrangements and ensuring that adequate funds are available for them. This should be carried out within the next three years and a report on the review should be tabled in Parliament (Part 17, pp 69-70).

1. Inquiry by the Regulation Review Committee

On 18 April 1996 the Regulation Review Committee resolved to inquire into and report to the Parliament on the Animal Research Regulation 1995. The inquiry was conducted as part of the Committee's function under section 9(2) of the Regulation Review Act of reporting to Parliament from time to time on the staged repeal program. The Animal Research Regulation was made in connection with that program. The purpose of the inquiry was to examine:

- compliance by the Minister with the provisions of the Subordinate Legislation Act 1989 in the making of this regulation;
- the regulatory impact statement for the regulatory proposal and the consultation conducted in respect of it;
- the provisions of the regulation relating to accreditation of research establishments and the licensing of persons to conduct research or to supply animals for research;
- the annual report made to the Director-General of Agriculture by accredited research establishments and licensees;
- the inspection of research establishments and land the subject of research licenses or animal suppliers' licenses;
- the provisions of the regulation relating to animals Ethics Committees (including subcomittees) and the operation of those committees;
- the Code of Practice prescribed by the Regulation; and
- related matters.

Notice of the inquiry was published in the Sydney Morning Herald on 28th September 1996. Individuals and organisations were invited to make a submission (in writing, typed or on disk) to assist the inquiry.

A list of submissions received is set out in Appendix 7. The Committee conducted public hearings at Parliament House, Sydney on the 25th and 26th March 1997 and 23rd October, 1997. The names of each witness at those hearings are set out in Appendix 8.

2. Inspection by Committee of research establishments

In conjunction with the inquiry members of the Committee carried out an inspection of the following research establishments:

University of New South Wales - 5 November, 1996 and 19 February, 1997
University of Sydney - 5 November, 1996
Garvan Institute of Medical Research - 5 November, 1996
Cyanamid-Websters Pty Ltd - 15 November, 1996
Royal Prince Alfred Hospital - 15 November, 1996
Royal North Shore Hospital - 19 February, 1997

These inspections were made to familiarise the Committee with the subject matter of the inquiry and they were undertaken with the permission of the particular research institutions.

3. The Regulation

The object of this Regulation[2] is to repeal and remake the provisions of the Animal Research Regulation 1990. The new Regulation deals with the following matters:

(a) the qualifications to be held by certain members of the Animal Research Review Panel (Part 2);

(b) the constitution and procedure for Ethics Committees and ethics subcomittees (Part 3);

(c) matters relating to accreditation and licensing (Divisions 1, 2 and 3 of Part 4);

(d) exemptions from the requirements for accreditation and licensing (Division 4 of Part 4);

(e) other matters of a minor nature (Parts 1 and 5).

In particular, the new Regulation prescribes a Code of Practice for the conduct of animal research and the supply of animals for use in connection with animal research. The Code of Practice is to comprise the "Australian code of practice for the care and use of animals for scientific purposes" (a code prepared jointly by the National Health and Medical Research Council, the Commonwealth Scientific and Industrial Research Organisation and the Australian Agricultural Council), supplemented by the following:

(a) provisions relating to animal research conducted in schools (Part I of Schedule I);

(b) provisions relating to animal research involving free-living animals (Part 2 of Schedule I);

(c) provisions relating to the care of animals by licensed animal suppliers (Part 3 of Schedule I);

(d) provisions relating to the supply of animals to licensed animal suppliers and certain impounding authorities (Part 4 of Schedule 1).

This Regulation is made under the Animal Research Act 1985, including section 62 (the general regulation making power) and sections 3, 6, 13, 15, 18, 29, 37 and 49.

This Regulation is made in connection with the staged repeal of subordinate legislation under the Subordinate Legislation Act 1989.

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2 The text of the Animal Research Regulation 1995 is set out in Appendix 3.

4. Adequacy of publicity and consultation in regard to the making of the regulation

Publicity

Under the provisions of the Subordinate Legislation Act the Minister is required to publish a notice setting out details of the regulatory proposal in the Government Gazette and in a newspaper circulating throughout New South Wales and, where appropriate, in any relevant trade, professional, business or public interest journal or publication. This notice must state the objects of the proposed regulation, advise where a copy of the regulatory impact statement and draft regulation may be obtained or inspected, and invite comments and submissions from the public.

Notice of the regulatory proposal was published in the Sydney Morning Herald of 12th July, 1995 and in the Government Gazette of 14 July 1995. The proposal was not published in any trade, professional business or public interest journal although it would have been appropriate to do so having regard to the statewide interest of scientific and animal welfare groups in the proposal. There were a number of relevant publications that could have been selected.[3] The reason given at the inquiry was the limited time frame within which the draft regulation had to be finalised.

The notice of the regulatory proposal gave the public the statutory minimum of 21 days within which to make submissions on the regulation. In his evidence, Dr R Sheldrake, Executive Director, Research Advisory and Education, NSW Agriculture, acknowledged that concerns had been expressed in relation to people wanting more time for formal public consultation on the regulatory impact statement and the draft regulation but he maintained the whole process was undertaken with as much effort and diligence as the situation allowed.[4]

In its written submission, NSW Agriculture took a stronger stance and declared *"this consultation period was entirely adequate to enable affected members of the community to participate in government decision making with a view to identifying the most efficient and equitable outcomes...."* Dr Sheldrake argued all key interest groups were identified and circulated with a draft regulation and impact statement and that the regulation had been reviewed in the first place by the Animal Research Review Panel which was a body representing community interests. This claim of adequacy of the consultation period needs to be examined against the views of the public and the limited role that the Panel had in developing and settling the regulation.

NSW Agriculture received 12 written submissions from the public. Eight of these claimed the period was inadequate:

- **Animal Societies Federation (NSW)** Ms Joan Papayanni, in a submission to NSW Agriculture dated 3 August 1995 on the draft Regulation, stated *"I wish to express, in the strongest terms, my concern at the time frame allowed for the process of consultation".*

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3 *Australian Veterinary Journal; Land Newspaper; National Parks Journal; Habitat; Australian Nature*

4 Evidence given by Dr Sheldrake on 25 March 1997

In a letter to the Committee dated 12 February 1997 the Federation advised:-

"Further to our communications regarding the review of the Animal Research Legislation which was conducted in July 1995, I wish to express in strong terms my concerns over the manner of the consultative process.

Consultation regarding changes to the Regulation occurred over a very tight time frame and although, with some difficulty, we met the specified deadline, we have not to date received a substantial response from the Department of Agriculture.

In fact, it is my recollection that the Animal Societies Federation had to request to be included in the consultative process.

Where there is little or no evidence that significant advances are being made to achieve the prime goals of refinement, reduction and replacement, it is vital that close communication with groups such as the Animal Societies Federation receives a high priority."

- **Humane Society International - Australia**, in a submission to NSW Agriculture dated July, 1995 on the draft regulation said *"we would have appreciated more time to allow us to prepare a thorough response to this document as it represents major changes to the way in which animals may be used in NSW".*

The Society, in a submission to the Regulation Review Committee dated 7 November 1996 stated:

"We note that between the Draft Regulation and the final Gazetted Regulation few changes have been made. Given the time constraints involved in the process we are concerned that there was never any real intention to reflect concerns raised during the public consultation phase in the final Gazetted Regulation.

Non Government Organisations expend many limited resources preparing submissions on these legislation processes, yet receive little or no feedback regarding their concerns. A report should be prepared including a list of submissions received, highlighting the comments and concerns of submission providers and how these concerns have been addressed."

The Regulation Review Committee believes this is a useful proposal and one that should be followed in the case of regulations such as the present one, which have generated substantial public comment.

- **The University of Newcastle** in a submission dated 31 July 1995 to NSW Agriculture on the draft regulation advised that *"the Committee wished to register its concern at the time allowed for comment on the document. The document was received by the Animal Welfare Officer on 10 July 1995 with comments to be submitted by 31 July 1995".*

- **Dr Steve Atkinson, University of New England,** in a letter dated 1 August 1995 to the Animal Welfare Unit, NSW Agriculture, stated *"Enclosed are my personal comments about the proposed changes to the Animal Research Regulation. Because of the lack of time allowed, the University of New England AEC has not been able to discuss the proposals, and no response has yet been produced."*

- **Australian Society for Laboratory Animals Science Inc**, in a letter dated 2 August

1995 to NSW Agriculture advised *"The executive of ASLAS did not directly receive a copy of the draft for comment, an omission on the mailing list that I now understand has been corrected. This was, I believe, a significant omission in the process of consultation, as the membership of ASLAS included facility managers, members of Ethics Committees and researchers - just those people in fact upon whom the regulation will impact and who would have a vested interest in commenting.*

Further, the amount of time provided for the consultation process has been substantially less than would be required for adequate broad-based dissemination and comment. A three week turn around time for institutions prevented distribution to Ethics Committee members, facility managers and researchers. From my point of view as President of ASLAS, given that my only copy of the draft came from my institution, the turn around time for ASLAS comment had been reduced to 7 days. The problems associated with this are self evident.

Nevertheless, ASLAS believes that it would be remiss of our association not to comment and so I have obtained a number of comments at short notice from members of ASLAS and present these views below. Let me say that all of my urgent respondents have indicated that they would have appreciated the opportunity to provide a more considered response."

- **State Forests**, in a letter of 10 August 1995 said it did not did not receive a copy of the draft legislation in time to respond by 31 July 1995.

- **The Australian Veterinary Association Ltd**, in a letter dated 7 August 1995 advised *"As the AVA consults widely with its members in arriving at a consensus opinion, it is imperative that sufficient time is allowed for this process to proceed efficiently. We therefore would appreciate more time to comment on any reviews in future."*

- **Animal Research Review Panel -** In a submission dated 7 November, 1996 to the Regulation Review Committee, Associate Professor Margaret Rose, Chairperson said:

"Panel members also expressed concern about the short time available for comment on the draft Regulation, which appears to be an inevitable consequence of the rigid timetable built into the Subordinate Legislation Act."

In an undated letter Dr Sheldrake advised Associate Professor Margaret Rose, in response to her submission on the draft regulation, that *"As you are aware, we are following a timetable set down by the Subordinate Legislation Act which requires gazettal of the Regulation by 1 September. However, there is scope for further consideration of issues after 1 September, free from the time constraints imposed by the Subordinate Legislation Act, and if necessary recommendations can be made for further changes to the Regulation by direct amendment. This was foreshadowed in the Regulatory Impact Statement (RIS) accompanying the draft Regulation, which flagged fees and statistics as issues subject to further review."* Dr Sheldrake made a similar response to each of the other complainants.

Ms K Stiles, member of the Animal Research Review Panel in correspondence to the Committee also makes the point that Ethics Committees like many community groups are run on a voluntary basis and meet at irregular intervals or may have numerous members who need to be contacted and their comments collated. Therefore these considerations need to be given proper weight when setting the period.[5]

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[5] Letter to the Regulation Review Committee dated 11 April 1997

It is difficult for the Committee to understand how NSW Agriculture, in the face of these genuine expressions of concern, could still conclude that the consultation period was "entirely adequate to enable affected members of the community to participate in government decision making." In fact the tenor of Dr Sheldrake's responses to the public submissions is a concession that the period was too short although responsibility for it was placed consistently at the foot of the Subordinate Legislation Act.

The Minister for Agriculture, in contrast to his officers, recognised there was a deficiency in the period allowed for submissions and consultation. In a letter to the Committee dated 2 September 1996 the Minister said that he had reviewed this matter with the Director-General, Dr K P Sheridan, and had been assured that it would be addressed.

Some explanation of why NSW Agriculture ran out of time can be found from an examination of the process followed by the Department in making the regulation. Its written submission to the inquiry gave the following outline of this process:

1991 -1994	*AWU[6] staff develop proposals for amendments to the Regulation, based on administrative difficulties and anomalies identified by staff and the Panel following initial implementation of the legislation.*
July 1994	*Subcommittee of ARRP[7] meets to consider proposed amendments to the Regulation.*
11 October 1994	*Drafting instructions endorsed by ARRP.*
14 October 1994	*Preliminary drafting instructions to Parliamentary Counsel sent to Minister for approval.*
18 October 1994	*Preparation of Regulatory Impact Statement (RIS) commenced - primary responsibility of Animal Welfare Unit [AWU] staff with advice from legal and economic services. Prepared in accordance with Schedule 2 of the Subordinate Legislation Act.*
2 March 1995	*First draft of regulation received from Parliamentary Counsel.*
27 March 1995	*Second draft of regulation received from Parliamentary Counsel.*
1 May 1995	*Approval from Economic Services Unit [ESU] on final draft RIS.*
17 May 1995	*Final draft of regulation received from Parliamentary Counsel.*
23 May 1995	*Minister's approval to public consultation on RIS and draft Regulation sought.*
21 June 1995	*Minister's approval given.*
10 July 1995	*RIS and draft regulation received by organisations and individuals identified in RIS, which were identified by AWU staff as being those on whom the regulatory proposal would impact most.*

6 Animal Welfare Unit

7 Animal Research Review Panel

12 July 1995	*Public notice in Sydney Morning Herald.*
2 August 1995	*Closing date for submissions (submissions received after this date were also considered).*
18 August 1995	*Additional drafting instructions sent to Parliamentary Counsel.*
18 August 1995	*Copies of public comments and responses sent to Chief Legal Officer for submission to Regulation Review Committee .*
1 September 1995	*Gazettal of Regulation.*[8]

Advice given to the Committee by the Parliamentary Counsel's Office shows that a facsimile was sent by NSW Agriculture to that office on the 27th February, 1995 containing preliminary instructions for the redrafting of the Animal Research Regulation. It will be seen in the outline of the process that NSW Agriculture stated they sent preliminary drafting instructions to the Minister for approval on the 14th October, 1994. NSW Agriculture has not provided any explanation as to why it took four and a half months for these instructions to get from the Minister to the Parliamentary Counsel. This was a significant loss of time.

The Department's outline says that the final draft of the regulation for public exhibition was received from the Parliamentary Counsel on the 17th May 1995. This does not accord with the records held by the Parliamentary Counsel. These show that Mr David Mills, of the Parliamentary Counsel's Office, released a draft regulation on the 28th April, 1995 to the Instructing Officer of NSW Agriculture for exhibition with the Regulatory Impact Statement. This was nearly three weeks earlier than stated by the Department. On the 23rd May, 1995, the Department sought the Minister's approval to release the regulatory impact statement and draft regulation for public exhibition. The Minister's approval was not given until the 21st June, 1995 which was a month later. This means that a period of approximately two and a half months elapsed from the time the Parliamentary Counsel completed his draft of the regulation until it was exhibited. In all there seems to have been a loss of nearly seven months in the process because of departmental inaction. This had the affect of forcing NSW Agriculture to set the minimum statutory time for public consultation. It also, as will be seen, meant that a large number of relevant issues raised in the public submissions could not be adequately examined within the remaining time.

The time allowed for submissions and consultation should be selected in accordance with the principles in section 5(3) of the Subordinate Legislation Act, that is, it must have regard to the impact likely to arise from the regulatory proposal for the public and relevant interest groups. The minimum statutory period shouldn't be used to serve departmental convenience, as in this case. The Department should take into account the significance of the issues involved in the regulatory proposal and the capacity of the public and interest groups to effectively address the issues within the period that is being set.

There was a particular need in this case to provide an adequate period so that all ethics committee members, on whom the effectiveness of the regulation largely depends, could be sufficiently informed so they could contribute to the regulation making process.

In the course of the inquiry, Ms Jones, Senior Legal Officer, Research, Advisory and

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8 Submission by NSW Agriculture to the Inquiry into the Animal Research Regulation 1995

Education, NSW Agriculture, referred to the obligation in section 5 of the Subordinate Legislation Act which was to comply as far as reasonably practicable. She said that although noting the concerns of some people wanting more time, the process was undertaken with as much effort and diligence as the situation allowed. She pointed out that contentious issues involved consultation over a much longer period of time and in these cases the public are advised that those issues would be considered at a later date. She said that in 1995 NSW Agriculture had 32 regulations due for renewal and that the Department had applied to the Premier for the postponement from repeal of some of these because of major legislative reviews connected with them. She said that unfortunately NSW Agriculture was only notified in March 1995 of the result of the postponement applications.

"As at March 1995 we were hit with a totally different picture to that of September the previous year. We ended up remaking nine regulations with a regulatory impact statement and four regulations that did not require regulatory impact statements. The balance of the 32 regulations were either amalgamated into new regulations, lapsed, or we obtained postponements eventually in respect of them. It was a huge process that was undertaken, and by 1 September 1995, all those regulations had been properly dealt with. There was no hiatus in relation to the continuance of any of those regulations."[9]

There was, however, no reason that the review of this large number of regulations could not have been staggered over different years so as to avoid attempting this task within the same 12-month period. Under the current arrangements the Parliamentary Counsel writes out to each department in September of each year alerting the department to those regulations that will sunset in September of the following year. That notification requests advice by November or December from the department of its intentions in regard to the particular regulations, that is, whether they will be remade, repealed, consolidated or a postponement sought. Mr David Mills of the Parliamentary Counsel's Office advised committee officers that only a few departments ever advise their intentions by that time and that usually it is left until March of the year in which the regulation sunsets. He said that unless a department has carried out a major part of its public consultation prior to the release of the regulatory impact statement that there may be insufficient time left following the release of the RIS to do justice to the public submissions. This is apparent from the difficulties of NSW Agriculture in regard to the Animal Research Regulation. As that department will be faced with similar difficulties in 5 years time, it should discuss the matter with the Parliamentary Counsel to work out a program of review that will not compromise its obligations under the Subordinate Legislation Act.

Consultation

Section 5 of the Subordinate Legislation Act contains both the requirements for publicising a regulatory proposal and for consultation on it. Though related, these are separate requirements. Under the Act, consultation has to be commensurate with the impact likely to arise for consumers, the public, relevant interest groups and any sectors of industry or commerce. The provisions in the Subordinate Legislation Act relating to the preparation of regulatory impact statements (Schedule 2) require a statement of the consultation program to be undertaken. The obligation in this case to consult was not satisfied by merely publicising the regulatory proposal and replying to correspondence on it.

The regulatory impact statement for the proposal did not contain any program of consultation, just advice that a copy of the statement would be sent to accredited research

[9] Ms Jones, evidence at the Inquiry before the Regulation Review Committee, 25 March, 1997.

establishments, the holders of animal suppliers' licences, the Animal Welfare League, the Animal Societies' Federation, Animal Liberation, the Cat Protection Society, the Fund for Animals, the Humane Society International, the RSPCA and the Animal Welfare Advisory Council. One submission to NSW Agriculture claimed that many of these organisations seemed not to have received a copy of the proposal.[10]

A large number of issues raised in public submissions by many such bodies were postponed by NSW Agriculture for further consideration after 1 September, 1995 "free from the time constraints of the Subordinate Legislation Act". This was sometimes done with the assurance that subsequent consultation would take place with the parties upon these matters[11]. Prior to the inquiry the various bodies affected were contacted by the Committee. The Humane Society International said that no consultation had taken place with it on the outstanding matters. Dr Steve Atkinson, from the University of New England, said that although informal discussions had taken place on general matters, no consultation had taken place with him on the particular outstanding matters raised by him. The position was similar with the National Parks and Wildlife Service, the Australian Society for Laboratory Animal Science Incorporated, the Animal Societies' Federation, Avondale College, the Australian Veterinary Association, State Forests and the University of Newcastle.

In the course of the inquiry, the representatives from NSW Agriculture conceded the regulatory proposals were not discussed with any particular public interest groups. On the evidence presented the Committee is satisfied NSW Agriculture did not adequately consult with relevant interest groups in preparing the regulatory proposal and failed to meet the requirements of the Subordinate Legislation Act in this respect.

Although the Panel participated in developing the instructions to the Parliamentary Counsel, when it came to examining the draft regulation, its submission was treated no differently by NSW Agriculture to any other public submission made on the regulation and it never became aware of - and perhaps is still not aware of - the details contained in any other public submission. This is clear from the evidence given at the inquiry by both the Panel members and officers of NSW Agriculture.

> ***MEMBER OF COMMITTEE**: Did you seek the views of the Animal Research Review Panel on each of the public submissions?*
>
> ***Ms BROOKS**: No*

The Panel was remiss in not seeking access to those submissions. When the Chairperson was asked whether the Panel was involved in examining the submissions she said it was an administrative matter.

> ***MEMBER OF COMMITTEE**: Could you tell the Committee whether the Panel was involved in examining and commenting upon the public submissions made on the RIS and the draft regulation, or was that handled by the Department of Agriculture? I ask that because the Committee received a submission made by one of the Panel members that actually said the Panel was never shown a copy of the submissions.*

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10 Letter dated 1st August 1995 to Dr R Burton from Dr S Atkinson, University of New England

11 This type of undertaking was given, for example, in response to submissions made by The University of Newcastle, the University of New England, the National Parks and Wildlife Service, the Australian Society for Laboratory Animal Science Inc and the Humane Society International - Australia

Associate Professor ROSE: That was an administrative matter which was handled by the Department. The Panel was one of the bodies which made a submission, and we received a response back from the Department with regard to the submission that we made.[12]

Associate Professor Rose, in her evidence, persisted with the view that the Panel was able to sufficiently inform itself from other sources, such as through her participation on the Code Liaison Group, an argument she put forward without apparently knowing the contents of the public submissions. It was evident she did this to put in the best light a relationship with NSW Agriculture that had not been of the Panel's making. Nevertheless the Panel has been complacent in accepting the limited role afforded it by the Department and it should have sought a greater participation in the processes that led to the final form and content of the regulation. The Panel left this crucial work to the Animal Welfare Unit of NSW Agriculture.

The purpose of public submissions is to give the Minister, the Department and the Panel the public's view on the strengths and weaknesses of the regulatory proposal, information which is central to the Panel's own role of effectively advising the Minister on the legislation.

The Panel was similarly excluded from the discussions that took place between departmental officers to decide the final text of the regulation following the public submission stage.

MEMBER OF THE COMMITTEE: Once the submissions had arrived what process was followed to review those submissions? Was that done solely by Mr Burton, Senior Veterinary Officer of the Animal Welfare Unit?

Ms JONES: Mr Burton and I sat down and reviewed them together and considered what should be done in relation to each of them. I am not aware of where else Mr Burton took them.

Ms BROOKS: I am afraid I am not aware, either. I was on leave at the time.

Ms JONES: The submissions were then put together into a recommended document which went to the Minister with a request that the Minister approve our approach to the Parliamentary Counsel to amend the regulation prior to it being submitted to the Governor for making.

It is apparent from the evidence given to the inquiry that (subject to any changes made by the Minister) the final form of the regulation was determined by the Senior Veterinary Officer and the Chief Legal Officer of the Animal Welfare Unit notwithstanding that the Government had available to it for advice an Animal Research Review Panel comprising twelve members drawn from industry, government, and animal welfare groups. The use of this expertise may have meant that fewer principal matters in the submissions would have been left unresolved. It would certainly not have resulted in the anomalous situation where members of the Panel actually expressed disagreement with some of the contents of the gazetted regulation.[13]

The Committee considers this is a completely unsatisfactory situation. The Panel, so that it can carry out its functions, must be kept fully informed of public submissions on the effectiveness of NSW animal research legislation. It should be an equal partner with NSW

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12 Evidence given by Associate Professor Rose at the Inquiry, 25 March 1997

13 In its written submission to the Committee the Panel said it had some significant concerns with the new regulation which differed in important respects from the drafting instructions endorsed by the Panel.

Agriculture in terms of considering those submissions and recommending to the Minister the final form of regulations.

Recommendation 1:

The Committee recommends that the Minister put in place guidelines to ensure that the public are adequately consulted and given sufficient time to make comments and submissions on regulatory proposals affecting the Animal Research Act and Regulations and that NSW Agriculture include each year, in its annual report, a statement as to compliance or otherwise with those guidelines.

Recommendation 2:

The Committee recommends that the Minister for Agriculture pursuant to section 9(d) of the Animal Research Act, 1985 confer on the Animal Research Review Panel the additional function of participating in the settlement of all future regulatory proposals under that Act and of being responsible, with NSW Agriculture, for recommending to the Minister the final form of any new or amending regulations proposed to be made under the Animal Research Act 1985.

5. Requirement to appropriately consider all comments and submissions on the regulatory proposal

Under section 5(2) of the Subordinate Legislation Act, before a statutory rule is made the Minister is required to ensure that all the comments and submissions received are appropriately considered. It is the Committee's view that NSW Agriculture did not satisfy this duty in respect of a number of material issues that were raised in the public submissions. The letters from the Executive Director of the Animal Welfare Unit to persons who made submissions on the draft regulation inappropriately postponed the examination of significant issues until they could be examined "free from the time constraints of the Subordinate Legislation Act". This showed a significant lack of understanding of that Act and the purposes of it. The subordinate legislation procedures worked well to produce submissions that had depth and merit but the large number of material issues that had to be postponed for further consideration substantially undermined the comprehensive review intended to be carried out for this regulation at this stage under the Subordinate Legislation Act. This should have made it necessary for NSW Agriculture to put a detailed case to the Governor, through the Minister and Premier, seeking postponement of the repeal of this regulation for 1 year so that its review could be effectively completed. At the inquiry Dr Sheldrake conceded that postponement would have been the preferred course. But he and his officers argued that an application for postponement would not have been granted under the grounds of postponement set out in the Premier's memorandum.[14] However, the Committee has been advised by the Cabinet Office that NSW Agriculture did not make an application for postponement of this particular regulation or discuss the prospects of such an application with Cabinet officers.

Appendix 4 to this report contains a list of all those matters postponed for further consideration after 1 September, 1995 by NSW Agriculture and the current status of action upon them. The Committee is satisfied that many of the unresolved issues have not been progressed at all or to any material degree since the Animal Research Regulation was gazetted on 1 September 1995 notwithstanding the undertaking by NSW Agriculture to do so. There is no justification for the lapse of two years in many of these cases before action upon them, particularly in regard to issues raised by the Panel.

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14 Premier's memorandum No. 94-42 *Arrangements Regarding the Staged Repeal of Statutory Rules* dated 17 November, 1994

6. Animal care and Ethics Committees

The need for a balanced membership

Each accredited research establishment is required to appoint an Ethics Committee (Clause 2.1.1. of the Australian Code). As a result of changes made by the Animal Research Amendment Act 1997, an Ethics Committee must now be appointed to supervise the holder of an animal supplier's licence.

The constitution and procedure for Ethics Committees for research establishments is contained in section 13(5) of the Act and Part 3 (which incorporates by reference the Australian Code) and in Schedule 2 of the regulations. The effect of these requirements is that an animal Ethics Committee (AEC) for a research establishment (other than a school-based establishment) must have at least four members including a separate person appointed to each of the following categories:

Category A. A person with qualifications in veterinary science, with experience relevant to the activities of the institution, or, in special circumstances, a person with qualifications and experience to provide comparable expertise;

Category B. A person with substantial recent experience in the use of animals in scientific or teaching activities;

Category C. A person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the institution, and who is not involved in the care and use of animals for scientific purposes. The person should, where possible, be selected on the basis of active membership of, and nomination by, an animal welfare organisation; and

Category D. An independent person who does not currently and has not previously conducted scientific or teaching activities using animals and who is preferably not an employee of the institution, except under defined circumstances[15].

The Code and the regulations do not limit the number of persons that can be appointed to an Ethics Committee by the research establishment and as a consequence the independent and animal welfare members are often exceeded by the appointment of persons with a scientific background usually employed by the research establishment.

The main justification given for this imbalance is that adequate advice must be available to an Ethics Committee to appraise the scientific merit of proposals in a number of areas and this makes it necessary to have several persons with scientific qualifications or experience on the committee.

The table below contains a summary of membership composition for New South Wales Ethics Committees. This information was obtained by the Regulation Review Committee by way of a questionnaire sent to 66 accredited research establishments, 44 of which responded.

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15 These categories follow the text of the revised code.

Category of Members

Ethics Committee	A	B	C	D	Number on Committee	Voting Method
No. 1	1	1	1	1	4	Majority voting but consensus has always been achieved
No. 2	1	1	1	1	4	Consensus
No. 3	1	1	1	1	4	Consensus
No. 4	1	1	1	1	4	Consensus
No. 5	2	1	1	1	5	Consensus
No. 6	1	2	1	1	5	Consensus
No. 7	1	2	1	1	5	Consensus
No. 8	1	1	1	3	6	Consensus or majority
No. 9	2	2	1	1	6	Consensus
No. 10	2	2	1	1	6	Consensus
No. 11	1	2	2	2	7	Consensus
No. 12	1	2	1	1	5	Consensus
No. 13	1	3	1	2	7	Majority "but strives for consensus"
No. 14	2	2	1	1	6	Consensus
No. 15	3	1	1	2	7	Consensus
No. 16	1	4	1	2	8	Consensus
No. 17	2	2	2	2	8	Consensus or majority
No. 18	2	3	1	2	8	Majority
No. 19	2	3	2	2	9	Consensus
No. 20	2	4	1	2	9	Consensus
No. 21	1	5	2	2	10	Consensus or majority
No. 22	2	2	2	4	10	Consensus
No. 23	1	6	2	2	11	Majority
No. 24	2	6	1	1	10	Consensus
No. 25	3	5	2	2	12	Consensus
No. 26	2	6	2	2	12	Consensus
No. 27	2	6	2	2	12	Consensus
No. 28	2	5	2	3	12	Majority although "consensus is usually reached"
No. 29	1	5	1	5	12	Consensus
No. 30	1	6	2	2	11	Consensus
No. 31	2	8	4	2	16	Consensus
No. 32	1	1	1	1	4	Consensus
No. 33	1	1	1	1	4	Consensus
No. 34	1	1	1	2	5	Consensus
No. 35	1	1	1	3	6	Consensus
No. 36	1	2	1	2	6	Consensus
No. 37	2	3	2	3	10	Consensus
No. 38	1	1	2	2	6	Consensus
No. 39	Operates under another animal Ethics Committee					

No. 40	Operates under another animal Ethics Committee
No. 41	Operates under another animal Ethics Committee
No. 42	Operates under another animal Ethics Committee
No. 43	Ceased animal research operations
No. 44	Ceased animal research operations

The preservation of a reasonable numerical balance between categories C and D and other representatives was an important concern of the Panel in its submission on the draft regulation. This was also discussed in various submissions by both accredited research institutions and animal welfare groups.[16]

The Animal Research Review Panel in its submission said that because most Ethics Committees had more members in categories A and B, category C and D members were always outvoted and therefore impotent. The Department's reply was that this matter could be reviewed after 1 September 1995 "free from the time constraints imposed by the Subordinate Legislation Act". This was an inadequate response. C and D members represent the public in the decision making process and the view by the Panel that current arrangements had reduced them to impotency called for a prompt and positive effort by the Department to correct the position. At the inquiry, NSW Agriculture was asked to provide an answer as to what action was intended to be taken in respect of this and other matters postponed for further consideration. On 16 May, 1997 Dr Sheridan advised the Committee that this issue would be the subject of regulations made following the passage of the Animal Research Amendment Bill. The Committee does not know the nature of the regulation planned.

The forceful submission made by the Panel on this point contrasted with the position taken by its Chairperson at the inquiry. Associate Professor Rose argued that to be constantly looking at the effectiveness of committees on the balance of membership and voting was to belittle what could be achieved by good dialogue. There is a lot of merit in this view but it must be wondered how attractive it would remain to the scientific community if committee representation was more evenly balanced.

This issue has been taken up by the Code Liaison group in its 1997 revision of the Code. The notes accompanying the revision state that "the requirement for balance of membership of an AEC has been addressed...". Clause 2.2.6 now states:

"If the committee has more than four members, Categories C plus D should represent no less than one third of the members." This Clause does not have any accompanying explanatory notes to show why the Code Liaison Group has not made it mandatory particularly in view of its statement about the *requirement* for balance. The use of the word "should" will leave it to the discretion of the particular research institution. There is no certainty that the revised wording of the Code, relying as it does on institutional discretion, will produce the intended change. Public concern about this issue warranted a mandatory rather than discretionary Clause. This change to the Code has also been accompanied by the inclusion in the Code of a provision that requires, for a valid quorum, the presence at the meeting of one member from each category A, B, C and D. This requirement is in addition to the existing provision in the regulations. This will make it necessary to alter the quorum provisions of the regulation (Clause 6 of Schedule 2) to make them consistent with the

16 Animal Research Review Panel; Animal Societies Federation (NSW); University of New England; Mr Keith Edwards; Humane Society International

Code.

Recommendation 3:

The Committee recommends that the provisions of regulation 6 be amended to make it mandatory that in any case where an Ethics Committee has more than four members, categories C plus D represent no less than one third of the members.

Voting

The Panel in its submission to the Committee said that it had a number of significant concerns about the final regulation. It said that decision making by majority vote conflicted with the spirit and letter of the Code of Practice:

"The new Regulation contains provisions related to procedures for AECs [Schedule 2}. These allow a quorum for an AEC to include less than one member from each category of membership and stipulate decision making by majority vote. These conflict with the spirit and letter of the Code of Practice."[17]

At the inquiry Ms Stiles said that the Panel had endorsed particular instructions to the Parliamentary Counsel about consensus voting which had not been implemented.

> ***MEMBER OF COMMITTEE:*** *In your written submission you made reference to the difficulty the Panel had briefing Parliamentary Counsel in formulating the regulations the Committee is considering today. You said that the final regulation in some instances bore little resemblance to the intentions or instruction of the Panel and that the public had insufficient time to examine the draft regulation. Would you comment further on those points and identify specific changes that the process would have made but did not make to the regulation?*
>
> ***Ms STILES:*** *The Panel made quite explicit instructions to the Parliamentary draughtsman for the review of regulations. Those instructions did not include things like changing the Ethics Committee process from consensus to majority vote. The draughtsman was never instructed to change the process setting up the quorum. It just happened. There were lots of things that happened within that drafting that were not at the instruction and certainly not at the wish of the Panel. These things came back to us at a time when time was critical. If the Panel had tried to change those things again to get them back to where they were, the sunset Clause would have come in and we would have ended up with no regulation at all, which we felt was more dangerous than having a regulation that was not perfect.*

It appears from the Committee's examination of this matter that, consistent with the submission made by the Panel to the Committee, the Panel did endorse drafting instructions requesting the repeal of the majority voting provision in the regulation but this was not acted upon. It seems NSW Agriculture intends to consider some change to the regulation on this subject. In a letter dated 16 May 1997, the Director-General flagged the matter as one that will be included in forthcoming improvements to the regulations.

The view taken by the Panel in its original submission to the Committee differed from a

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[17] Submission by Animal Research Review Panel to the Inquiry into the Animal Research Regulation 1995

subsequent submission made to the inquiry. In that supplementary submission the Panel had this to say on the subject:

"Method of voting by AECs
The mechanisms for operating AECs are at the discretion of each AEC. The Code of Practice requires that the process by which decisions are made must be "acceptable to all AEC members" (Clause 2.2.17) and "preferably made on the basis of unanimous agreement" (Clause 2.2 2). The November 1996 draft of the Code of Practice expands on this by way of a footnote "Where two or more members oppose a proposal it should not be approved until the AEC has explored ways of modifying 2.2.21 and the project that may lead to consensus" (footnote 18- Attachment G).

There are differing views on the value of majority vote verses unanimous agreement. An argument against majority voting is that members, especially external members, may be consistently outvoted. An argument against unanimous agreement is that members, especially external members, may feel pressured to approve protocols when majority vote would allow formal dissent.

The 1995 Chairs meeting included a workshop on committee dynamics. This included discussion of methods of decision making. In practice, the majority of AECs use decision by consensus."

It will be seen from this extract that the Panel does not appear to be recommending any change to the existing requirements. As most committees voluntarily favour a unanimous voting method there is no practical justification, at this stage, to consider altering the regulations to make such a practice mandatory.

The method of voting, although a contentious and substantive provision of the regulation, was not examined in the RIS which inadequately restricted its comments to the choice between retaining the existing provisions or having no regulatory provisions to govern the constitution and procedures for Ethics Committees. The examination in the RIS of the regulatory provisions governing the constitution and procedure for animal care and Ethics Committees occupied barely 20 lines in the impact statement and did not examine a single substantive provision in a subject matter considered by both the Panel and the Minister as being of core importance to the effectiveness of the regulatory scheme. The Committee can only conclude that NSW Agriculture did not have expertise available to prepare the assessment or that it does not regard the duty of effectively doing so as being very important.

Documenting reasons for the approval or rejection of research proposals

Evidence given at the inquiry shows that Ethics Committees do not document the reasons for approving a research proposal. However, if an application is refused, reasons are given. Several reasons have led the Regulation Review Committee to the conclusion that an Ethics Committee should adequately document the basis of its decision to approve or reject a research proposal.

The first of these is that a research proposal can only be approved if it conforms to all the requirements of the Australian Code of Practice. This is a precondition to a valid approval (2.2.1 (iii)) of the Code). This necessitates more than the recording of a bare approval of

the project. The public should be able to satisfy itself that the Ethics Committee has followed due process in approving an application and has sufficiently taken into account each of the requirements of the Code and regulation. The legislation makes strict adherence to those requirements, the price for immunity against prosecution under the Prevention of Cruelty to Animals Act. It is difficult to see how the defence against prosecution under that Act, which is set out in section 24, could be satisfactorily invoked by the research institution or the holder of an animal research authority unless they could adequately demonstrate that the research approval had been granted having regard to each of the requirements of the Code and regulation.

In these circumstances the Ethics Committee has an obligation to the researcher, and to the public, to carry out and document a scrupulous appraisal of the proposal so that the committee can be satisfied it meets each of the requirements of the legislation. This will also make it more expeditious for the Panel to check compliance.

A further reason why it is necessary to document the decision of the Ethics Committee arises from evidence given in the course of the inquiry. Concern was expressed by some members of the Animal Research Review Panel on whether fundamental issues are currently being addressed by Ethics Committees in examining research proposals[18]. This principally refers to the requirement under the Code that experiments on animals may only be performed when they are essential to obtain and establish significant information relevant to the understanding of humans or animals, to the maintenance and improvement of human or animal health and welfare, to the improvement of animal management or production, or to the achievement of educational objectives. (1.1 of the Code) The Code also says that experiments using animals may be performed only after a decision has been made that they are justified, weighing the scientific or educational value of the experiment against the potential effects on the welfare of animals. (1.2 of the Code)

> ***Ms STILES:*** *One major issue we must address is that we go straight to the impact on the animals and do not actually look at "is this is absolutely essential". It is taken as said that if a scientist puts this up and there is this argument in words of more than one syllable that it should go ahead and there is a presumption that the research will go ahead, but it is how we modify it to lessen the impact. A major issue that must be addressed is going back to the fundamentals.*
>
> ***MEMBER OF COMMITTEE:*** *How do you determine if it is necessary? From what Ms Stiles has said, it appears that that issue is not adequately addressed?*
>
> ***Associate Professor ROSE:*** *There has been concern that once somebody puts up a case that something was justified de facto, it should proceed. It has been a criticism of what is happening. There are reasons for us looking at that more rigorously. If someone has gone through that process in the first place and if you do not think something is worthwhile and it is not justified, the researcher should not put it to the committee. I am aware of many cases where that has occurred. People do stop and think. There is a first port of call in saying yes or no, which is at the researcher level. What comes to the committee has to be tested and we certainly have been discussing it. I am concerned that we make sure that we look at the balance of the dynamics. That is why the model form has been developed the way it has. It is to remind people that once you look at justification and impact, you have a final decision to make. That final decision will probably differ around that room as it would around this*

[18] The Regulation Review Committee was told, in response to its questionnaire mentioned on page 14 of this report, that 5 Ethics Committees did not assess the scientific merit of research proposals.

room I suspect. That is the dilemma we have when dealing with this issue. That is why we have a group of people to try to make what seems to be a fair and reasonable decision, which will differ from time to time.

MEMBER OF COMMITTEE: *How do you address the issue raised by Ms Stiles? Does the Panel address that issue or is it on the agenda for discussion?*

Associate Professor ROSE: *It is definitely on the agenda for discussion.*

Another Panel member, Dr Wilson, also gave evidence on this matter.

Dr WILSON: *Documenting the approval process would be very cumbersome in terms of Ethics Committees because they ensure that the code of practice is complied with. By documenting an approval you could say you are complying with the code of practice, and that could be something you could put into the computer, or you could reproduce the code of practice each time. It is more important that you document the reasons for disapproval. One of the reasons that harks back to the educative aspects of this process is educating scientists that we do not really want to know about protein x and procedure y: we want to know how they are looking after the animals and how they are looking after the animals before and after whatever experimentation is performed on them.*

That is the hardest educative task for ethic committees. It has largely been a function of deficient forms in the past. The model protocol form will change that. People are beginning to realise that we want to know that pain and suffering will be minimised by any procedures undertaken by scientists. That is the whole emphasis of Ethics Committees, whereas they regard us as something like the NH and MRC, "I'm going to cure cancer and you really should approve my protocol because of that" rather than, "We don't give a hoot about whether you want to cure cancer, we want to know how the animals are being treated."

Dr Wilson seems to be incorrectly arguing here that the principal emphasis of an Ethics Committee should be to consider how the animals will be looked after in the course of the experiment without first establishing the essential and significant nature of the research itself. This is the approach objected to by Ms Stiles. This issue involves the difficult question of applying the Code which requires an Ethics Committee to reach some decision on the essential and significant nature of the research in advance of it actually being carried out.

Professor Perry, who has been involved in the review of the Code for some years, gave evidence on this issue. He referred to the research done by Mr Peter Doherty in 1980 as an example of why it was not possible to determine the outcome in advance of particular scientific work. Professor Perry seemed to be of the view however that this would not prevent an Ethics Committee from judging the scientific merit of a proposal in circumstances where the committee was unsure of the outcome of the research in terms of the knowledge that would be gained by the particular experiments.

Professor Perry[19] in subsequent correspondence to the Committee set out his view on how this task should be carried out:

"The first section of the Code sets out the criteria, in general terms, which have to be met to

[19] Letter to Regulation Review Committee dated 7 May, 1997

justify animal use and the responsibilities on the researcher/teacher that go along with using animals. The intent of the Code is very clear - animals must only be used to obtain significant information relevant to the understanding of humans or animals or to satisfy the other criteria listed at Clause 1.1 in the revised Code of Practice. It is essential that research applications to the institutional AEC address how the project will increase our understanding of humans or animals. This is specifically requested by the Code under section 2.2.11, covering written proposals.

Assuming that the applicant does submit a proposal that aims to obtain new information about human or animal function, then the animal Ethics Committee has to evaluate whether or not the acquisition of that knowledge warrants the use of the animals required. Such a decision requires the weighing up of the cost in terms of animal welfare versus the gain in knowledge. The difficulty of the decision for the Ethics Committee will depend on the impact of the proposed experiment on the animal. If the animal is to experience considerable discomfort then the process of weighing cost versus benefit will be longer and more difficult than for a protocol in which the experiment causes the animal minimal if any discomfort. The diversity in backgrounds of the members of the committee would allow a balanced decision to be made. There is, however, no simple formula to solve such ethical problems.

The point which I tried to make to the Regulation Review Committee is that in trying to reach a decision as to whether a particular research project justified the use of animals, an Ethics Committee member should not place a low value on basic research, the aim of which is to understand how this tissue or that may work, compared to a very applied research protocol, the aim of which is to cure this cancer or that infection. Time has proven that major advances in medical science have come as much if not more from basic research than from applied research. These two approaches to science should be seen as supporting one another."

These comments, in the Committee's view, set out a reasonable approach for Ethics Committees to this matter. They should be read against the background of recognised research purposes which are defined in section 3 of the Animal Research Act.

The evidence presented to the Committee shows there is a need for greater legal certainty that these crucial requirements of the Code are being complied with by Ethics Committees. While these doubts exist they will continue to give rise to justified public concern. A first step in this process is to ask Ethics Committees to give specific attention to this issue. The pro forma recommended by the Committee will do this.

Recommendation 4:

The Committee recommends that a regulation be made under the Animal Research Act to require an Ethics Committee to document the basis of its decision in regard to a research proposal in accordance with Appendix 6.

Ethics

Clause 1.7 of the Code says that investigators and teachers must take into account all ethical aspects in their proposals and 3.2.1 requires them to address whether the project is ethically justified. Paragraph 2.2.1 of the Code says that ethical considerations have to be taken into account by an Ethics Committee in deciding whether or not to approve a protocol. One submission made to the Committee expressed concern that current Ethics Committees do not have an ethics expert, that they do not understand the different schools of thought, that they have not received ethics training and that ethics are not being discussed[20]. This submission was of assistance to the inquiry because it usefully raised several fundamental points that required clarification.

The Committee sought expert advice on this from the John Plunkett Centre for Ethics. The Director of that centre, Dr Bernadette Tobin, agreed to make a written submission to the Committee on the matter and to appear and give evidence. Her written submission on each of the issues raised follows:

"John Plunkett Centre for Ethics in Health Care

St Vincent's Hospital
Darlinghurst 2010

Submission to
Inquiry into the Operation of the Animal Research Regulations 1995

The following five issues have been raised by Mr Jefferis, the Director of the Regulation Review Committee, in his letter of 6th March 1997 to me as Director of the John Plunkett Centre for Ethics at St Vincent's Hospital.

1 Current Ethics Committees do not have an ethics expert

1.1 Under the NHMRC Code of Practice ('the Code'), animal Ethics Committees are required to include four categories of appointee, a separate person being appointed to each category (the membership requirements are set out in paras 2.2.2 to 2.2.8 of the Code). Under the Animal Research Act 1985 Regulations, a distinction is made between research establishments which are (a) non school-based: see regulation 6; and (b) school-based establishments governed by regulation 7. In each case at least one member of the committee must fulfil the requirements of the Act as to independence and non-involvement with animal research. The non school-based committees are to satisfy the NHMRC Code as to categories (as incorporated in the Animal Research Act Regulations) while the school-based committees are to satisfy the requirements specifically spelled out in those Regulations.

1.2 It is notable that neither the Code nor the Regulations make it necessary for a committee to include someone trained in the discipline of philosophical ethics. A justification for this may well be that these committees do not have responsibility for formulating the

20 Submission by Ms L Shanley dated 10 November 1996. The University of Newcastle in its submission dated 18 November 1996 also raised the issue of ethics. The University argued that a person should be appointed to the Panel to provide an ethical viewpoint.

ethical considerations which arise when research is done on animals: their responsibility is rather to ensure that all facets of animal care and use meet the requirements of the ethical considerations which are set out in the Code These requirements set out the ethical issues in a clear and unambiguous manner (see point 5 below).

1.3 Thus the function of the animal Ethics Committees is practical: it is to see that the treatment of animals actually being used in research is ethical, ie complies with the Code. They are not concerned with revising and reformulating the Code. That task is very much within the role of the Animal Welfare Committee of the National Health and Medical Research Council and the Animal Care and Ethics Committee of the Animal Welfare Unit of NSW Agriculture. There is thus a much stronger argument that these bodies, responsible for formulating the relevant code of practice. should include in their membership an 'ethics expert'.

1.4 One further question concerns who should count as an 'ethics expert'? Philosophers are people trained to carry out the sometimes complicated reasoning required if an ethically-sound decision is to be made. But since ethics is essentially a practical and not a theoretical inquiry, those who are engaged in doing that reasoning, whether professional philosopher or ethicist or not, may be an 'expert' in the relevant sense. That is to say: in ethics as a practical enquiry, there rightly are no 'experts'.

2 Current Ethics Committees do not understand the different schools of [ethical] thought

For the reasons discussed in 1.4 there should be no requirement that members of institutional committees need to understand the different schools of ethical thought. Their deliberations are practical ones (see point 5). However there is a much stronger argument for requiring that the committees which have the responsibility for formulating the ethical requirements should include someone trained in ethics.

3 Members of Ethics Committees have not received ethics training

See discussion above

4 Ethics are not being discussed by Ethics Committees

The day to day work of animal Ethics Committees is discussion of ethical issues. Therefore, when the criticism is made that 'ethics are not being discussed', it is obviously directed to another issue: whether the Code is adequate, whether there should be any experimentation allowed on animals at all. In this context, a 'discussion about ethics' might take one of the following three forms: (i) a discussion of the main 'theories' of ethics: for example deontology, consequentialism, virtues-based ethics, (2) a discussion of specific obligations and challenges (the 'principles') derived from the theories which might be thought to be relevant to the matter of doing research on animals, and (3) a discussion of whether a particular research proposal will be ethically-sound in the light of those principles.

It will be seen that a discussion about ethics in (1) and (2) is deeply involved with the ultimate questions which animal Ethics Committees deal with, but is not necessarily the meeting-to-meeting function of the Ethics Committees themselves. Institutional Ethics Committees have the responsibility primarily to consider specific research proposals in the light of the obligations and challenges set out for them by others.

However it would be odd if their discussions never raised issues about the adequacy of the principles themselves. It is important, therefore, that there is a regular opportunity for members

of institutional Ethics Committees to review both their own deliberations and the principles on which they make their decisions. To this end, the Animal Care and Ethics Committee of the Animal Welfare Unit organises an annual meeting of the members of the committees.

5 Does a consideration of the issues set out in the pro forma application constitute, when taken together, a consideration of the ethics of a particular research proposal?

5.1 As already argued, there is a distinction between a discussion of different theoretical approaches in ethics and the adequacy of different ethical principles on the one hand and a practical discussion of whether some specific research proposal is permissible on the other. In my opinion, on the whole the deliberations of institutional Ethics Committees should concentrate on the latter.

5.2 There are four clusters of issues which should arise in the ethical evaluation of specific research projects: (1) whether there is a sound justification for using animals (why the use of animals is thought to be necessary); (2) what will actually happen to the animals during the research; (3) whether their well-being will be ensured at each stage of the research, in particular whether any pain or other suffering will be inflicted on the animals and if so, how that will be monitored and minimised; and (4) if the research is destructive: how their lives will be ended. The Model Protocol Form issued by the Director-General's Animal Care and Ethics Committee requires committees to assess projects in the light of all four issues. For this reason I think that a consideration of the issues set out in the pro forma application does constitute, when taken together, a consideration of the ethics of a particular research proposal.

5.3 However the first issue, whether there is a sound justification for using animals in the first place, raises what is perhaps the crux of many criticisms of the conduct of animal Ethics Committees. Some people are critical not so much of the conduct of animal Ethics Committees as they currently operate as they are of the very idea of using animals for scientific research. Some people think that there is something intrinsically wrong with using animals for experimental research, whatever the actual consequences for any particular animals. This view is defended by powerful arguments in philosophy (as well as some weaker ones). It would be odd if members of an Ethics Committee never adverted to this objection. However I do not think they are morally required to revisit this question at each of their meetings. Rather it is legitimate for them to proceed on the assumption that, for the moment at least, so long as it meets the requirements set out in the Code, research on animals is ethically-permissible. The present law proceeds on the assumption that some forms of experimentation on animals are ethically-permissible. The deeper question, whether there really are intrinsic objections to experimentation on animals, is a matter for debate by the Australian society and for judgment by individual conscience.

Bernadette Tobin
Director
John Plunkett Centre for Ethics in Health Care
26 March 1997"

The Committee accepts the view of Dr Tobin that there is a strong argument that a person trained in the discipline of philosophical ethics should be included in the membership of the Animal Welfare Committee of the National Health and Medical Research Council.

Recommendation 5:

The Committee recommends to the Minister for Agriculture that he seek the appointment to the Animal Welfare Committee of the National Health and Medical Research Council of a person trained in the discipline of philosophical ethics.

Functions of ethics subcommittees

Section 16(1) of the Animal Research Act states that the Code of Practice may empower an Ethics Committee to delegate specific functions to its ethics subcommittees. The only functions subcommittees can have are those delegated in accordance with this power (s16(2))

'Code of Practice' is defined in section 3 of the Act as the code referred to in section 4. That section authorises the regulations to prescribe a Code of Practice. This has been done in regulation 4 which defines it as comprising the Australian Code of practice for the care and use of animals for scientific purposes and Schedule 1 of the Regulations.

The Australian Code of Practice does not refer to ethics subcommittees but it does authorise an Ethics Committee to establish an Executive "to approve minor modifications to projects and deal with emergencies". However, the Executive may not approve research proposals (Clause 2.2.14) This limitation is accentuated further by Clause 2.2.20 which says that "Proposals must be considered and approved only at meetings of the AEC".

Schedule 1 to the regulation deals with supplementary provisions of the Code of Practice. Part 1 of the Schedule covers conditions to be observed in relation to animal research conducted in schools; Part 2 covers conditions to be observed in relation to animal research involving free-living animals; Part 3 deals with conditions governing licensed animal suppliers in relation to dogs and cats; Part 4 with conditions to be observed in relation to the supply of dogs and cats to licensed animal suppliers and impounding authorities. None of these provisions authorise the delegation of powers from an Ethics Committee to a subcommittee.

The only provision in the regulation relating to delegation is regulation 10 which reads: " For the purposes of section 16 of the Act, an Ethics Committee may delegate any of its functions to its ethics subcommittees." This provision is in conflict with section 16 of the Act and with the intentions of Clause 2.2.14 of the Australian Code of Practice.

To comply with section 16 any provision for delegation must be contained in the "Code of Practice", that is, in either the Australian code of practice for the care and use of animals for scientific purposes or in the supplementary provisions to the code contained in Schedule 1 to the regulation. Regulation 10 is not part of either of these instruments that make up the Code of Practice. Accordingly, research proposals cannot legally be authorised by an ethics subcommittee.

The basis for the prohibition in Clause 2.2.14 of the Code of Practice lies in the constitution of the Executive or subcommittee which by its nature is not representative of the full committee and legally requires the inclusion of only one member of the Ethics Committee. It would consequently not be in the spirit of the legislation for a subcommittee to perform the principal functions of an Ethics Committee with such limited representation.

The Animal Research Review Panel in its submission dated 8 November 1996 to the Inquiry said that it had some significant concerns about the draft regulation which differed in some

important respects from the drafting instructions endorsed by the Panel. It said these concerns were reinforced when it viewed the new regulation at its next meeting. The Panel listed three of its most serious concerns, one of which was that: "the new Regulation allows animal care and Ethics Committee (AEC) approval of protocols to be delegated to a subcommittee (Clause 10) which is contrary to the intent of the Code of Practice that proposals should be considered by a properly constituted AEC".

However, an examination of the draft regulation (Appendix 1) shows that it did not include any provision to allow an Ethics Committee to delegate its powers to a subcommittee. Clause 10 of the regulation must therefore have been included sometime between the public exhibition of the draft regulation and the gazettal of the final regulation. This seems to indicate that the Panel was not consulted on the inclusion of this provision, particularly as the Panel opposes it and has taken steps to have it modified. The fact that two years has passed since the Panel identified the problem shows that NSW Agriculture has not been active to rectify it.

The Committee in correspondence with accredited research establishments and with the holders of research licences requested details of whether ethics subcommittees had been set up and, if so, what powers had been delegated to them. Information received by the Committee shows that only TAFE has set up sub committees and delegated to them power to approve research proposals. However the TAFE subcommittees are in fact Ethics Committees as they satisfy the membership requirements of the Code.

Recommendation 6:

The Committee recommends that Regulation 10 be repealed.

Replacement, reduction and refinement

On 21 May, 1997, the Minister for Agriculture, during debate on the Animal Research Amendment Bill, said that we should act to replace animal experimentation with alternative systems such as the use of computer models and information from other experiments. He said that where it was impossible to conduct some tests without animals, the number of animals used should be greatly reduced. He said this was his goal in reforming legislation dealing with animal research in New South Wales. At the conclusion of the debate the Minister said he would ensure that there was a comprehensive review of all aspects of the original legislation "including reporting and putting more pressure on institutions to reduce or find alternatives to using animals in experiments".

These statements represent the government policy on this subject and it is useful to examine the regulation to see the manner in which it is being implemented.

A principal purpose of the Australian Code is to establish animal Ethics Committees "to ensure adherence to the principles of replacement, reduction and refinement"[21].

These terms refer to:

- the replacement of animals with other methods;
- the reduction in the number of animals used; and

[21] Introduction to the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes

- the refinement of techniques used to reduce the impact on animals.

The Code requires techniques which replace or complement animal experiments to be actively sought and used wherever possible (1.9). Ethics Committees must ensure that all animal care and use within institutions incorporate the principles of replacement, reduction and refinement (2.2). Written proposals also have to comply with these principles (2.2.9).

The Panel in its submission to the Committee said:

"The Panel agrees that alternatives to animals should actively be sought and used wherever possible. This includes the replacement of animals with non-animal alternatives as well as the reduction and refinement of animal use. The development and use of alternatives is a complex and ongoing process and it is difficult to define what constitutes "sufficient effort" in their pursuit.

Efforts that the Panel has made in the area of alternatives include:

a) Site inspections
Ideas gained during inspection for innovations in the "3 Rs" (reduction, replacement and refinement) are shared with other institutions, directly or via the newsletter (Animal Ethics Update).

b) Model form
A model research application form developed by the Panel in conjunction with AEC representatives has a section which focuses attention on the need to use animals and places the responsibility on the investigator to explain why alternatives cannot be used. (Question 15 "Why is it necessary to use animals in this experiment?"; Question 16 "What alternatives to animals have been considered and why is it not possible to use these?").

c) Education workshop
In 1996 the Panel ran two workshops on alternatives to the use of animals in education.

d) Meeting for AEC Chairs topics
The 1996 AEC Chairs meeting included a workshop with the deliberately provocative title "Alternatives - how seriously are they being investigated?" which was designed to promote discussion about practical means of investigating the use of alternatives.

e) Toxicology Technical Advisory Group
Toxicology Technical Advisory Group (TTAG) has been established to deal with toxicology matters, particularly in the area of alternatives. The area of legal requirements for drug testing is one in which it may be feasible to reduce animal use.

f) Support of individual institutions
A large drug company was granted exemption from conducting an invasive test (requirement of the UIC Veterinary Medicines Directorate) after seeking Panel support on this issue.

A drug company approached the Panel about the need to conduct animal tests to meet New Zealand legislative requirements. The Panel is currently investigating on behalf of the company and has referred the issue to the TTAG.

g) Monoclonals
A survey by the Panel has been conducted on monoclonal antibody production with the

aims of identifying practical developments in the refinement of current techniques and moves towards replacement by non-animal methods. The results of the survey have not yet been published and further action is under consideration. The holding of a seminar to promote methods which reduce and refine animal use is being considered.

h) Blood collection
Guidelines from the UK on blood collection (BVA/FRAME/UFAW "Removal of blood from laboratory mammals and birds") was circulated by the Panel to all AECs. This was followed by a survey by the Panel on current practices for blood collection. The purpose of the survey was to promote available guidelines and references and to identify and promote refinements in blood collection that improve the welfare of animals used. The results of the survey are yet to be collated, however, information gained in the course of the survey has been used in refining procedures and monitoring of animals that are subject to repeated blood collection for biological products."

Ms Stiles, Panel member, in her written submission to the Committee argued that all proposals should be designed by a biometrician to ensure the minimum number of animals was used. She was referring here to paragraph 1.10 of the Code which says that studies must be scientifically and statistically valid and must use only the minimum number of animals necessary. At the inquiry Ms Stiles was questioned on her submission.

> ***MEMBER OF COMMITTEE:*** *In your written submission you referred to a proposal about a biometrician examining each research proposal to make sure that the minimum number of animals was used. Can you explain what you meant by that? Are you saying that without a biometrical assessment an Ethics Committee would not be able to tell whether the minimum number of animals was being used?*
>
> ***Ms STILES:*** *It is very difficult to know that. Scientists are not all biometricians. It is important that every study done is scientifically valid, and that means that there are enough animals to get a scientifically valid result, but not too many. I think it requires the input of someone like that to ensure that that happens. It would be very easy to say take 10, because then you can work out percentages relatively easily, but that might not be the minimum number. It requires somebody with that expertise to have input in that area.*
>
> ***MEMBER OF COMMITTEE:*** *How many cases have you come across where too many animals have been used?*
>
> ***Ms STILES:*** *What about the cases that I have not found that are out there as well?*
>
> ***MEMBER OF COMMITTEE:*** *You are not a biometrician either. How would you know that too many are being used?*
>
> ***Ms STILES:*** *What we are finding is that a lot of the experiments that are ongoing have been refined, that they are now using fewer animals, or that when the proposal from the scientist goes to the Committee through discussion it is decided that that experiment can actually happen with far fewer animals—and that is without the valued expertise of a biometrician. There are refinements happening which would indicate very strongly that it is not perhaps fair to place the entire burden of that biometrical analysis on the scientists, that we could actually be supporting them by doing this.*
>
> ***MEMBER OF COMMITTEE:*** *You will find that animals cost money, the feeding of*

animals costs money, and experiments cost money. Therefore, the general scientist who is thoughtful and thinking and wishes to spend money normally gets the advice of a biometrician because the general scientist knows that he does not have the ability to analyse the results himself.

Associate Professor Rose examined the issue in an article published in ANZCCART News in 1994[22]. She made the following remarks on the requirements of the Australian Code:

"The Australian Code of Practice for the care and use of animals for scientific purposes (section 1.9) requires that in those circumstances where experiments are scientifically valid and it is not possible to replace the use of animals, no more animals are used than the minimum number needed. Reduction is defined by Russell and Burch (1959) in terms of the number of animals needed 'to obtain information of a given amount and precision'. There is an ethical and scientific imperative to use that number of animals which will provide statistically valid scientific data. Appropriate experimental design and statistical analysis of data are the key strategies in achieving valid results with the least number of animals. The principle of Reduction embodies the ethical demands of scientific validity and minimal numbers. In these circumstances it is equally problematic to use too few as too many animals."

Later in the article she listed some strategies to ensure the use of the minimum number of animals in experiments.

"With the considerable public interest in reducing the numbers of animals used, outside the question of Replacement, there has been little discussion of other strategies to achieve this goal. This is reflected, for example, in the programme of the first World Congress on Alternatives and Animal Use in the Life Sciences (Baltimore, November 1993) where there was only one paper devoted to the issue of Reduction.

However, two recent review articles outline a range of strategies to ensure the use of the minimum number of animals in an appropriate experimental design (Erb 1909; Mann, et al., 1991). Having set the lower limits for group sizes using appropriate statistical methods, ways by which the numbers of animals used can be reduced include: increasing the effect size; reducing variability; use of control groups; repeated samples from the same animals; and employment of different methods of statistical analysis such as using a one-tailed rather than a two-tailed test.

Thus in the application of the three Rs, particularly the principle of Reduction, the ethical imperative is the use of the appropriate number of animals to achieve meaningful results."

Associate Professor Rose's article demonstrates the complexity of the issues facing an Ethics Committee in attempting to determine whether a proposed experimental study is scientifically and statistically valid. Most committee members would need to rely here on the judgment of the category B member of the Committee, that is, the person with substantial recent experience in the use of animals in scientific activities. If that person does not have the specialist knowledge then the opinion of an independent scientific referee should be sought.[23]

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22 ANZCCART News Vol 7. No 2. June 1994

23 Mr A Brennan, Chair of the AEEC, the University of Western Australia recommends this course in his article on Ethics Committees in ANZCCART News Vol 9. No 2 June 1996

Ms G Oogjes[24] in her evidence said that there was concern in the animal welfare community about the effectiveness of the Act in achieving the aims of reduction, refinement and replacement. She referred to the Panel's annual report for 1994-1995 which showed only 30 instances where these objectives had been met. This compared with 45 instances listed in the earlier 1992-1993 report, suggesting no ongoing improvement.

Ms Oogjes concludes this part of her evidence with the following criticism:

> *"Then I thought I would look at the overall numbers of animals used in these two reports. When I looked at the 1992-93 report the figures were extremely bewildering. I will not go into the details, but in one chart there are 268,000 examples; in another chart there are 29,000 examples. I would have thought that would have covered at least all of them, although the statistics are not at all clear. When I look at the 1994-95 report for the number of animals used overall, it comes to something like 1,400,000 animals, which is actually more than would appear to be the case in the 1992-93 chart, although, as I say, the statistics are bewildering. So if we look at hard figures, which is all we have to look at, we cannot see that progress is being made. We are dependent on information for these reports from the Animal Research Review Panel. This is the only official source of information we have, and the information here is very sparse, very bald, and at times unclear."*

Mr Edwards, Panel member, in his evidence said that the presentation of statistics in the annual report did not give much indication about the implementation of the three Rs. There is, consequently, no collected data on which any overall assessment can be made of the implementation by Ethics Committees of these principles. Evidence presented at the inquiry shows that although the Panel has carried out a variety of initiatives to promote these principles it has not undertaken an in-depth review of the operation of Ethics Committees in relation to them. The importance of Ethics Committees in the successful implementation of this legislation warrants such a study being undertaken.

The Committee received a submission from Parnell Laboratories (Aust) Pty Ltd on an issue affecting the manufacturers of veterinary pharmaceuticals in which it was claimed that animals were being used unnecessarily to carry out repetitive safety trials.

Part of that submission reads:

"We only carry out a very small number of trials each year. Many of these are product safety trials which are required prior to the registration of products in New Zealand. Typically, the sort of trial protocol required by the New Zealand authorities involves the treatment of 10 individual animals of the relevant target species with twice the normal dose of the drug. The result is that a significant number of animals are used in these safety trials which, although usually innocuous in nature, for the most part are unnecessary, repetitive and essentially meaningless. The evidence for this is listed below.

- *In the majority of cases the so-called "new" products are already registered and in widespread clinical use in Australia or another country with a well-developed regulatory system for veterinary chemicals (such as the USA, Canada, the UK or the European Union), prior to registration being sought for them in New Zealand.*

[24] Ms Glenys Oogjes, Director, Australian and New Zealand Federation of Animal Societies Inc.

- *Alternatively, it is likely that other products which are either identical or closely similar to the product in question are already registered and in widespread clinical use in such countries, often including New Zealand itself.*

- *Safety data provided as part of registration dossiers is generally confidential to the company concerned. This means that repetitive and unnecessary safety trials, involving products already in widespread clinical use in other countries, must not only be conducted by the company registering the original version of a "new" product in New Zealand but must also be repeated by other companies seeking to register products which are images of, or closely similar to, that original version.*

- *In other words, the term "new" is used somewhat loosely by the New Zealand regulatory authorities in this context. Genuinely new products based on completely new active constituents, or radically new combinations of active constituents and excipients, are only developed occasionally, and it is really only in these small number of cases that the conduct of safety trials is necessary and justifiable.*

- *Due to variation in bodyweight among individual animals, and because veterinarians in the field tend to modify the dosage and frequency of therapy according to the severity of the condition being treated, the widespread clinical use of these products includes dose rates which are similar to the high dose rates required in New Zealand safety trials.*

- *Countries with effective regulatory systems for veterinary chemicals have a register which lists adverse drug reaction reports. Over a whole country a very large number of animals is likely to be treated with a particular product. This would include treatment under a wide variety of clinical and animal husbandry conditions. Furthermore, the range of dose rates and frequency of therapy used by veterinarians in the field would also tend to be extensive. Therefore, those products which are genuinely unsafe are likely to appear with some frequency in these registers. A satisfactory report from a regulatory authority in a country with an adverse drug reaction scheme would provide far more compelling evidence of the safety of a product then a safety trial conducted in a small number of animals.*

- *Safety trials really only provide direct evidence of the safety of the material in the container(s) from which the test material was drawn. With some extrapolation they could be considered a reasonable indication of the safety of that particular manufacturing batch. However, a safety trial based on material from one manufacturing batch cannot guarantee the safety of subsequent manufacturing batches. This is partly why drug regulatory authorities around the world have moved to license manufacturers based on their compliance with Good Manufacturing Practice (GMP) principles. These are based on the philosophy that the best way to ensure the safety of products is to incorporate well-designed quality control and quality assurance programs into standard manufacturing procedures. The advent of a GMP licensing scheme in Australia should further reduce the need for routine safety tests."*

In its submission, the Company claimed this was an obvious area where the number of animals used in research could be reduced. This also raises the related issue of whether such companies are being put to unnecessary expense. Mr Mark White, Research & Development Manager, Parnell Laboratories in his evidence said:

> *"In the submission I have made a list of the reasons we believe these safety trials*

were, in most cases, unnecessary. It is probably not necessary to go through them at the moment. Essentially, we are caught between two different government bodies - one that tells us we have to do trials in order to get products registered and another that tells us that if we are going to do trials we have to do them in a formal way which, for a small organisation like us, represents a large imposition".

This is a matter that should be drawn to the attention of the Minister as the National Competition Principles Agreement states that legislation, including regulations, should not restrict competition unless it can be demonstrated that the benefits of the restriction to the community as a whole outweigh the costs. The Committee considers that the issues raised by Parnell Laboratories warrant detailed examination by the Minister in conjunction with the competition policy review he is conducting of the legislation, with a view to determining whether the issues justify being set down for discussion at a forthcoming Ministerial Council Meeting[25].

Recommendation 7:

The Committee recommends that the Animal Research Review Panel carry out in the next 2 years an in-depth review of the operation of Animal Ethics Committees to determine whether they are carrying out their duty under paragraph 2.2 of the Australian Code to ensure that all animal care and use within research institutions incorporate the principles of replacement, reduction and refinement. That report should be tabled by the Minister in Parliament and should contain recommendations as to any action that may be necessary and a program under which that action can be implemented.

Recommendation 8:

The Committee recommends that the issues raised by Parnell Laboratories in its submission be examined by the Minister for Agriculture in conjunction with the competition policy review of the Animal Research Act with a view to determining whether they should be placed on the agenda of a forthcoming Ministerial Council Meeting.

The Animal Societies Federation (NSW) in a submission to the Committee was critical of the lack of a formal program by the Panel to monitor the level of compliance with the requirements of the Animal Research Act and Regulations.

"In carrying out its function of ensuring the 'effective and efficient implementation of the statutory requirements of the Animal Research Act', it would reasonably be anticipated that processes of ongoing monitoring would be put in place to evaluate

- *the effectiveness of the functioning of ARRP itself*
- *the level of compliance with the requirements of the Act and Regulation*
- *the degree of stakeholder satisfaction with the implementation of the Act and Regulation.*

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25 The Ministerial Council is a formal meeting of Ministers which is convened on a regular basis for the purpose of intergovernmental consultation, cooperation, joint policy development or joint action. Ministerial Councils comprise representatives from the Commonwealth, States and Territories.

However, although a four-year plan was drawn up for the period 1993-96, wherein mention is made of monitoring the effectiveness of ARRP program strategies, no planned program clearly sets out details of how this monitoring is to occur. 'Strategies' include monitoring the level of compliance with the code of practice and monitoring the effectiveness of the Panel in improving the welfare of animals used for scientific purposes, but details of how the monitoring is to occur are not provided.

Presumably, to some extent, this monitoring is seen as occurring as part and parcel of site visits. However, as, in most cases, a specific site is visited only once every three to five years, the validity of the process as providing the basis for information on how the Panel's activities are 'improving' the welfare of animals could be seen to be dubious."[26]

The Animal Societies Federation also argued that the Panel should be examining more fundamental issues.

"The Act specifies that one of the functions of the Panel is 'the investigation of matters relating to the conduct of animal research...'. It is disappointing, given this breadth of focus, that the Panel does not initiate research projects addressing broad fundamental issues of animal-based research.

For example, funding could be sought for a research project to determine the cost-effectiveness of animal-based research. The cost-effectiveness of alternatives to animal-based research as a means of promoting human health and well-being could also be investigated."[27]

Some of the issues that the Federation would like to be addressed are likely to be examined in the course of the review mentioned by the Minister for Agriculture during debate on the Animal Research Amendment Bill 1997.

"As I previously announced, in conjunction with the review of this Act under the competition policy I will ensure that there is a comprehensive review of all aspects of the original legislation and these amendments, which have received the support of both sides; including reporting and putting more pressure on institutions to reduce or find alternatives to using animals in experiments. The legislation will be the subject of the competition review policy, and in light of the well-researched contributions by members on both sides of the House I will expand the review under the Hilmer process to encompass many other issues. The members of the Regulation Review Committee have given guidance. All the issues raised by the committee will give me, the department and the Government guidance in how to restructure the legislation through the comprehensive review I have announced. I thank honourable members for their contributions."[28]

The comprehensive review mentioned by the Minister should be carried out under the supervision of persons qualified in cost benefit/effectiveness analysis.

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26 Submission dated 7 August 1997 by the Animal Societies Federation (NSW).

27 Ibid.

28 Minister for Agriculture, debate on Animal Research Amendment Bill 1997, Legislative Assembly, 21 May 1997.

7. Monitoring animal housing

What are the standards?

The Australian Code contains detailed principles for the housing of animals that must be complied with in animal research. Their governing requirement is that animals must be housed under conditions which are appropriate to the behavioural and biological needs of the species.

Whose responsibility is it to comply with these standards?

Institutions

Each institution has the responsibility of providing relevant staff with details of the institution's policy on the care and use of animals. It must ensure that the animal Ethics Committee develops guidelines for animal care and use within the institution and that these are implemented (2.1.1(xii)). The institution must ensure facilities are appropriately constructed, equipped and maintained to achieve a high standard of animal care (4.4.2). Animal holding facilities must be supervised by persons with appropriate veterinary or animal care qualifications or experience (4.5.1)

Investigators and Teachers

Investigators and teachers are responsible for the standard of animal care and have direct responsibility for all matters relating to the welfare of the animals they use. Their responsibility extends to all facets of the care and use of animals in projects approved by an animal Ethics Committee (3.1.2). The investigator must identify in the research proposal all aspects of housing which may impact on an animal's well-being (2.2.11(viii)).

Ethics Committees

Ethics Committees can only approve scientific activities which conform to all the requirements of the Australian Code and legislation (2.2.1 (iii)). They have the obligation to ensure that all animal care and use within the institution is conducted in compliance with the Code (2.2). Ethics Committees must keep adequate housing records and carry out regular inspections of all animal housing and laboratory areas (2.2.27). If there is a breach of the Code the Ethics Committee must ensure that the activity ceases immediately and that appropriate action is taken (2.2.28)

Are the standards being met?

This issue was examined in the course of the inquiry and it was the subject of a written submission from NSW Agriculture and various written submissions from members of the Animal Research Review Panel. The questionnaire[29] that was sent to 66 research establishments asked for details of inspections of animal housing facilities made by Ethics

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29 Questionnaire dated 16 October 1996 sent by the Regulation Review Committee to accredited research establishments

committees during the period 1 July 1995 - 30 June 1996. The responses showed that five Ethics Committees did not carry out any inspections during that period. Some organisations advised that an inspection of animal housing is carried out after each Ethics Committee meeting. Other organisations advised of annual inspections by their Ethics Committee. Persons involved in these inspections ranged from the full Ethics Committee to inspections on a roster basis.

NSW Agriculture said that inspections of research institutions had revealed examples of substandard accommodation and that appropriate action had been taken to rectify these situations. It said that some cases were identified in which housing was so substandard as to be having a severely detrimental effect on the animals housed. NSW Agriculture said that a number of facilities had been closed down or were no longer housing animals as a result of conditions imposed after inspections. It also said: *"In cases where the standard of housing has less of an impact on animals and replacement housing would be extremely costly, institutions have been given a set time to comply, allowing changes to be phased in gradually. This has applied, for example, with the replacement of wire tops on rat cages with "high top" lids which provide more room for movement."* This is a practical approach to take but inspectors of NSW Agriculture do not legally have the authority to allow particular animal research to continue which is in breach of the Code. Associate Professor Rose, Chairperson of the Panel, said that over the 10-year time frame of this legislation the conditions under which animals are housed had improved out of sight. Dr Wilson, Panel member, in his evidence said the Panel, over the last four years, had encountered quite a number of what he regarded as serious breaches of animal welfare.[30] Two other Panel members made similar observations. Ms Stiles said the standard of housing for most research animals is deplorable.[31] Mr Edwards, Panel member, in his written submission said:

"*The Code requires that "animals must be provided with environmental conditions which suit their behavioural and biological needs..." and that caging must take into account "species-specific behavioural requirements, including free movement and activity, sleeping, privacy, and contact with others of the same species". The holding of rabbits or rats in wire cages, the holding of animals in isolation, or the lack of provision of material for mice to hide in cannot meet these requirements, yet all occur widely in research establishments."*[32]

At the inquiry the following exchanges took place on this issue:

> ***MEMBER OF COMMITTEE:*** *Two submissions made to the Committee by members of the Animal Research Review Panel state that the standard of housing for many research animals contravenes the code which states that animals must be provided with environmental conditions which suit their behavioural and biological needs, and that caging must take into account species-specific behavioural requirements, including free movement and activity, sleeping, privacy and contact with others of the same species. Before I ask the chairperson for comments on this claim I would like to quote from the submission of Ms Karen Stiles, who is a welfare representative on the Animal Research Review Panel. She states:*
>
> *Despite the fact that many studies have been done and suitable housing exists, often at a*

30 Evidence at inquiry

31 Evidence at inquiry

32 Submission to Committee dated 8 November, 1996

similar or lower cost to inappropriate caging, the standard of housing for most research animals is deplorable. The situation is particularly appalling for rabbits, which are often kept for YEARS in small barren cages with no opportunity to socialise or exercise and with no environmental enrichment whatsoever. This situation is totally unacceptable and must be urgently addressed by the research community.

Would you like to comment on this situation?

Associate Professor ROSE: *I think it is important that we deal with this in a structured and considered way. If you look at the issue, for example, of rabbit housing, there are differences of opinion as to what is adequate and what meets behavioural and biological needs. Ms Stiles has her opinion. There are other opinions, and what we are trying to do is balance some of those ideas and inputs.*

MEMBER OF COMMITTEE: *Is there an accepted standard, such as best practice?*

Associate Professor ROSE: *No, there is not, and I think there is also very little information. I am afraid I have to disagree with her. There is not a lot of published information in this area. It is an area I particularly have an interest in, so I am concerned that we try to develop this in as considered and structured a way as we can. When we have gone on site inspections and if we have seen rabbits in particular—or any animal—that have been sitting in cages for periods of time, we really want to make sure why they are there and what they are being used for. On occasions we have found animals that have been there without anything happening to them for much longer periods than should have been acceptable and we have acted immediately to deal with that issue.*

There is then the question about adequacy of exercise and the social needs of a whole range of species. There are differing views as to whether or not they are better off in floor pens, for example, with a lot of other rabbits, or in small individual cages, or how the needs can be balanced. We are trying to encourage people to use floor pens for rabbits but in other areas that may not be suitable. Rabbits fight, depending on the social mix, so sometimes it will not work. We are actively encouraging people to put them in floor pens or at least give them exercise runs. We are moving with those issues. I might say, though, that we are probably pushing the standards that we want to push beyond what you will see anywhere else. There is then a legitimate claim that this is what is regarded as acceptable standards and why do we want to push it that far.

I indicated that I have a particular interest in this area and I certainly am actively in correspondence, by E-mail and otherwise, with the very few groups internationally who are conducting research in this area, particularly related to rat, mice and rabbit housing. As that information becomes available we will certainly seek to promote it and to ensure that people deal with it. There are differences of opinion as to whether rabbits are better off exclusively in floor pens. Some people found they had an increased incidence of disease in those situations. I am not making a value judgment on that particular issue but I think there is a lot of scope here to look more critically at what we do.

MEMBER OF COMMITTEE: *How does the Panel interpret the code? It seems to me that that is the fundamental issue because the code specifies such things as free movement. How does the Panel determine that? Is any guidance available? You said that there was not much guidance, so how do you determine that aspect?*

Associate Professor ROSE: *This is a worldwide problem; it is not just a problem that we are facing. What we tend to do in the first instance is to see if we have any hard evidence to show that the animals are not growing at a normal rate, have any disease or have any problems with reproduction. They are the normal things that would be determined by an animal that is physically stressed. We also see if there is any behavioural evidence of stress. In those circumstances we have a very clear-cut case for saying, "What you have is not adequate". If one reads the code, not only that part of it but the whole code in context, it gives the basis under which we can argue that certain things have to be done. When the animals are not necessarily demonstrating those kinds of problems it becomes a very grey area. For example, in much of the material that is around relating to housing, and it is not a lot, the basis is that people have looked at different sorts of housing and such things as normal physiological data and behavioural data and have not been able to show any difference—which is a great disappointment to me because I would like to get some hard data and start moving on this.*

Those people have ended up with some preference data, that is, if you give the animal a choice, which way does it go? There are arguments about the pros and cons of preference data. I would prefer to give the animal the benefit of the doubt, and it is that kind of information that we have moved on. In the same way we have actually had hard data on rodents relating to behavioural responses to lighting levels, to the types of flooring in the boxes and to the height of the boxes so that the animals can behave in the normal way, and we have in fact been quite definite about what we require. We are aware that we ought to be doing something more in this area and we have resolved to prepare a policy paper on it. As a result of our experience we can at least set some general benchmarks.

MEMBER OF COMMITTEE: *It would be difficult to have compliance with the code if there is no clear guidance available to people. I am not blaming the Panel; I am merely suggesting that it would be difficult to say people were not complying with the code when they are not sure what actual compliance is.*

Associate Professor ROSE: *I have expressed to you the sort of criteria we have used. If in a breeding program people have problems such as poor performance, behavioural problems, incidence of disease and poor growth rates clearly there is a major problem. That makes it very easy for us to move in. We have something to go on.*

MEMBER OF COMMITTEE: *Have you ever experienced that situation?*

Associate Professor ROSE: *Yes, we have.*

MEMBER OF COMMITTEE: *Have you been able to say, "It appears that you are in breach of the code"?*

Associate Professor ROSE: *We have included as a requirement in the conditions of accreditation for licensing that those things must be rectified immediately and we follow them up as a matter of urgency.*

The following points emerge from these exchanges:

- there are differences of opinion, particularly amongst the Panel members, on whether current animal housing in institutions complies with the Code;

- there are no species-specific guidelines to assist Ethics Committees in applying the requirements of the Code to common laboratory animals;

- the Animal Research Review Panel is aware that it ought to be doing something more in the area of animal housing and the Panel has resolved to prepare a policy paper on this;

- as a result of its experience the Panel is in a position to set some housing benchmarks.

During the inquiry Associate Professor Rose argued that there was not a lot of published information in this area and that there were few groups internationally who were conducting research on this subject.

Ms Oogjes, Director, Australian and New Zealand Federation of Animal Societies, in her evidence disputed these claims. She said ANZFAS was about to publish guidelines for best practice housing standards for animals kept in a laboratory situation.

> *"Contrary to what we heard yesterday, I do believe there has been a lot of research into the behavioural and physiological needs of particularly laboratory-housed rabbits, mice, guinea pigs and rats, for example, and we believe that that research gives us good reason to believe that we can put forward best practice. That is important because the code, and therefore the legislation in all States, including New South Wales, does say that animals should be housed in conditions that are consistent with their behavioural and physiological needs. We do believe it is important for those standards to be set and for researchers and institutions to provide facilities for that."*[33]

On 21 May, 1997 Ms Oogjes made a supplementary written submission in which she provided material to support her evidence. She enclosed ANZFAS draft best practice standards for laboratory animal housing relating to the rabbit, the guinea pig, the mouse and the rat. Ms Oogjes also produced a detailed list of research papers on this subject.

The inquiry into this aspect of the regulation demonstrated to the Committee that there is an urgent need for species-specific codes of practice for the housing of common laboratory animals to be developed based on the requirements of the Australian Code. The Australian Code requires such standards to be applied and it must be assumed that the Code Liaison Group believes this can be done otherwise the Code would be limited in its practical application and usefulness. The absence of these standards creates practical difficulties for the Panel, institutions, researchers and Ethics Committees in meeting their obligations to enforce or comply with the Code. Institutions have an obligation under the Code to develop such guidelines but even if this was carried out it would not produce the necessary uniformity.

On the 29 May 1997 the Committee wrote to the Chairperson of the Panel referring to the Panel's resolution to prepare a policy paper on the subject. The Panel was asked whether it intended as part of this project to publish species-specific best practice standards for common laboratory animals to complement the Australian Code.

On 11 August 1997 the Panel advised that subsequent to its resolution, other groups including ANZCCART, have been in the process of developing documents on housing

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33 Ms Glenys Oogjes - evidence before the inquiry 26 March, 1997

standards. Therefore, to avoid duplication of effort, the Panel intends to assess the ANZCCART document and other relevant information with a view to deciding if further elaboration of standards will be necessary.

Details of the intended ANZCCART publication relating to the "Housing of Laboratory Animals" were provided to the Committee by Dr R M Baker, Executive Officer of ANZCCART. In a letter dated 18 August 1997 he advised that rats, mice, rabbits and guinea pigs are the subject of a monograph on animal housing written for ANZCCART by Dr Ann Hargreaves, an agricultural scientist from Melbourne. This is being edited by Associate Professor Margaret Rose and Dr Susan Maastricht. Dr Baker said he hoped it would be ready for publication before the end of 1997 and that the monograph would summarise international best practice for the housing of rats, mice, rabbits and guinea-pigs and that its recommendations should be very useful and relevant to researchers and animal Ethics Committees.

Dr Baker subsequently advised the Committee's Secretariat that ANZCCART had not made a decision on whether guidelines would be prepared for other species listed in his letter which were also commonly kept in laboratories i.e. dogs, cats, sheep, pigs, chickens, fish and amphibians.

There will clearly be a need for the Panel to monitor the adequacy of the publication and this task is part of the Panel's operational plan for 1997-1998.

The development of species-specific codes of best practice will need to be accompanied by a policy applied in all research establishments of ensuring that any future animal housing facilities that are installed conform to the code. Ethics Committees should take the principal responsibility for this in conformity with the requirements placed upon them by the code. It will be far easier to ensure that adequate pens, cages and containers are installed than to attempt to correct inadequate housing at a later stage. This is borne out by the current situation. Mr Edwards, in his evidence, said institutions opposed better housing because it was too expensive to change it, not because they already complied with the code.

Evidence presented to the Committee showed that NSW retailers and manufacturers of animal housing were confused about the requirements of the Australian code. When questioned, they said that neither NSW Agriculture nor the Panel had ever approached them to provide guidance as to the application of the code. At present, retailers and manufacturers are never certain whether housing equipment manufactured in accordance with any particular overseas code complies with NSW requirements. This again underlies the need for species-specific guidelines to be produced to assist in the application of the Australian code.

Recommendation 9:

The Panel should take action to ensure the availability of species-specific codes of best practice for the housing of common laboratory animals.

The Panel should ensure that NSW manufacturers and retailers of pens, cages and containers used in animal research in NSW are clearly advised as to the requirements of the Australian code.

The Panel should advise each research institution and Ethics Committee of their obligations to ensure that animal accommodation complies with the Code.

The Panel should, within the next 3 years, complete a survey of the adequacy of housing in each of the accredited research institutions and prepare a report on the findings and action taken by it. That survey should also examine the feasibility of introducing a system for the accreditation of animal housing. The report should be tabled in Parliament by the Minister.

8. Accreditation

The Animal Research Review Panel has the function of investigating applications by corporations for accreditation as research establishments and applications by persons for animal suppliers' licences. These applications are made to the Director-General of the Department of Agriculture and they are referred by him to the Panel for investigation and report in accordance with sections 19 and 38 of the Act. Applications must be in an approved form, include particulars prescribed in the regulations and identify the land on which the applicant intends to carry on the business of animal research. During 1994-95 the Panel processed 58 applications for accreditation, 27 applications for suppliers' licences and 67 applications for school accreditation.[34]

It is the practice of the Director-General, on the recommendation of the Panel, to accredit an applicant without any prior inspection of the land and premises where the research is to be conducted. Accreditation is usually issued subject to the condition that a site inspection must be satisfactory. This practice was criticised by the Animal Societies Federation in its submission made on the RIS and draft regulation.

The regulatory impact statement prepared by the Department indicates that if the assessment of an application had to be accompanied by a site inspection a "vastly increased inspectorate would be required to carry out annual assessments" although the Department concedes in the RIS that a more accurate assessment would be possible.

A further reason would seem to lie in the Act itself which authorises the Panel to request the Director-General to cause an inspection to be made of the designated land of an accredited research establishment or of an animal supplier's licence (section 10). This power does not extend to give access to the site at the application stage. An inspector's powers under section 50 are similarly limited. A remaining reason that would support the Panel's policy in the case of an initial application is the fact that an applicant would be unlikely to have risked putting in place arrangements and infrastructure for a research establishment prior to accreditation or licensing.

Although these reasons explain why the Director-General of Agriculture accredits an establishment prior to a site inspection they do not justify the amount of time that elapses between accreditation and inspection or following re-accreditation. Under the Panel's procedures at least a year can pass before an accredited establishment receives its first inspection. As accreditation previously ran for a maximum of 12 months the initial accreditation or licence in these cases would already have expired before the first inspection.

The 1994/1995 report of the Review Panel sets out its future policy on reinspections as follows: "In the future, the Panel will commence a program of full reinspections for all institutions and licence holders. The aim is for each institution to have a complete visit and assessment for reaccreditation every 3-5 years. Announced and unannounced spot checks and visits to look at specific aspects of operation will be carried out between full visits." This means that some research establishments may only receive one visit by the inspectorate and Panel in 6 years apart from spot checks on specific aspects.

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[34] Report of Animal Research Review Panel 1994-1995

Although section 62 of the Animal Research Act contemplates that regulations will be made setting out the procedures to be followed by the Animal Research Review Panel in relation to the investigation of applications for accreditation, this has not been done. The regulatory impact statement does not mention the matter except to explain that the regulation has been drafted to require the applicant to submit the minimum particulars consistent with accreditation or licensing.

The inadequacy of the appraisal at the accreditation stage is demonstrated by the Panel's own statement in its 1994/1995 Annual Report which says that the assessment of an institution must be based on the requirements of the Code:

"During inspections, the Code of Practice provides the criteria against which institutions are assessed. For example, the Code requires that the comfort of animals must be promoted throughout the post-operative period. Attention must be given to warmth, hygiene, fluid and food intake, control of infection and the use of analgesics and tranquillisers. To determine whether this requirement is being adhered to, the inspection team might examine records, ask about monitoring procedures, talk with staff, look at facilities or post-operative recovery and discuss controversial procedures with the AEC.

Assessment commences with an examination of written material provided by the institution or individual. This includes lists of the protocols considered by the AEC and people issued with animal research authorities; Ethics Committee minutes; annual report and records of inspections conducted; information about the procedures of the committee and the institutional policy on the committee's operation and decisions.

The examination is carried out by an Animal Welfare Unit Veterinary Officer and the Panel members who have been nominated to participate in the inspection. Once again, the Panel has established set criteria to ensure that this assessment is consistent across institutions. This pre-inspection evaluation allows likely problem areas to be identified and a general idea to be gained of how the establishment is operating.

After examination of written material, the inspection team looks at the animals and the facilities before meeting with the committee. At the meeting with the AEC, the team discusses problems identified in the course of the inspection of the facilities and examination of protocols. The committee's procedures are also discussed with particular emphasis on obtaining the views of the external members. Another important consideration is how the committee liaises with researchers and whether it has developed its own policies or guidelines for procedures of particular concern, such as the use of Freund's adjuvant, or the recognition and relief of pain.

Any serious concerns are immediately referred to the institution at the appropriate level. Generally, the response has been prompt and effective. A letter is usually sent to the institution within a week of the visit, providing the general impressions of the site visit team and reinforcing the need to deal with any serious problems which may have been identified during the visit.

As soon as possible after the inspection, a detailed report is prepared. The report covers an evaluation of the AEC, assessment of the well-being of the animals, housing and holding, cages, pens or compounds and animal care and monitoring, including emergency procedures. Once the Panel has considered the report, recommendations can arise which will alter the terms of accreditation or licence. Conditions of an earlier accreditation may have been met or the Panel may feel additional conditions should be imposed. For example,

a condition may be that appropriate post-operative procedures must be implemented.

The Panel also conducts revisits to institutions (and individuals) which have been inspected previously. To date, these have been conducted primarily to evaluate an institution's response to recommendations and conditions imposed after a previous visit. This has been necessary where the Panel has had particular concerns about one or more aspects of the activities of an accredited establishment or licence holder.

In the future, the Panel will commence a program of full reinspections for all institutions and licence holders. The aim is for each institution to have a complete visit and assessment for reaccreditation every 3-5 years. Announced and unannounced spot checks and visits to look at specific aspects of operation will be carried out between full visits."

In setting a relatively short period for the term of accreditation, Parliament must have intended that the suitability of the research institution would be appraised or reappraised at the commencement of each term.

During the Committee's inquiry, Panel members commented on the current practice of accrediting in advance of a site inspection. Associate Professor Rose said the general objective was to make inspections as useful as possible and that if the institution was not actually functioning a formal inspection would not help. Mr Edwards said that the Panel was currently carrying out a trial under which a site inspection was conducted as part of the accreditation.

The public have a right to be assured that research institutions have been subject to a stringent examination before being authorised to undertake research on animals or to supply animals for research. It is not in the spirit of the Act for that detailed examination to take place a year or more after accreditation or up to 5 years after re-accreditation.

Under the Act, the Panel is required to investigate applications for accreditation. The Act uses the word "investigate" which carries the normal dictionary meaning of "examine in detail". The Panel's 1994/95 annual report says applications are referred to the Panel for "consideration" which suggests a lesser level of scrutiny. This may not have been intentional but it is consistent with the fact that accreditation of institutions in NSW is paper based; that is, no site inspection is made prior to accreditation. The Panel limits its investigation to the details provided by the institution in its application form.

The Panel's statutory duty to investigate applications may not be legally satisfied by restricting it to an assessment of particulars in an application form. The Director-General must be able to satisfy himself on the basis of the Panel's investigation as to the competency of the research establishment to meet the comprehensive duties arising under the Australian code of practice for the care and use of animals for scientific purposes. Doubts on the adequacy of a paper based appraisal for that purpose are strengthened when viewed against what the Panel itself says is necessary for an effective assessment of an institution.

In its submission the Panel expressed concern at the reduced range of offences applicants for accreditation must disclose under the regulation; that is, offences under the Animal Research Act and POCTA. The Panel argued it should be able to take into account offences under relevant Acts in other States. NSW Agriculture told the Panel that the Parliamentary Counsel had said this proposal was contrary to Government policy. The Committee's Secretariat checked with the Parliamentary Counsel who queried this comment. He said the reason for the provision was that section 20 prohibited accreditation of a "disqualified

corporation" which section 17 defined as one convicted within the last three years of an offence under the Animal Research Act or POCTA. The regulations therefore were concerned with getting particulars about NSW offences not offences committed in other States. The Parliamentary Counsel said if the Panel wanted to take into account offences committed in other States it should expand the disqualification provisions of section 20. The Panel's submission had merit and there was no reason it could not have been considered for inclusion in the Animal Research Amendment Bill 1997.

Also the Panel in its submission to NSW Agriculture said the regulation should be altered to require institutions and licensees to notify the Panel within a period of 30 days of changes in any particulars for accreditation or licensing. NSW Agriculture deferred consideration of this matter to determine an appropriate time limit. In Appendix 4 of this report, NSW Agriculture has categorised this submission as among "issues raised with respect to drafting which would have been inconsistent with the Act, the Code, 'Best Practice' regulation or general policy". The Committee can not follow the sense of this objection as in comparable cases, NSW Corporations law provides various time periods for the notification of changes in name or particulars of companies. The Committee considers the Panel's suggestion should be acted upon by making an appropriate change to the regulations.

Recommendation 10:

The Committee recommends that the current accreditation practices of the Panel should be reviewed by the Minister for Agriculture. An examination should be made of options that would ensure a detailed assessment of institutions and licensees is carried out in conjunction with the act of accreditation or licensing. A regulation should be made under section 62 of the Animal Research Act with respect to the procedures to be followed by the Panel in relation to the investigation of applications for accreditation or licensing. This should be done as soon as practicable so that Parliament can satisfy itself as to the adequacy of the investigation procedures.

Recommendation 11:

The Committee recommends that NSW Agriculture examine whether section 20 of the Animal Research Act should be amended so as to allow the making of a regulation requiring applicants for accreditation and licences to disclose offences committed under relevant interstate acts.

Recommendation 12:

The Committee recommends that the Animal Research Regulation be amended to require accredited institutions and licensees to notify the Animal Research Review Panel within 30 days of changes in particulars for accreditation or licensing.

9. Animal Research Review Panel - no power to enter on land except in company of inspector

The Animal Research Review Panel carries out inspections, investigations and other monitoring activities to ensure that the standards of the Act and Code are met. The Committee would reasonably expect that such duties would be accompanied by some power to enter research establishments to carry them out. However, the Panel does not have any separate power to enter land. If a Panel member wishes to enter the land of a research establishment then the Panel, under section 10 of the Act, has to request the Director-General of Agriculture to cause an inspection to be made of the research establishment. The Panel may then, in writing, authorise a member of the Panel to accompany the inspector.

Inspectors of NSW Agriculture do not have any statutory obligation to make site inspections. That service to the Panel seems based on an administrative arrangement. At present the frequency of inspections of each research institution is once every three to five years. There is dispute about whether this is adequate.

Panel members should have the power to enter research establishments to carry out their duties without the need to await the availability of an inspector from NSW Agriculture. This is not to suggest that members of the Panel would like to make more inspections and are being held back by the unavailability of inspectors. That is not the situation. NSW Agriculture, in its submission to the Committee, stated that it has met the expectations of the Panel with respect to the provision of inspectorial support. Unfortunately, the fact emerges from the Panel's report covering the year 1994/95 that fifty per cent of its members did not go on any site inspections for that year. The figures of 1995/96 are only marginally better - forty per cent of members failed to attend any inspections. The situation highlights a problem that should be quickly addressed by the Minister. A person should not be appointed or remain as a member of the Panel unless he or she can devote adequate time to each of their responsibilities.

Recommendation 13:

The Committee recommends that the Animal Research Act be amended to give members of the Panel in the course of their duties the right to enter designated land within the meaning of section 3 of that Act.

10. Research involving protected fauna

Under section 92 of the National Parks and Wildlife Act the Director-General of the National Parks and Wildlife Service (NPWS) is the authority for the protection and care of fauna. Protected fauna (any fauna of a species not listed in schedule 11 of the National Parks and Wildlife Act) is the property of the Crown. It is an offence under section 98 to harm protected fauna and this carries a penalty of $3,000 or imprisonment for 6 months. It is a defence to a prosecution under this section if the person proves the act was under and in accordance with or by virtue of the authority conferred by a general licence under section 120 of the National Parks and Wildlife Act.

Animal research on native animals is conducted under the authority of those licences. The licences can be issued by an authorised officer to a person authorising that person to harm or obtain any protected fauna for the purpose of carrying on any scientific investigation. The licences can authorise the person to hold or to keep in their possession any protected fauna for the purpose of carrying on any scientific investigation. The licences may be issued subject to conditions or limitations. The licence can authorise any specified person (in addition to the person to whom the licence is issued) to do the things authorised by the licence.

The standard application form for research proposals developed by the Panel asks for details of the relevant licence issued by the NPWS. This means that NPWS considers the application before it comes before the Ethics Committee. Consequently NPWS has no evidence before it to show whether the research proposal is scientifically justified. In fact, in his evidence, Mr Hardy, Manager, Wildlife Licensing Unit, NPWS, said NPWS does not take into account the scientific value of a proposal only its conservation implications.

Under the Australian Code, animals should be taken from natural habitats only if animals bred in captivity are not available or are unsuitable for the specific scientific purpose (5.1.3). Again, proposals can only be approved by an Ethics Committee if they are for the purpose of significant scientific research. It is anomalous that NPWS is called upon, under current administrative procedures, to decide whether or not to issue a licence to harm or obtain protected fauna when it has no way of knowing if the use of native animals is justified or whether the scientific proposal has the necessary significance for it to be approved by an Ethics Committee. These considerations indicate the proposal should be examined by an Ethics Committee before its referral to NPWS.

On 13 November, 1996 the Committee sought details of licences granted under section 120 by the NPWS to accredited research institutions. The Minister for the Environment[35] advised that the Service did not generally issue licences to research institutions to undertake scientific research on native fauna. The Minister said the exceptions to this were the Australian Museum and the CSIRO National Collection in Canberra.

This seems incorrect. The Committee's inquiry shows scientific research on native animals is or has been conducted by the Charles Sturt University and the Universities of Sydney, New South Wales, Western Sydney and Newcastle, all of which are accredited research

[35] Letter dated 25 February 1997 from the Minister for the Environment (Appendix 5)

institutions. Other accredited institutions may be conducting similar research. This research extends to frogs, lizards, snakes, turtles, platypus, emus, kangaroos, wallabies and possums. In each case this research is conducted under the authority of a licence issued by the NPWS.

The Minister's letter said that NPWS was not able to give the Committee details of the licences that had been issued because this would involve a search of 3,500 scientific licence files.

"The Director-General has further advised that the licensing of researchers has not yet been computerised, though software is presently being developed. It would therefore be a very time consuming task to individually examine in excess of 3500 scientific licence files to determine which researchers had undertaken relevant investigations through an accredited research institute during the year ending 30 June 1996. However, resources are not available within the National parks and Wildlife Service to perform this task and I regret that I cannot, therefore, provide the copies of relevant licences which you seek."[36]

At the inquiry Mr Hardy, Manager, Wildlife Licensing Unit, National Parks and Wildlife Service, was asked what type of program the Service used to keep track of these licences.

> ***MEMBER OF COMMITTEE:*** *On 13 November 1996 the Committee sought details of licences granted to research institutions. The Minister was not able to give the Committee all of the details it sought because that would have involved a search of 3,500 files dealing with current research licences issued by the National Parks and Wildlife Service. Can you tell the Committee what type of program the service uses to keep track of what happens under these licences?*
>
> ***Mr HARDY:*** *We do not keep track of what is happening under these licences at the present time. We simply are not resourced to be able to do that. Until November this year we have not had a computer database to keep track of licences. It has all been done by a manual system. Staffing in the Wildlife Licensing Unit has decreased over the years to the extent that there are five of us in the unit. One person processes all scientific licence applications, and that occupies about 50 per cent of that person's time. The licences are then passed on to me for review. If I pick up a problem, it will go back for reappraisal or I will seek more information on it. Otherwise I will sign the licences and they are sent out.*
>
> ***MEMBER OF COMMITTEE:*** *What happens subsequently?*
>
> ***Mr HARDY:*** *There is no follow-up because it is a manual system. We do not have the resources to do that.*
>
> ***MEMBER OF COMMITTEE:*** *A resubmit system would not take all that much time, would it?*
>
> ***Mr HARDY:*** *We do not have a resubmit system.*
>
> ***MEMBER OF COMMITTEE:*** *Do you now have a computer system available?*
>
> ***Mr HARDY:*** *We are not given the resources to input historic data. The only input of data*

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36 Ibid

will be as new licence applications come in.

MEMBER OF COMMITTEE: *Is that happening?*

Mr HARDY: *Yes it is.*

MEMBER OF COMMITTEE: *Under section 92 of the National Parks and Wildlife Act the Director-General of National Parks and Wildlife is the authority for the protection and care of fauna. When members of the Committee visited the University of Sydney they were told by a research officer that, to his knowledge, National Parks and Wildlife Service officers never made any inspection to check on the conditions that had been set up. Can you tell the Committee whether the service visits establishments that conduct research on native animals?*

Mr HARDY: *No, we do not conduct those sorts of oversighting inspections. Through resource limitations we confine our supervision, monitoring or authorisation of activities involving wildlife to animals being observed or utilised in the wild. Once the animals are authorised to be taken out of the wild, it becomes an animal welfare issue and is outside our responsibility to pursue. In other words, they are lost to conservation.*

Although Mr Hardy in his evidence said new licence applications were computerised, this seems to be contradicted by the Minister in her letter where she says that the Director-General has advised that the licensing of researchers has not yet been computerised though software is presently being developed. However, the Minister may be talking in terms of a program covering all current licences not just new ones.

Overall, the evidence shows that NPWS does not have a practicable means of identifying the persons or organisations to whom it has issued licences or of monitoring the conditions of those licences. This is an unacceptable situation because each of those licences authorises its holder to harm or obtain protected fauna for the purposes of scientific investigation. This is only permitted where that research complies with the conditions of the licence otherwise it gives rise to the substantial penalties mentioned in section 98. The Director-General of NPWS, as the authority for the protection and care of fauna, has an obligation to ensure those licences are responsibly monitored.

One of the conditions attached to all section 120 licences requires a detailed report of operations and results prior to the expiry date of the licence (condition 4). Another of the conditions requires a copy of the thesis or final report and any scientific papers relating to the work to be forwarded to the Director-General of NSW Agriculture (condition 5). These conditions show that NPWS must be informed of the results of the research and whether any scientific benefit arose from it. The lack of any monitoring of individual licences or any overall program to use the scientific data recovered from them to assess the costs and benefits of the licensing system suggests that NPWS is not administering the scheme responsibly .

On 1 August, 1995 the NPWS made a submission on the draft Animal Research Regulation 1995 to NSW Agriculture. That submission contained specific recommendations that had obviously arisen from a careful examination by the Service of the existing regulation. NSW Agriculture, in response to the recommendations, said they would all receive due consideration after 1 September 1995 and that they would be the subject of further consultation.

In the course of the Inquiry, NSW Agriculture was asked to advise the Committee whether any action had been taken in respect of the recommendations by NPWS as no change had been made to the Animal Research Regulation 1995 since its gazettal. There was, of course, nothing to prevent NPWS implementing its own recommendations by including them as conditions of any licence granted under section 120.

On 16 May, 1997 the Director-General of NSW Agriculture advised that the issues raised by the NPWS were considered during the recent review of the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes. However, he did not go on to explain whether any of the recommendations had been adopted. This can be assessed by examining the Code which now includes a new section 5 headed "Wildlife Studies". This section has provisions covering the capture of wildlife, the handling and restraint of wildlife, and the transport, identification and field techniques to be used. These provisions will supersede those contained in Schedule 1 to the regulations.

Capture

NPWS requested that nesting, lactating or pregnant animals should not be held in captivity or taken as voucher specimens. (Sched 1. Part 2. Clause 10 of the regulation)

Comment: No provision of this type has been included in the Code.

Metabolic injury

NPWS recommended that provisions relating to metabolic injury should refer specifically to hypoglycaemia, hypothermia and hyperthermia.

Comment: This is now covered by Clause 5.2.3

Transport

Containers in which animals are transported should be labelled with name, contact phone number of researcher, date and time of collection and conditions required (Sched 1. Part 2. Clause 12).

Comment: Not implemented in Code although NPWS said correct labelling was imperative.

Wet Pitfall Trapping

NPWS said this practice should be banned except under very specific circumstances to be defined by the Animal Research Review Panel.

Comment: Clause 5.2.6 states the use of wet pitfall traps is unacceptable for the capture of vertebrates but can be used for the capture of invertebrates. The NPWS recommendation has only been followed in the case of vertebrates.

Voucher specimens

NPWS recommended the number be limited to one male and one female per species for taking of voucher specimens.

Comment: This is not implemented in the Code.

NPWS in their submission on the regulation put forward various other suggestions relating to research on native animals which need not be referred to in this report.

Mr Hardy in the course of his evidence said NPWS was preparing a manual on the ethical handling of Australian native wildlife and this was expected to be completed by mid 1998. He agreed it would be appropriate for NPWS to follow up discrepancies between its submission and the text of the revised Code. This should now be done.

Recommendation 14:

That NPWS expedite the computerisation of its records relating to the issue of s120 licences and draw up guidelines to be followed by its officers for the administration of those licences;

That NPWS undertake a study to evaluate the costs and benefits of the s120 licensing scheme and that this assessment be tabled in Parliament by the Minister within 12 months;

That animal research proposals involving the use of native animals be considered by an Ethics Committee prior to their referral to the National Parks and Wildlife Service;

That the National Parks and Wildlife Service follow up with the Code Liaison Group the discrepancies that exist between the changes recommended by the National Parks and Wildlife Service and the text of the present code.

11. Use of pound animals in research

The provisions that govern the supply of dogs and cats from pounds for use in animal research are contained in Part 4 of Schedule 1 of the regulations. These provisions authorise individuals, on certain conditions, to supply dogs or cats to an impounding authority for use in connection with animal research. They also authorise an impounding authority to supply to a licensed animal supplier, subject to detailed checks and conditions, any animal for use in connection with animal research. These include animals supplied to the impounding authority by individuals or seized by the impounding authority under the Impounding Act 1993 or the Dog Act 1966.

This subject will receive full examination in the course of preparation of the proposed NSW Companion Animals Act. Ms R Riordan, Policy Adviser, Office of Minister for Local Government, in her evidence to the Regulation Review Committee, said that the Working Party on that Bill had recommended for inclusion in the exposure bill, a provision prohibiting the release of pound animals for research or experimentation.

Ms Riordan said that recommendation was made on the basis of several factors:

- a lack of resources in some local councils may result in an insufficiency of checks on ownership of animals coupled with the fact that there is no consistency in the number of animals being microchipped. Some pounds do not have access to a reader which can scan microchips;

- information from the Animal Research Review Panel indicated that some councils may not understand the requirements governing the release of pound animals for research;

- the main reason the Working Party recommended against the use of pound animals was on the basis of animal welfare which involved a duty of care to animals. This is central to the Companion Animals legislation.

"The majority of animals which go into a pound are highly stressed. If they are kept for a longer period of time and then moved from the pound to another facility, they undergo even more stress. So the working party was looking at the welfare of animals and at the quickest, most effective and most humane outcome for the animals. That does not include providing those animals for research." [37]

The use of pound animals was considered by the Senate Select Committee on Animal Welfare and its report[38] examines the arguments for and against such use in teaching and research and the legislative controls in the various States in force at that time.

The Senate Select Committee concluded that dogs from pounds may be used in experiments provided that, where registered dogs are surrendered to pounds, their owners have given written consent to their use by institutions. It accepted the argument that if a dog is used in an experiment from which it will not recover consciousness, there is no difference between euthanasia in a pound and destruction at an institution. It said that if by the use of pound animals, which will be destroyed anyway, there is a reduction in the destruction of purpose-bred animals, then animal welfare is enhanced overall. This argument is based on

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37 Ms Riordan, evidence at the Inquiry before the Regulation Review Committee, 26 March 1997.

38 Report by the Senate Select Committee on Animal Welfare, 1989.

the premise that facilities for treatment of the dogs in institutions are of an appropriate standard. The Senate Committee did not support the supply of cats from pounds for research.

These conclusions are at variance with those reached by the Working Party set up for the purposes of the Companion Animals legislation and will need further examination by the Minister for Local Government in the context of the public responses which will be generated in due course following release of the Companion Animals Exposure Bill.

The regulatory impact statement for the Animal Research Regulation contains no examination or justification for the inclusion in the regulation of the provisions in Schedule 1 authorising the use of pound animals for animal research. The lack of any appraisal at the time the regulation was made may explain why the Minister for Agriculture on 9 April 1997, in answer to a question in Parliament, said he had called upon universities and other teaching institutions and local councils to justify by 31 July 1997 their continued use of animals from council pounds in research experiments[39]. In his answer, the Minister also said that he had recently announced the formation of a working party to inquire into the issue of pound sourced animals for research. That working party (distinct from that set up by the Minister for Local Government for the Companion Animals legislation) is chaired by Ms J Hall MP and includes a representative of the Minister for Local Government and representatives from the Royal Society for the Prevention of Cruelty to Animals, the Humane Society International and the Animal Research Review Panel. The Minister for Agriculture said that the aim of this working party is to find alternatives to the random sourcing of animals and to progressively reduce the number of animals used in experiments.

The Animal Research Review Panel had also initiated a review of the provisions relating to supply of animals from pounds[40].

This means that three bodies are currently deliberating on the animal welfare and research considerations arising out of the use of pound animals in research. The possibility of duplication and conflict in their findings will be reduced by the fact that representatives of Local Government and the Panel will be present on the review committee set up by the Minister for Agriculture. Out of these deliberations should come an overall government policy which will dictate whether the existing provisions in the Animal Research Regulation relating to pound animals will be retained or repealed.

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39 Legislative Assembly, 9 April 1997, Minister for Agriculture in answer to a question.

40 In her evidence to the Committee, Ms R Brooks said the Panel had commenced this review by conducting a survey of the use of pound dogs by research establishments.

12. Fees

Fee for accreditation	$500
Fee for animal suppliers licence	$200

These fees have not changed since they were prescribed on 1 September 1990. If the fees had been varied by CPI increases from 1 September 1990 to 1 September 1995 (date of operation of new regulation), the fees would have increased by 13.8%. If they had been set and reviewed on a user-pays principle, the fees would have increased substantially bearing in mind the operating costs of the Animal Research Review Panel and the Animal Welfare Unit, NSW Agriculture. The Annual Report of the Animal Research Review Panel does not include details of revenue and expenditure. However, the Annual Report of NSW Agriculture (1994/95) shows that total operating expenses for the Animal Welfare Unit was $1.2 million. There is no published information on revenue received by the Unit. The Chairperson of the Panel in a letter to the Committee dated 28 January, 1997 advised that fees do not cover the costs of processing the applications.

The Animal Societies Federation (NSW) in a submission to the Animal Welfare Unit in respect of the regulatory impact statement for the 1995 Animal Research Regulation stated:

"The Animal Societies Federation considered that this is an area where the "user pays" principle should be enforced. Current fees are amazingly and inappropriately low. A fee structure based on the number and species of animals used would be appropriate. Greatly increased fines for infringements could also fund increased inspections".

The 1993/94 Annual Report of the NSW Animal Research Review Panel says a subcommittee considered the issue of application fees and the Panel is mentioned as having reviewed fees for applications set in the Regulation. The 1994/95 Annual Report of the Panel also states that a subcommittee of the Panel is reviewing fees. The Report notes the Panel has agreed to a new fee structure proposed by the subcommittee of Dr Sheldrake, Mr Bowen and Dr Wilson. It says this proposal is to be circulated for comment with a view to replacing the existing structure after consultation. The proposal recommended a sliding scale of fees, depending on the size of the institution. The intention of this proposal is to reflect the relative cost of assessment of applications and inspection of the different sized institutions. This is a satisfactory approach.

The circulation of the proposed fee structure to interested groups does not seem to have taken place. The Chairperson of the Panel, when asked about the position, was uncertain:

> ***MEMBER OF THE COMMITTEE:*** *What happened to the position paper on fees which was to be circulated suggesting a sliding scale?*
>
> ***Associate Professor ROSE:*** *There was a paper that was circulated to the Panel. There were some comments made and some suggestions made and it was referred back and from memory that has not come back to us yet. The fees will be part of, I suspect, the package that we are talking about in terms of the amendments to the regulation.*
>
> ***MEMBER OF THE COMMITTEE:*** *It is part of that?*

Associate Professor ROSE: It is all part of that, yes.

The regulatory impact statement did not consider the issue of fees because of the ongoing review which has apparently stalled.

Recommendation 15:

The Regulation Review Committee recommends to the Minister that the review of fees be re-activated and finalised, by the making of an amending regulation within 6 months from this report.

13. Inspectorate

Inspectors appointed under the Animal Research Act have a central role in the enforcement of the regulation as they are the only persons authorised by the Act to enter the land of accredited research establishments or licensees. Members of the Panel can only enter such land in the company of an inspector.

The Panel, in its 1994/95 Report said that for some years it had been "pushing for an amendment to allow POCTA officers to investigate genuine cases of cruelty." It said:

"As the Prevention of Cruelty to Animals Act (POCTA) was originally gazetted, inspectors under that Act could not investigate possible breaches which had occurred on land designated under the Animal Research Act. This meant that some gross acts of cruelty could not be investigated under POCTA. For some years the Panel has been pushing for an amendment to POCTA to allow POCTA officers to investigate genuine cases of cruelty.

In December 1994, amendments to POCTA were passed which allow inspectors under POCTA to exercise their powers on designated land. These powers are in relation to matters other than those involving authorised animal research or the supply of animals for research. This means that an RSPCA or Animal Welfare League Inspector can now investigate a complaint of cruelty to an animal which is not in a research project. Previously, all such complaints had to be referred to the Panel."

Although this extract reads as if there has been a substantial improvement, this is not the case. The changes made by the 1994 amendments only modified the original prohibition to the extent of permitting POCTA officers to enter school-based research establishments and land solely devoted to the supply of animals for animal research. Officers under the Prevention of Cruelty to Animals Act still cannot exercise any powers in relation to animal research authorised to be carried out on land by an animal research authority unless the officer is also an inspector under the Animal Research Act.

The Minister for Agriculture has never appointed any POCTA officers as inspectors for the purposes of the Animal Research Act even though some of them would be qualified for appointment by virtue of being veterinary surgeons. The definition of "officer" in section 3 of the POCTA Act includes an inspector appointed under the Animal Research Act so legally those inspectors could enforce the POCTA Act so long as they hold a prescribed authority issued under the regulation.[41] However, they do not currently exercise this role and even if they chose to do so inspections on a 3-5 year basis would be unacceptable for this purpose.

"Prescribed authorities" are not issued to NSW Agriculture inspectors because of policy reasons. These reasons were set out in a letter dated 26 march 1997 to the Regulation Review Committee from Dr R Sheldrake, Executive Director (Research, Advisory and Education) of NSW Agriculture. The part of the letter relevant to this issue reads:

"The Committee asked Ms Lynette Chave whether she was an inspector under the

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41 This is an authority in writing, signed by the Minister, stating that the particular person is entitled to exercise the powers contained in section 25(1) and 26 of the Act. (Clause 18(2)(b) of the Prevention of Cruelty to Animals (General) Regulation 1996).

Prevention of Cruelty to Animals Act [POCTA]. Ms Chave holds an Authority issued under the Animal Research Act. Although the POCTA defines an "officer" to include an inspector under the Animal Research Act, powers afforded to officers under the POCTA apply only to those officers who hold a prescribed authority. Such authorities are prescribed by Clause 18(2)(b) of the POCTA (General) Regulation 1996 as "an authority, bearing the photograph of the officer, in a form approved by the Minister". Ms Chave does not hold such an authority. An authority issued under the Animal Research Act is not a prescribed authority under the POCTA. An inspector holding only an authority under the Animal Research Act has neither the power nor the obligation to enforce the POCTA.

Section 25(2) of POCTA limits the powers of officers who hold prescribed authorities to situations which do not involve animal research authorised by an animal research authority or animal research licence carried out on designated land, unless the officer is also an inspector under the Animal Research Act.

NSW Agriculture policy is that specialist Animal Research Act inspectors should investigate compliance with and possible breaches of the Animal Research Act. POCTA inspectors employed by the RSPCA and Animal Welfare League should investigate compliance with and possible breaches of the POCTA. Should an Animal Research Act inspector become aware of a possible breach of POCTA in the course of an inspection, this would be referred to the RSPCA or the Animal Welfare League for investigation."

The last paragraph of this extract shows that it is the intention of NSW Agriculture that breaches of the POCTA Act that occur in the course of animal research should be referred to POCTA officers for investigation. This is also the course supported by the Minister for Agriculture.

During the second reading debate on the Prevention of Cruelty to Animals Amendment Bill 1997 he said:

"The Honourable member for Kiama raised the issue of the rights and facilities of inspectors under the Prevention of Cruelty to Animals Act - POCTA. Under the Act these officers have access to research and education facilities to investigate breaches. The Act was amended two years ago to allow that practice to continue."

Animal research is not exempt from the provisions of the Prevention of Cruelty to Animals Act. Section 24(1)(e) makes it a defence in any proceedings under that Act if the accused person satisfies the court that the act or omission was done in the course of, and for the purpose of:

"(i) carrying out animal research, or
(ii) supplying animals for use in connection with animal research,

in accordance with the provisions of the Animal Research Act 1985."

This protection is lost in those cases where the research is not being conducted in accordance with the Animal Research Act including the Australian Code of Practice and the regulations.

In the present situation where a breach of the code or act or regulation occurs in the course of animal research there is no practical means to investigate whether proceedings should be instituted under the Prevention of Cruelty to Animals Act because POCTA officers are

prohibited from investigating the breach and inspectors under the Animal Research Act have no role in enforcing the POCTA Act. This means the Prevention of Cruelty to Animals Act is currently not being enforced by the Minister in respect of research institutions. This situation is contrary to Parliament's clearly expressed intention.

The RSPCA in its submission to the Committee has specifically sought the power to enforce the POCTA Act in research institutions and the evidence given to the Committee shows that this would be in agreement with both the views of the Minister for Agriculture and NSW Agriculture. In his evidence, Mr Charles Wright, Chief Executive Officer, RSPCA, said that what the RSPCA wants is the ability to respond, both announced and unannounced, to complaints quickly and effectively as they come in.[42] The Committee supports that change.

Recommendation 16:

The Committee recommends that sections 25 and 26 of the Prevention of Cruelty to Animals Act be amended so as to permit authorised officers to inspect research institutions.

[42] In Queensland and Tasmania, RSPCA officers may enter research premises

14. Prosecutions

There have been no prosecutions initiated under the Animal Research Act or regulation. At the inquiry the Panel was asked if it had a policy on the matter.

> ***MEMBER OF THE COMMITTEE:*** *What is the Panel's policy on enforcement of the Act and regulations through prosecutions? Doctor Bowen you have already mentioned that briefly in answer to another question. Has the Panel ever recommended prosecution of a research institution or a licensee?*
>
> ***Associate Professor ROSE:*** *To this point in time we have not but we have recommended, in fact, one step less than that which is a formal reprimand. That was on the advice that in the nature of the situation that we would be in a much better position, that we may not necessarily have a successful prosecution or, in fact, it would be dealt with in a fairly lenient way and if we went through the process of formal reprimand then the chances of us actually having a successful and substantive prosecution on the next step, if that was necessary, would enhance our chances of doing so. It is important in this sort of area if you do have a prosecution that it is successful, and if you have got to that point and it is one that does actually send a message if that is necessary. If it is dealt with in a fairly lenient way it is not necessarily going to help the situation.*
>
> ***MEMBER OF THE COMMITTEE:*** *Does the Panel have a policy on prosecution.*
>
> ***Associate Professor ROSE:*** *At this stage, no we have not.*
>
> ***MEMBER OF THE COMMITTEE:*** *Non prosecution?*
>
> ***Associate Professor ROSE:*** *No, we have not a policy on either.*

The lack of any prosecutions means that they cannot act to screen out, from animal research, institutions and persons who might otherwise be disqualified corporations or disqualified individuals (sections 17, 20(2)(b), and 25(4) of the Animal Research Act).

One of the criticisms made to NSW Agriculture by the Panel of the draft regulation was that the prescribed particulars to accompany applications under the Animal Research Act only required applicants to provide details of offences committed under that Act or the Prevention of Cruelty to Animals Act. The Panel sought the inclusion of particulars of offences committed under other NSW or interstate animal welfare statutes or regulations. This clear recognition by the Panel of the value of legal proceedings for relevant offences is not reflected in its own practice or that of NSW Agriculture.

During debate on the Animal Research Amendment Bill 1997, the Minister has undertaken to address this issue in his follow-up review of the legislation. So far the Panel's practice of achieving compliance has been based exclusively on educating institutions and researchers to voluntarily meet the requirements of the code and regulations. This is central to the scheme of self-regulation but it must be balanced by enforcement, in appropriate cases, through the courts.

15. Complaints

The right to make a complaint is intended to provide the public with a means of ensuring compliance with the Act and regulations. Although the right of a member of the public to make a complaint and the procedures governing its investigation and determination are extensively set out in the legislation, it is difficult to exercise these intended rights or to produce the evidence required by the Panel because the public have no legal access to research establishments or to the information relating to them. A résumé of the rights of the public to make a complaint will demonstrate the difficulties of doing so.

Section 22 of the Animal Research Act authorises the making of a complaint where a research establishment does not have a duly constituted animal care and Ethics Committee. This right could not be exercised because the names and qualifications of the persons that act on Ethics Committees are not available to the public. The Panel's annual report generally does not give the name of any research establishment or its Ethics Committees. Where it refers to a research establishment, it usually does so by a number (see for example the statistical details in the Panel's 1994/95 report).

Section 22 also authorises the public to make a complaint where animal research is being carried out on behalf of the establishment by an individual who is not the holder of an animal research authority. Again, the list of holders of animal research authorities is not available to the public.

Similarly, the public may make a complaint where the animal research is being carried out otherwise than with the approval of the Ethics Committee or in contravention of the Code of Practice. As the public have no legal access to the research establishment or to the terms of a research approval by an Ethics Committee it would not generally be possible to exercise this right.

As access by officers under the Prevention of Cruelty to Animals Act is also, except in the case of school-based research, prohibited this means that the only likely source of complaint is from a member of the Ethics Committee or from an animal technician or attendant[43].

The right of complaint was not intended to be limited principally to members of Ethics Committees as they already have powers to enforce compliance. Little purpose is served by giving rights which can only be exercised by an extremely limited section of the public. Although it would not be practicable to provide general access for members of the public to research establishments some access on their behalf is undoubtedly justified. When the Minister introduced the Animal Research Bill into Parliament on 2 October 1985 he stated that scientists should be publicly accountable for their treatment of animals used in research. This main tenet of the legislation would be promoted by permitting access at six monthly intervals to persons or organisations prescribed by regulation. Such persons or organisations would need to be given access to the terms of approval of the relevant research authorities so they could be sufficiently informed for the purposes of their inspection. This would afford at least a section of the public adequate access for the purpose of satisfying themselves as to compliance with the Code. In its 1989 report the Senate Select Committee said that research institutions should be open and forthcoming

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43 The difficulty found by institutional staff reporting breaches of the Code was mentioned by Ms Lotte Sutton in her submission: "... Animal Technicians and Animal Attendants working with research animals are encouraged to report misconduct in research procedures. If they are not able to speak with their supervisors we suggest they consult the Animal Welfare Section, NSW Agriculture. This body is usually supportive, but in reality the individuals often lose their jobs and nothing is achieved".

about their experimental practices. It also said that welfare organisations should be able to inspect facilities.

"The most potent weapon in the armoury of research institutions is public opinion. If the public is satisfied that animals are being used humanely in experiments, there is little threat to such use. It is important, therefore, for institutions to be open and forthcoming about their experimental practices. Responsible animal welfare organisations should also be able to inspect institutional facilities. This would help to allay suspicions that animals are being housed in poor facilities or are not being given proper care."[44] The Minister, during debate on the Animal Research Amendment Bill 1997, said that he supported comments made by the Member for Swansea about transparency of experimentation. This referred to a question by Ms Hall MP about the justification for the perceived secrecy about experiments in institutions. The Minister said that *"if secrecy is the appropriate word, the answer is that there is no justification for withholding information".*

In the course of the inquiry it was drawn to the Committee's notice that one complainant had been threatened with legal action by the person who was the subject of the complaint. As a consequence the committee sought advice from the Panel on whether a person lodging a complaint in accordance with the Animal Research Act was protected from an action of that type. It seemed to the Committee that if the Panel had not previously received legal advice on this matter it would be appropriate to seek the views of the Crown Solicitor as it would be a matter that would have a significant bearing on the efficient administration of the Act.

In response to this suggestion the Panel advised on 11 August 1997 that it would consider the need for legal advice on a case by case basis. This seems an unsatisfactory approach to take to such a significant issue. A complainant is entitled to know whether he or she is protected from an action for defamation in the event of lodging a complaint in accordance with the Act. The Committee recommends that the Minister ask the Crown Solicitor to clarify the matter.

Recommendation 17:

The Committee recommends that an amendment be made to the Animal Research Act 1985 to permit such persons or organisations as may be prescribed by regulation to have access to research institutions at six monthly intervals under conditions approved by the Minister.

Recommendation 18:

An examination should be made by NSW Agriculture and the Panel to determine whether it would be in the public interest for a register to be set up under the regulations in which certain particulars could be recorded that would enhance the Government's objectives of greater transparency of experimentation.

Recommendation 19:

From the point of view of transparency and Parliamentary scrutiny, the Committee recommends the making of a regulation under section 62 of the Animal Research Act with respect to the procedures to be followed by the Panel in relation to the investigation of complaints referred to it under the Act.

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44 Animal Experimentation Report by the Senate Select Committee on Animal Welfare

Recommendation 20:

The Committee recommends that the Minister for Agriculture seek advice from the Crown Solicitor on whether a complainant is protected from an action of defamation in the event of lodging a complaint in accordance with the Animal Research Act.

16. Adequacy of statistics - annual returns on the use of animals

The Animal Research Regulation 1995 requires accredited research establishments (other than schools) to send a report to the Director-General of Agriculture on activities during the 12 months ending on 30 June in that year. This report must contain:

- the number and kind of animals allocated to each project;
- the number and kind of animals allocated more than a year ago to each project and still allocated to it;
- the objective of each project;
- the techniques developed during that period to reduce the total amount of pain or stress or to reduce the number of animals used or both;
- the number of meetings held by the Ethics Committee for the establishment;
- the number of proposals prepared by the establishment and approved by the Ethics Committee for the establishment;
- the number of ongoing proposals prepared by the establishment and reviewed and reapproved by the Ethics Committee for the establishment;
- the number of projects terminated before completion by the Ethics Committee for the establishment;
- the number of proposals revoked by the Ethics Committee for the establishment.

The Animal Research Review Panel has conceded for some years that the data in the returns and the published statistics are inadequate. Its annual report for 1993-4 identified the following weaknesses:

- *The respective statutory time limits for submission of annual returns and submissions of the Panel's annual report are not synchronised. Therefore, statistics on animal research in previous reports has related to the year preceding the year to which the annual report relates.*

- *Asking researchers to assign research to categories (such as 'human benefit' or 'animal benefit') results in problems with interpretation, as well as the creation of artificial divisions which may not assist in understanding what is taking place in animal research.*

- *The statistics do not inform people about critical aspects of the research being conducted. These include how invasive the animal research procedures are, their justification, or their potential to cause pain or distress. The Panel is able to provide qualitative information of this kind on the basis of information gathered during site inspections, but this may be insufficient to allay public concerns.*

- *Comparison of total numbers of animals used does not provide a meaningful indication of progress towards refinement, reduction and replacement of animal use*[45]*. For example, the total number of mice used may increase. However, this may*

[45] This was illustrated by Ms Lotte Sutton. In her submission she said "... the statistical returns the NSW TAFE Commission submits to the Director General may be misleading. I fill in one of these returns at the end of each financial year and have been instructed to list each individual animal every time it is used for

be due to the introduction of a new procedure using large numbers of animals, but with little impact on them, rather than a procedure using smaller numbers with significant impact on individual animals.

- *The statistics do not give an indication of the activities of animal suppliers, particularly the numbers of animals bred for research which are culled or 'wasted' without ever being used for research. This is an issue of concern to many in the community.*

- *Current reports are time consuming for institutions to complete and for the Animal Welfare Unit to process. They do not appear to provide an acceptable return for this input.*

In its next annual report, the Panel provided some further remarks on these difficulties and what was being done about them.

"A discussion paper was circulated at the 1994 Chairs of AECs meeting. Responses to this paper were generally positive, with emphasis being placed on the need to develop uniformity between States and the Commonwealth. Keith Edwards and Ross Burton are continuing to work on a refined data collection and presentation system for New South Wales, in tandem with a national review being conducted with the review of the Australian Code of Practice. This is a long-term project, as it will take time to formulate a national approach. In the meantime, data will continue to be collected and published under the old system so that there will be, at least, some reference material."[46]

Mr K Edwards, Panel member, in an article *Animal Use Statistics* says that the data presented in the Panel's annual reports provide only a superficial view of what is occurring in animal research. He says the data gives little insight into animal-based research, and no indication of the pain and distress involved or the end point of procedures. Mr Edwards argues that:

"The minimum requirements for statistical data on animals used in research and teaching should be:

- numbers of animals;
- species of animals;
- severity of procedures imposed on animals;
- duration of this imposition on animals;
- whether there is repeated use of animals;
- fate of animals;
- implementation of the 3Rs (replacement, refinement and reduction)"

The extent of data currently being collected by the Panel does not meet these standards or the standards recommended in the report of the Senate Select Committee on Animal Welfare 1989. That 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,

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demonstration, handling etc. For example the number of mice we used last year was 720, when in reality a far smaller number of mice were available for use over a nine week period of the subject, Mouse Care. At the end of this particular teaching period only two mice were euthanased for class purposes. My point is that an independent person looking at the TAFE statistical returns would reach a totally inaccurate conclusion regarding the numbers of animals used".

46 Animal Research Review Panel Annual Report 1994-95

government authorities should provide some analysis of the statistics to make them meaningful to the public, and to reduce the potential for misinterpretation."[47]

At the Committee's inquiry, Mr Edwards re-iterated his concern about the recording and presentation of statistics on the use of animals for research, teaching and other purposes.

Mr Edwards said that the typical annual report basically gave the numbers of different species that were being used but did not give any information about the impact on the animals, how long they had been involved in certain procedures or where they ended up when the procedure was finished. He also said that the statistics did not give much indication about the implementation of the three Rs - reduce, replace and refine.

Mr Edwards, speaking for the Panel on this issue, said that "the figures, as they stand at the moment, do not give us much of an idea of what is going on."

These comments show that it is not possible for the Panel or for NSW Agriculture to accurately gauge from data in the annual returns and published statistics whether the Code is being adequately implemented.

The position at present was revealed in answers at the inquiry:

> ***MEMBER OF COMMITTEE:*** *What has changed since 1993-94 when it was acknowledged that the figures did not inform the public?*
>
> ***Mr EDWARDS:*** *We decided to look at that and there was general agreement within the Panel that it was not satisfactory. I think we all acknowledged that. We started looking at that and, at the same time, made noises about the requirement for a need to have consistent national statistics so that we can look, generally speaking, at how the code is being implemented across the countryside. One of the issues of concern is, if we are imposing harsher conditions in New South Wales than in another State or vice versa, will there be movement of animals from one State to another to try to escape certain conditions? At the moment there is no way of knowing.*
>
> *The National Consultative Committee on Animal Welfare was interested in this topic as was the liaison group that has developed the Australian code. There was much talking and at this stage there is a prototype which has been put together in South Australia. It gives an idea of the numbers, species and impacts on animals. It is quite likely that we will end up using that or something similar in New South Wales. We have not debated it yet. It has not come to the Panel formally because it is quite new. It seems to be a really good starting point for preparing some improved statistics for this State and will provide a consistent set of figures across the country as well.*
>
> ***MEMBER OF COMMITTEE:*** *So that the Panel is not waiting for national action ? you are doing something at the New South Wales level.*
>
> ***Mr EDWARDS:*** *No, we will probably end up utilising this South Australian prototype so that we have this consistency from State to State. There have been discussions. It was not developed in South Australia in isolation; it was developed after consultation with State*

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47 Animal Experimentation in Australia: Report by the Senate Select Committee on Animal Welfare, No 396, 1989

bodies all around the countryside.

MEMBER OF COMMITTEE: *Are you trying to get national consensus?*

Mr EDWARDS: *Yes, which makes it difficult, of course.*

MEMBER OF COMMITTEE: *What will happen if that appears to be quite some time away? What are you doing at the New South Wales level to change things apart from that? That could take some years.*

Mr EDWARDS: *Hopefully it will be sooner rather than later. One of the problems is that institutions consider it to be an onerous task to collect and collate these statistics and send them to the Animal Welfare Unit where they are compiled into a statewide set of figures. It would be unwise to change the system twice in a relatively short period of time. We acknowledge that the figures are not good enough at the moment. We do not want to change them now and then perhaps change them in a couple more years time so that they are consistent on a national basis; that would be counterproductive. At least at the moment we have a moderately consistent set of data; we may have five or six years of data we can look at to see if there are any trends over that period of time rather than changing it in the midstream. There is movement, though perhaps not as quick as we would all like, but something is happening certainly.*

During debate on the Animal Research Amendment Bill 1997, Mr Cruickshank MP also raised the possibility that a national scheme could take years to put in place and that because of the great difference in legislation between the States he was of the view that New South Wales was justified in proceeding independently.

The Minister for Agriculture in reply said:

"The annual report process has been criticised. A system to collect statistics nationally has been developed with the cooperation of the States. This system aims to provide more useful information about the type of procedures to which animals are subjected.

Concern was expressed that all States have been asked for their endorsement of this system. I sought advice from my Animal Research Review Panel on the practicality of introducing the system in New South Wales - a matter raised by the honourable member for Murrumbidgee. He said that if we have to wait many months or years, for example, to set up the South Australian protocol, perhaps we should go it alone. I will seek advice as to whether that is practicable. In the meantime I endorse the principle of national comprehensive statistics on animal use. That will be to the benefit of all. As I have already said, there could be a cross-State supply of animals into New South Wales."[48]

The Regulation Review Committee believes that this matter has been allowed to drift on for too many years. The Panel's submission shows that the information which accredited research establishments are asked to record and submit as an animal return is based on recommendations by the Panel in 1988, and that this was prepared prior to the commencement of the substantive provisions of the Act and without the benefit of close contact with the research community.

This matter was of sufficient importance to warrant full examination in the regulatory impact

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48 The Minister for Agriculture, Animal Research Amendment Bill 1997, 21 May, 1997

statement in accordance with Schedule 2 of the Subordinate Legislation Act. That was not attempted. The reason given was that at the date of preparation of the 1995 regulation consultation was still taking place with the lay and scientific communities with a view to reviewing the type of information required to be submitted and the reporting format. The RIS acknowledged that criticism had been directed at the quality of information collected to date and said that through consultation it was hoped to identify the community's requirements for information. On this issue the RIS concluded by saying that it should be possible to collect information of better quality while reducing administrative costs.

The Committee finds the examination of this issue in the RIS unsatisfactory. The present regulation was preceded by the Animal Research Regulation 1990 which contained similar provisions governing annual returns on animal use. NSW Agriculture and the Animal Research Review Panel had 5 years in which to appraise the effectiveness of these provisions and to carry out consultation on the extent and nature of the annual returns which should be made by accredited research establishments.

NSW Agriculture should have examined the need for various types of information against the background of the objectives of the Act, Regulations and Code and in terms of the responsibilities placed by those instruments on the Animal Research Review Panel. Instead, the Department, in its RIS, appears to see the function of annual returns as solely to satisfy the public's need for adequate information about what is going on. Although important for that purpose, the information is equally relevant to assist the Department and Review Panel to measure the effectiveness of current controls.

NSW Agriculture has the responsibility for further progress on this matter. In a letter dated 15 April 1997 Dr R Sheldrake, Executive Director (Research, Advisory & Education) said that if the standardised national reporting format is endorsed by the Minister it will be adopted in NSW in lieu of the existing provisions. It seems, however, that the Minister's endorsement will depend on endorsement by all other States.

Recommendation 21:

The Committee recommends that the proposal for a national reporting format be actively pursued by the Minister with a view to gaining consensus on a standardised reporting scheme. If agreement cannot be reached with the other States within 12 months, NSW should introduce its own revised regulatory scheme.

17. Animal research conducted in schools

Certain schools may carry on business of animal research without accreditation

Regulation 20 exempts from accreditation schools belonging to, or associated with, the Association of Independent Schools or the Catholic Education Commission (NSW) so long as the animal research is carried out with the authority of an Ethics Committee and in accordance with the Code of Practice.

The power to make this regulation is contained in section 62 of the Act which says a provision of a regulation may exempt from the operation of any specified provision of the Act any specified person or body or specified class of persons or bodies, either unconditionally or subject to conditions.

During debate on the Animal Research Bill in the Legislative Council on 13 November 1985, the Hon J H Jobling MLC asked the Minister to inform Parliament of the circumstances where this exemption provision would be used.

" The Hon J H Jobling inquired initially about Clause 62(2)(d). My advice is that this wide ranging exemption Clause is fairly standard in regulation-making powers. The exemption would be required for people who might be licensed to supply animals. Someone may wish to donate an animal to a research unit for particular medical research, but may not be a licensed authority. It may seem a perfectly reasonable and acceptable thing to do."[49]

The Minister's reply shows that the Government did not, at that stage, contemplate using this provision to exempt independent or catholic schools from the need for accreditation.

The regulatory impact statement prepared in connection with the draft 1995 regulation examined three options relating to this issue. The first was to allow no exemptions. The second was to "exempt Catholic schools from the need to apply individually for accreditation if they apply as a group under the Catholic Education Commission."

Under this option, which was said to apply at that time, the Catholic Education Commission applied for accreditation as a single entity on behalf of approximately 630 schools. The third option, which was preferred, was to "exempt Catholic schools and non Catholic independent schools from the need for individual accreditation applications if they are covered by an umbrella group." Under this option it was stated that the 150 member schools of the Association of Independent Schools would be able to apply by way of a single application for accreditation.

The Regulation Review Committee understands that the practice followed at present is that the Catholic Education Commission is accredited on behalf of the 630 schools it represents but that the independent schools have chosen to seek individual rather than group accreditation.

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49 The Hon J R Hallam MLC, Animal Research Bill, 13 November, 1985

The regulatory impact statement, the Panel's annual reports and its submission on the regulation proceed on the basis that accreditation, either individually or by group, will be mandatory for all school-based corporations under the 1995 regulation.

However, from the commencement of regulation 22 of the Animal Research Regulation on 1 September 1990, any school incorporated under the provisions of the Roman Catholic Church Trust Property Act 1936 or the Roman Catholic Church Communities' Lands Act 1942 was exempted from accreditation provided only that the research was done with the authority of an AEC of the Catholic Education Commission (NSW) and in accordance with the Code. As from 1 September 1995 (the commencement of the Animal Research Regulation 1995) this exemption was reworded to refer to any non-government school belonging to, or associated with, the Catholic Education Commission (NSW) and it was extended to cover, on similar conditions, any non-government school that belonged to, or is associated with, the Association of Independent Schools.

This shows that the terms of the current regulation do not reflect the wishes of either NSW Agriculture or the Panel and should be revised by the Parliamentary Counsel.

Recommendation 22:

The Committee recommends that regulation 22 of the Animal Research Regulation be reviewed by the Parliamentary Counsel to determine if it accords with the intentions of the Animal Research Review Panel and NSW Agriculture.

School students may carry out animal research without an animal research authority

Section 47 prohibits a person carrying on animal research without an animal research authority. Regulation 21 exempts students from this requirement "so long as the animal research is carried out under the supervision, and in accordance with the directions, of the holder of an animal research authority or animal research licence."

At the inquiry Mr James Scott, Chief Education Officer, Science, Department of Education was asked whether the supervision requirements of regulation 21 were being complied with.

> ***MEMBER OF COMMITTEE:*** *The supervision of regulation 21 is important. The regulation exempts students from the need to hold an authority or licence only if the research is carried out under the supervision and direction of the holder of an animal research authority or licence. Would you please explain whether current arrangements accord with that provision? For example, is there a holder of an animal research authority or animal research licence at each school? You might already have touched on this.*
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> ***Mr SCOTT:*** *For the record, what happens is that once the school as a corporation has been granted a licence it becomes an accredited research establishment. Each year formal advice is provided by the systems to each school indicating that they are entitled to use animals for the purpose of animal research or teaching provided they have an animal schools welfare liaison officer and provided the activities that they are carrying out are done in accordance with this book.*
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> ***MEMBER OF COMMITTEE:*** *But the short answer to the question is that each school does not in fact have to be the holder of an animal research authority or animal research*

licence?

Mr SCOTT: *That is correct.*

MEMBER OF COMMITTEE: *How many are there in the whole State?*

Mr SCOTT: *There are 3,000 schools.*

MEMBER OF COMMITTEE: *No, how many holders of those licences?*

Mr SCOTT: *There would be none in this State at this point in time because we have had literally five applications in the last three years for research outside the guidelines and there are none current at the moment.*

This evidence shows there is confusion between the requirements of regulation 21 relating to the appointment of the holder of an animal research authority to supervise and the obligation in Schedule 1 of the regulation for a school to seek an Ethics Committee approval for a procedure not on the list of approved procedures. These are two different matters. Where a holder of an animal research authority has not been appointed to supervise in accordance with regulation 21 the research would be contrary to section 47.

On 6 June 1997, Mr James Scott, Chair of NSW Schools Animal Care and Ethics Committee sent a facsimile to the Regulation Review Committee advising the action being taken to conform with regulation 21. He said:

"Attached is the proposed Animal Research Authority which we will be asking each of the three school systems to endorse. The form will be sent to each school following Animal Research Review Panel (ARRP) accreditation of the school system.

The intention is that each school will complete the required information and hold it in the Principal's office. The Authority would be asked for during any routine or other inspection of the school by Schools Animal Care and Ethics Committee or Animal Research Act inspector.

ARRP endorsement for this Authority form will also be sought as soon as practicable this year."

Records to be kept

School-based establishments are exempt from the record requirements of regulation 26. These requirements are detailed elsewhere in this report[50]. They require research establishments to send an annual report to the Director-General of Agriculture containing specified information relating to the kind and number of animals used, the number of proposals approved, re-approved or terminated, the objectives of the projects and the techniques adopted to promote replacement, reduction and refinement.

Although school-based establishments are exempt from the requirement to make an annual return on these matters to the Director-General they are not exempt from the need to keep records. Schedule 1 of the regulations requires the Ethics Committee for a school-based establishment to keep records of each proposal examined by the Ethics Committee

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50 Adequacy of Statistics p 60-64

(Schedule 1, Part 1, Clause 2(4)).

These are proposals that are not on the list of approved procedures. It is the responsibility of the class teacher to enter in the school register any activity that is carried out that is on the relevant list of approved procedures. (Schedule 1, Part 1, Clause 5(2)(a)). Under this scheme each school-based establishment should have a record of the animal research activities that it has carried out. The revised Australian Code has the additional requirement for the keeping of complete animal care records (7.3.6.).

At the inquiry, Mr Scott[51] was asked whether there would be any difficulty in schools supplying statistical information.

> ***MEMBER OF COMMITTEE:*** *Do you see any difficulty supplying annual statistical information required by the director-general?*
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> ***Mr SCOTT:*** *Yes, we would. That would entail a considerable effort in requiring schools to collate information and forward it in a form that could be used. At the present time, as far as the regulation is concerned, we do not see that we have that requirement. We require it to be kept at school level for the purposes of our monitoring and for school management of its animals.*

The Committee received a number of submissions critical of the exemption granted to schools. The basis of the exemption is not referred to or justified in the regulatory impact statement. This is a matter of substance that should have been examined. Although Mr Scott in his evidence says that it would entail considerable effort, this might be counterbalanced by the usefulness of the returns. The matter should be properly examined by the Panel and NSW Agriculture.

Recommendation 23:

The Committee recommends that the Animal Research Review Panel and NSW Agriculture assess the costs and benefits of requiring school-based establishments to submit annual returns in accordance with Regulation 26.

Observance of conditions applying to animal research in schools

The argument for school-based institutions to make an annual return to the Director-General of Agriculture receives additional support from claims made that the conditions of animal research set out in Schedule 1 of the regulation are not being complied with in schools.

The Panel in its submission to NSW Agriculture said it understood that neither the Association of Independent Schools nor the Catholic Education Commission was in a position to supervise its member schools. The Panel's 1994-95 Annual Report does not mention these doubts and there is no evidence they have been followed up either by NSW Agriculture or the Panel. The Panel's report devoted only a few paragraphs to schools and these did not attempt to appraise any of the activities carried on. A full and professional treatment by the Panel was warranted of this important subject.

Mr Edwards, Panel member, in his written submission to the Committee said he had

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[51] Mr James Scott, Chief Education Officer, Science, Department of Education

concerns about whether the general principles regarding justification of the use of animals in schools and minimisation of numbers of animals used are being met.

These concerns were also reflected in the evidence of the Chairman of the Schools Animal Care and Ethics Committee (SAEC), Mr Scott, which showed the Ethics Committee was not satisfied with the standard of compliance.

> ***MEMBER OF COMMITTEE:*** *In your animal welfare guidelines for teachers publication of 1991 two of the general principles specify that animals are to be used in teaching only where there is no practicable alternative to achieving educational objectives. The second principle is that projects must be designed to use the minimum number of animals necessary. Do you have any comments on that?*
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> ***Mr SCOTT:*** *Yes. We would hope that the principle is being practised and used by schools in making those decisions but in monitoring what is happening in schools we are not satisfied that that is being done to the extent that we would like. But it is part of the process that I have mentioned in my submission, which indicates that we will be picking that up in the revision of this and emphasising more strongly that schools should consider alternatives. We will be providing alternatives scattered throughout this for teachers to consider when choosing animals or non-animal alternatives for the research.*

In his written submission Mr Scott said SAEC monitors compliance with the legislation by a combination of school visits and an annual survey to schools. He said the Panel had endorsed an annual program of 12 visits to randomly selected schools and an annual survey to a sample of schools as the primary means for monitoring school compliance. The current budget for ongoing monitoring is approximately $10,000 a year.

Under Schedule 1 of the regulations an animal care and Ethics Committee for a school has the responsibility to monitor animal research carried out at the school and to ensure that it complies with the requirements of Schedule 1 and all other relevant provisions of the Code of Practice. This obligation carries with it the duty to supervise, and to make sure the school complies with the requirements. It is doubtful that the single Ethics Committee that has been set up could be said to be performing this obligation by carrying out an annual site inspection of 12 schools out of approximately 3,000 schools and by sending out a written annual survey to some other schools. Although Mr Scott recognised the inadequacy of the current compliance level the Ethics Committee has not proposed any new initiatives other than a review of the guidelines to correct the problem. More positive steps than this will be required, possibly the creation of other Ethics Committees so that an effective program of supervision can be put in place. That should also be accompanied by a costing of the program to determine a realistic budget.

Recommendation 24:

> **The Committee recommends that the Panel and NSW Agriculture review the current arrangements governing the monitoring of animal research in school-based institutions with a view to improving those arrangements and ensuring that adequate funds are available for them. This should be carried out within the next 3 years and a report on the review tabled in Parliament.**

In the course of his evidence Mr Charles Wright was asked about his concerns relating to school-based animal research.

> ***MEMBER OF COMMITTEE:*** *During your evidence I gained the impression that you had*

serious concerns about some actions that take place in schools?

Mr WRIGHT: *Yes.*

MEMBER OF COMMITTEE: *How many complaints about incidents or procedures in schools do you receive in a normal year?*

Mr WRIGHT: *We have a number of complaints about schools, period. You may have heard of a few instances involving schools.*

MEMBER OF COMMITTEE: *A number can be anything between one and infinity.*

Mr WRIGHT: *If you are referring to research or teaching matters, all we get is phone calls from various people who report instances of cruelty, but we tell them it is beyond our control to get involved in that. If an animal was abused by one of the students within the school grounds on a muck-up day or something like that we can act, but if it is within the teaching facility we cannot.*

MEMBER OF COMMITTEE: *How many times a year would you become involved to the point of having to act?*

Mr WRIGHT: *Something like 200, but I would have to get the exact figure from our statistical information on schools. That is just complaints that come from schools using animals. If we receive a complaint and it refers to a research matter, we say we cannot do anything about it, so it is not recorded as a call.*

MEMBER OF COMMITTEE: *What about TAFE colleges?*

Mr WRIGHT: *We do not have many problems with TAFE colleges.*

MEMBER OF COMMITTEE: *There appear to be two groups: kids who are up to mischief or displaying irresponsible behaviour, and research?*

Mr WRIGHT: *That is right.*

MEMBER OF COMMITTEE: *Will you explain the depth of the problem in both areas as you perceive it?*

Mr WRIGHT: *The regulation was changed to allow the RSPCA to take action against the former—students being blatantly cruel to an animal on a school ground on a muck-up day. In the other area, if animals are declared to be used for teaching purposes—in other words, if they are kept in facilities or a research experiment is carried out on them which we would regard as cruel—we cannot take action.*

MEMBER OF COMMITTEE: *How many of the 200 complaints relate to students being irresponsible and how many to research?*

Mr WRIGHT: *The bulk of them would relate to children being irresponsible.*

In this evidence Mr Wright puts forward the view that POCTA officers cannot investigate

complaints as to breaches of the POCTA Act arising out of school-based research. Mr Wright is referring here to the powers of POCTA officers set out in section 25 (powers of officers in respect of certain places) and section 26 (powers of officers, generally). Each of these sections prohibits the exercise of the powers by POCTA officers (unless they are inspectors under the Animal Research Act) in respect of designated land "in relation to any animal research authorised to be carried out on that land by an animal research authority". However although section 47 of the Animal Research Act prohibits a person carrying out animal research unless they hold an animal research authority, schools are exempted from this provision by regulation 21, which is headed: "School students may carry out animal research without authorities or licences". That regulation was made under section 62 of the Animal Research Act which authorises a regulation to exempt from any specified provision of the Act any specified person or class of persons. In this case the class of persons are school students.

It would follow from this that the animal research conducted in schools is not authorised to be carried out by an animal research authority within the meaning of sections 25 and 26 of the POCTA Act. Accordingly POCTA officers can enforce that Act in school-based research establishments.

18. Further consideration of these matters by the Regulation Review Committee

The Regulation Review Committee will reconvene its inquiry into this regulation at the expiration of one year to examine what action has been taken to address the various issues which form the subject of this report.